easterly along said boundary line to its intersection with the northwestern boundary line of Kern County; easterly along said boundary line to its intersection with the northwestern boundary line of San Bernardino County; southerly along the Kern-Bernardino boundary line to its intersection with U.S. Hwy 395; southerly along U.S. Hwy 395 to its junction with CA Hwy 58; easterly along CA Hwy 58 to its junction with I-15 near Barstow; easterly on I-15 to Yermo; southerly along unnumbered county road from Yermo to its junction with I-40 at Daggett; westerly on I-40 to its junction with CA Hwy 247; easterly and southerly on CA Hwy 247 to its junction with CA Hwy 62 at or near Yucca Valley; easterly on CA Hwy 62 to its junction with an unnumbered county road at or near Twentynine Palms; southwesterly and southeasterly along said unnumbered county road, through Joshua Tree National Monument, to its junction with CA Hwy 111 at or near Mecca; southerly along CA Hwy 111 to its junction with CA Hwy 115 at or near Calipatria; southerly along CA Hwy 115 to its junction with I-8 at or near Holtville; easterly along I-8 to its juction with CA Hwy 98; south along an imaginary line to its junction with the international boundary line between the United States and the Republic of Mexico; west along the international boundary line between the United States and the Republic of Mexico to the Pacific Ocean; northerly along the shoreline of the Pacific Ocean to points of beginning, including the commercial zone, of any point traversed by the boundaries of said Territory. (Hearing site: Los Angeles, CA.)

Note.—The purpose of this application is to convert existing Certificate of Registration issued to applicant in MC 96697 Sub 8, together with certain extensions in the territories to be served.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-36709 Filed 11-28-79; 8:45 am]

BILLING CODE 7035-01-M

Sunshine Act Meetings

Federal Register
Vol. 44, No. 231
Thursday, November 29, 1979

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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1

[M-257, Amdt. 1; Nov. 26, 1979]

CIVIL AERONAUTICS BOARD.

Notice of addition of items to the November 28, 1979, meeting agenda.

TIME AND DATE: 9:30 a.m., November 28, 1979.

PLACE: Room 1027 (Open), Room 1011 (Closed), 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT:

6a. Dockets 36782 and 37062; Hughes Airwest's petition for review of staff action taken in Order 79-10-125, an award of Boise-Eugene authority to Frontier Airlines under 401(d)(5)(A); application of Frontier Airlines for an exemption under 416(b) to provide nonstop Boise-Eugene service. (BDA)

10a. Dockets 36594 and 36651; Aspen Airways' notice to suspend service at Gunnison, CO. (BDA)

STATUS: Open (Items 1-23), Closed (Item 24).

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary, (202) 673-5068.

SUPPLEMENTARY INFORMATION: Frontier Airlines plans to begin service in the market at issue on December 1, 1979. Therefore, the Board should consider Hughes Airwest's petition for review of the order granting this authority as soon as possible. Due to processing delays in the Bureau of Domestic Aviation, Item 6a was not submitted before the deadline for the November 28, 1979 agenda. The staff has just completed their analysis and request that the Board consider Item 10a so that all parties concerned can be given a time allowance before the suspension of service. The date of suspension is December 6, 1979. Accordingly, the following Members have voted that Items 6a and 10a be added to the November 28, 1979 agenda and that no earlier announcement of these additions was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S-2311-79 Filed 11-27-79; 3:34 pm]

BILLING CODE 6320-01-M

2

FEDERAL DEPOSIT INSURANCE CORPORATION.

Notice of Agency Meeting.

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 2 p.m. on Monday, December 3, 1979, to consider the following matters:

Disposition of minutes of previous meetings.

Recommendations with respect to payment for legal services rendered and expenses incurred in connection with receivership and liquidation activities:

Bronson, Bronson & McKinnon, San Francisco, California, in connection with the receivership of United States National Bank, San Diego, California.

Morgan, Lewis & Bockius, Philadelphia, Pennsylvania, in connection with the liquidation of assets acquired by the corporation from Farmers Bank of the State of Delaware, Dover, Delaware.

Powell, Goldstein, Frazer & Murphy, Atlanta, Georgia, in connection with the liquidation of The Hamilton Bank and Trust Company, Atlanta, Georgia.

Sidley & Austin, Chicago, Illinois, in connection with the liquidation of The Drovers' National Bank of Chicago, Chicago, Illinois.

Kantrow, Spaht, Weaver & Walter, Baton Rouge, Louisiana, in connection with the liquidation of Republic National Bank of Louisiana, New Orleans, Louisiana.

Memordandum re: Changes in FDIC Regulations to amend delegations of authority, to amend the definition of "phantom" bank merger, and to correct an error in a prior publication.

Memorandum re: Supervisory Policy regarding the purchase and sale of U.S. Government guaranteed loans by financial institutions.

Reports of committees and officers:

Report of the Executive Secretary regarding his transmittal of "no significant effect" competitive factor reports.

Minutes of the actions approved by the Committee on Liquidations, Loans and Purchases of Assets pursuant to authority delegated by the Board of Directors.

Reports of the Director of the Division of Bank Supervision with respect to applications or requests approved by him and the various Regional Directors pursuant to authority delegated by the Board of Directors.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located 550—17th Street, NW., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 398-44-5.

Dated: November 26, 1979.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-2307-79 Filed 11-27-79; 11:44 am]

BILLING CODE 6714-01-M

3

FEDERAL DEPOSIT INSURANCE CORPORATION.

Notice of Agency Meeting.

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:30 p.m. on Monday, December 3, 1979, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, by vote of the Board of Directors pursuant to sections 552b(c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of title, 5, United States Code, to consider the following matters:

Applications for Federal deposit insurance:

First Missouri Bank of Ellisville, a proposed new bank, to be located at 1353 Manchester Road, Ellisville, Missouri, for Federal deposit insurance.

Farmers Branch Bank, a proposed new bank, to be located at 2350 Valley View Lane, Farmers Branch, Texas, for Federal deposite insurance.

Request for exemption pursuant to section 348.4(b)(2) of the Corporation's rules and regulations entitled "Management Official Interlocks":

Farmers Branch Bank, Farmers Branch, Texas.

Recommendations regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 44,130-L—Franklin National Bank, New York, New York.

Case No. 44,143-L—Banco Credito y Ahorro Ponceno, Ponce, Puerto Rico.

Case No. 44,146—Farmers Bank of the State of Delaware, Dover, Delaware.

Recommendation with respect to payment for expenses incurred by Casey, Lane and Mittendorf, New York, New York, in connection with the liquidation of Franklin National Bank, New York, New York.

Recommendations with respect to the initiation or termination of cease-and-desist proceedings, termination-of-insurance proceedings, or suspension or removal proceedings against certain insured banks or officers or directors thereof:

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(6), (c)(8), and (c)(9)(A)(ii)).

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2) and (c)(6)).

The meeting will be held in the Board Room on the sixth foor of the FDIC Building located at 550—17th Street, N.W., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation at (202) 389-4425.

Dated: November 26, 1979.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-2308-79 Filed 11-27-79; 11:44 am]

BILLING CODE 6714-01-M

4

LEGAL SERVICES CORPORATION.

BOARD OF DIRECTORS MEETING.

TIME AND DATE: 9 a.m.-5 p.m.—Thursday and Friday, December 6-7, 1979.

PLACE: Hyatt Regency Hotel, Embarcadero Room A, Five Embarcadero Center, San Francisco, California.

STATUS: Open Meeting.

MATTERS TO BE CONSIDERED:

1. Adoption of Agenda.
2. Approval of Minutes of September 7, 1979 Meeting
3. Remarks by Leonard Janifsky, President of the American Bar Association.
4. Reports from Committee on Appropriations and Audit—
   - Final Report on Fiscal Year 1979 Expenditures
   - Report on Audit of Legal Services Corporation for Fiscal Year 1979.
   - Review of Fiscal Year 1981 Budget Request.
   - Allocation of One Time Funds During Fiscal Year 1980.
5. Report from Committee on Provision of Legal Services
   - Resolution concerning Native American Legal Services
6. Overview of the Activities of the National Support Centers
7. Authorization of Board Committees.
8. President's Report
9. Future Meeting Dates
10. Other Businesses

CONTACT PERSON FOR MORE INFORMATION: Dellanor Young, Office of the President, telephone (202) 272-4040.

Issued: November 26, 1979.

Dan J. Bradley,

President.

[S-2306-79 Filed 11-26-79; 5:08 pm]

BILLING CODE 6820-35-M

5

INTERSTATE COMMERCE COMMISSION.

TIME AND DATE: 9:30 a.m., Tuesday, December 4, 1979.

PLACE: Hearing Room "A", Interstate Commerce Commission Building, 12th Street and Constitution Avenue, NW., Washington, D.C. 20423.

STATUS: Open Special Conference.

MATTER TO BE DISCUSSED: Rail Rate Bureaus.

CONTACT PERSON FOR MORE INFORMATION: Douglas Baldwin, Director, Office of Communications, Telephone: (202) 275-7252.

The Commission's professional staff will be available to brief news media representatives on conference issues at the conclusion of the meeting.

[S-2309-79 Filed 11-27-79; 1:06 pm]

BILLING CODE 7035-01-M

6

UNITED STATES RAILWAY ASSOCIATION.

TIME AND DATE: 9 a.m., December 6, 1979.

PLACE: 955 L'Enfant Plaza North, SW., Board Room, Room 2-500, Fifth Floor, Washington, D.C.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED BY THE BOARD OF DIRECTORS:

Portions Closed to the Public (9 a.m.)

1. Consideration of internal personnel matters.
2. Review of Conrail proprietary and financial information for monitoring and investment purposes.
3. Review of Delaware and Hudson Railway Company proprietary and financial information for monitoring and investment purposes.
4. Litigation report.

Portions Open to the Public (1 p.m.)

5. Approval of minutes of the November 1, 1979 Board of Directors meeting.
6. Legislative report.
7. Consideration of Delaware and Hudson requests.
8. Report on Conrail monitoring.
9. Consideration of Conrail First Quarter Investment Commitment request.
10. Consideration of Conrail Drawdown request for December.
11. Consideration of representation budget.
12. Contract Actions (extensions and approvals).

[S-2310-79 Filed 11-27-79; 3:18 pm]

BILLING CODE 8240-01-M

federal register

Thursday
November 29, 1979

Part II

Department of Health, Education, and Welfare

Office of Human Development Services

Vocational Rehabilitation and Independent Living Rehabilitation Programs; Proposed Rulemaking

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Human Development Services

45 CFR Parts 1361, 1362, and 1363

Vocational Rehabilitation and Independent Living Rehabilitation Programs; Proposed Rulemaking

AGENCY: Department of Health, Education, and Welfare, Office of Human Development Services, Rehabilitation Services Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Rehabilitation Services Administration is proposing regulations to implement the new vocational rehabilitation and independent living rehabilitation authorities contained in the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95-602). These include revisions to the existing State plans under which State vocational rehabilitation agencies provide vocational rehabilitation services to handicapped individuals and the development of new State plans for providing independent living rehabilitation services to severely handicapped individuals in order to assist them to achieve a greater level of control over the daily management of their lives.

In addition, the regulations cover a number of new special purpose grants and other assistance programs authorized by the 1978 Amendments under which public and other nonprofit agencies and organizations may apply directly to the Commissioner of the Rehabilitation Services Administration for financial assistance.

The proposed regulations also revise certain existing regulations which were published to implement the Rehabilitation Act of 1973 (Pub. L. 93-112), as amended by the Rehabilitation Act Amendments of 1974 (Pub. L. 93-516). These regulations are being revised in order to make them easier for the public to use and understand.

DATE: Written comments and suggestions will be considered if received no later than February 27, 1980.

ADDRESS: Written comments and suggestions on the proposed regulations should be sent to the Commissioner, Rehabilitation Services Administration, Department of Health, Education, and Welfare, Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Harold F. Shay, Director, Division of Manpower Development, Rehabilitation Services Administration, Room 3321, Mary E. Switzer Building, 330 C Street, S.W., Washington, D.C. 20201, (Area Code (202) 245-0079) or TTY: ((202) 245-0591).

SUPPLEMENTARY INFORMATION: The Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 significantly extended the scope of public and voluntary agency programming in providing rehabilitation services to handicapped individuals. These changes expanded the ongoing vocational rehabilitation service programs in each State, extended the range of special categories of project support and other assistance available directly from the Federal Government, and established State independent living service programs for severely handicapped individuals.

Insofar as State vocational rehabilitation reprogramming is concerned, the 1978 Amendments revised the State vocational rehabilitation service plan requirements to include provisions:

—To expand and improve the use of rehabilitation facilities in the delivery of vocational rehabilitation services;

—To ensure the availability of vocational rehabilitation personnel able to communicate in clients' native languages or able to communicate to clients who relay on special modes of communication;

—To ensure coordination with State special education agencies in the delivery of vocational rehabilitation services;

—To provide newly specified vocational rehabilitation services; including telecommunications systems, recorded material for blind individuals, and captioned materials for deaf individuals; and

—To establish information and referral programs within each State vocational rehabilitation program.

Other revisions to the State vocational rehabilitation service programs under the 1978 Amendments were:

—The identification of the "designated State unit" as the administering organizational unit responsible for directly carrying out the State vocational rehabilitation service program under the Rehabilitation Act;

—The conversion of the State plan for vocational rehabilitation services from an annual plan to a three-year plan;

—The establishment of a mechanism for selecting a substitute agency to carry out the vocational rehabilitation service program in a State when necessary because funds have been withheld;

—The revision of procedures affecting individualized written rehabilitation programs to require both that the director of the designated State unit review any decision with which a client is dissatisfied and that the Secretary of the Department of Health, Education, and Welfare make recommendations to the State unit director about the disposition of any case still unresolved after the director's review.

The 1978 Amendments also authorized a number of new and expanded Federal grant programs and related assistance. These included:

—A new grant program under Section 130 of the Act to enable American Indian tribes to provide vocational rehabilitation services to handicapped American Indians residing on Federal and State reservations;

—A new program under Section 303 of the Act to guarantee loans made for the construction of rehabilitation facilities;

—A new grant program under Section 304 of the Act for training interpreters for deaf persons through the Office of Information and Resources for the Handicapped;

—A new grant program under Section 305 of the Act for establishing and operating comprehensive rehabilitation centers which provide direct rehabilitation services and serve as information and referral resources for handicapped individuals and for other community agencies which serve handicapped individuals;

—A new grant program under Section 314 of the Act for providing reading services for blind individuals and for expanding and improving existing reading service resources;

—A new grant program under Section 315 of the Act for States to establish and maintain interpreter service programs for deaf individuals;

—A new grant program under Section 316 of the Act for initiating special recreation programs for handicapped individuals; and

—A new program of grants and contracts under Section 622 of the Act available directly to handicapped individuals who wish to establish or operate commercial or other enterprises.

Revisions to existing grant authorities included:

—Adding a focus on ensuring assistance necessary for protecting the rights of handicapped individuals under the Client Assistance Program under Section 112 of the Act and removing the ceiling on the number of projects which may be funded;

—Removing the limits on Staffing Grants under Section 301 of the Act to meeting only the "initial" staff requirements of the rehabilitation facilities being assisted;

—Identifying the fields of rehabilitation psychiatry and rehabilitation job placement for funding within the scope of the rehabilitation long-term training grant program under Section 304 of the Act;

—Extending services under the revised Special Projects and Demonstrations authority under Section 311 of the Act to handicapped persons irrespective of age or vocational potential, and providing for the construction of facilities;

—Authorizing the Helen Keller National Center for Deaf-Blind Youths and Adults under Section 313 of the Act to seek reimbursement for certain costs of services; and

—Adding an emphasis within the Projects with Industry Program under Section 621 of the Act on special supportive services, work facilities and equipment adaptation, and the distribution of special aids, appliances, or special equipment to handicapped individuals.

Finally, the 1978 Amendments added an extensive new State-Federal formula grant program providing independent living rehabilitation services to severely handicapped individuals. In addition to the new State-Federal independent living service program, the 1978 Amendments added new discretionary grant programs related to independent living including:

—A program under Section 711 of the Act for establishing and operating independent living centers which provide a broad range of independent living skills and related assistance to severely handicapped persons;

—A program under Section 721 of the Act for providing special independent living rehabilitation services to older blind individuals; and

—A program under Section 731 of the Act for assisting States to establish protection and advocacy systems for severely handicapped individuals who are receiving independent living services.

The regulations, as revised, are divided into three parts:

—Part 1361 covering the State plans for vocational rehabilitation services;

—Part 1362 covering discretionary grants, and other forms of assistance available to further rehabilitation efforts on behalf of physically and mentally handicapped persons; and

—Part 1363 covering the State plans for independent living services.

More specifically, Part 1361 continues to contain all requirements under the State plans for vocational rehabilitation services. This is the basic vocational rehabilitation service program under which State vocational rehabilitation agencies have been providing direct services to handicapped individuals over the years in order to help them to secure and maintain suitable employment. Part 1361 includes all administrative and programmatic requirements placed on State vocational rehabilitation program agencies in their administration of State vocational rehabilitation services.

Also covered in Part 1361 is the special program of innovation and expansion project grants which are administered by State agencies under the State vocational rehabilitation service plans. Finally, Part 1361 includes procedures for conducting hearings on conformity issues involving the disapproval of a State plan and on noncompliance issues in the administration of an approved plan.

Part 1362, as revised, includes all grant programs and other special forms of direct Federal assistance for which the Commissioner of the Rehabilitation Services Administration is responsible.

Subpart A of Part 1362 includes a number of general requirements which apply under all categories of assistance available under Part 1362. Subpart B covers grants for projects to provide vocational rehabilitation services to different groups of physically and mentally disabled individuals. Subpart C covers different types of assistance available to rehabilitation facilities. Subpart E covers the different types of grants available for tranining rehabilitation personnel. Subpart F covers the Helen Keller National Center for Deaf-Blind Youths and Adults. Subpart H contains a new group of project categories providing differents types of assistance extending beyond traditional vocational rehabilitation service needs.

As proposed, Part 1362 does not include the regulations for the rehabilitation research program which had previously been included under Subpart D of Part 1362. The 1978 Amendments transferred authority for the administration of the rehabilitation research program to the newly established National Institute of Handicapped Research and that office is expected to publish regulations for the rehabilitation research program in the near future.

Part 1363 is a new set of regulations which establishes requirements for the State plans for independent living rehabilitation services. Under this new program, State vocational rehabilitation organizational units will be providing independent living services to individuals who generally are considered to be too severely handicapped to be eligible for vocational rehabilitation services without a more general type of preliminary assistance.

Unless otherwise indicated below, the proposed regulations reflect changes specifically required by the 1978 Amendments to the Rehabilitation Act. In the case of the requirements for the new State plans for independent living rehabilitation services, the proposed regulations also reflect an effort to provide appropriate consistency with the requirements for the State plans for vocational rehabilitation services.

Part 1361

Within Part 1361, the following specific significant regulatory changes are proposed:

Subpart A

§ *1361.1 Terms.* The number of terms defined in this section has been reduced to remove those terms defined in the Act which are used relatively infrequently in the regulations. Certain other definitions have been relocated within the regulation in order to relate them more closely to the content area being discussed. In addition, certain new definitions have been added to reflect changes made by the 1978 Amendments.

More specifically within this section, the terms "designated State unit" and "State unit" have been added to refer to that organizational unit within the sole State agency for vocational rehabilitation which is directly responsible for the delivery of vocational rehabilitation services to handicapped individuals.

Throughout Part 1361, the terms "designated State unit" and "State unit" have been introduced to distinguish the different levels of responsibility. The term "State agency" is used within the regulations to refer to the highest level vocational rehabilitation administrative organization in the State which is responsible for supervisory and fiscal controls over the State's vocational rehabilitation program. The term "State unit" is used to indicate that unit which directly carries out the State's vocational rehabilitation program and provides services to handicapped individuals within the State.

In some States, the State unit and the State agency may be the same organizational entity. In other States, however, the State unit is located within the State agency. When the term "State agency" is used in the regulations, therefore, it can be understood as appropriate to apply to both the "State agency" and the "State unit."

The definition of "establishment of a rehabilitation facility" has been revised to reflect the fact that assistance under

this authority is no longer limited to "initial staffing" or "initial equipment." Both initial and additional staffing and equipment assistance may now be provided.

The definition of "physical and mental restoration services" has been revised to add "therapeutic recreation services." This revision is in line with the overall concern throughout the 1978 Amendments for the importance of recreation activities and services for handicapped persons.

The definition of "physical or mental disability" has been revised to clarify the relationship in the existing definition between an individual's disability and his or her vocational functioning. All clients of State vocational rehabilitation programs are required to have medically recognizable disabilities and to require services in order to enable them to secure employment. Any service provided under the State vocational rehabilitation program must be directly related to assisting the individual to overcome the barriers to employment imposed by the physical or mental disability.

A definition for "reservation" has been added to assist in identifying State unit responsibilities for providing services to handicapped American Indians in those States where special tribal vocational rehabilitation service projects may be operating.

The definition of "State" has been revised to include the Northern Mariana Islands.

The definition of "vocational rehabilitation services" has been revised to include newly specified services relating to the use of existing telecommunications systems and the use of special materials for blind and deaf individuals.

The definition of "severely handicapped individual" has not been revised. Although considerable effort has been undertaken to refine the definition previously adopted, it does not appear that there has as yet been sufficient experience to propose revisions to this definition.

Subpart B

§ *1361.2 The State plan: General requirements.* This section has been revised to provide for a three-year State plan instead of the annual State plan previously in effect. This revised section also includes a requirement for the submittal of financial and program information which had previously been required in a separate "Program and Financial Plan."

§ *1361.4 State plan approval and disapproval.* This section has been revised to change the State plan submittal date to July 1 because of the change in the Federal fiscal year.

§ *1361.7 Organization of the State agency.* This section has been revised to identify the organizational requirements affecting the location of the "designated State unit" within a sole State agency. Since the 1978 Amendments clarified the role, function, and responsibilities of the State unit, certain non-regulatory descriptive material previously found in this section has been omitted. This material had described the factors to be considered by the Commissioner in evaluating the comparability of the organizational level and status of the vocational rehabilitation unit within the State agency. It is expected that the new statutory base for the State unit will resolve much of the confusion about areas of functional responsibility which have arisen in recent years as a result of State agency reorganization.

§ *1361.14 Cooperative programs involving funds from other public agencies.* This section has been revised to include a new administrative requirement for an annual review by the State unit of each cooperative program in order to assure compliance with the terms of written agreements between the State unit and other public agencies. Special attention in these annual reviews will be given to the use of certified funds which have been identified by the U.S. General Accounting Office and the Audit Agency of the Department of Health, Education, and Welfare as an area in which there is evidence of some improper practice in the past.

§ *1361.15 Staffing of the State's vocational rehabilitation program.* This section has been revised to include a new requirement that a State unit make necessary arrangements to ensure the availability of staff able to communicate in the native languages of minority groups which constitute substantial segments of the State's population. This section has also been revised to require that the State unit staff include personnel able to communicate with handicapped clients such as deaf, blind, and deaf-blind individuals who rely on special methods of communication. It is not expected that all personnel under this section will be full-time employees of the State unit although this would be likely in the case of rehabilitation counselors skilled in manual communication. The services of these personnel may be secured by the State unit under special contractual, volunteer, or other arrangements and on an as needed basis. It would be highly desirable in the case of clients from a minority group numerous in the State if the State unit staff person was not only fluent in the native language but was also familiar with the culture of the minority group with special reference to cultural attitudes toward disability.

§ *1361.16 Standards of personnel administration.* This section has been revised to reflect the fact that Section 602(a) of the Civil Service Reform Act (Pub. L. 95–454) amended Section 208 of the Intergovernmental Personnel Act to abolish all statutory personnel requirements established as a condition for the receipt of grants-in-aid by State and local governments. This amendment does not apply, however, to those programs which are required by statute to adhere to the Federal merit system standards of personnel administration. Since Section 101(a)(7)(A) of the Rehabilitation Act requires personnel standards to be established but does not require adherence to the Federal merit system standards, the amendment provided the Commissioner with an opportunity either to remove all personnel standard requirements in vocational rehabilitation or to apply the Federal merit system standards throughout the State-Federal vocational rehabilitation system. In line with the intent of the amendment to avoid inconsistent and conflicting approaches to State and local government personnel administration and to encourage uniform use of the Federal merit system standards, the Commissioner has chosen to propose that the Federal merit system standards be required under the State Plans for vocational rehabilitation services.

§ *1361.20 Cooperation with other public agencies.* This section has been revised to require that State vocational rehabilitation programs make specific arrangements for coordination with special education and vocational education agencies to provide services to any handicapped persons who might be eligible for assistance under an education program as well as under the vocational rehabilitation program and whose rehabilitation could be expected to be enhanced by a coordinated joint effort.

§ *1361.21 Establishment and maintenance of information and referral resources.* This section has been added to cover the new State Plan requirement concerning information and referral systems. It is expected that the State unit will utilize available resources to the greatest extent to ensure that information services and referral assistance are available to all handicapped persons in the State interested in vocational rehabilitation and related social and medical service

programs. The primary purpose of the State vocational rehabilitation program effort in this area will be to provide accurate information about service resources to its own clients, and to applicants for vocational rehabilitation services, and when necessary to make appropriate referral to other service providers.

This information and referral resource is expected to utilize available media to assist in keeping in touch with handicapped persons in the State. Special use can be expected to be made of newspapers, journals, and other publications which are directed to readership of handicapped persons.

§ *1361.22 State plan for rehabilitation facilities.* This section has been added to require the State unit to maintain an inventory of rehabilitation facilities and rehabilitation facility service needs in order to assist in meeting the overall mandate of the 1978 Amendments for an expanded and a more effective use of rehabilitation facilities. The State rehabilitation facilities plan will not be submitted as part of the State plan for vocational rehabilitation services but will be maintained separately by the State unit as a basis for planning and developing effective rehabilitation facility services. In addition to maintaining a list of facilities and a prioritized determination of facility needs, a State unit might also wish to include such data as the type of available services, the number of people served by each facility, and the extent to which facilities in the State are accredited.

§ *1361.23 Utilization of rehabilitation facilities.* This section has been added to cover the new State plan requirement affecting the establishment of specific policies to ensure appropriate State unit use of rehabilitation facilities. It is expected that the development of these policies will be related to each State's rehabilitation facilities plan and will lead to the preparation of specific operating guidelines governing referral to facilities by State unit counselors.

§ *1361.25 General administrative and fiscal requirements.* This is a new section applying certain current HEW regulations to State grants for vocational rehabilitation services. Insofar as the HEW regulations implementing OMB Circular A-102 are concerned, the use of in-kind matching is specifically prohibited. It is expected that additional HEW regulations will be issued in the future which will also apply to the State vocational rehabilitation program.

§ *1361.31 Eligibility for vocational rehabilitation services.* This section has been revised to provide for an opportunity for an interim determination of eligibility by State units in the case of applicants who have records of physical or mental disability and demonstrated difficulty in securing employment because of their disability. Under this approach a State unit which chooses to do so, would be able to initiate services to an individual immediately on application because of the likelihood on the basis of the presenting case records that the individual will be found eligible after a formal evaluation is completed.

State units will be expected to develop the policies under which services will be provided on the basis of an interim determination of eligibility and the procedures to be followed in achieving the final determination. The final determination of eligibility is required to be completed within 90 days.

This procedure is not derived from the 1978 Amendments nor is it intended to replace established procedures for the formal determination of eligibility. Its use, however, is based on the understanding that an individual's history of physical or mental disability and the clinical impressions gained by a professional rehabilitation worker at the time of initial contact can frequently be sufficient for determining the feasibility of providing vocational rehabilitation services to an applicant for services. The ability to begin a program of vocational training services and other services immediately on the basis of an interim determination of eligibility is expected to reduce many of the delays currently experienced by severly handicapped applicants for vocational rehabilitation services.

Special attention will be given to reviewing the experience of those State units which experiment with the use of an interim determination of eligibility. It is expected that States might wish to demonstrate the effectiveness of this approach with certain groups of severely handicapped individuals or in selected locations within a State.

The regulations do not propose specific criteria to be adopted by all States in applying an interim eligibility methodology. Public comment is especially desired on factors which might be considered in developing such criteria and whether they should be uniformly applied in all State programs.

Consideration was also given to revising § 1361.31 to add a special eligibility determination requirement for individuals with specific learning disabilities who are referred for State vocational rehabilitation agency services. When these individuals have a physical or mental disability in connection with their learning disability, they may of course be determined to be eligible for vocational rehabilitation services. A learning disability in and of itself is not considered either a physical or a mental disability for purposes of determining vocational rehabilitation eligibility, however, and these individuals are therefore frequently not found to be eligible under the vocational rehabilitation service program. It is recognized that appropriate diagnostic evaluations often provide evidence of minimal brain dysfunctions or other physical or mental disabilities and it has been suggested, therefore, that § 1361.31 be revised to require special diagnostic examinations for each person with a specific learning disability to determine whether a physical or mental disability does in fact exist.

Public comment is invited on the feasibility of adding this special requirement for this group of applicants for vocational rehabilitation services.

§ *1361.32 Evaluation of vocational rehabilitation potential: Preliminary diagnostic study.* This section has been revised in order to reduce processing time for applicants wishing vocational rehabilitation services by providing that available current medical information will be used to the greatest extent possible in carrying out the preliminary diagnostic study. This administrative revision will eliminate the need for a special medical examination to be carried out for most applicants for vocational rehabilitation services.

There has been considerable discussion in recent years about the elimination of a requirement for a general medical examination under the preliminary diagnostic study as another way to reduce administrative processing time. It must be pointed out therefore that there has in fact never been a regulatory requirement for a general medical examination of this type. The need for an appraisal of an applicant's current health status continues to be apparent, however, and this requirement has been retained.

§ *1361.33 Evaluation of rehabilitation potential: Thorough diagnostic study.* This section has been revised to require that a visual examination be provided to all deaf clients of State vocational rehabilitation units. For many years, State units have been required to provide hearing examinations to individuals with visual problems and rehabilitation workers concerned with the vocational rehabilitation of deaf individuals have frequently pointed out a need for a comparable procedure for deaf persons. Since resources for visual examinations are readily available to the public, it does not appear that this new administrative requirement will place a

processing or a financial burden on State units.

§ *1361.35 Certification: Eligibility; extended evaluation to determine vocational potential; ineligibility.* This section has been revised to provide for the possible referral to the State's independent living service program of individuals determined not to be eligible for vocational rehabilitation services.

This section has also been revised to cover those situations when a case is closed after an application has been submitted but before a determination of eligibility has been made. This administrative change is necessary to govern those situations where, for certain reasons, applicants do not follow through on their stated intentions to secure vocational rehabilitation services.

§ *1361.38 Services to handicapped American Indians.* This new section has been added to ensure that vocational rehabilitation services are available to handicapped American Indians in each State in a manner and at a level fully consistent with services available to other handicapped individuals in the State.

A new discretionary grant program of vocational rehabilitation services has been authorized under the 1978 Amendments for those handicapped American Indians who reside on Federal or State reservations. If a State continues to estimate its population for allocation purposes by including those Indians on reservations being served under a special project, the State unit will continue to be responsible for providing services on those reservations.

§ *1361.41 The individualized written rehabilitation program: Content.* This section has been revised to provide for the joint development of individualized programming for individuals eligible for both special education and vocational rehabilitation services.

§ *1361.42 Scope of State unit programs: Vocational rehabilitation services for individuals.* This section has been revised to clarify that "maintenance" and "transportation" are supportive vocational rehabilitation services which are provided only in conjunction with other vocational rehabilitation services contributing directly to achieving rehabilitation objectives.

This section has also been revised to broaden the definition of "institutions of higher education" in which vocational training services may be provided to include vocational schools, technical institutes and hospital schools of nursing. As revised, the definition is consistent with that used by the U.S. Office of Education in the administration of general student aid programs.

§ *1361.45 Standards for facilities and providers of service.* This section identifies standards to be adopted by State units as regards facilities to be used for providing services. It is recognized that certain States have established standards more stringent than those standards identified in the regulations. Where the construction of a facility is involved, it is expected that the more stringent State standards will be applied.

§ *1361.48 Administrative review of agency action and fair hearings.* This section has been revised to reflect the new opportunity available to handicapped individuals to request the Secretary of Health, Education, and Welfare to review any decision made by a State unit director with which the individual is dissatisfied. This procedure is in addition both to the formal procedures for administrative review and fair hearing and to the procedures available to a handicapped person under Section 504 of the Act.

§ *1361.49 Protection, use, and release of personal information.* This section has been revised in order to clarify the ways in which personal information about State unit clients and applicants may be obtained and released. This section also identifies policies covering the different uses for which the personal information may be released.

The revisions to this section have been made to bring about administrative consistency with the requirements of the Privacy Act and to deal with specific problems of information sharing which have been identified in recent years but which have not been resolved by the existing regulations. These revisions strengthen the safeguards for the rights of handicapped individuals to maintain the confidentiality of their personal information and emphasize the need for securing the consent of the individual before information may be released.

Requirements affecting the release of information about clients are not fully consistent among all public agencies which provide services to handicapped individuals. It is expected that State vocational rehabilitation programs will enter into organizational agreements covering this matter in order to bring about the greatest possible degree of consistency.

§ *1361.51 Scope of State unit program: Establishment of rehabilitation facilities.* This section has been revised to indicate that staffing assistance under an establishment project may now provide for "additional" as well as "initial" staff of a rehabilitation facility. In addition, under the revised section the need for an "establishment" project must be identified in the State plan for rehabilitation facilities required under § 1361.23.

§ *1361.52 Scope of State unit program: Construction of rehabilitation facilities.* This section has been revised to provide that the need for a construction project must be identified in the State plan for rehabilitation facilities required under § 1361.23.

§ *1361.54 Scope of State unit program: Telecommunications systems.* This section has been added to cover the newly authorized group service under the State plan designed to facilitate the use of different types of existing telecommunication systems.

§ *1361.55 Scope of State unit program: Special materials for blind individuals and deaf individuals.* This section has been added to cover the newly authorized group service under the State plan enabling State unit use of special materials for deaf individuals, blind individuals, and to the extent possible, deaf-blind individuals. In communities where there are substantial numbers of handicapped individuals from particular minority groups, it is expected that whenever possible the native language of these individuals will be used in connection with these special materials.

§ *1361.57 Utilization of profitmaking organizations.* This section has been added to cover the new State plan requirement that permits the State unit to enter into contractual arrangements with profitmaking organizations in order to provide on-the-job training for handicapped individuals participating under the projects with industry program (§ 1362.43 of the regulations) and the business opportunities for handicapped individuals program (§ 1362.107). Because of its specific applicability to these two assistance programs, it is expected that the use of this service will be somewhat limited.

Subpart C

§ *1361.71 Vocational rehabilitation services for individuals.* This section has been revised to clarify that certain special costs may be provided by State units under the State plan. These include the State unit costs of determining the eligibility of a handicapped individual to participate in the business opportunity program for handicapped individuals under § 1362.107 and the costs of native healing practitioners who provide services to handicapped American Indians under the ongoing vocational rehabilitation service program.

§ *1361.74 Construction of rehabilitation facilities.* This section has been revised to provide that Federal financial participation in the cost of construction of any rehabilitation facility will be no more than 50 percent of the total costs of the construction project.

Under the Act, the Federal share in the costs of a construction project is required to be the same percentage as that established under Section 645(g) of the Public Health Services Act, popularly known as the Hill-Burton program. Although the authority for this program is still in effect, there have been no appropriations under it since 1974 and matching rates have not been established and distributed by the Hill-Burton State agencies since 1976. In view of this, a Federal matching rate of 50 percent is being proposed for construction projects under the Rehabilitation Act since this percentage had been the most frequently used rate for the construction of rehabilitation facilities under the Hill-Burton program.

§ *1361.75 Other vocational rehabilitation services for the benefit of groups of handicapped individuals.* This section has been revised to provide that Federal financial participation will be available for the costs of the newly authorized services for groups of handicapped individuals.

§ *1361.76 State and local funds.* This section has been revised to clarify the use of certified funds to secure Federal matching funds under special cooperative programs with other agencies. The policy announced by the Commissioner in Program Instruction RSA–PI–78–22 dated June 5, 1978, "Termination of Federal Financial Participation for Third Party Funding Agreements," has been withdrawn and the use of these funds will be continued in accordance with this proposed section.

§ *1361.85 Allotment of Federal funds for vocational rehabilitation services.* This section has been revised to prescribe the special allotment procedures to be followed when a special project for vocational rehabilitation services for handicapped American Indians has been awarded under Section 130 of the Act. Under the procedures to be followed, the State will not begin to subtract the population of American Indians residing on reservations being served under a special project from its population estimates until after the end of the first full fiscal year in which the tribal project is operating.

§ *1361.86 Payments for allotments for vocational rehabilitation services.* This section has been revised to eliminate the previous requirement that States meet the Secretary's General Standards for Evaluation in order to receive payments under Title I of the Act. The 1978 Rehabilitation Act Amendments removed the requirement that failure to meet these General Standards be used as a basis for denying funds to a State vocational rehabilitation service program.

§ *1361.88 Liquidation of unpaid obligations.* This new section has been added to require that all obligations be liquidated within one year of the close of the fiscal year in which they were incurred. This section incorporates the policy promulgated by the Commissioner in "Program Instruction 77–20," dated May 5, 1977, intended to bring about greater administrative efficiency.

Subpart D

Subpart E

Subpart D of Part 1361, covering Payment of Costs of vocational Rehabilitation Services for Disabled Beneficiaries from the Social Security Trust Funds, and Subpart E governing Vocational Rehabilitation Services for Supplemental Security Income Recipients are not being revised at this time since the 1978 Amendments to the Rehabilitation Act did not directly affect these programs.

Subpart F

Subpart F of Part 1361 covers the program of grants for the innovation and expansion of vocational rehabilitation services. Within Subpart F, the following regulatory changes are proposed.

§ *1361.151 Special project requirements.* This section has been revised to provide that any construction of a rehabilitation facility undertaken under an innovation and expansion project must be essential to the conduct of the project and must be reflected in the State plan for rehabilitation facilities. The section has also been revised to clarify that grants may not be made solely for the purpose of planning future activities.

This section has not been revised insofar as the length of the project period for an innovation and expansion project is concerned. Although it appears that there may have been some legislative intent to extend the project period under this program from three years to five years, Section 121(b) of the Act, which controls the length of the project period, was not revised under the 1978 Amendments.

§ *1361.153 Payments from allotments.* This section has been revised to clarify that the matching rate for the construction of a rehabilitation facility under the innovation and expansion program is 50 percent—the same rate in effect elsewhere under the State plan for vocational rehabilitation services.

Subpart G

A new Subpart G has been added to Part 1361 to formalize the procedures to be followed when a hearing is necessary either because a State plan has been disapproved on the basis of its not meeting Federal requirements or because of a failure on the part of the State to administer the plan in compliance with the required provisions of the plan. These formal hearings procedures identify prehearing requirements which must be followed, the conduct of the hearing itself, and the post hearing procedures including the final determination made as a result of the hearing.

Although it is not expected that the procedures identified in this subpart will be extensively used, their publication in the regulations will clarify roles and responsibilities of all parties if a hearing should be necessary. Subpart G is based on the "Ad Hoc Rules of Practice and Procedure for Hearings on Conformity of State Plans for Vocational Rehabilitation Services with Federal Requirements under Title I of the Rehabilitation Act of 1973, as amended," which was published in the **Federal Register** of May 25, 1976.

Part 1362

Part 1362 has been substantially revised to update regulatory requirements affecting previously authorized discretionary grant and other assistance programs and to implement new discretionary programs authorized under the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978.

Subpart A

Subpart A of Part 1362 includes revised general provisions which apply to all projects and other activities assisted under Part 1362.

Within Subpart A, the following significant regulatory changes are proposed:

§ *1362.2 Application content and procedures for submitting applications.* This new section has been added to identify procedures which the Commissioner will follow in announcing the availability of funds in any program category covered under Part 1362 when there is a competition between applicants for available program funds.

These procedures reflect current Departmental practice in this regard.

§ *1362.3 State unit review and approval of applications.* This section has been revised to require State unit prior approval of applications for Federal support for only those proposals which include the direct provision of vocational services to handicapped individuals. Under previous regulations, State vocational rehabilitation units were expected to approve a broad range of applications for Federal grant assistance. If the application was not approved by the State unit, it was not considered eligible for Federal funding. Since there is no longer any basis for this practice under the Rehabilitation Act of 1973, as amended, the State unit prior approval function will be exercised only in those cases where the proposed project involves vocational rehabilitation services delivery to State unit clients. State unit approval is essential in projects of this type in order to ensure the cooperative responsibility which leads to project success.

§ *1362.4 Project period.* This section establishes 5 years as the maximum period of time for which the Rehabilitation Services Administration will generally commit funds for a multi-year period. If a grant with a multi-year project period has been awarded, the grantee is assured of support during the entire period provided that project management has been effective and funds for the overall program category have been appropriated by the Congress. A grantee in this situation is not required to compete with other applicants for the available funds since a commitment has been made.

At the end of the multi-year project period, however, there is no longer a Federal commitment and any grantee wishing additional support must compete with other applicants. After a five-year project period has terminated, a grantee may submit an application for extended support through an additional requested period of time. At this time there is no Federal commitment and the grantee must compete on the same terms and conditions as all other applicants for available grant funds.

Where a project support commitment level of other than five years has been established, the individual program regulation discussions in Part 1362 so indicate.

§ *1362.5 Matching requirements.* This section establishes 90 percent as the maximum Federal matching rate in Rehabilitation Services Administration discretionary projects. Where a Federal matching rate other than 90 percent is established, the individual program regulation discussions in Part 1362 so indicate.

§ *1362.8 Special requirements for projects which involve construction.* This section has been added to combine all requirements affecting projects in which construction activities are to be carried out. These requirements reflect both general Department of Health, Education, and Welfare requirements and requirements which are specific to the Rehabilitation Act.

§ *1362.10 Advisory committee membership.* This section has been added administratively to require that when project committees are established, their membership must be broadly representative and must include handicapped persons in order to ensure the relevance of project activities to service needs.

§ *1362.11 Special requirements affecting handicapped individuals with special communication problems.* This section has been added to extend to discretionary grant programs the State plan requirement that project staff be available which is able to communicate in the native languages of ethnic minorities or able to communicate with handicapped persons with special communication problems such as blind or deaf individuals. This extension is intended to bring about consistency within the State vocational rehabilitation service delivery system and ensure that all handicapped individuals with communication problems be provided an equal opportunity for assistance. For purposes of this requirement, project staff need not be full-time paid personnel but may include persons employed on a temporary or part-time basis specifically for this purpose. It is expected that volunteer personnel will also be available to a limited extent to meet this requirement.

§ *1362.12 Accessibility to project activities by handicapped persons.* This section has been added to require that facilities used in projects assisted with Rehabilitation Services Administration funds meet all the requirements of the Architectural Barriers Act of 1968. The section also requires that any facilities to be used for carrying out programs funded under Part 1362 be free from transportation or communication barriers which might in any way restrict the participation of any handicapped person in project activities.

§ *1362.16 Other HEW regulations which apply.* This new section has been added to identify those current Departmental regulations which apply to project activities funded under Part 1362.

Subpart B

Subpart B of Part 1362 includes those grant programs specifically designed for the provision of vocational rehabilitation services to handicapped individuals. Under this group of projects, the services are of the same type as those provided under State vocational rehabilitation programs and the individuals receiving the services are generally clients of the State vocational rehabilitation programs.

Within Subpart B the following significant regulatory changes are proposed:

§ *1362.40 Special projects and demonstrations: Improved services to severely handicapped individuals.* This section has been revised to reflect the fact that the authority for these projects under Section 311 of the Act, which had previously been under Section 304(b), was substantially changed under the 1978 Amendments.

In the first place, the revised authority refers to the persons to be served as "handicapped individuals . . . irrespective of age or vocational potential." Since the term "handicapped individual" is defined in Section 7(7) of the Act to mean a handicapped individual who is at or near working age and for whom a vocational potential is apparent, this use of the term presented many problems in the development of regulations. Because of this unusual use of the term "handicapped individual," it is expected that the scope of services within these projects will extend beyond vocational rehabilitation services and the individuals to be served will include other handicapped persons in addition to handicapped clients of the State vocational rehabilitation service programs.

This grant authority was also changed by the elimination of the previous special reference to "older blind individuals" and "deaf individuals whose maximum vocational potential has not been reached." Although some special projects and demonstrations under this section will continue to focus on services to blind or deaf individuals, the focus on these specific categories is expected to be less direct than it had previously been.

The revised authority also provides authority for the construction of a rehabilitation facility in connection with carrying out a special project or demonstration. The construction of a rehabilitation facility under this authority is intended to occur only when demonstrated to be essential for the conduct of a program of service delivery, however, and existing facilities

will be utilized for service delivery to the very greatest extent possible.

§ *1362.43 Projects with industry.* This section has been revised to reflect the expanded authority for the Projects with Industry Program under Section 621 of the Act. Under the expanded program, the scope of a project includes job modification, the distribution of special aids, appliances or equipment adapted to the needs of handicapped individuals, the modification of facilities and equipment, and the establishment of specialized job placement services.

The State vocational rehabilitation unit is expected to maintain a continuing relationship with the handicapped individuals participating in any project in order to ensure a continuity of vocational rehabilitation service delivery. If employment should be terminated for any handicapped individual within a three-year period, the Commissioner shall be entitled to require the repayment of a portion of funds made available to the employer.

In addition to these programmatic revisions, the 1978 Amendments imposed a ceiling of 80 percent on the amount of the total project costs which may be borned by the Rehabilitation Services Administration. Any currently operating project under this program will be required to finance the appropriate match when the next grant award is made.

§ *1362.45 Projects for American Indian vocational rehabilitation services.* This section has been added to cover a new grant program of vocational rehabilitation services for handicapped American Indians who reside on Federal or State reservations. Under this program a governing body of an Indian tribe may develop and implement a program of vocational rehabilitation services provided that the services are comparable to those services provided by the State unit to other handicapped persons in the State. In order to ensure that the tribal vocational rehabilitation program is in fact comparable, the tribal program will be required to meet certain of the basic State plan requirements met by the State unit in the administration of the State program. Special attention is to be paid by the tribal program to the priority to be given to severely handicapped persons in the provision of services, the reliance on an individualized written rehabilitation program to structure service planning and delivery for each client, the use of similar benefits for which clients may be eligible, and the participation of handicapped American Indians in tribal policy and program development.

General administrative requirements specified under the Indian Self-Determination and Education Assistance Act are also applicable under this program. In line with these requirements, it is expected that all applications which meet acceptable standards of program quality will be approved to the extent that funds are available and technical assistance will be provided to tribes where necessary to assist in meeting minimum program standards.

Services are to be provided under these projects only to those handicapped American Indians who are actually residing on reservations. Services are not to be provided to those American Indians who live near reservations. Those handicapped American Indians who for any reason have regularly lived away from the reservation during the week but return to the reservation on weekends, however, are considered to be residents of the reservation.

Subpart C

Subpart C of Part 1362 continues to cover assistance available to sheltered workshops and other rehabilitation facilities which are concerned with providing vocational rehabilitation services to handicapped individuals.

Within Subpart C the following significant regulatory changes are proposed:

§ *1362.52 Rehabilitation facility staffing.* This section has been revised to reflect the elimination of the "initial" staffing limitation under Section 301 of the Act.

Staffing grants for rehabilitation facilities may now be made to meet identified needs for additional staff for any facility which was constructed after September 26, 1973, the day on which the Rehabilitation Act of 1973 was enacted.

§ *1362.54 Grants for establishing or operating comprehensive rehabilitation centers.* This section has been added to implement a newly authorized program under Section 305 of the Act for establishing and operating comprehensive rehabilitation centers in communities throughout the country. The concept of a "comprehensive rehabilitation center" is a flexible one which may be fitted to meet any community's special service needs for handicapped individuals. A comprehensive rehabilitation center may mean a single facility which provides direct rehabilitation services to physically and mentally disabled persons; a consortium of facilities which are located throughout a community and which are coordinating their services under the comprehensive rehabilitation center program in order to achieve better information, referral and service delivery potential; or a community facility which serves primarily as an information and referral resource center which assists handicapped persons and other community agencies and facilities in securing needed services but which does not itself provide services to handicapped persons.

Comprehensive rehabilitation centers are seen primarily as focal points within a community for information and referral resources for handicapped persons. Interpreters for deaf persons, readers for blind individuals, attendants, legal assistance personnal and other essential service providers might be available from the centers which will retain rosters of persons who are available to provide services directly to handicapped persons or to other community facilities or agencies. The comprehensive rehabilitation centers are also expected to be important community resources for providing technical assistance to community agencies and facilities concerned with meeting the special requirements imposed under Section 504 of the Rehabilitation Act.

It is expected that existing facilities will be used as community comprehensive rehabilitation centers and very few new centers will be constructed specifically for the purpose of implementing this program.

Grants will be awarded by the Rehabilitation Services Administration only to designated State units for vocational rehabilitation. The State units may in turn award subgrants or contracts to community agencies or facilities which will directly operate comprehensive rehabilitation center programs.

§ *1362.55 Loan guarantees for rehabilitation facilities.* This section implements a new authority for the Commissioner to guarantee the payment of principal and interest on loans for the construction of rehabilitation facilities. These loans may be made by non-Federal lenders and by the Federal Financing Bank. Any rehabilitation facility for which a loan guarantee is to be provided under this program is required to meet those standards which are applied to facilities constructed with direct Federal construction grant support and must be identified in the State plan for rehabilitation facilities.

This section describes procedures for securing and repaying loans and defines the provisions of the Loan Guarantee Agreement which must be completed between the Commissioner and each applicant.

Subpart D

Subpart D is reserved for additional regulations which the Rehabilitation Services Administration may develop at some time in the future. Subpart D currently contains regulations governing the rehabilitation research program. The Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 transferred responsibility for this program to the National Institute of Handicapped Research which will be administering the program in close consultation with the National Council on the Handicapped.

The National Institute of Handicapped Research has not yet proposed regulations for the implementation of the expanded rehabilitation research program but it is expected that these regulations will be proposed after the National Institute has been fully established and organized.

Subpart E

Subpart E of Part 1362 covers the different categories of training supported under the rehabilitation training program. Although no new major training categories were authorized under the 1978 Amendments, the regulations have been revised to identify the existing training grant program categories more clearly than they have been in the past.

Within Subpart E, the following significant regulatory changes are proposed:

§ *1362.70 Rehabilitation long-term training.* This section covers long-term academic and non-academic training grants in the different established rehabilitation disciplines and grants for the support of special experimental or innovative rehabilitation training efforts.

The 1978 Amendments added the fields of rehabilitation psychiatry and rehabilitation job placement to the list of fields in which long-term training grants are to be made available under the rehabilitation training grant program. The 1978 Amendments also broadened the scope of the training to be supported by identifying as a purpose of the program the training of medical, social, and psychological rehabilitation service personnel in addition to the vocational rehabilitation service personnel who had previously been identified in the Act. It is expected that training in certain professional fields such as physical medicine and rehabilitation, prosthetics-orthotics, physical therapy and occupational therapy will therefore be required to be somewhat less directly linked to the State vocational rehabilitation service program in order to be eligible for funding in the future.

§ *1362.71 State vocational rehabilitation unit in-service training.* This section provides specific requirements for the State in-service training grant program. These in-service training grants have been awarded under the rehabilitation training grant program since 1959 but they never before been distinctly identified in the regulations. Grants are awarded to the designated State units in each State since these units are the primary providers of rehabilitation services.

§ *1362.72 Rehabilitation continuing education program.* This section identifies specific requirements for the rehabilitation continuing education programs. These programs make training available to rehabilitation personnel who are employed in either public or private agency settings. The training under these programs is intended to meet recurrent staff development needs and generally includes training which is more efficiently conducted on a multi-State basis.

§ *1362.73 Rehabilitation short-term training.* This section consolidates in a single section regulatory material previously located throughout Subpart E concerning the rehabilitation short-term training program.

§ *1362.74 Rehabilitation research fellowships.* This new section consolidates in a single section regulatory material previously located throughout Subpart E concerning the rehabilitation research fellowship program.

Under this program fellowships have been awarded for many years to individuals wishing to undertake an advanced research project or preparing for careers as researchers in the rehabilitation of physically and mentally disabled persons. The 1978 Amendments revised the authority for the rehabilitation research fellowship program by omitting any specific reference to it. Because there is no evidence of a Congressional intent to repeal authority for the rehabilitation research fellowship program and because of its longstanding authorization in connection with the authority for "short-term training and instruction," it is planned that the program will continue to be administered within the Rehabilitation Services Administration as part of the rehabilitation training grant program.

Subpart F

Subpart F of Part 1362 covers the Helen Keller National Center for Deaf-Blind Youths and Adults.

This subpart, as revised, now provides that, to the extent feasible, the Helen Keller National Center shall seek reimbursement from other programs for the costs of services provided by the Center.

Subpart G

Subpart G is reserved for additional regulations which the Rehabilitation Services Administration may develop at some time in the future.

Subpart G currently contains regulations concerned with program evaluation. Since the Commissioner carries out program evaluation studies under contract and since program requirements are included within the scope of each contract, special regulations in this area are not considered to be necessary.

It is also important to note that under the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, the use of the Secretary's General Standards for Evaluation has been substantially changed and there is no longer a requirement that the General Standards be used to determine whether funds for any programs or projects under the Act should be withheld. The General Standards will now be used as a tool for program development rather than as a measure of program compliance. As a result, Part 1370 which contains these General Standards will be removed from the Code of Federal Regulations and will no longer be published as regulations.

It is planned that the General Standards will be published in the **Federal Register** as a Notice for the use of State units, public and other nonprofit grantees, and others interested in the evaluation of rehabilitation programs. Although Federal funds may no longer be cut off because of a failure to meet the General Standards, the Standards can be expected to continue to be a useful and valuable tool in the conduct of program evaluation studies.

Subpart H

Subpart H of Part 1362 is a new subpart combining a number of different special project authorities which extend beyond the traditional scope of vocational rehabilitation service delivery. Some of these new programs relate to independent living services while others are designed to provide services which extend beyond the traditional vocational rehabilitation purposes.

Within Subpart H, the following significant regulatory changes are proposed:

§ *1362.100 Projects for the establishment of centers for independent living.* This section has been added to implement a new grant program to assist in establishing and operating centers for independent living. These centers are expected to be multi-purpose facilities able to provide a broad range of assistance to severely handicapped persons in order to help them to achieve greater independence in either their family or community living situations. Severely handicapped persons will be substantially involved in the management and operation of centers operating under this program but no attempt has been made to establish by regulation a specific percentage requirement defining the necessary extent of participation by handicapped persons in center management and operation. The extent to which handicapped persons are responsible for center operations can be expected to be an important factor to be considered in the competitive review of applications, however, and the development of self-help organizations will be encouraged under this program.

For the first six months of any fiscal year, only the designated State units which administer the State's independent living program will be eligible to apply for a grant. If a State indicates by that time that it does not intend to apply for a grant, any local public agency or private nonprofit organization in the State will be eligible to apply directly for Federal funds. Every effort will be made in the administration of this program to ensure that the availability of funds is announced in a timely manner so that all eligible applicants may have an adequate opportunity to participate.

§ *1362.101 Grants for independent living rehabilitation services for older blind individuals.* This section has been added to implement a new grant program designed to assist older blind individuals in adjusting to the onset of blindness and in learning to function independently in spite of their disability. This program is intended to be primarily short-term in its effect and it is not intended to provide services to any single individual for an extended period of time.

Individuals to be assisted under this program will be 55 years of age or older and will be expected to have experienced a severe loss in visual acuity.

Applications for Federal grants may be made only by the State units administering the State's independent living service program. The State units may in turn award subgrants to other public and nonprofit agencies and organizations in the State.

When any methods demonstrated under one of these projects have been found to be unusually effective, they will be expected to be integrated within the ongoing State programs for independent living services carried out under State plans.

§ *1362.102 Grants for the protection and advocacy of the rights of severely handicapped individuals.* This section has been added to cover a newly authorized program of protection and advocacy assistance for severely handicapped individuals being provided independent living services under either the State program for independent living services or under any other special project concerned with independent living under Subpart H.

These protection and advocacy projects will play a role in independent living programming similar to that played by the client assistance programs in the vocational rehabilitation program. Whereas only a State vocational rehabilitation program may apply for client assistance program funds, however, the State vocational rehabilitation program unit is specifically prohibited from administering a protection and advocacy project under this section.

It is expected that many of these protection and advocacy programs will be administered by the same agency which administers the State's system for protection and advocacy of individual rights under the Developmental Disabilities Assistance and Bill of Rights Act. In order to provide maximum administrative flexibility to States in designating an agency under this program, however, eligibility for applying for grant funds has not been limited to agencies which are currently administering protection and advocacy systems.

§ *1362.103 Client assistance projects.* This section has been relocated in Subpart I and revised to strengthen the role of the client assistance project staff in working with the State vocational rehabilitation programs.

§ *1362.104 Project grants for interpreters for the deaf.* This section has been added to implement a new program of interpreter services for deaf individuals. Under this program, designated State units will be able to make special arrangements to provide interpreter services directly to deaf individuals and to other agencies and organizations which work with deaf individuals. No agency or organization will be charged for these services during the first year in which interpreter services are provided to them, but after that time they will be expected to reimburse the State unit for services which are provided. A primary purpose of this program is to assist those agencies and organizations which are having difficulty in meeting requirements under section 504 of the Act designed to eliminate barriers to the full participation of deaf and other communcatively disabled persons. It is expected that after an initial period of outside assistance under this grant program, these agencies will be better able to develop their own resources for meeting these responsibilities.

Interpreters participating in this program shall be expected to be certified by any national certifying organization recognized by the Commissioner or by a recognized State certifying agency or organization. The regulations do not propose a single national certification requirement.

§ *1362.105 Special projects for the training of interpreters for the deaf.* This section has been added to cover a newly authorized grant program for the training of interpreters for deaf persons. Although significant training of interpreters for deaf persons has been supported over the years under the rehabilitation training grant program (Subpart E), the training has been focused primarily on assisting deaf persons in matters related to their vocational rehabilitation. Under this new program which will be administered by the Office of Information and Resources for the Handicapped in the Office of Human Development Services, no special reference to the vocational rehabilitation service program will be required and the employment goals of trainees will be broad.

These grants will assist in the establishment of new training programs or the expansion of existing ones but no more than a total of twelve programs may be assisted nationally.

§ *1362.116 Projects for reading services for blind individuals.* This section has been added to implement a newly authorized grant program to provide a broad scope of reading services to blind individuals. State units and agencies and organizations with a national scope may apply for these grants which will support such project activities as direct reading from printed materials, transcription into braille, radio reading services and tactile reading for deaf-blind persons.

It is expected that existing reading service resources will be utilized to the greatest extent possible with special reliance being put on the Library of Congress and its network of libraries serving blind and visually handicapped

individuals. Reading services under this program, however, are expected to be made available only for handicapped persons not eligible to receive them under any other program.

§ *1362.107 Business opportunities for handicapped individuals.* This section has been added to cover a new program of direct Federal support for handicapped persons who wish to establish and operate commercial or other kinds of enterprises. In order to participate in this program, each handicapped individual must be certified as eligible by the State unit in the State in which he or she resides. Most handicapped individuals interested in participating in the program will already be clients of State vocational rehabilitation programs at the time that they request to be certified. Other individuals may also request to be certified, however, and in these cases, the State unit will secure sufficient information not only to determine whether the individual is eligible for services under the State vocational rehabilitation program but also to assess the individual's capacity to operate an enterprise of the general type being planned. A State unit might begin a program of vocational rehabilitation services for any handicapped individual who had not previously been a client but who has been determined to be eligible for vocational rehabilitation services because of a request for certification under this program.

The State unit evaluation is focused on the capacity of the handicapped individual to establish or operate an enterprise and will not be concerned with the likelihood that the enterprise being proposed by the handicapped individual will be successful. The State unit may assist the handicapped individual in preparing the comprehensive business plan which is required as part of the application for Federal assistance and in assisting the individual in applying to the Small Business Administration for Handicapped Assistance Loan program funds.

The purpose of this program is not to provide rehabilitative services but rather to assist in opening up business opportunities. There is no limitation on the type of profit-making enterprise which may be established and operated and the form of the enterprises may include proprietorships, corporations, and cooperatives. It is expected that assistance will be provided to a large number of enterprises engaged in developing or marketing products which meet special needs of handicapped persons throughout the country.

A limitation on the amount of Federal assistance provided to any enterprise has been set at $100,000. This amount reflects the experience gained in the administration of other Federal programs of assistance for handicapped persons and persons from minority groups who wish to establish or operate business enterprises.

It is expected that the Handicapped Assistance Loan Programs of the Small Business Administration will continue to be the primary Federal resource for handicapped persons interested in establishing commercial or other enterprises. A grant will not be awarded if sufficient funds are available on reasonable terms from private sources, or from other local, State, or Federal programs. The Commissioner will generally refer to the Small Business Administration and individual who has not yet explored the availability of loans from that office. Grant funds may be used to supplement a Handicapped Assistance Loan and, in addition, funds awarded by the Commissioner may be used by the individual to attract additional necessary capital from other sources.

Because of the unusual nature of this new authority, the Commissioner may utilize different administrative approaches in its implementation. The objective of pursuing alternative administrative approaches will be to demonstrate ways to develop the closest possible working relationships with the Small Business Administration.

Section 622 of the Act under which this program is authorized provided that "within ninety days after the effective date of this section, the Commissioner shall promulgate regulations to carry out this section." Because of the fact that funds to initiate this program were not included in the FY 1979 budget for the Rehabilitation Services Administration and because of a desire to propose all regulations implementing the 1978 Rehabilitation Act Amendments simultaneously, the publication of these regulations has been delayed until this time.

§ *1362.108 Special projects and demonstrations for making recreation activities accessible to handicapped individuals.* This section has been relocated in Subpart H but has not been significantly revised. This program is primarily intended to be a demonstration program focusing on ways in which recreation activities can be made fully accessible to handicapped individuals.

§ *1362.109 Project grants for the initiation of special recreation programs for handicapped individuals.* This section has been added to cover a new grant program to assist communities in initiating programs of recreation services to handicapped individuals. The recreation services are expected be broad in scope and to provide equal opportunity in recreation for handicapped individuals.

§ *1362.110 Technical assistance.* For many years the Rehabilitation Services Administration has provided technical assistance to rehabilitation facilities to assist them in improving their overall level of program operations. The 1978 Amendments included a special authority in Section 506 for the Secretary to provide technical assistance in matters relating to the removal of architectural, transportation and communication barriers but did not include specific authority for the generalized technical assistance program to assist rehabilitation facilities which had been carried out successfully for many years.

Section 12 of the Act provides a general authority for the Commissioner to provide "technical assistance" and it is planned that the ongoing technical assistance program for rehabilitation facilities will be continued under this authority. Since it appears that the Congress intended that the Commissioner provide technical assistance relating to the removal of architectural, transportation, and communication barriers in addition to the ongoing technical assistance for rehabilitation facilities, this expand focus has been reflected in Subpart H.

Part 1363

A new Part 1363 is being added to implement the State plan for independent living rehabilitation services newly authorized under Title VII of the Act. Under this State-Federal service program, the State unit which provides vocational rehabilitation services in each State under Title I may, if the State so desires, provide independent living services to severely handicapped individuals. Independent living services are rehabilitation services aimed at assisting a severely handicapped individual to gain maximum control over the management of his or her life activities and to minimize reliance on others in providing for one's self-maintenance. These services do not necessarily have a vocational objective and may include a number of services not otherwise easily available for severely handicapped persons in the State such as attendant care, housing, health maintenance and therapeutic treatment. Independent living services may also include basic vocational rehabilitation services such as interpreter services for deaf persons

and reader services for blind persons which—when provided under Title VII—are provided for the purpose of assisting a severely handicapped individual to achieve independent living goals.

The independent living program is distinguished from the vocational rehabilitation service program primary by the fact that one of the purposes of providing the services is to assist the individual to improve or maintain his ability to function more independently in family and community rather than to achieve a vocational goal. Title VII also provides that an objective of independent living rehabilitation services is to assist a severely handicapped individual to "engage or continue in employment," however, so there can be expected to be some individuals who will be eligible concurrently for service under both the vocational rehabilitation and independent living services programs in a State. In such cases, it is generally expected that the vocational rehabilitation program will be the primary service provider and services will be provided under Title I.

It is expected that for the most part individuals receiving independent living services will be persons who have been considered too severely disabled to benefit meaningfully from vocational rehabilitation in terms of their employability. On the other hand, it is expected that many severely handicapped persons who will receive independent living services will demonstrate a vocational potential and will be referred to the State's vocational rehabilitation program for eventual vocational placement. It must be pointed out in this regard, however, that the Title VII program is not intended to replace the "extended evaluation" provisions under Title I. Where the feasibility of providing vocational rehabilitation services is unusually difficult to determine for an applicant for vocational rehabilitation services, it is expected that the "extended evaluation" procedures will continue to be followed.

The State plan for independent living services will be administered under a State plan separate from the State plan for vocational rehabilitation services. The proposed regulations for the State plan for independent living services have to a great extent been modeled on the regulations for the State plan for vocational rehabilitation services. Certain areas of the independent living State plan, nonetheless, will be quite distinct from the State vocational rehabilitation program regulations since they respond to unique statutory requirements of Title VII.

Within Part 1363, the following State plan provisions of special significance are proposed:

§ *1363.1 Terms.* A definition of "independent living rehabilitation services" is being proposed to include a broad scope of services which may be designed to assist an individual to function more independently in family and community living activities and, where appropriate, to assist the individual to engage or continue in employment. Since the Act indicates that vocational rehabilitation may also be provided as independent living services, the definition specifically includes those services identified in Part 1361.

Group services under the State vocational rehabilitation plan are also included as independent living services and these include both the establishment and construction of a rehabilitation facility. Many centers for independent living meet the definition of "rehabilitation facility" under the Rehabilitation Act on the basis of their functional responsibilities and it is expected that these facilities may be developed under the Title VII authority.

A definition of "severely handicapped individual" is being proposed to describe a client of the State independent living service program. This definition is different from the definition of "severely handicapped individual" used for purposes of ensuring priority of service under the State's vocational rehabilitation program under Part 1361.

§ *1363.2 The State plan: General requirements.* This section proposes requirements for the State plan for independent living services. If a State wishes, it may submit a State plan which consolidates the State's plan for vocational rehabilitation and developmental disabilities with the State's independent living plan.

§ *1363.6 State unit for administration.* This section provides that only the State unit designated under the vocational rehabilitation program may serve as the State unit for independent living. This designation includes those State units which provide vocational rehabilitation services only to blind persons. The State unit shall be solely responsible for decisions affecting the provision of independent living services under its program.

§ *1363.7 Staffing of designated State unit.* This section sets minimal staffing requirements for the independent living service programs and it is not expected that the rehabilitation counselor model will be uniformly transferred without modification from the vocational rehabilitation service program in all States.

§ *1363.9 State unit studies and evaluations.* This section requires the State unit to carry out studies to determine the relative effectiveness of different possible means of providing independent living services. The State unit will also be expected to conduct periodic evaluations to measure the overall performance of the unit in providing services. These studies and evaluations are expected to be reflected in the State's independent living services program. In addition, the State unit will be expected to seek the advice of providers and other persons interested in independent living services as policies and procedures are developed under this program.

§ *1363.11 Provision of technical assistance in poverty areas.* This section requires the State unit to make special effort to provide technical assistance to public and other nonprofit agencies and organizations located in areas of urban or rural poverty.

§ *1363.13 Utilization of local public and private nonprofit agencies, organizations, and facilities.* This section requires that the State unit will extensively utilize local public and private nonprofit agencies, organizations, and facilities in providing independent living rehabilitation services. In order to encourage the broadest participation by these agencies, organizations, and facilities, it is required that at least 20 percent of the funds received by a State will be used to make grants to these agencies unless a special waiver from this requirement has been granted by the Commissioner. Any grant made by a State unit will be designed primarily to support a program of independent living rehabilitation services for severely handicapped persons eligibile under the State plan program.

§ *1363.14 Independent living services for older blind individuals.* This section requires the State unit to integrate into its program of services any approaches or methods demonstrated under a discretionary project grant under § 1362.101 to be particularly successful in working with older blind individuals.

§ *1363.16 Other administrative and fiscal requirements.* This section applies to the State independent living service program certain regulatory requirements in effect under the State vocational rehabilitation service program and certain other regulatory requirements in effect throughout the Department of Health, Education, and Welfare. This section further provides that in-kind matching is acceptable under the Title

VII program and that costs of administering the Title VII program are to be borne under Title VII.

§ *1363.31 Eligibility.* This section provides that in determining eligibility for independent living services there will be a determination that services can feasibly be expected to assist an individual to function more independently or maintain his or her ability to function independently in family or community or to engage or continue in employment.

§ *1363.32 Determination of eligibility for independent living rehabilitation services.* This section requires that the determination of eligibility under this program will be based to the greatest extent possible on existing case record information. Special diagnostic studies will be conducted in connection with eligibility determination only where absolutely essential.

The purpose of the evaluation will be both to determine eligibility for independent living services and to identify the services which need to be provided.

§ *1363.33 Certification of eligibility and ineligibility.* This section provides that a certification of eligibility or ineligibility will be completed and reviewed under this program in a manner similar to that carried out under the State vocational rehabilitation program.

§ *1363.34 Order of selection for services.* This section identifies those groups of severely handicapped individuals specified by the State to be given priority in the provision of independent living services when services cannot be provided to all eligible persons who apply. Special priority is to be given to severely handicapped individuals, including the homebound, who are not receiving vocational rehabilitation services, institutionalized individuals, and individuals in danger of becoming institutionalized. In addition, the Commissioner may identify from time to time other groups of severely handicapped individuals to whom priority is to be given in selecting for service.

§ *1363.35 The case record for the individual.* This section provides that a case record will be maintained for each individual and further provides that the progress of each individual will be reviewed within the record at least annually.

§ *1363.36 The individualized written rehabilitation program for independent living rehabilitation services.* This section provides that an individualized written rehabilitation program will be developed for all individuals served under Title VII. Among other things, the individualized written rehabilitation program will indicate the amount of time estimated to be necessary for the provision of services for each individual.

The procedures for the development of the individualized written rehabilitation program will be similar to those procedures in effect under the State vocational rehabilitation program.

§ *1363.37 Scope of State program: Independent living rehabilitation services for individuals.* This section sets out the full scope of the independent living rehabilitation services which may be provided to severely handicapped individuals under the State plan.

Some of the independent living services are the same as vocational rehabilitation services provided under Part 1361. When an individual who is eligible for vocational rehabilitation is being provided services solely for the purpose of continuing or engaging in employment, it is required that the individual be served under the vocational rehabilitation program.

§ *1363.38 Case closure.* This section provides that a case will be closed when the objectives which were set for the individual in his or her individualized written rehabilitation program have been achieved.

§ *1363.39 Duration.* This section requires that no overall durational requirement be established under the State plan limiting the provision of services. The anticipated duration of each service for any individual must be identified in that individual's written rehabilitation program.

§ *1363.41 Scope of State unit program: Establishment and construction of rehabilitation facilities.* This section provides that the establishment and construction of rehabilitation facilities supported under the State plan will be expected to be intended primarily to provide independent living services for severely handicapped individuals. Although independent living centers are not specifically identified within the definition of "rehabilitation facility," it is noted that many of these centers fall under this definition and are considered to be rehabilitation facilities.

Operation Common Sense: In addition to specific identified policy revisions, these proposed regulations include existing regulations rewritten in an attempt to simplify them and make them generally easier to understand. These revisions have been made in line with the principles of the Department's Operation Common Sense.

Public Participation: These proposed regulations were developed on the basis of an extensive and broadly focused public participation effort. To begin this effort, a national workshop was held January 17–19, 1979 to discuss the full range of policy development issues presented by the 1978 Amendments. Participating in the workshop were approximately 200 representatives of organizations of handicapped individuals, State vocational rehabilitation and developmental disabilities agency personnel, rehabilitation facility personnel, developmental disabilities State planning council staff and members, researchers, and representatives of other Federal agencies.

Individuals attending the national workshop and other individuals representing national organizations with a rehabilitation orientation were encouraged to send written comments and suggestions concerning the policy development activity. Approximately 75 letters were received and these letters were carefully reviewed.

In addition, a series of discussion meetings was organized around specific areas of program development in order to discuss the proposed regulations in the very early stages of their development. Participating in these meetings were providers of services, handicapped consumers and their representatives, and others interested in rehabilitation services.

The National Conference on Independent Living was conducted March 7–9, 1979 for the purpose of securing consumer guidance in the area of independent living. Approximately 100 consumers, attendants and service providers participated in this conference.

Over and above this specific consultation, special attention has been paid to the recommendations made at the recent White House Conference on Handicapped Individuals. Wherever possible, these recommendations are reflected in the proposed regulations.

Invitation To Comment: Interested persons are invited to submit written comments, suggestions, and recommendations to be considered prior to the issuance of the final regulations. Comments, suggestions, or recommendations may be sent to the address given at the beginning of these proposed regulations. All comments received on or before the 90th day after publication of these proposed regulations will be considered. All comments submitted in response to this notice will be available for public inspection both during and after the comment period in Room 3323 Mary E. Switzer Building, 330 C Street, S.W., Washington, D.C. 20201 between the

hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except on Federal holidays.

Authority: These proposed regulations are issued under the authority of section 12(c) of the Rehabilitation Act of 1973, as amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978.

(Catalog of Federal Domestic Assistance Program Numbers 13.624, Rehabilitation Services and Facilities—Basic Support; 13.626, Rehabilitation Services and Facilities—Special Projects; 13.628, Rehabilitation Training)

Dated: June 5, 1979.

Robert R. Humphreys,

Commissioner, Rehabilitation Services Administration.

Approved: September 27, 1979.

Arabella Martinez,

Assistant Secretary for Human Development Services.

Approved: November 6, 1979.

Patricia Roberts Harris,

Secretary.

It is proposed to amend Chapter XIII of Title 45 of the Code of Federal Regulations as follows:

1. Part 1361 is revised to read a follows:

PART 1361—THE STATE VOCATIONAL REHABILITATION SERVICES PROGRAM

Subpart A—Definitions

Sec.

1361.1 Terms.

Subpart B—State Plans for Vocational Rehabilitation Services

State Plan Content: Administration

1361.2 The State plan: General requirements.
1361.3 Review of State plan by Governor.
1361.4 State plan approval and disapproval.
1361.5 Withholding of funds.
1361.6 State agency for administration.
1361.7 Organization of the State agency.
1361.8 [Reserved]
1361.9 State unit director.
1361.10 Local administration.
1361.11 Methods of administration.
1361.12 Shared funding and administration of special joint projects or programs.
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1361.14 Cooperative programs involving funds from other public agencies.
1361.15 Staffing of the State's vocational rehabilitation program.
1361.16 Standards of personnel administration.
1361.17 Staff development.
1361.18 State studies and evaluations.
1361.19 Policy development consultation.
1361.20 Cooperation with other public agencies.

Sec.

1361.21 Establishment and maintenance of information and referral resources.
1361.22 State plan for rehabilitation facilities.
1361.23 Utilization of rehabilitation facilities.
1361.24 Reports.
1361.25 General administrative and fiscal requirements.

State Plan Content: Provision and Scope of Service

1361.30 Processing referrals and applications.
1361.31 Eligibility for vocational rehabilitation services.
1361.32 Evaluation of vocational rehabilitation potential: Preliminary diagnostic study.
1361.33 Evaluation of vocational rehabilitation potential: Thorough diagnostic study.
1361.34 Extended evaluation to determine vocational rehabilitation potential.
1361.35 Certification: Eligibility; extended evaluation to determine vocational rehabilitation potential; ineligibility.
1361.36 Order of selection for services.
1361.37 Services to civil employees of the United States.
1361.38 Services to handicapped American Indians.
1361.39 The case record for the individual.
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1361.41 The individualized written rehabilitation program: Content.
1361.42 Scope of State unit program: Vocational rehabilitation services for individuals.
1361.43 Individuals determined to be rehabiliated.
1361.44 Authorization of services.
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1361.46 Rates of payment.
1361.47 Participation by handicapped individuals in the costs of vocational rehabilitation services.
1361.48 Administrative review of agency action and fair hearing; review by Secretary.
1361.49 Protection, use, and release of personal information.
1361.50 Scope of State unit program: Management services and supervision for small business enterprises for severly handicapped individuals.
1361.51 Scope of State unit program: Establishment of rehabilitation facilities.
1361.52 Scope of State unit program: Construction of rehabilitation facilities.
1361.53 Scope of State unit program: Facilities and services for groups of handicapped individuals.
1361.54 Scope of State unit program: Telecommunications systems.
1361.55 Scope of State unit program: Special materials for blind individuals and for deaf individuals.
1361.56 Utilization of community resources.
1361.57 Utilization of profitmaking organizations for on-the-job training in connection with selected projects.
1361.58 Periodic review of extended employment in rehabilitation facilities.

Subpart C—Financing of State Vocational Rehabilitation Programs

Sec.

Federal Financial Participation

1361.70 Effects of State rules.
1361.71 Vocational rehabilitation services to individuals.
1361.72 Management services and supervision for small business enterprises for severely handicapped individuals.
1361.73 Establishment of rehabilitation facilities.
1361.74 Construction of rehabilitation facilities.
1361.75 Other vocational rehabilitation sevices for the benefit of groups of handicapped individuals.
1361.76 State and local funds.
1361.77 Shared funding and administration of joint projects or programs.
1361.78 Waiver of Statewideness.

Allotment and Payment

1361.85 Allotment of Federal funds for vocational rehabilitation services.
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1361.87 Methods of computing and making payments.
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Subpart F—Grants for Innovation and Expansion of Vocational Rehabilitation Services

1361.150 Purpose.
1361.151 Special project requirements.
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Subpart G—Procedures for Hearings on State Plan Conformity and Compliance

1361.170 General provisions.
1361.171 How to request a hearing.
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1361.173 What the purpose of a hearing is.
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1361.179 Discovery.
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1361.182 What the record is.
1361.183 Posthearing briefs.
1361.184 Decisions.
1361.185 When a decision is effective.
1361.186 How the State may appeal.

Authority: Section 12(c) of the Rehabilitation Act of 1973, (29 U.S.C. 711(c)).

Subpart A—Definitions

§ 1361.1 Terms.

For the purpose of this part—

"Act" means the Rehabilitation Act of 1973 (29 U.S.C. § 701 et seq.) as amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95–602).

"Blind" or "blind individual" means a person who is blind within the meaning of the law relating to vocational rehabilitation in each State.

"Commissioner" means the Commissioner of the Rehabilitation Services Administration.

"Construction of a rehabilitation facility" means:

(a) The construction of new buildings, the acquisition of existing buildings, or the expansion, remodeling, alteration or renovation of existing buildings which are to be utilized for rehabilitation facility purposes; or

(b) The acquisition of initial equipment of such new, newly acquired, newly expanded, newly remodeled, newly altered or newly renovated buildings.

"Designated State unit" or "State unit" means either:

(a) The State agency vocational rehabilitation bureau, division, or other organizational unit which is primarily concerned with vocational rehabilitation or vocational and other rehabilitation of handicapped individuals and which is responsible for the administration of the vocational rehabilitation program of the State agency; or

(b) The independent State commission, board, or other agency which has vocational rehabilitation, or vocational and other rehabilitation as its primary function.

"Eligible" or "eligibility," when used in relation to an individual's qualification for vocational rehabilitation services, refers to a certification that:

(a) An individual has a physical or mental disability which for that individual constitutes or results in a substantial handicap to employment; and

(b) Vocational rehabilitation services may reasonably be expected to benefit the individual in terms of employability.

"Employability" refers to a determination that the provision of vocational rehabilitation services is likely to enable an individual to enter or retain employment consistent with his capacities and abilities in the competitive labor market; the practice of a profession; self-employment; homemaking; farm or family work (including work for which payment is in-kind rather than in cash); sheltered employment; homebound employment; or other gainful work.

"Establishment of a rehabilitation facility" means:

(a) The acquisition, expansion, remodeling, or alteration of existing buildings, necessary to adapt them or increase their effectiveness for rehabilitation facility purposes;

(b) The acquisition of initial or additional equipment for these buildings essential for providing vocational rehabilitation services; or

(c) The initial or additional staffing of a rehabilitation facility for a period, in the case of any individual staff person, not longer than 4 years and 3 months.

"Evaluation of vocational rehabilitation potential" means, as appropriate, in each case:

(a) A preliminary diagnostic study to determine that an individual is eligible for vocational rehabilitation services;

(b) A thorough diagnostic study consisting of a comprehensive evaluation of pertinent factors bearing on the individual's handicap to employment and vocational rehabilitation potential, in order to determine which vocational rehabilitation services may be of benefit to the individual in terms of employability;

(c) Any other goods or services necessary to determine the nature of the handicap and whether it may reasonably be expected that the individual can benefit from vocational rehabilitation services in terms of employability;

(d) Referral to other agencies or organizations, when appropriate; and

(e) The provision of vocational rehabilitation services to an individual during an extended evaluation of rehabilitation potential for the purpose of determining whether the individual is a handicapped individual for whom a vocational goal is feasible. "Family member" or "member of the family" means any relative by blood or marriage of a handicapped individual and other individual living in the same household with whom the handicapped individual has a close interpersonal relationship.

"Handicapped individual" except in § 1361.16(c), § 1361.51(e), § 1361.52(g), and § 1362.7, means an individual:

(a) Who has a physical or mental disability which for that individual constitutes or results in a substantial handicap to employment; and

(b) Who can reasonably be expected to benefit in terms of employability from the provision of vocational rehabilitation services, or for whom an extended evaluation of vocational rehabilitation potential is necessary to determine whether he or she might reasonably be expected to benefit in terms of employability from the provision of vocational rehabilitation services;

"Handicapped individual," for purposes of § 1361.16(c), § 1361.51(e), § 1361.52(g), and § 1362.7, means an individual:

(a) Who has a physical or mental impairment which substantially limits one or more major life activities;

(b) Who has a record of such an impairment; or

(c) Who is regarded as having such an impairment. "Local agency," unless the context clearly indicates differently, means an agency of a unit of general local government or of an Indian tribal organization (or combination of such units or organizations) which has the sole responsibility under an agreement with the State agency to conduct a vocational rehabilitation program in the locality under the supervision of the State agency in accordance with the State plan.

"Nonprofit," refers to a rehabilitation facility, agency, or organization owned and operated by one or more nonprofit corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual and the income of which is exempt from taxation under section 501(c)(3) of the Internal Revenue Code of 1954.

"Physical and mental restoration services" means:

(a) Medical or corrective surgical treatment;

(b) Diagnosis and treatment for mental or emotional disorders by a physician skilled in the diagnosis and treatment of such disorders or by a psychologist licensed or certified in accordance with State laws and regulations;

(c) Dentistry;

(d) Nursing services;

(e) Necessary hospitalization (either inpatient or outpatient care) in connection with surgery or treatment and clinic services;

(f) Convalescent or nursing home care;

(g) Drugs and supplies;

(h) Prosthetic, orthotic or other assistive devices essential to obtaining or retaining employment;

(i) Eyeglasses and visual services, including visual training, and the examination and services necessary for the prescription and provision of eyeglasses, contact lenses, microscopic lenses, telescopic lenses, and other special visual aids, prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;

(j) Podiatry;
(k) Physical therapy;
(l) Occupational therapy;
(m) Speech or hearing therapy;
(n) Psychological services;
(o) Therapeutic recreation services;
(p) Medical or medically related social work services;
(q) Treatment of either acute or chronic medical complications and emergencies which are associated with or arise out of the provision of physical and mental restoration services; or which are inherent in the condition under treatment;
(r) Special services for the treatment of individual suffering from end-stage renal disease, including transplantation, dialysis, artificial kidneys, and supplies; and
(s) Other medical or medically related rehabilitation services. "Physical or mental disability" means a physical or mental condition which materially limits, contributes to limiting or, if not corrected, will probably result in limiting an individual's employment activities or vocational functioning.

"Rehabilitation facility" means a facility which is operated for the primary purpose of providing vocational rehabilitation services to handicapped individuals, and which provides singly or in combination one or more of the following services for handicapped individuals:
(a) Vocational rehabilitation services, including under one management, medical, psychiatric, psychological, social, and vocational sevices;
(b) Testing, fitting, or training in the use of prosthetic and orthotic devices;
(c) Prevocational conditioning or recreational therapy;
(d) Physical and occupational therapy;
(e) Speech and hearing therapy;
(f) Psychological and social services;
(g) Evaluation of rehabilitation potential;
(h) Personal and work adjustment;
(i) Vocational training with a view toward career advancement (in combination with other rehabilitation sevices);
(j) Evaluation or control of specific disabilities;
(k) Orientation and mobility services and other adjustment services to blind individuals; and
(l) Transitional or extended employment for those handicapped individuals who cannot be readily absorbed in the competitive labor market.

"Reservation" means a Federal or State Indian reservation, public domain Indian allotment, former Indian reservation in Oklahoma, and land held by incorporated Native groups, regional corporations and village corporations under the provisions of the Alaska Native Claims Settlement Act.

"Secretary" means the Secretary of Health, Education, and Welfare.

"Severely handicapped individual" means a handicapped individual:
(a) Who has a severe physical or mental disability which seriously limits one or more functional capacities (mobility, communication, self-care, self-direction, work tolerance, or work skills) in terms of employability; and
(b) Whose vocational rehabilitation can be expected to require multiple vocational rehabilitation services over an extended period of time; and
(c) Who has one or more physical or mental disabilities resulting from amputation, arthritis, blindness, cancer, cerebral palsy, cystic fibrosis, deafness, heart disease, hemiplegia, hemophilia, respiratory or pulmonary dysfunction, mental retardation, mental illness, multiple sclerosis, muscular dystrophy, musculo-skeletal disorders, neurological disorders (including stroke and epilepsy), paraplegia, quadriplegia, and other spinal cord conditions, sickle cell anemia, and end-stage renal disease, or another disability or combination of disabilities determined on the basis of an evaluation of rehabilitation potential to cause comparable substantial functional limitation.

"State agency" means the sole State agency designated to administer (or supervise local administration of) the State plan for vocational rehabilitation services. The term includes the State agency for the blind, if designated as the sole State agency with respect to that part of the plan relating to the vocational rehabilitation of blind individuals.

"State plan" means the State plan for vocational rehabilitation services, or the vocational rehabilitation services part of a consolidated rehabilitation plan under § 1361.2(d).

"Substantial handicap to employment" means that a physical or mental disability (in light of attendant medical, psychological, vocational, educational, and other related factors) impedes an individual's occupational performance, by preventing his obtaining, retaining, or preparing for employment consistent with his capacities and abilities.

"Vocational rehabilitation services" when provided to an individual, means those services listed in § 1361.42 of this part.

"Vocational rehabilitation services" when provided for the benefit of groups of individuals, also means:
(a) In the case of any type of small business enterprise operated by severely handicapped individuals under the supervision of the State unit, management services, and supervision and acquisition of vending facilities or other equipment, and initial stocks and supplies;
(b) The establishment of a rehabilitation facility;
(c) The construction of a rehabilitation facility;
(d) The provision of other facilities and services, including services provided at rehabilitation facilities, which promise to contribute substantially to the rehabilitation of a group of individuals but which are not related directly to the individualized written rehabilitation program of any one handicapped individual;
(e) The use of existing telecommunications systems; and
(f) The use of services providing recorded material for blind persons and captioned films or video cassettes for deaf persons. "Work of art" means those items, including fixtures, that are incorporated in facilities primarily because of their esthetic value. The cost of a work of art which is a fixture is the estimated additional cost of incorporating those special esthetic features which exceed the general requirement of excellence of architecture and design.

"Workshop" means a rehabilitation facility, or that part of a rehabilitation facility, engaged in production or service operation for the primary purpose of providing gainful employment as an interim step in the rehabilitation process for those who cannot be readily absorbed in the competitive labor market or during such time as employment opportunities for them in the competitive labor market do not exist.

Subpart B—State Plans for Vocational Rehabilitation Services

State Plan Content: Administration

§ 1361.2 The State plan: General requirements.

(a) *Purpose.* In order for a State to be eligible for grants from the allotment of funds under Title I of the Act, it must submit an approvable State plan covering a three-year period and meeting Federal requirements. The State plan must provide for financial participation by the State, or if the State chooses, by the State and local agencies jointly, and must provide that it will be in effect in all political subdivisions of the State, except as specifically provided in § 1361.12 (Shared funding and administration of special joint projects or programs) and § 1361.13 (Waiver of Statewideness).

(b) *Form and content.* The State plan must contain, in the form prescribed by the Commissioner, a description of the State's vocational rehabilitation program, the plans and policies to be followed in carrying out the program and other information requested by the Commissioner. The State plan must consist of:

(1) A part providing detailed commitments specified by the Commissioner which must be amended or reaffirmed every three years; and

(2) A part containing a fiscal year programming description, based on the findings of the continuing Statewide studies (§ 1361.18), the annual evaluation of the effectiveness of the State's program (§ 1361.18), and other pertinent reviews and studies. This annual programming description must include:

(i) Changes in policy resulting from the continuing Statewide studies and the annual evaluation of the effectiveness of the program;

(ii) Estimates of the number of handicapped individuals who will be served with funds provided under the Act;

(iii) A description of the methods used to expand and improve services to those individuals who are the most severely handicapped;

(iv) A description of the order of selection (§ 1361.36) of groups of handicapped individuals to whom vocational rehabilitation services will be provided (unless the designated State unit assures that it is serving all eligible handicapped individuals who apply);

(v) A description of financial, personnel, facility, and other resources required to achieve short and long range State goals, and a description of plans for achieving these goals; and

(vi) A statement of the general outcome and service goals to be achieved for handicapped individuals in each priority category within the order of selection in effect in the State and the time within which these goals may be achieved. These goals must include those objectives, established by the State unit and consistent with those set by the Commissioner in instructions concerning the State plan, which are measurable in terms of service expansion or program improvement in specified program areas, and which the State unit plans to achieve during a specified period of time.

(c) *Separate part relating to rehabilitation of the blind.* If a separate State agency for the blind administers or supervises the administration of that part of the State plan relating to the rehabilitation of blind individuals, that part of the State plan must meet all requirements applicable to a separate State plan.

(d) *Consolidated rehabilitation plan.* The State may choose to submit a consolidated rehabilitation plan which includes the State plan for vocational rehabilitation services and either the State plan for independent living rehabilitation services or the State's plan for its program for persons with developmental disabilities, or both. If the State's plan for persons with developmental disabilities is included, the State planning and advisory council for developmental disabilities and the agency or agencies administering the State's program for persons with developmental disabilities must have concurred in the submission of the consolidated rehabilitation plan. A consolidated rehabilitation plan must comply, and be administered in accordance with, this Act and the Developmental Disabilities Assistance and Bill of Rights Act. The Commissioner may approve the consolidated rehabilitation plan to serve as the substitute for the separate plans which would otherwise be required.

(e) *Amendment.* The State plan must be amended whenever necessary to reflect any material change in any applicable phase of State law, organization, policy, or agency operations which affects the administration of the State plan. The State must submit an amendment before the change is put into effect or shortly after that time.

(f) *Designation of a new State agency or a new State unit.* Before designating a new State agency or a new State unit, the chief administrative officer of the State agency must assure the Commissioner in writing that the vocational rehabilitation program will continue to operate in conformity with the most recent approved State plan, until a new State plan is submitted. The State must submit a new State plan within 90 days following the designation of a new State agency or a new State unit.

(g) *Transition to new State agency or State unit.* When a State agency or a new State unit is designated under paragraph (f) of this section, the State agency must turn over to that agency program and financial records and other pertinent information and resources necessary for the effective conduct of the vocational rehabilitation program.

§ 1361.3 Review of State plan by Governor.

The State agency must submit the State plan to the State Governor for review and comments. The Governor is given an opportunity to review and comment on all State plan amendments and long-range program planning projections or other periodic reports, except for periodic statistical or budget and other fiscal reports. The Office of the Governor has 45 days to review this material. The State submits any comments to the Commissioner with the documents.

§ 1361.4 State plan approval and disapproval.

(a) *State plan approval.* The State plan must be submitted for approval for each three-year period no later than July 1 of the year preceding the first fiscal year for which the State plan is submitted. The Commissioner approves any State plan or amendment meeting the requirements of the Act and of this part.

(b) *State plan disapproval.* The Commissioner does not disapprove any State plan or modification until reasonable effort has been made to resolve any problem and the State has been given reasonable notice and opportunity for a hearing.

§ 1361.5 Withholding of funds.

(a) *When withheld.* When after a reasonable notice and opportunity for hearing has been given to the State agency, the Commissioner finds that:

(1) The State plan, or the vocational rehabilitation services part of the consolidated rehabilitation plan, has been so changed that it no longer conforms with the requirements of section 101(a) of the Act; or

(2) In the administration of the State plan, or the vocational rehabilitation services part of the consolidated rehabilitation plan, there is a failure to comply substantially with any provision of the approved plan, further payments under section 111 or 121 may be withheld, suspended, or limited as provided by section 101(c) of the Act. The State agency is notified of the decision.

(b) *Judicial review.* The decision to withhold, suspend, or limit payments described in paragraph (a) of this section may be appealed to the U.S. Court of Appeals for the circuit in which the State is located, in accordance with section 101(d) of the Act.

(c) *Informal discussions.* Hearings described in paragraph (a) of this section are not called until after reasonable effort has been made to resolve the questions involved by conference and discussion with State officials.

§ 1361.6 State agency for administration.

(a) *Designation of sole State agency.* The State plan must designate a State

agency as the sole State agency to administer the State plan, or to supervise its administration in a political subdivision of the State by a sole local agency. In the case of American Samoa, the State plan must designate the Governor; in the case of the Trust Territory of the Pacific Islands, the State plan must designate the High Commissioner.

(b) *Designated State agency.* The State plan must provide that the designated State agency, except for American Samoa, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands, and except for a designated State agency for the blind as specified in paragraph (c) of this section, must be:

(1) A State agency primarily concerned with vocational rehabilitation, or vocational and other rehabilitation of handicapped individuals. This agency must be an independent State commission, board, or other agency, which has as its major function vocational rehabilitation, or vocational and other rehabilitation of handicapped individuals. The agency must have the authority, subject to the supervision of the Office of Governor to define the scope of the vocational rehabilitation program within the provision of State and Federal law, and to direct its administration without external administrative controls; or

(2) The State agency administering or supervising the administration of education or vocational education in the State; or

(3) A State agency which includes at least two other major organizational units, each of which administers one or more of the State's major programs of public education, public health, public welfare, or labor.

(c) *Designated State agency for the blind.* Where the State commission for the blind or other agency which provides assistance or services to the blind is authorized under State law to provide vocational rehabilitation services to blind individuals, this agency may be designated as the sole State agency to administer the part of the plan under which vocational rehabilitation services are provided for the blind or to supervise its administration in a political subdivision of the State by a sole local agency.

(d) *Authority.* The State plan must set forth the authority under State law for the administration or supervision of the administration of the program by the sole State agency and the legal basis for administraton by sole local rehabilitation agencies, if applicable.

(e) *Responsibility for administration.* The State plan must assure that all decisions affecting eligibility for the nature and scope of available vocational rehabilitation services, and the provision of these services are made by the State agency through its designated State unit, or by a designated vocational rehabilitation unit of a local agency under the supervision of the designated State unit. This responsibility may not be delegated to any other agency or individual.

§ 1361.7 Organization of the State agency.

(a) *Organization.* The State plan must describe the organizational structure of the State agency, including a description of organizational units, the programs and functions assigned to each, and the relationships among these units within the State agency. These descriptions must be accompanied by organizational charts reflecting:

(1) The relationship of the State agency to the Governor and his or her office and to other agencies administering major programs of public education, public health, public welfare, or labor of parallel stature within the State government; and

(2) The internal structure of the State agency and the designated State unit, if applicable. The organizational structure must provide for all the vocational rehabilitation functions for which the State agency is responsible, for clear lines of administrative and supervisory authority, and must be suited to the size of the vocational rehabilitation program and the geographic areas in which the program must operate.

(b) *Designated State unit.* Where the designated State agency is of the type specified in § 1361.6(b) (2) or (3), or § 1361.6(c), the State plan must assure that the agency (or each agency, where two agencies are designated), includes a vocational rehabilitation bureau, division or other organizational unit which:

(1) Is primarily concerned with vocational rehabilitation, or vocational and other rehabilitation of handicapped individuals, and is responsible for the administration of the State agency's vocational rehabilitation program, which includes the determination of eligibility for and the provision of vocational rehabilitation services under the State plan;

(2) Has a full time director in accordance with § 1361.9; and

(3) Has a staff, all or almost all of whom are employed full time on the rehabilitation work of the organizational unit.

(c) *Location of designated State unit.* (1) The State plan must assure that the designated State unit, specified in paragraph (b) of this section, is located at an organizational level and has an organizational status within the State agency comparable to that of other organizational units of the agency, or in the case of an agency described in § 1361.6(b)(2), the unit must be so located and have that status, or the director of the unit must be the executive officer of the State agency.

(2) In the case of a State which has not designated a separate State agency for the blind as provided for in § 1361.6 the State may assign responsibility for the part of the plan under which vocational rehabilitation services are provided to blind individuals to one organizational unit of the State agency and may assign responsibility for the rest of the plan to another organizational unit of the agency, with the provisions of paragraphs (b) and (c)(1) of this section applying separately to each of these units.

§ 1361.8 [Reserved]

§ 1361.9 State unit director.

The State plan must assure that there will be a full-time director who directs the State agency specified in § 1361.6(b)(1) or the designated State unit specified in § 1361.7(b).

§ 1361.10 Local administration.

(a) Scope of written agreement. The State plan must assure that any local administration of the plan by a sole local agency is based on a written agreement between the local agency and the State agency which:

(1) Indicates that the local agency will conduct a vocational rehabilitation program through its designated unit under the supervision of the designated State unit in accordance with the State plan and in compliance with Statewide standards established by the designated State unit;

(2) Assures that the designated unit of the local agency will be responsible for carrying out the vocational rehabilitation program and will meet the requirements for this unit specified in § 1361.7(b);

(3) Describes the methods to be followed by the designated State unit in its supervision of the local agency's vocational rehabilitation program;

(4) Indicates the basis on which the designated State unit participates financially in its locally administered vocational rehabilitation programs;

(5) Indicates whether the local agency will utilize another local public or nonprofit agency in providing vocational rehabilitation services to handicapped individuals, and the arrangements to be made; and

(6) Assures that the sole local agency will be responsible for the administration of the vocational rehabilitation program and will employ staff for carrying out the vocational rehabilitation program including a full-time director.

(b) *Responsibility of local agency.* If the State plan provides for local administration, it must assure that the sole local agency is responsible through its designated unit for the administration of the program within the political subdivision which its serves. A separate local agency serving the blind may administer that part of the plan relating to vocational rehabilitation of the blind, under the supervision of the designated State unit for the blind.

§ 1361.11 Methods of administration.

The State Plan must assure that the State agency employs those methods found necessary by the Commissioner for the proper and efficient administration of the plan, and for carrying out all functions for which the State is responsible under the plan and this part.

§ 1361.12 Shared funding and administration of special joint projects or programs.

(a) *Procedural requirements.* In order to carry out a special joint project or program to provide services to handicapped individuals, the State agency must request the Commissioner to authorize it to share funding and administrative responsibility for a joint project or program with another agency or agencies of the State, or with a local agency. The Commissioner approves a request for the shared funding and administration of a special joint project or program which he has determined will more effectively accomplish the purpose of the Act and may also waive the provisions of § 1361.2(a) that the State plan must be in effect in all political subdivisions of the State.

(b) *Scope of written agreement.* The State plan must assure that each special joint project or program is based on a written agreement which:

(1) Describes the nature and scope of the joint project or program, the services to be provided, the respective roles of each participating agency in the provision of services and in their administration, and the share of the costs to be assumed by each;

(2) Specifies the period of the joint project or program, and plans for anticipated continuation;

(3) Provides a budget showing for each fiscal year the financial participation by the State agency and each participating agency;

(4) Provides written assurance that funds will be legally available for purposes of the joint project or program;

(5) Provides that the State agency shall annually evaluate the effectiveness of each project or program with special attention to its vocational rehabilitation objectives;

(6) Assures that the State agency and each participating agency will furnish information and reports required by the Commissioner to determine whether the activities are achieving the purposes of the project or program and warrant continuation; and

(7) Assures that the State agency's portion of the joint project or program will comply with applicable requirements of the Act and this part.

§ 1361.13 Waiver of statewideness.

(a) *Purpose of waiver.* If the State agency desires to carry out activities in one or more political subdivisions through local financing in order to promote the vocational rehabilitation of substantially larger numbers of handicapped individuals with particular types of disabilities, the State plan must identify the types of activities to be carried out in this manner.

(b) *Procedural requirements.* The State plan must assure in these cases that the State agency:

(1) Obtains a written description of any activity to be carried out in a particular political subdivision;

(2) Obtains written assurance from the political subdivision that the non-Federal share of funds is available to the State;

(3) Requires that its approval be given to each proposal before the proposal is put into effect in a political subdivision;

(4) Has sole responsibility for administration (or supervisions if the vocational rehabilitation program is administered by local agencies) of the program in a particular local political subdivision in accordance with § 1361.6, except to the extent that funding and administrative responsibility is shared with respect to a joint program under § 1361.12.

(5) Assures that all requirements of the State plan apply to these activities, except the requirement that the program be in effect in all political subdivisions of the State, and except that the provisions of § 1361.78 may be applicable for Federal financial participation in expenditures for carrying out these activities; and

(6) Furnishes other information and reports required by the Commissioner.

§ 1361.14 Cooperative programs involving funds from other public agencies.

(a) *Scope of written agreement.* The State plan must assure that, when the State's share of the cost of a cooperative program for providing or administering vocational rehabilitation services is made available in whole or in part by a State or local public agency other than the designated State unit, the cooperative program is based on a written agreement which:

(1) Describes program goals and the activities to be undertaken to achieve these goals;

(2) Assures only individuals eligible for vocational rehabilitation services will be served;

(3) Assures that the vocational rehabilitation services are not services of the cooperating agency to which the handicapped individual would be entitled if he were not an applicant or client of the designated State unit and represent new services or new patterns of services of the cooperating agency.

(4) Provides for an annual budget;

(5) Provides that expenditures for vocational rehabilitation services and the administration of these services will be under the direct control and at the discretion of the designated State unit.

(6) Assures that the costs of administrative activities are not costs which are attributable to the general expense of the State or locality in carrying out the administrative functions of the State or local government;

(b) *Annual review.* The State must review each cooperative program annually to determine its effectiveness and to assure that it is being operated in compliance with the requirements of the written agreement.

§ 1361.15 Staffing of the State's vocational rehabilitation program.

(a) *General staffing requirement.* The State plan must assure that staff in sufficient number and with appropriate qualifications is available to carry out all functions required under this part, including program planning and evaluation, staff development, rehabilitation facility development and utilization, medical consultation, and rehabilitation counseling services for severely handicapped individuals.

(b) *Special communication needs staffing.* The State plan must further assure that the designated State unit includes on its staff or makes available personnel able to communicate in the native languages of handicapped individuals with limited English-speaking ability from ethnic groups which represent significant segments of the population of the State. The State plan must assure that the State unit

includes on its staff or arranges to have available individuals able to communicate with handicapped individuals who rely on special modes of communication such as manual communication, tactile, oral, and non-verbal communication devices.

§ 1361.16 Standards of personnel administration.

(a) *State merit system administration.* The State plan must assure that methods of personnel administration are established and maintained in conformity with the Standards for a Merit System of Personnel Administration, 5 CFR Part 900 which incorporate the intergovernmental Personnel Act Merit Principles (Pub. L. 91-648), prescribed by the U.S. Office of Personnel Management under Section 208 of the Intergovernmental Personnel Act of 1970, as amended.

(b) *Affirmative action plan for handicapped individuals.* The State plan must also assure that the State agency develops and implements a plan to take affirmative action to employ and advance in employment qualified handicapped individuals. This plan must provide for specific action steps, timetables, and complaint and enforcement procedures necessary to assure affirmative action.

§ 1361.17 Staff development.

The State plan must assure that there is a program of staff development for all classes of positions within the State agency which are involved in the administration and operation of the State's vocational rehabilitation program. The staff development program must include, as a minimum:

(a) A systematic determination of training needs and a system for evaluating the effectiveness of the training activities provided:

(b) An orientation program for new staff; and

(c) An operating plan for providing training opportunities for all classes of positions consistent with the determination of training needs.

§ 1361.18 State studies and evaluations.

(a) *General provisions.* The State plan must assure that the State conducts continuing Statewide studies of the needs of handicapped individuals within the State, including the State's need for rehabilitation facilities, and the methods by which these needs may be most effectively met.

(b) *Scope of Statewide studies.* The continuing Statewide studies must:

(1) Determine the relative needs for vocational rehabilitation services of different significant segments of the population of handicapped individuals, with special reference to the need for expanding services to individuals with the most severe handicaps;

(2) Review a broad variety of means and methods to provide, expand, and improve vocational rehabilitation services in order to determine which means and methods are the most effective;

(3) Review the appropriateness of the criteria used by the designated State unit in determining individuals to be ineligible for vocational rehabilitation services;

(4) Determine the capacity and condition of rehabilitation facilities and rehabilitation facility services within the State and identify ways in which the overall effectiveness of rehabilitation facility services within the State might be improved; and

(5) Otherwise contribute to the orderly and effective development of vocational rehabilitation services and rehabilitation facilities within the State.

(c) *Annual evaluation.* The State plan must assure that the State conducts an evaluation of the effectiveness of the State's vocational rehabilitation program in achieving service goals and priorities, as established in the plan. This evaluation must measure the adequacy of State unit performance in providing vocational rehabilitation services especially to those individuals with the most severe handicaps and must be conducted according to the general standards for evaluation developed by the Secretary. Findings derived from the annual evaluation must be reflected in the State plan, its amendments and in the development of plans and policies for the provision of vocational rehabilitation services either directly by the State unit or within rehabilitation facilities.

(d) *Availability of reports.* Reports of the continuing Statewide studies and annual evaluations must be available to the public for review and inspection.

§ 1361.19 Policy development consultation.

(a) *General provisions.* The State plan must assure that the designated State unit, or as appropriate, the State unit and any vocational rehabilitation unit of a local agency, takes into account, in connection with matters of general policy development and implementation arising in the administration of the State plan, the views of individuals and groups who are:

(1) Current or former recipients of vocational rehabilitation services, or as appropriate, their parents, guardians, or other representatives;

(2) Providers of vocational rehabilitation services; and

(3) Others active in vocational rehabilitation.

(b) *Public access.* The State plan must further assure that the State unit establishes and maintains a written description of the methods used to obtain and consider views on policy development and implementation. This description must be available to the public for review and inspection, as well as a report of activities which were actually undertaken in this regard during the previous fiscal year.

§ 1361.20 Cooperation with other public agencies.

(a) *General provisions.* The State plan must assure that, where appropriate, the State agency enters into cooperative arrangements with, and utilizes the services and facilities of, the State agencies administering the State's social services and financial assistance programs; other programs for handicapped individuals such as the State's developmental disabilities program, veterans' programs, health and mental health programs, education programs, workers' compensation programs, manpower programs and public employment offices; the Social Security Administration; the Office of Workers' Compensation Programs of the Department of Labor, the Veterans' Administration; and other Federal, State and local public agencies providing services related to the rehabilitation of handicapped individuals.

(b) *Coordination with education programs.* The State plan must also assure that specific arrangements are made for the coordination of services for any individual who is eligible for vocational rehabilitation services and is also eligible for services under Part B of the Education of Handicapped Children Act or the Vocational Education Act.

(c) *Coordination with veterans' programs.* The State plan must also assure that there will be maximum coordination and consultation with programs relating to the rehabilitation of disabled veterans.

(d) *Reciprocal referral services with separate agency for the blind.* Where there is a separate State agency for the blind, the two State agencies must establish reciprocal referral services, utilize each other's services and facilities to the extent feasible, jointly plan activities to improve services to the handicapped individuals in the State, and otherwise cooperate to provide more effective services.

§ 1361.21 Establishment and maintenance of information and referral resources.

(a) *General provisions.* The State plan must assure the establishment and maintenance of information and referral programs adequate to ensure that handicapped individuals within the State are given accurate information about State vocational rehabilitation services and independent living services, vocational rehabilitation services available from other agencies, organizations, and rehabilitation facilities, and, to the extent possible, other Ferderal and State services and programs which assist handicapped individuals. The State plan must also assure that the State unit will refer handicapped individuals to other appropriate Federal and State programs which might be of benefit to them and will utilize existing information and referral systems in the State.

(b) *Special information and referral resources.* The State plan must further assure that, to the greatest extent possible, information and referral services utilize interpreters for the deaf, existing telecommunication systems, specialized media systems for handicapped persons and special materials for blind individuals and deaf individuals.

§ 1361.22 State plan for rehabilitation facilities.

The State plan must assure that the designated State unit maintains a State rehabilitation facilities plan which includes an inventory of rehabilitation facilities and rehabilitation facility services available within the State and a description of the utilization patterns of the facilities and their utilization potential. The inventory must also include a determination of needs for new, expanded or otherwise modified rehabilitation facilities or rehabilitation facility services and a prioritized list of facility projects necessary to achieve short-range State unit goals. The State plan must also assure that the inventory of facilities is developed with the active participation of a representative group of providers and recipients of vocational rehabilitation services and is available to the public for review and inspection.

§ 1361.23 Utilization of rehabilitation facilities.

The State plan must assure that the designated State unit utilizes existing rehabilitation facilities to the maximum extent feasible to provide vocational rehabilitation services to handicapped individuals. The State plan must describe the methods used to ensure appropriate use of these facilities and must provide for appropriate means for entering into agreements with the operators of these facilities for the provision of vocational rehabilitation services.

§ 1361.24 Reports.

The State plan must assure that the State agency submit reports in the form and detail and at the time required by the Commissioner, including reports required under special evaluation studies. The State agency must also comply with any requirements necessary to assure the correctness and verification of reports.

§ 1361.25 General administrative and fiscal requirements.

(a) *General provisions.* The State plan must assure that the State agency adopts policies and methods pertinent to the fiscal administration and control of the vocational rehabilitation program, including sources of funds, incurrence and payment of obligations, disbursements, accounting, and auditing. The State plan must assure that the State agency maintains accounts and supporting documents necessary for an accurate and expeditious determination at any time of the status of Federal grants, including the disposition of monies received and the nature and amount of charges claimed against these grants.

(b) *Awards made by State agency.* The State plan must assure that the State agency adopts policies and methods necessary to assure sound administration and control of funds awarded by the State agency to any public or other nonprofit agency or organization to carry out a program of vocational rehabilitation services.

(c) *Applicability of Part 74.* The provisions of Part 74 of this title, establishing uniform administrative requirements and cost principles, apply to all grants made under this part except for the requirement concerning in-kind contributions under Subpart G of Part 74 of this title.

(d) *Applicability of other HEW regulations.* Several other HEW regulations also apply under this part. These include:

45 CFR Part 19—Limitations on Payment or Reimbursement for Drugs
45 CFR Part 46—Protection of human subjects
45 CFR Part 75—Informal grant appeals procedures (Indirect cost rates and other cost allocations)
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health, Education, and Welfare—Effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedures for hearings under Part 80
45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs
45 CFR Part 90—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance

(e) *Limitations on joint funding.* The provisions of the Joint Funding Simplification Act (Pub. L. 93–510) and Title V of the Omnibus Territories Bill (Pub. L. 95–134) do not apply to any activities supported under this part.

State Plan Content: Provision and Scope of Service

§ 1361.30 Processing referrals and applications.

The State plan must assure that the State unit establishes and maintains written standards and procedures to assure expeditious and equitable handling of referrals and applications for vocational rehabilitation services.

§ 1361.31 Eligibility for vocational services.

(a) *General provisions.* (1) The State plan must assure that eligibility requirements are applied by the designated State unit without regard to sex, race, age, creed, color, or national origin of the individual applying for service. The State plan must also assure that no group of individuals is excluded or found ineligible solely on the basis of type of disability. With respect to age, the State plan must assure that no upper or lower age limit is established which will, in and of itself, result in a finding of ineligibility for any handicapped individual who otherwise meets the basic eligibility requirements specified in paragraph (b) of this section.

(2) The State plan must assure that no residence requirement, durational or other, is imposed which excludes from services any individual who is present in the State.

(b) *Basic conditions.* The State plan must assure that eligibility is based only upon:

(1) The presence of a physical or mental disability which for the individual constitutes or results in a substantial handicap to employment; and

(2) A reasonable expectation that vocational rehabilitation services may benefit the individual in terms of employability.

(c) *Interim determination of eligibility.* The State plan may provide for vocational rehabilitation services to be initiated for an individual on the basis of an interim determination of eligibility. If the State chooses this approach, it must identify the criteria established for making an interim determination of eligibility, the

procedures to be followed, the services which may be provided, and the period, not to exceed 90 days, during which services may be provided until a final determination of eligibility is made.

§ 1361.32 Evaluation of vocational rehabilitation potential: Preliminary diagnostic study.

(a) *Basic conditions.* The State plan must assure that, in order to determine whether any individual is eligible for vocational rehabilitation services, there is a preliminary diagnostic study to determine:

(1) Whether the individual has a physical or mental disability which for that individual constitutes or results in a substantial handicap to employment; and

(2) Whether vocational rehabilitation services may reasonably be expected to benefit the individual in terms of employability, or whether an extended evaluation of vocational rehabilitation potential is necessary to make this determination.

(b) *Scope of diagnostic study.* The State plan must assure that the preliminary diagnostic study includes examinations and diagnostic studies to make the determinations specified in paragraph (a) of this section. In all cases, the evaluation places primary emphasis upon determining the individual's potential for achieving a vocational goal.

(c) *Special evaluations.* The State plan must also assure that the preliminary diagnostic study includes an appraisal of the current general health status of the individual based, to the maximum extent possible, on available medical information. The State plan must further assure that in all cases of mental or emotional disorder, an examination is provided by a physician skilled in the diagnosis and treatment of such disorders, or by a psychologist licensed or certified in accordance with State laws and regulations, in those States where laws and regulations pertaining to the practice of psychology have been established.

§ 1361.33 Evaluation of vocational rehabilitation potential: Thorough diagnostic study.

(a) *General provision.* The State plan must assure that, as appropriate in each case, when an individual's eligibility for vocational rehabilitation services has been determined, there will be a thorough diagnostic study to determine the nature and scope of services needed by the individual. This study consists of a comprehensive evaluation of pertinent medical, psychological, vocational, educational, and other factors relating to the individual's handicap to employment and rehabilitation needs.

(b) *Purpose.* The State plan must assure that the thorough diagnostic study is sufficient in each case to determine which vocational rehabilitation services are needed to attain vocational goals of the handicapped individual. The findings of the study must be recorded in the individual's case record.

(c) *Special evaluation for visually impaired individuals.* The State plan must assure that in all cases of visual impairment, an evaluation of visual loss is provided by a physician skilled in the diseases of the eye or by an optometrist, whichever the individual may select. In the case of blindness, a screening for hearing loss is obtained from a physician skilled in the diseases of the ear or from an audiologist licensed or certified in accordance with State laws or regulations.

(d) *Special evaluation for hearing impaired individuals.* The State plan must assure that in all cases of hearing impairment, an evaluation of the auditory system is obtained from a physician skilled in the diseases of the ear, and based upon this physician's findings, a hearing evaluation may be provided by such a physician or by an audiologist licensed or certified in accordance with State laws or regulations. In the case of deafness, an evaluation of visual capacity is obtained from a physician skilled in the diseases of the eye or from an optometrist, whichever the individual may select.

(e) *Special evaluation for mentally retarded individuals.* The State plan must assure that in all cases of mental retardation, a psychological evaluation is obtained which includes a valid test of intelligence and an assessment of social functioning and educational progress and achievement.

(f) *Scope of thorough diagnostic study.* The State plan must assure that the thorough diagnostic study includes in all cases to the degree needed, an appraisal of the individual's personality, intelligence level, educational achievement, work experience, personal, vocational, and social adjustment, employment opportunities, and other pertinent data helpful in determining the nature and scope of services needed. The State plan must also assure that the thorough diagnostic study includes, as appropriate for each individual, an appraisal of the individual's patterns of work behavior, ability to acquire occupational skill and capacity for successful job performance. Simulated or real work experience may be used to assess the individual's capacity to perform in a work environment.

§ 1361.34 Extended evaluation to determine vocational rehabilitation potential.

(a) *Basic conditions.* The State plan must assure that the furnishing of vocational rehabilitation services under an extended evaluation to determine vocational rehabilitation potential is based only upon:

(1) The presence of a physical or mental disability which for the individual constitutes or results in a substantial handicap to employment; and

(2) An inability to make a determination that vocational rehabilitation services might benefit the individual in terms of employability unless there is an extended evaluation to determine vocational rehabilitation potential.

(b) *Duration and scope of services.* Vocational rehabilitation services necessary for determination of rehabilitation potential, including those provided within a thorough diagnostic study, may be provided to a handicapped individual for a total period no longer than 18 months.

(c) *Other conditions.* (1) The extended evaluation period begins on the date of certification for extended evaluation to determine rehabilitation potential required in § 1361.35(b). Only one 18-month maximum period is permitted during the time that the case is open. If a case has been closed because of a determination that the handicapped individual's needs have changed, the case may be re-opened and a subsequent evaluation of vocational rehabilitation potential may be carried out.

(2) Vocational rehabilitation services, authorized after the expiration of the extended evaluation period, are provided only if the certification of eligibility required in § 1361.35(a) has been executed by an appropriate State unit staff member.

(d) *Review.* The State plan must assure a thorough assessment of the individual's progress as frequently as necessary but at least once every 90 days during the extended evaluation period. This assessment includes periodic reports from the facility, or person providing the services, to determine the results of the services and to determine whether the individual may be determined to be eligible or ineligible.

(e) *Termination.* The State plan must assure that at any time before the end of an 18-month extended evaluation

period, the extended evaluation must be terminated when:

(1) The individual is found eligible for vocational rehabilitation services since there is a reasonable assurance that he or she can be expected to benefit in terms of employability from vocational rehabilitation services; or

(2) The individual is found ineligible for any additional vocational rehabilitation services since it has been determined that he or she cannot be expected to benefit in terms of employability from vocational rehabilitation services. In this case, the procedures described in §1361.40(d) are to be followed and the individual is considered for referral for services under the State's independent living rehabilitation program under Part 1363 of this chapter.

§ 1361.35 Certification: Eligibility; extended evaluation to determine vocational rehabilitation potential; ineligibility.

(a) *Certification of eligibility.* The State plan must assure that, before or at the same time that the State unit accepts a handicapped individual for vocational rehabilitation services, there must be a certification that the individual has met the basic eligibility requirements specified in § 1361.31(b). The State plan must further assure that the certification of eligibility is dated and signed by an appropriate State unit staff member.

(b) *Certification for extended evaluation to determine vocational rehabilitation potential.* The State plan must assure that before, and as a basis for providing an extended evaluation to determine vocational rehabilitation potential, there must be a certification that the individual has met the requirements in § 1361.34(a). The State plan must further assure that the certification is dated and signed by an appropriate State unit staff member.

(c) *Certification of ineligibility.* (1) The State plan must assure that, whenever the State unit determines an applicant or recipient of vocational rehabilitation to be ineligible for services, there must be a certification dated and signed by an appropriate designated State unit staff member.

(2) The State plan must further assure that the certification indicates the reasons for the ineligibility determination and is made only after full consultation with the individual or, as appropriate, his or her parent, guardian, or other representative, or after giving a clear opportunity for this consultation. In this case, the designated State unit notifies the individual in writing of the action taken and informs the individual of his or her rights and the means by which he or she may express and seek remedy for any dissatisfaction, including the procedures for administrative review and fair hearings under § 1361.48. When appropriate, the individual is provided a detailed explanation of the availability of the resources within a client assistance project established under Part 1362 of this chapter, and referral is made to other agencies and facilities, including when appropriate, the State's independent living rehabilitation program under Part 1363 of this chapter.

(d) *Review of ineligibility determination.* The State plan must further assure that when an applicant for vocational rehabilitation services has been determined on the basis of the preliminary diagnostic study to be ineligible because of a finding that he or she cannot be expected to achieve a vocational goal, the ineligiblity determination will be reviewed within 12 months. This review need not be conducted in situations where the individual has refused it, the individual is no longer present in the State, his or her whereabouts are unknown, or his or her medical condition is rapidly progressive or terminal.

(e) *Closure without eligibility determination.* The State plan must provide that the State unit may close a case without any determination of eligibility when an applicant is unavailable during an extended period of time to complete an evaluation of vocational rehabilitation potential and the State unit has made repeated effort to contact the invididual and to encourage his or her participation.

§ 1361.36 Order of selection for services.

(a) *General provisions.* The State plan must show the order to be followed in selecting groups of handicapped individuals to be provided vocational rehabilitation services when these services cannot be provided to all eligible individuals or all individuals determined to be in need of an extended evaluation of vocational rehabilitation potential to determine eligibility.

(b) *Priority for severely handicapped individuals.* The State plan must assure that those groups of individuals with the most severe handicaps are selected for service before any other groups of handicapped individuals.

(c) *Disabled public safety officers.* The State plan must also assure that special consideration will be given to those handicapped individuals whose handicapping condition arose from a disability sustained in the line of dutywhile performing as public safety officer and the immediate cause of such disability was a criminal act, apparent criminal act, or a hazardous condition resulting directly from the officer's performance of duties in direct connection with the enforcement, execution, and administration of law or fire prevention, firefighting, or related public safety activities.

§ 1361.37 Services to civil employees of the United States.

The State plan must assure that vocational rehabilitation services are available to civil employees of the U.S. Government who are disabled in line of duty, under the same terms and conditions applied to other handicapped individuals.

§ 1361.38 Services to handicapped American Indians.

The State plan must assure that vocational rehabilitation services are provided to handicapped American Indians residing in the State to the same extent that these services are provided to other significant groups of the State's handicapped population. The State plan must further assure that the designated State unit continues to provide vocational rehabilitation services to handicapped American Indians on reservations served by a special tribal program under § 1362.45, if the population estimates used for determining the State's allotment include the population of Indians residing on these reservations.

§ 1361.39 The case record for the individual.

The State plan must assure that the designated State unit maintains for each applicant for, and recipient of, vocational rehabilitation services a case record which includes, to the extent pertinent, the following information:

(a) Documentation concerning the preliminary diagnostic study supporting the determination of eligibility, the need for an extended evaluation of vocational rehabilitation potential, and, as appropriate, documentation concerning the thorough diagnostic study supporting the nature and scope of vocational rehabilitation services to be provided;

(b) In the case of an individual who has applied for vocational rehabilitation services and has been determined to be ineligible, documentation specifying the reasons for the ineligibility determination, and noting a review of the ineligibility determination carried out not later than twelve months after the determination was made;

(c) Documentation supporting any determination that the handicapped individual is a severely handicapped individual;

(d) Documentation as to periodic assessment of the individual during an

extended evaluation of vocational rehabilitation potential;

(e) An individualized written rehabilitation program as developed under § 1361.40 and § 1361.41 and any amendments to the program;

(f) In the event that physical and mental restoration services are provided, documentation supporting the determination that the clinical status of the handicapped individual is stable or slowly progressive unless the individual is being provided an extended evaluation of rehabilitation potential;

(g) Documentation supporting any decision to provide services to family members;

(h) Documentation relating to the participation by the handicapped individual in the cost of any vocational rehabilitation services if the State elects to continue the provision of services on the financial need of the individual;

(i) Documentation relating to the eligibility of the individual for any similar benefits, and the use of any similar benefits;

(j) Documentation that the individual has been advised of the confidentiality of all information pertaining to his case, and documentation and other material concerning any information released about the handicapped individual with his or her written consent;

(k) Documentation as to the reason for closing the case including the individual's employment status and, if determined to be rehabilitated, the basis on which the employment was determined to be suitable;

(l) Documentation of any plans to provide post-employment services after the employment objective has been achieved, the basis on which these plans were developed, and a description of the services provided and the outcomes achieved;

(m) Documentation concerning any action and decision involving the handicapped individual's request for an administrative review of agency action or fair hearing under § 1361.48; and

(n) In the case of an individual who has been provided vocational rehabilitation services under an individualized written program but who has been determined after the initiation of these services to be no longer capable of achieving a vocational goal, documentation of any reviews of this determination in accordance with § 1361.40(d).

§ 1361.40 The individualized written rehabilitation program: Procedures.

(a) *General provisions.* The State plan must assure that an individualized written rehabilitation program is initiated and periodically updated for each eligible individual and for each individual being provided services under an extended evaluation to determine rehabilitation potential. The State plan must also assure that vocational rehabilitation services are provided in accordance with the written program. The individualized written rehabilitation program must be developed jointly by the designated State unit staff member and the handicapped individual or, as appropriate, his or her parent, guardian or other representative. A copy of the written program, and any amendments, must be provided to the handicapped individual or, as appropriate, his or her parent, guardian, or other representative.

(b) *Initiation of program.* The individualized written rehabilitation program must be initiated after certification of eligibility under § 1361.35(a) or certification for extended evaluation to determine rehabilitation potential under § 1361.35(b).

(c) *Review.* The State plan must assure that the individualized written program will be reviewed as often as necessary but at least on an annual basis. Each handicapped individual, or, as appropriate, his or her parent, guardian or other representative must be given an opportunity to review the program and, if necessary, jointly redevelop and agree by signature to its terms.

(d) *Review of ineligibility determination.* The State plan must assure that if services are to be terminated under a written program because of a determination that the handicapped individual is not capable of achieving a vocational goal and is therefore no longer eligible, or if in the case of a handicapped individual who has been provided services under an extended evaluation of vocational rehabilitation potential, services are to be terminated because of a determination that the individual cannot be determined to be eligible, the following conditions and procedures will be met or carried out.

(1) This decision is made only with the full participation of the individual, or, as appropriate, his or her parent, guardian, or other representative, unless the individual has refused to participate, the individual is no longer present in the State or his or her whereabouts are unknown, or his or her medical condition is rapidly progressive or terminal. When the full participation of the individual or a representative of the individual has been secured in making the decision, the views of the individual are recorded in the individualized written rehabilitation program;

(2) The rationale for the ineligibility decision is recorded as an amendment to the individualized written rehabilitation program certifying that the provision of vocational rehabilitation services has demonstrated that the individual is not capable of achieving a vocational goal, and a certification of ineligibility under § 1361.35(c) is then executed; and

(3) There will be a periodic review, at least annually, of the ineligibility decision in which the individual is given opportunity for full consultation in the reconsideration of the decision, except in situations where a periodic review would be precluded because the individual has refused services or has refused a periodic review, the individual is no longer present in the State, his or her whereabouts are unknown, or his or her medical condition is rapidly progressive or terminal. The first review of the ineligibility decision is initiated by the State unit. Any subsequent reviews, however, are to be undertaken at the request of the individual.

§ 1361.41 The individualized written rehabilitation program: Content.

(a) *Scope of content.* The State plan must assure that the individualized written rehabilitation program places primary emphasis on the determination and achievement of a vocational goal, and as appropriate includes, but is not necessarily limited to, statements concerning:

(1) The basis on which the determination of eligibility has been made, or the basis on which a determination has been made that an extended evaluation of vocational rehabilitation potential is necessary to make a determination of eligibility;

(2) The long-range and intermediate rehabilitation objectives established for the individual;

(3) The determination of the specific vocational rehabilitation services to be provided in order to achieve the established rehabilitation objectives;

(4) The projected date for the initiation of each vocational rehabilitation service, and the anticipated duration of each service;

(5) A procedure and schedule for periodic review and evaluation of progress toward achieving rehabilitation objectives based upon objective criteria, and a record of these reviews and evaluations;

(6) The views of the handicapped individual, or, as appropriate, his parent, guardian, or other representative, concerning his goals and objectives and the vocational rehabilitation services being provided;

(7) The terms and conditions for the provision of vocational rehabilitation services including responsibilities of the handicapped individual in implementing the individualized written rehabilitation program, the extent of client participation in the cost of services if any, the extent to which the individual is eligible for similar benefits under any other programs; and the extent to which these similar benefits have been used;

(8) An assurance that the handicapped individual has been informed of his or her rights and the means by which he may express and seek remedy for any dissatisfaction, including the opportunity for an administrative review of agency action or fair hearing under § 1361.48;

(9) Where appropriate, assurance that the handicapped individual has been provided a detailed explanation of the availability of the resources within a client assistance project established under Part 1362 of this chapter;

(10) The basis on which the individual has been determined to be rehabilitated under § 1361.43; and

(11) Any plans for the provision of post-employment services after a suitable employment goal has been achieved and the basis on which such plans are developed.

(b) *Coordination with education agencies.* When services are being provided to a handicapped individual who is also eligible for services under the Education for Handicapped Children Act, the individualized written rehabilitation program is prepared in coordination with the appropriate education agency and includes the content of the individualized education program for that individual.

§ 1361.42 Scope of State unit program: Vocational rehabilitation services for individuals.

(a) *Scope of services.* The State plan must assure that, as appropriate to the vocational rehabilitation needs of each individual, the following vocational rehabilitation services are available:

(1) Evaluation of vocational rehabilitation potential, including diagnostic and related services incidental to the determination of eligibility for, and the nature and scope of services to be provided;

(2) Counseling and guidance, including personal adjustment counseling, to maintain a counseling relationship throughout a handicapped individual's program of services, and referral necessary to help handicapped individuals secure needed services from other agencies;

(3) Physical and mental restoration services, necessary to correct or substantially modify a physical or mental condition which is stable or slowly progressive;

(4) Vocational and other training services, including personal and vocational adjustment, books, tools, and other training materials except that no training or training services in institutions of higher education (universities, colleges, community/junior colleges, vocational schools, technical institutes, or hospital schools of nursing) may be paid for with funds under this part unless maximum efforts have been made by the State unit to secure grant assistance in whole or in part from other sources;

(5) Maintenance, including payments, not exceeding the estimated cost of subsistence and provided at any time after vocational rehabilitation services have begun through the time when post-employment services are being provided. Maintenance covers a handicapped individual's basic living expenses, such as food, shelter, clothing, and other subsistence expenses which are necessary to support and derive the full benefit of the other vocational rehabilitation services being provided;

(6) Transportation, including necessary travel and related expenses including subsistence during travel (or per diem payments in lieu of subsistence) in connection with transporting handicapped individuals and their attendants or escorts for the purpose of supporting and deriving the full benefit of the other vocational rehabilitation services being provided. Transportation may include relocation and moving expenses necessary for achieving a vocational rehabilitation objective;

(7) Services to members of a handicapped individual's family when necessary to the vocational rehabilitation of the handicapped individual;

(8) Interpreter services for the deaf, including tactile interpreting for deaf-blind individuals;

(9) Reader services, rehabilitation teaching services, and orientation and mobility services for the blind;

(10) Telecommunications, sensory and other technological aids and devices;

(11) Recruitment and training services to provide new employment opportunities in the fields of rehabilitation, health, welfare, public safety, law enforcement and other appropriate public service employment;

(12) Placement in suitable employment;

(13) Post-employment services necessary to maintain suitable employment;

(14) Occupational licenses, including any license, permit or other written authority required by a State, city or other governmental unit to be obtained in order to enter an occupation or enter a small business, tools, equipment, initial stocks (including livestock) and supplies; and

(15) Other goods and services which can reasonably be expected to benefit a handicapped individual in terms of employability.

(b) *Written policies.* The State plan must also assure that the State unit establishes and maintains written policies covering the scope and nature of each of the vocational rehabilitation services specified in paragraph (a) of this section, and the conditions, criteria, and procedures under which each service is provided.

(c) *Special requirements.* In the case of telecommunications, sensory, and other technological aids and devices, the written policies must ensure that individualized prescriptions and fittings are performed only by individuals licensed in accordance with State licensure laws, or by appropriate certified professionals. Any hearing aid recommended on the basis of an evaluation of the auditory system must be fitted in accordance with the specifications of the findings obtained under § 1361.33. Newly developed aids and devices not requiring individualized fittings must meet any engineering and safety standards recognized by the Commissioner.

§ 1361.43 Individuals determined to be rehabilitated.

(a) *Minimum requirements.* The State plan must assure that an individual determined to be rehabilitated, must have been, as a minimum:

(1) Determined to be eligible under § 1361.35(a);

(2) Provided and evaluation of vocational rehabilitation potential, and counseling and guidance as essential vocational rehabilitation services;

(3) Provided appropriate and substantial vocational rehabilitation services in accordance with the individualized written rehabilitation program developed under § 1361.40 and § 1361.41; and

(4) Determined to have achieved and maintained a suitable employment goal for at least 60 days.

(b) *Post-employment services.* The State plan must also assure that after an individual has been determined to be rehabilitated, the State unit will provide post-employment services when necessary to assist an individual to maintain suitable employment.

§ 1361.44 Authorization of services.

The State plan must assure that written authorization is made, either before or at the same time as the purchase of services. Where a State unit employee is permitted to make oral authorization in an emergency situation, there must be prompt documentation and the authorization must be confirmed in writing and forwarded to the provider of the services.

§ 1361.45 Standards for facilities and providers of services.

(a) *General provisions.* The State plan must assure that the designated State unit adopts and maintains written minimum standards for the various types of facilities and providers of services utilized by the State unit in providing vocational rehabilitation services. The State unit must make these standards readily available to unit personnel and to the public.

(b) *Rehabilitation facility standards.* The State unit must establish written standards covering physical plant, equipment, personnel administration and management, and safety for rehabilitation facilities. Insofar as workshops are concerned, the State unit must also establish standards applicable to health conditions, wages, hours, working conditions, and workmen's compensation or liability insurance. These standards must incorporate applicable standards established by the Commissioner and must conform with regulations of the Secretary of Labor relating to occupational safety and health standards for rehabilitation facilities. These standards must also assure that all medical and related health services provided in a rehabilitation facility are prescribed by, or under the formal supervision of persons licensed to prescribe or supervise the provision of these services in the State. State unit standards must assure that any rehabilitation facility utilized in the provision of vocational rehabilitation services fully complies with the requirements of the Architectural Barriers Act of 1968 and, the "American Standards Specification for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," No. A117.1–1961, as amended, and its implementing standards 41 CFR Part 101–19.6 et seq.

(c) *Rehabilitation facility personnel and providers of services.* The Commissioner exercises no authority concerning the selection, method of selection, tenure of office, or compensation of any individual employed in any facility or personnel utilized in providing services.

§ 1361.46 Rates of payment.

The State plan must assure that the State unit establishes and maintains written policies to govern rates of payment for all purchased vocational rehabilitation services. Any vendor providing services authorized by the State unit must agree not to make any charge to or accept any payment from the handicapped individual or his or her family for the service unless the amount of the charge of payment is previously known and, where applicable, approved by the State unit.

§ 1361.47 Participation by handicapped individuals in the cost of vocational rehabilitation services.

(a) *Financial need.* (1) There is no Federal requirement that the financial need of a handicapped individual be considered in the provision of any vocational rehabilitation services.

(2) If the State chooses to consider the financial need of handicapped individuals for purposes of determining the extent of their participation in the costs of vocational rehabilitation services, the State unit must maintain written policies covering the determination of financial need, and the State plan must specify the types of vocational rehabilitation services for which the unit has established a financial needs test.

(3) The State plan must assure that no financial needs test is applied as a condition for furnishing the following vocational rehabilitation services:

(i) Evaluation of rehabilitation potential, except for those vocational rehabilitation services other than of a diagnostic nature which are provided under an extended evaluation of rehabilitation potential under § 1361.34;

(ii) Counseling, guidance, and referral services; and

(iii) Placement.

(b) *Consideration of similar benefits.* (1) The State plan must assure that, in all cases, the State unit gives full consideration to any similar benefits available to a handicapped individual, or to members of a handicapped individual's family, under any program to meet, in whole or in part, the cost of any vocational rehabilitation services except the following:

(i) Evaluation of vocational rehabilitation potential except as provided under paragraph (b)(4) of this section;

(ii) Counseling, guidance and referral;

(iii) Vocational and other training services, including personal and vocational adjustment training, books, tools, and other training materials, which are not provided in institutions of higher education;

(iv) Placement; and

(v) Post-employment services consisting of the services listed under paragraphs (b)(1) (i)–(iv) of this section.

(2) The State plan must assure that the designated State unit gives full consideration to any similar benefits available under any other program to a handicapped individual to meet, in whole or in part, the cost of physical and mental restoration services and maintenance unless it would significantly delay the provision of services to an individual;

(3) The State plan must also assure that when an individual is eligible for similar benefits, these benefits must be utilized insofar as they are adequate and do not interfere with achieving the rehabilitation objective of the individual.

(4) The State plan must also assure that the State unit gives full consideration to any similar benefits available to a handicapped individual who is being provided any of the services under paragraphs (b)(1) and (b)(2) of this section under an extended evaluation of vocational rehabilitation potential.

§ 1361.48 Administrative review of agency action and fair hearing; review by Secretary.

(a) *General provisions.* The State plan must assure that an applicant for or a recipient of vocational rehabilitation services under the State plan who is dissatisfied with any action concerning the furnishing or denial of services may file a request for an administrative review and redetermination of that action by the supervisory staff of the designated State unit. The State plan must also provide that an individual who is dissatisfied with the finding of this administrative review, is given an opportunity for a hearing before the State unit director or his designee.

(b) *Review by State unit director.* When a recipient is dissatisfied with any decision or determination made under an individualized written rehabilitation program, the individual, or as appropriate, his or her parent, guardian or other representative, may also request that the decision or determination be reviewed by the State unit director. The final decision made on the basis of the review must be made in writing by the director. The procedures established by the State unit in this regard mut provide that the responsibility for making the final decision may not be delegated to any other officer or employee of the designated State unit.

(c) *Review by Secretary or Assistant Secretary.* When a recipient is

dissatisfied with a final decision made by the State unit director concerning a determination or decision made by a State unit representative under an individualized written rehabilitation program under this section, the individual may request the Secretary to review the decision. When this request is made, the Secretary or an Assistant Secretary designated by the Secretary reviews the State unit director's decision and makes recommendations to the director concerning action to be taken to resolve the issue and dispose of the matter. Within 60 days of receiving these recommendations, the director advises the handicapped individual and the Secretary of the final disposition of the matter.

(d) *Informing applicants and recipients.* Each applicant or recipient of vocational rehabilitation services must be informed of the opportunities available under this section.

§ 1361.49 Protection, use and release of personal information.

(a) *General provisions.* The State plan must assure that the State agency will adopt and implement policies and procedures to safeguard the confidentiality of all personal information received by the agency, its representatives, or its employees. These policies and procedures must assure that:

(1) All information is the property of the State agency;

(2) Specific safeguards protect current and stored personal information;

(3) All applicants, clients, representatives of applicants or clients, service providers, cooperating agencies, and interested persons are informed of the confidentiality of personal information and the conditions for accessing and releasing this information;

(4) All applicants or their representatives must be informed about the State unit need to collect personal information and the policies governing its use, including:

(i) Identification of the authority under which information is collected;

(ii) Explanation of the principal purposes for which the State unit intends to use or release the information;

(iii) Explanation of whether the individual's providing the information is mandatory or voluntary and the effects of not providing requested information to the State unit;

(iv) Identification of those situations where the State unit requires informed written consent of the individual before information may be released; and

(v) Identification of other agencies to which information is routinely released.

(5) All explanations to applicants, clients or their representatives about State policies and procedures affecting personal information must be in the individual's native language or must be through appropriate modes of communication for those individuals who rely on special modes of communicating; and

(6) These policies and procedures must prevail over less stringent State laws and regulations.

(b) *State program use.* All personal information in the possession of the State agency must be used only for purposes directly connected with the administration of the vocational rehabilitation program. In the administration of the program, the State unit may obtain personal information from, and share it, with service provides and cooperating agencies under assurances that the information may not be further divulged, except as provided under paragraphs (c), (d) and (e) of this section;

(c) *Release to involved individuals.* (1) When requested in writing by the involved individual or his or her representative, the State unit must make personal information in the case record accessible to the individual or release it to him or her or a representative in a timely manner. Medical or psychological information which the State unit believes may be harmful to the individual may not be released directly to the individual but must be provided through his or her representative, a physician or a licensed or certified psychologist;

(2) When personal information has been obtained from another individual, agency, or organization covered by other Federal laws and regulations governing the release of information, the information may be released only by the providing individual, agency, or organization.

(d) *Release for audit, evaluation, and research.* Personal information may be released to an organization, agency, or individual engaged in audit, evaluation, or research only for purposes directly connected with the administration of the vocational rehabilitation program and only if the organization, agency, or individual assures that:

(1) The information will be used only for the purposes for which it is being provided;

(2) The information will be released only to persons officially connected with the audit, evaluation or research;

(3) The information will not be released to the involved individual; and

(4) The final product will not reveal any personal identifying information without the informed written consent of the involved individual, or his or her representative.

(e) *Release for other program purposes.* (1) The State unit may release to another public agency for other program purposes only that personal information which may be released to the involved individual under paragraph (c) of this section. Additional personal information may be released when the other public agency assures the State unit that the additional information will be used only for the purpose for which it is being provided and will not be further released to the involved individual, except as provided under paragraph (c) of this section.

(2) Personal information must be released, unless expressly prohibited by Federal or State laws or regulations, to any legally constituted public investigative or judicial authority; and

(3) Personal information may also be released in order to protect the individual or others when the individual poses a threat to his or her safety or to the safety of others.

§ 1361.50 Scope of State unit program: Management services and supervision for small business enterprises for severely handicapped individuals.

(a) *General provisions.* The State plan may provide for establishing small business enterprises operated by severely handicapped individuals and may also provide for management services and supervision for these enterprises. "Management services and supervision" includes inspection, quality control, consultation, accounting, regulating, in-service training, and related services provided on a systematic basis to support and improve small business enterprises operated by severely handicapped individuals. "Management services and supervision" does not include those services or costs which pertain to the ongoing operation of the individual business enterprise after the initial establishment period.

(b) *Special policies.* If the State plan provides for management services and supervision, it must assure that the State unit maintains:

(1) A description of the types of small business enterprises to be established;

(2) A description of the policies governing the acquisition of vending facilities or other equipment and initial stocks (including livestock) and supplies for business enterprises;

(3) A description of the policies governing the management and supervision of the program;

(4) A description of how management and supervision will be accomplished either by the State unit or by some other

organization as the nominee of the unit subject to its control; and

(5) An assurance that only severely handicapped individuals will be selected to participate in this supervised program.

(c) *Set-aside funds.* If the State unit chooses to set aside funds from the proceeds of the operation of business enterprises, the State plan must also assure that the State maintains a description of the methods used in setting aside funds, and the purpose for which funds are set aside. Funds may be used only for small business enterprises program purposes and any benefits for operators must be provided on an equitable basis.

§ 1361.51 Scope of State unit program: Establishment of rehabilitation facilities.

If the State plan provides for the establishment of public or other nonprofit rehabilitation facilities, it must assures that:

(a) The State unit will determine that the need for the establishment of any rehabilitation facility assisted under this section has been demonstrated in the State's inventory of rehabilitation facilities under § 1361.22;

(b) Any rehabilitation facility to be established will meet the State standards for rehabilitation facilities maintained under § 1361.45;

(c) The primary purpose of any rehabilitation facility to be established is to provide vocational rehabilitation services or transitional or extended employment to handicapped individuals;

(d) Initial or additional staffing assistance will be available only for personnel who are engaged in new or expanded program activities of the rehabilitation facility; and

(e) Any rehabilitation facility established under this part will develop and implement a plan to take affirmative action to employ and advance in employment qualified handicapped individuals which provides for specific action steps, timetables, and complaint and enforcement procedures.

§ 1361.52 Scope of State unit program: Construction of rehabilitation facilities.

If the State plan provides for the construction of public or other nonprofit rehabilitation facilities, it must assures that:

(a) The State unit will determine that the need for the construction of any rehabilitation facility assisted under this section has been demostrated in the State's inventory of rehabilitation facilities under § 1361.22;

(b) Any rehabilitation facility to be constructed will meet the State standards for rehabilitation facilities maintained under § 1361.45;

(c) The primary purpose of any rehabilitation facility to be constructed under this section is to provide vocational rehabilitation services or transitional or extended employment to handicapped individuals;

(d) The total Federal financial participation in the expenditures for the construction of rehabilitation facilities for a fiscal year will not exceed 10 percent of the State's allotment for that year under section 110 of the Act;

(e) For fiscal year the amount of the State's share of expenditures for vocational rehabilitation services under the plan, other than for the construction of rehabilitation facilities and the establishment of rehabilitation facilities, will be at least equal to the average of its expenditures for the other vocational rehabilitation services for the preceding three fiscal years;

(f) In addition to any other requirement imposed by law, each proposal will be subject to the requirements for the construction of a rehabilitation facility under Part 1362 of this chapter and the condition that the applicant will furnish and comply with all assurances set forth in the application; and

(g) Any rehabilitation facility constructed under this part will develop and implement a plan to take affirmative action to employ and advance in employment qualified handicapped individuals which provides for specific action steps, timetables, and complaint and enforcement procedures.

§ 1361.53 Scope of State unit program: Facilities and services for groups of handicapped individuals.

The State plan may provide for facilities and services, including services provided at rehabilitation facilities, which may be expected to contribute substantially to the vocational rehabilitation of a group of individuals, but which are not related directly to the individualized rehabilitation program of any one handicapped individual. If the State plan includes these facilities and services, it must assure that the State unit establishes and maintains written policies covering their provision.

§ 1361.54 Scope of State unit program: Telecommunications systems.

The State plan may provide for the use of existing telecommunications systems which have the potential for substantially improving vocational rehabilitation service delivery methods and developing appropriate programming to meet the particular needs of handicapped individuals, especially those who are homebound, those who live in rural areas, and those who rely on special modes of communication. These telecommunications systems shall include telephone, television, satellite, tactile-vibratory devices, and similar systems, as appropriate. If the State plan includes these systems, it must assure that the State unit establishes and maintains written policies covering their use.

§ 1361.55 Scope of State unit program; special materials for blind individuals and for deaf individuals.

The State plan may provide for the use of special services available to provide recorded material for blind individuals, captioned television, films or video cassettes for deaf individuals, tactile materials for deaf-blind individuals, and other special materials providing tactile, vibratory, auditory, and visual readout. If the State plan includes these materials, it must assure that the State unit establishes and maintains written policies covering their provision. These policies must ensure that the special communication services are available in the native languages of handicapped individuals from ethnic groups which represent substantial segments of the population of the State.

§ 1361.56 Utilization of community resources.

The State plan must assure that, in providing vocational rehabilitation services, maximum utilization is made of public or other vocational or technical training facilities or other appropriate community resources.

§ 1361.57 Utilization of profitmaking organizations for on-the-job training in connection with selected projects.

The State plan must assure that the State unit has the authority to enter into contracts with profitmaking organizations for the purpose of providing on-the-job training and related programs for handicapped individuals under § 1361.43 (projects with industry) or § 1362.117 (business opportunities for handicapped individuals). The State plan must also assure that profitmaking organizations are utilized by the State unit when it has been determined that they are better qualified to provide needed services than nonprofit agencies, organizations, or facilities in the State.

§ 1361.58 Periodic review of extended employment in rehabilitation facilities.

The State plan must assure periodic review and revaluation at least annually, of the status of those handicapped individuals who have been

placed by the State unit in extended employment in rehabilitation facilities, to determine the feasibility of their employment or their training for future employment in the competitive labor market. The State plan must assure that maximum effort is made to place these individuals in competitive employment or training for competitive employment whenever feasible.

Subpart C—Financing of State Vocational Rehabilitation Programs

Federal Financial Participation

§ 1361.70 Effect of State rules.

Subject to the provisions and limitations of the Act and this part, Federal financial participation is available in expenditures made under the State plan (including the administration thereof) in accordance with applicable State laws, rules, regulations, and standards governing expenditures by State and local agencies.

§ 1361.71 Vocational rehabilitation services to individuals.

(a) Federal financial participation is available in expenditures made under the State plan for providing an evaluation of vocational rehabilitation potential, and for providing specified vocational rehabilitation services to handicapped individuals as appropriate. Other goods and services not specified under this part and necessary to determine the vocational rehabilitation potential of a handicapped individual or to be of benefit in terms of his or her employability may also be provided. (This may include expenditures for short periods of medical care for acute conditions arising during the course of rehabilitation, which, if not cared for, would constitute a hazard to the evaluation of vocational rehabilitation potential or to the achievement of the rehabilitation objective.)

(b) Federal financial participation may also be available for costs necessary to determine an individual's eligibility to participate in the business opportunity program under § 1362.117 and the costs of native healing practitioners when services are being provided to handicapped American Indians under the State plan.

(c) Federal financial participation is not available in any expenditure made, either directly or indirectly, for the purchase of any land, or for the purchase or erection of any building (except for a shelter under § 1361.72) for any one handicapped individual or for a group of handicapped individuals under § 1361.53.

§ 1361.72 Management services and supervision for small business enterprises for severely handicapped individuals.

(a) Federal financial participation is available in expenditures made under the State plan for the acquisition of equipment, and initial stocks (including livestock) and supplies for small business enterprises (including vending facilities) for severely handicapped individuals, and management services and supervision provided by the State unit to improve the operation of these small business enterprises (including vending facilities). "Equipment" includes shelters, which are those facilities for a business undertaking which are customarily furnished to the operator of a similar business occupying premises under a short-term lease. Federal financial participation is not available in any expenditure for the purchase of any land, nor for the purchase or erection of any building. This exclusion with respect to buildings does not apply to shelters as described in this paragraph.

(b) Federal financial participation is available for expenditures specified under paragraph (a) of this section, which are made from funds set-aside by the State unit from the proceeds of the operation of small business enterprises for the most severely handicapped individuals under its management and supervision.

§ 1361.73 Establishment of rehabilitation facilities.

(a) Federal financial participation is available in expenditures made under the State plan for the establishment of public and other nonprofit rehabilitation facilities for the following types of expenditures, except as limited in paragraph (b) of this section:

(1) Acquisition of existing buildings, and where necessary, the land in connection therewith;

(2) Remodeling and alteration of existing buildings;

(3) Expansion of existing buildings;

(4) Architect's fees;

(5) Site survey and soil investigation;

(6) Initial and additional fixed or movable equipment of existing building;

(7) Initial and additional staffing of rehabilitation facilities; and

(8) Such other direct expenditures as are appropriate to the establishment project.

(b) Federal financial participation is not available in any expenditure:

(1) For the acquisition of an existing building when the Federal share of the cost of acquisition of the building under this section is more than $200,000;

(2) For the rental of land, or rental of buildings in connection with the establishment of rehabilitation facilities;

(3) For the remodeling or alteration of an existing building when the estimated cost of remodeling or alteration exceeds the fair market value of the building prior to its remodeling or alteration;

(4) For the expansion of an existing building which has not been completed in all respects;

(5) For the expansion of an existing building to the extent that the total size of the resultant expanded building, determined in square footage of usable space, will be greater than twice the size of the original existing building; or

(6) For the expansion of an existing building if the method of joining the expanded portion of the existing building indicates that, in effect, a separate structure is involved.

(c) The amount of Federal financial participation in the establishment of a rehabilitation facility, including initial equipment, and initial and additional staffing for a period not longer than 4 years and 3 months, shall be 80 per cent.

(d) Funds made available to a private nonprofit agency for the establishment of a rehabilitation facility must be expended by that agency in accordance with procedures and standards equivalent to those of the State agency in making direct expenditures for similar purposes.

§ 1361.74 Construction of rehabilitation facilities.

(a) Federal financial participation is available in expenditures made under the State plan for the construction of public or other nonprofit rehabilitation facilities for the following types of expenditures:

(1) Acquisition of land in connection with the construction of a rehabilitation facility;

(2) Acquisition of existing buildings;

(3) Remodeling, alteration or renovation of existing buildings;

(4) Construction of new buildings and expansion of existing buildings when the expansion is extensive enough to be tantamount to new construction;

(5) Architect's fees;

(6) Site survey and soil investigation;

(7) Initial fixed or movable equipment of such new, newly acquired, expanded, remodeled, altered or renovated buildings;

(8) Works of art in an amount not to exceed 1 per cent of the total cost of the project; and

(9) Other direct expenditures appropriate to the construction project, except that Federal financial participation is not available for costs of off-site improvements.

(b) The amount of Federal financial participation in the construction of a rehabilitation facility may not be more than 50 per cent of the total cost of the project.

(c) Funds made available to a private nonprofit agency for the construction of a rehabilitation facility must be expended by that agency in accordance with procedures and standards equivalent to those of the State unit in making direct expenditures for similar purposes.

§ 1361.75 Other vocational rehabilitation services for the benefit of groups of handicapped individuals.

Federal financial participation is available in expenditures made under a State plan for the provision of other facilities and services including services provided at rehabilitation facilities which may be expected to contribute substantially to the rehabilitation of a group of handicapped individuals but which are not related directly to the rehabilitation of any one handicapped individual. Federal financial participation is also available in expenditures for the use of existing telecommunications systems and for the use of special materials for blind individuals and deaf individuals.

§ 1361.76 State and local funds.

For purpose of this part, "State or local funds" means:

(a) Funds made available by appropriation directly to the State or local agency, funds made available by allotment or transfer from any other unit of State or local government, or expenditures made by any unit of State or local government under a cooperative program under § 1361.14.

(b) Contributions by private organizations or individuals, which are deposited in the account of the State or local agency in accordance with State law, for expenditure by, and at the sole discretion of, the State or local agency. Contributions earmarked for meeting the State's share for providing particular services, for serving certain types of disabilities, for providing services for special groups identified on the basis of criteria which would be acceptable for the earmarking of public funds, or for carrying on types of administrative activities so identified may be considered to be State funds, if permissible under State law, except that Federal financial participation will not be available in expenditures that revert to the donor's use or facility;

(c) Funds set aside pursuant to § 1361.72(b); or

(d) Contributions by private agencies, organizations or individuals deposited in the account of the State or local agency in accordance with State law, which are earmarked, under a condition imposed by the contributor, for meeting (in whole or in part) the State's share for establishing or constructing a particular rehabilitation facility, if permissible under State law. These funds may be used to earn Federal funds only with respect to expenditures for establishing or constructing the particular rehabilitation facility for which the contributions are earmarked.

§ 1361.77 Shared funding and administration of joint projects or programs.

Where the Commissioner approves a request by the State unit to participate in a joint project or program with another agency or agencies of the State, or with a local agency in accordance with § 1361.12. Federal financial participation is available in the State unit share of costs for which there is Federal participation under the Act.

§ 1361.78 Waiver of Statewideness.

If the approved State plan provides for activities to be carried out in one or more political subdivisions through local financing (§ 1361.13), Federal financial participation is available in expenditures made under the State plan for vocational rehabilitation services and administration in connection with these activities except that funds made available to the State unit by these political subdivisions of the State (including funds contributed to such a subdivision by a private agency, organization or individual) may be earmarked for use within a specific geographical area or for use within a specific facility or for the benefit of a group of individuals with a particular disability. Nothing in this paragraph, however, authorizes the further earmarking of funds for a particular individual or for members of a particular organization, and Federal financial participation is not available in expenditures that revert to the donor's use or facility where the donor is a private agency, organization or individual.

Allotment and Payment

§ 1361.85 Allotment of Federal funds for vocational rehabilitation services.

(a) The allotment of Federal funds for vocational rehabilitation services for each State is computed in accordance with the requirements of section 110 of the Act.

(b) Where the State plan designates separate agencies to administer (or supervise the administration of) the part of the plan under which vocational rehabilitation services are provided for the blind, and the rest of the plan, respectively, the division of the State's allotment is a matter for State determination.

(c) The total Federal financial participation in the expenditures for construction for a fiscal year may not exceed 10 per cent of the State's allotment for that year. The amount of the State's share of expenditures for vocational rehabilitation services other than for the establishment of rehabilitation facilities must be at least equal to the average of its expenditures for those other vocational rehabilitation services for the preceding 3 fiscal years.

(d) When a special project has been awarded for the provision of vocational rehabilitation services to handicapped American Indians residing on a reservation under § 1362.45, and the State unit does not intend to continue to provide vocational rehabilitation services to these American Indians, the allotment for the State in which the reservation is located is computed by subtracting from the population under paragraph (a) of this section:

(1) 33 percent of the total number of American Indians residing on the reservation to be served in the first full fiscal year during which the special project is in operation;

(2) 66 percent of such American Indians in the second full fiscal year during which the special project is in operation; and

(3) 100 percent of such American Indians in the third full fiscal year during which the special project is in operation.

§ 1361.86 Payments from allotments for vocational rehabilitation services.

(a) Except as provided in § 1361.85(c), the Commissioner pays to each State an amount computed in accordance with the requirements of Section 111 of the Act. The Federal share for each State is 80 per cent (except for the cost of construction of rehabilitation facilities).

(b) Amounts otherwise payable to a State under this section for any fiscal year are reduced by the amount (if any) by which expenditures from non-Federal sources, as specified in § 1361.76 (except for expenditures with respect to which the State is entitled to payments under Subpart F of this part) for that fiscal year under the State's approved plan for vocational rehabilitation services are less than expenditures under the plan for the fiscal year ending June 30, 1972. If a reduction in payments for any fiscal year is required in the case of a State where separate agencies administer (or supervise the administration of) the part of the plan under which vocational

rehabilitation services are provided for blind individuals, and the rest of the plan, respectively, the reduction is made in direct relation to the amount by which expenditures from non-Federal sources under each part of the plan are less than they were under that part of the plan during the fiscal year ending June 30, 1972.

§ 1361.87 Method of computing and making payments.

(a) *Estimates.* Before the beginning of each fiscal quarter or other prescribed period, the Commissioner estimates the amount to be paid to each State from its allotment for vocational rehabilitation services under section 110 of the Act, and its allotment for innovation and expansion projects under section 120 of the Act. This estimate is based on records of the State and information furnished by it, and any other investigation found necessary by the Commissioner.

(b) *Payments.* The Commissioner pays, from the allotment available, the amount estimated for the determined period. In making any payment, additions and subtractions are made as necessary in balancing the Federal-State account for any prior period on the basis of the State's accounting. Payments are made prior to audit or settlement by the General Accounting Office through the disbursing facilities of the Treasury Department in installments set by the Commissioner.

§ 1361.88 Liquidation of unpaid obligations.

All State agency obligations under the State plan are liquidated within one year of the close of the fiscal year in which the obligation was incurred except for obligations in connection with the establishment or construction of rehabilitation facilities. Where State law permits liquidation of obligations beyond one year of the date of incurrence, the State may request an exemption from this requirement from the Commissioner.

§ 1361.89 Refunds.

Any amount refunded or repaid by the State is credited to the Federal account in proportion to the Federal participation in the expenditures by reason of which the refunds or repayments were made. These sums are considered as granted from the State's allotment.

§ 1361.90 Determining to which fiscal year expenditures are chargeable.

In determining to which Federal fiscal year expenditures are chargeable, States are governed by the following:

(a) Expenditures are chargeable to a particular fiscal year in accordance with State laws or regulations. In the absence of applicable provisions of State laws or regulations, the actual date of the expenditure is controlling;

(b) In the event that a State's fiscal year does not coincide with the Federal fiscal year, appropriate State laws or regulations governing the recording of expenditures govern;

(c) In those States which appropriate funds for a biennium, the principles provided in State laws, regulations and practices for determining to which year of the biennium an expenditure is charged apply.

§ 1361.91 Audits.

(a) Whenever considered necessary and appropriate, the operations of the State agency are audited. These audits are made to determine whether the State agency is being operated in a manner that:

(1) Encourages prudent use of program funds; and

(2) Provides a reasonable degree of assurance that funds are being properly expended for the purpose for which appropriated and provided under the Act and the State plan.

(b) Final determination as to action to be taken as a result of an audit is made by the Commissioner.

§ 1361.92 Appeals procedures and expenditures settlement.

The State agency has the right to appeal proposed audit exceptions in which it has not concurred. This appeal must be made within 45 days of receiving the notice and in accordance with the requirements of 45 CFR Part 16. When expenditures have not been accepted by the Commissioner and the State has not made proper restitution, the claim is deducted from subsequent grants made to the State agency.

Subpart F—Grants for Innovation and Expansion of Vocational Rehabilitation Services

§ 1361.150 Purpose.

Under section 121(a) of the Act, grants may be made for the purpose of paying a portion of the cost of planning, preparing for, and initiating special programs under the State plan in order to expand vocational rehabilitation services, including:

(a) Programs to initiate or expand services to individuals who are the most severely handicapped, or

(b) Special programs to initiate or expand services to classes of handicapped individuals who have unusual and difficult problems in connection with their rehabilitation, particularly handicapped individuals who are poor and the responsibility for whose treatment, education, and rehabilitation is shared by the designated State unit with other agencies.

§ 1361.151 Special project requirements.

(a) All project activities to be performed under this subpart must either be included within the scope of the approved State plan, or the State plan must be amended to include them.

(b) Grants may be made to a State unit or at the option of the State unit to a public or nonprofit organization or agency.

(c) The approval of the appropriate designated State unit must be secured before funds may be granted to any organization or agency other than the designated State unit for the provision of direct services to handicapped individuals or for establishing or maintaining facilities which provide direct services to handicapped individuals.

(d) Written program descriptions of activities to be conducted under grants under this subpart, including a budget, must be submitted in the detail and according to the procedures required by the Commissioner.

(e) Federal financial participation in the cost of any project under this subpart is not available for any period longer than 36 months.

(f) The construction of a rehabilitation facility may not be undertaken unless it has been demonstrated to be essential to carrying out a project for providing services under this subpart. In addition, the need for the facility must have been demonstrated in the State's inventory of rehabilitation facilities under § 1361.23.

(g) Grants may not be made solely for the purpose of planning or determining the feasibility of initiating a vocational rehabilitation service program.

(h) In order to receive assistance, a public or other nonprofit organization or agency, including a public or other nonprofit rehabilitation facility, must develop and implement an affirmative action plan for equal employment opportunity and advancement opportunity for qualified handicapped individuals. The affirmative action plan must provide for specific action steps, timetables, and complaint and enforcement procedures.

§ 1361.152 Allotment of Federal funds.

(a) The allotment and any reallotment of Federal funds under this subpart is computed in accordance with the requirements of section 120 of the Act.

(b) If at any time after the start of any fiscal year, or after a review after May 1

of that fiscal year, the Commissioner determines that any amount will not be utilized by a State in carrying out the purpose of this subpart, he makes that amount available to one or more other States which he determines will be able to use additional amounts during the fiscal year. Any amount made available to any State under this paragraph of this section is regarded as an increase in the State's allotment for the year.

(c) Where the State plan designates separate agencies to administer (or supervise the administration of) the part of the plan under which vocational rehabilitation services are provided for the blind, and the rest of the plan, respectively, the division of the State's allotment is a matter for State determination.

(d) Within each State's allotment, the Commissioner may require that up to 50 percent of available funds must be expended in connection with projects which he has first approved. If the Commissioner so requires, he notifies the States of any established program priorities at least 90 days prior to the beginning of each fiscal year.

§ 1361.153 Payments from allotments.

From the sums allotted under § 1361.152, the Commissioner pays to each State for any project approved under this subpart, an amount up to 90 percent of the costs of the project, (except for a project for construction of a rehabilitation facility where the amount is no more than 50 percent of the total cost of the project) consistent with annual instructions or program guidelines. The amount of Federal financial participation in the costs of construction of a rehabilitation facility is the same percentage specified in § 1361.74(b).

§ 1361.154 Methods of computing and making payments.

Computing and making payments are done in accordance with § 1361.87. The provisions of § 1361.88 through § 1361.92 also apply.

§ 1361.155 Matching requirements.

(a) The non-Federal share may be in cash or in-kind and may include funds spent for project purposes by a cooperating public or private nonprofit agency. These cash or in-kind contributions may not be included as a cost in any other federally financed program.

(b) For purposes of this subpart, Federal financial participation will be provided pursuant to the matching and cost-sharing requirements prescribed by Subpart G and Subpart Q of Part 74 of this title.

§ 1361.156 Reports.

A grantee must submit reports required by the Commissioner and must comply with any requirements necessary to assure the correctness and verification of these reports. These reports include an annual report of program accomplishments reflecting the extent to which programs of vocational rehabilitation services have been initiated or expanded for severly handicapped individuals or for other individuals who have unusual and difficult problems in connection with their rehabilitation.

Subpart G—Procedures for Hearings on State Plan Conformity and Compliance

§ 1361.170 General provisiosns.

(a) *Scope.* These hearing procedures apply to notice and opportunity for a hearing on:

(1) Disapproval of a State plan or amendment; and

(2) Determination that the State agency has failed in the administration of its approved plan to comply substantially with the provisions of its plan.

(b) *Negotiations.* Nothing in this subpart limits negotiations between the Rehabilitation Services Administration and the State. Negotiations on hearing issues are not part of the hearing and are not subject to the rules in this subpart.

(c) *How to get records.* Papers filed in connection with a hearing may be inspected and copied in the office of the Rehabilitation Services Administration Hearing Clerk. Individuals may direct inquiries to the Rehabilitation Services Administration Hearing Clerk, Department of Health, Education, and Welfare, 330 C Street SW., Washington, D.C. 20201.

(d) *How to file and serve papers.* (1) Anyone who wishes to submit papers for the docket shall file with the Rehabilitation Services Administration Hearing Clerk an original and two copies except that only originals of exhibits and testimony transcripts need be filed.

(2) Anyone who wishes papers to be part of the record shall also serve copies on the parties by personal delivery or by mail, and file proof of this service with the Rehabilitation Services Administration Hearing Clerk. Service on a party's designated attorney is the same as service on the party.

(e) *When rules are suspended.* After notifying the parties, the Commissioner or the individual he designates as presiding officer may modify or waive any rule in this subpart if it is decided that the action is equitable and will not unduly prejudice the rights of any party.

§ 1361.171 How to request a hearing.

(a) *Time limit.* A State agency has 60 days from receipt of the Commissioner's written notice of proposed disapproval of a State plan or plan amendment, or intended compliance action to request a hearing. The agency shall make its request in writing to the Commissioner.

(b) *What happens if a State agency does not request a hearing.* If The State agency does not request a hearing within the time allowed by paragraph (a) of this section, the Commissioner makes a final determination and notifies the agency by letter of his decision to withhold either all further payments under the plan or only payments for those portions of the plan affected.

(c) *How request is acknowledged.* (1) *Notice of hearing.* Within 30 days of receiving a hearing request, the Commissioner notifies the State agency in writing of the date, time, and place of the hearing and of the issues to be considered. The Commissioner publishes the hearing notice in the **Federal Register.** The hearing will be held in a building accessible to physically handicapped persons.

(2) *When hearing is held.* The date set for a hearing is 20 to 60 days from the date the State agency receives the hearing notice. However, the State agency and the Commissioner may agree in writing to a different date.

§ 1361.172 Hearing issues.

(a) *What the hearing issues are.* (1) *General rule.* The issues at a hearing are those included in the Commissioner's notice to the State agency.

(2) *How the Commissioner may add issues.* At least 20 days before a hearing, the Commissioner notifies the agency by letter of any additional issues to be considered. The Commissioner publishes this notice in the **Federal Register.** If the agency does not receive its notice of additional issues in the required time, any party may request that the Commissioner postpone the hearing. If a request is made, the Commissioner sets a new hearing date that is 20 to 60 days from the date the agency received the notice of additional issues.

(3) *How actions by the State may cause the Commisioner to* add, modify, or remove issues. The Commissioner may add, modify, or remove issues if the State agency:

(i) Conforms its plans to Federal requirements; or

(ii) Changes its practices or organization to comply with its approved State plan.

(4) *What happens if State action causes the Commissioner to add, modify, or remove issues.* (i) If the Commissioner specifies new or modified issues, the hearing proceeds on these issues.

(ii) (A) If the Commissioner removes an issue, the hearing proceeds on the remaining issues. If the Commissioner removes all issues, the Commissioner terminates the hearing proceedings. The Commissioner may terminate hearing proceedings or remove issues before, during, or after the hearing.

(B) Before removing an issue, the Commissioner notifies the parties other than the Rehabilitation Services Administration and the State agency of the issue and the reasons for removing the issue. Within 20 days of the date of this notice, the parties may submit comments in writing on the merits of the proposed removal. The Commissioner considers these comments and they become part of the record.

§ 1361.173 What the purpose of a hearing is.

The purpose of the hearing is to receive factual evidence and testimony, including expert opinion testimony, related to the issues. The presiding officer may not allow argument as evidence.

§ 1361.174 Who presides.

The presiding officer at a hearing is the Commissioner or a person he designates. If the Commissioner designates a presiding officer, the Commissioner sends copies of the designation notice to the parties.

§ 1361.175 How to be a party or an amicus curiae to a hearing.

(a) *Rehabilitation Services Administration and State agency.* The Rehabilitation Services Administration and the State agency are parties to a hearing without having to request participation.

(b) *Other parties or amicus curiae.* An individual or group wishing to be a party or amicus curiae to a hearing may file a petition with the Rehabilitation Services Administration Hearing Clerk no more than 15 days following publication of the hearing notice in the **Federal Register.** A petitioner who wishes to be a party must also provide a copy of the petition to each party of record at that time.

(c) *What must be in a petition.* A petition must state concisely: (1) Whether the petitioner wishes to be a party or an amicus curiae;

(2) The petitioner's interest in the proceedings;

(3) Who will appear for the petitioner;

(4) The issues on which the petitioner wishes to participate; and

(5) Whether the petitioner intends to present witnesses, if the petitioner wishes to be a party.

§ 1361.176 What happens to a petition.

(a) *Petitions to be a party.* (1) The presiding officer determines if the issues to be considered at the hearing have caused the petitioner injury and if the petitioner's interest is within the zone of interest protected by the governing Federal statute. The presiding officer permits or denies the petition accordingly and promptly sends the petitioner a written notice of the decision. If the presiding officer denies the petition, the officer states the reasons in the notice.

(2) Before making this determination, the presiding officer will allow any party to file comments on the petition to be a party. Any party who wishes to file comments must do so within 5 days of receiving the petition.

(3) If the presiding officer decides that parties by petition have common interest, the officer may require that they designate a single representative, or may recognize two or more of these parties to represent all of them.

(b) *Petitions to be amicus curiae.* The presiding officer determines if the petitioner has a legitimate interest in the proceedings and may contribute materially to the proper settlement of the issues. The officer also determines if the petitioner's participation would unduly delay the proceedings. The presiding officer permits or denies the petition accordingly and promptly sends the petitioner a written notice of the decision. If the presiding officer denies the petition, the officer states the reason in this notice.

§ 1361.177 Rights of parties and amicus curiae.

(a) *What rights parties have.* A party may:

(1) Appear by counsel or other authorized representative in all hearing proceedings;

(2) Participate in any prehearing conference held by the presiding officer;

(3) Stipulate facts that, if uncontested, become part of the record;

(4) Make opening statements;

(5) Present relevant evidence;

(6) Present witnesses who must be available for cross-examination;

(7) Present oral arguments at the hearing; and

(8) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

(b) *What rights an amicus curiae has.* An amicus curiae may:

(1) Present an oral statement at the hearing at the time specified by the presiding officer;

(2) Submit a written statement of position to the presiding officer before the hearing begins; and

(3) Submit a brief or written statement at the same time the parties submit briefs

If the amicus curiae submits a written statement or brief, the amicus shall serve a copy on each party.

§ 1361.178 Authority of presiding officer.

(a) *General rule.* The presiding officer conducts a fair hearing, avoids delay, maintains order and makes a record of the proceedings. In so doing, he or she has authority that includes:

(1) Regulating the course of the hearing;

(2) Regulating the participation and conduct of parties, amici curiae, and others at the hearing;

(3) Ruling on procedural matters and, if necessary, issuing protective orders or other relief to a party against whom discovery is sought;

(4) Taking any action authorized by the rules in this subpart;

(5) Making a final decision, if the Commissioner is the presiding officer;

(6) Administering oaths and affirmations;

(7) Examining witnesses;

(8) Receiving or excluding evidence; and

(9) Ruling on or limiting evidence or discovery.

(b) *What the presiding officer may not do.* The presiding officer may not compel by subpoena the production of witnesses, papers, or other evidence.

(c) *When the presiding officer's authority is limited.* If the presiding officer is not the Commissioner, the officer certifies the entire record to the Commissioner, including a recommended decision on each issue in the hearing, but may not:

(1) Make a final decision; or

(2) Recommend reduction or withholding of payments.

§ 1361.179 Discovery.

A party has the right to conduct discovery against other parties. These discovery proceedings are subject to Rules 26–37, Federal Rules of Civil Procedure. The presiding officer promptly rules on any written objection to discovery and may restrict or control discovery to prevent undue delay in the hearing. If a party fails to respond to discovery procedures, the presiding officer may issue any order and impose any sanction (other than contempt orders) authorized by Rule 37 of the Federal Rules of Civil Procedure.

§ 1361.180 How evidence is handled.

(a) *Testimony.* Witnesses, under oath or affirmation, give oral testimony at a hearing. Witnesses must be available at a hearing for cross-examination by the parties.

(b) *Rules of evidence.* Technical rules of evidence do not apply to hearings described in this subpart. The presiding officer applies any rules or principles necessary to ensure disclosure of the most credible evidence available and to subject testimony to cross-examination. Cross-examination may be on any material matter, regardless of the scope of direct examination.

§ 1361.181 What happens to unsponsored written material.

Letters and other written material regarding matters at issue, if not submitted specifically on behalf of a party, become part of the correspondence section of the docket. This material is not part of the evidence or the record.

§ 1361.182 What the record is.

(a) *Official transcript.* The Rehabilitation Services Administration designates the official reporter for a hearing. The Rehabilitation Services Administration Hearing Clerk has the official transcript of testimony, and other material submitted with the official transcript. The parties and the public may obtain transcripts of testimony from the official reporter at rates that do not exceed the maximum fixed by contract between the reporter and the Rehabilitation Services Administration. Upon notice to the parties, the presiding officer may authorize transcript corrections that involve matters of substance.

(b) *Record.* The record for the hearing decision is the transcript of testimony, exhibits, and all other papers and requests filed in the proceedings except for the correspondence section of the docket. The record includes rulings and any recommended decision.

§ 1361.183 Posthearing briefs.

The presiding officer fixes the time for filing posthearing briefs. They may contain proposed findings of fact and conclusions of law. The presiding officer may permit filing of reply briefs.

§ 1361.184 Decisions.

(a) *If the Commissioner is the presiding officer.* If the Commissioner is the presiding officer, the Commissioner issues a final decision 60 days after the time allowed for filing posthearing or reply briefs ends. The Commissioner provides copies of the decision to all parties and any amici curiae.

(b) *If the Commissioner appoints a presiding officer.* (1) No later than 30 days after the time for filing post-hearings or reply briefs ends, the presiding officer certifies the entire record, including his or her recommended decision, to the Commissioner.

(2) The Commissioner provides a copy of the recommended decision to the parties and any amici curiae. Within 20 days, a party may file with the Commissioner, exceptions to the recommended decision. The party must file a supporting brief or statement with the exception.

(3) The Commissioner reviews the record, and, within 60 days of the date of receipt of the presiding officer's recommended decision, the Commissioner issues a final decision. The Commissioner provides copies of the decision to all parties and any amici curiae.

(c) If the Commissioner decides, after a hearing, that the plan or plan amendment is not approvable, or substantial noncompliance exists, the final decision indicates whether RSA will withhold all further payments or only payments under portions of the plan affected.

§ 1361.185 When a decision is effective.

(a) The Commissioner's decision, which constitutes "final agency action" within the meaning of 5 U.S.C. 704 and a final determination under section 101(b) and (c)(1) of the Act, specifies the effective date for RSA's reduction or withholding of the State's grant. This effective date may not be earlier than the date of the Commissioner's decision or later than the first day of the next calendar quarter.

(b) The decision remains in effect unless reversed or stayed on judicial appeal, or until the plan or State agency administration of the plan meets all Federal requirements, except that the Commissioner may modify or set aside his or her decision before the record of the proceedings under this subpart is filed in court.

§ 1361.186 How the State may appeal.

A State may appeal to the U.S. Court of Appeals which has jurisdiction in the State, the final decision of the Commissioner disapproving the State plan or plan amendment or finding noncompliance. The State must file the appeal within 30 days after receiving the Commissioner's final decision.

2. Part 1362 is revised to read as follows:

PART 1362—PROJECT GRANTS AND OTHER ASSISTANCE IN VOCATIONAL REHABILITATION AND INDEPENDENT LIVING REHABILITATION.

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Subpart H—Projects and Other Assistance for the Provision of Special Rehabilitation Services

1362.100 Projects for the establishment and operation of centers for independent living.
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1362.103 Client Assistance projects.
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1362.106 Projects for reading services for blind individuals.
1362.107 Business opportunities for handicapped individuals.
1362.108 Special projects and demonstrations for making recreation activities accessible to handicapped individuals.
1362.109 Project grants for the initiation of special recreation programs for handicapped individuals.
1362.110 Technical assistance.

Authority: Section 12(c) of the Rehabilitation Act of 1973, (29 U.S.C. 711(c)).

Subpart A—General Provisions

§ 1362.1 Terms.

(a) The following terms were defined in § 1361.1 of this chapter:

"Act"
"Blind"
"Commissioner"
"Construction of a rehabilitation facility"
"Designated State unit"
"Employability"
"Establishment of a rehabilitation facility"
"Handicapped individual"
"Local agency"
"Maintenance"
"Nonprofit"
"Physical or mental disability"
"Rehabilitation facility"
"Secretary"
"Severely handicapped individual"
"State"
"State agency"
"State plan"
"State unit"
"vocational rehabilitation services"
"Works of art"
"Workshop"

The term "independent living rehabilitation services" or "independent living services" has the same meaning as § 1363.1 of this chapter.

§ 1362.2 Application content and procedures for submitting applications.

All applications for Federal support under this part must be submitted in the detail, and in accordance with procedures, required by the Commissioner. Where there is a competition for grant funds, the Commissioner publishes a Notice in the **Federal Register** announcing the competition for each program. The Commissioner publishes this Notice at least 60 days before the deadline date for submittal of applications.

§ 1362.3 State unit review and approval of applications.

(a) The Commissioner gives the appropriate State unit an opportunity to review and comment on applications and other requests for Federal support submitted from within the State which it serves.

(b) The applicant must secure the approval of the appropriate State unit for any application which significantly involves providing direct vocational rehabilitation services to handicapped individuals. This approval need not be secured if the scope of the proposed project extends beyond a single State.

§ 1362.4 Project period.

(a) A project under this part may generally be initially approved for a project period of up to 5 years.

(b) Any extension of the project beyond a previously approved project period which involves additional Federal funds may also be approved for a period of up to 5 years. An extension may be approved only after a competitive review of the application on the same terms and conditions placed on new applications.

(c) Where different project period limits are in effect, they are specified in the individual program regulations in this part.

§ 1362.5 Matching requirements.

Federal assistance under this part may generally pay only a part of the costs of project activities to be carried out. The Federal share may generally not be more than 90 percent of the total cost of the project. Where different Federal matching requirements are in effect, they are specified in the individual program regulations in this part.

§ 1362.6 Services to handicapped individuals

Vocational rehabilitation services or independent living services provided in projects assisted under this part must be provided in the same manner as services provided under the State plan for vocational rehabilitiation services under Part 1361 of this chapter or the State plan for independent living rehabilitation services under Part 1363 of this chapter.

§ 1362.7 Affirmative action plans.

A recipient of Federal assistance must develop and implement an affirmative action plan to employ and advance in employment qualified handicapped individuals in accordance with the requirements of 45 CFR Part 84.

§ 1362.8 Special requirements for projects which involve construction.

(a) A project which involves construction (the construction of new buildings and the acquisition, expansion, remodeling, alteration, and renovation of existing buildings) under this part must meet the following requirements:

(1) The grantee must have or must get a fee simple or other interest in the site, including right of access, sufficient to insure the grantee's undisturbed use or possession of the facilities for not less than the useful life of the facilities or 50 years, whichever is longer;

(2) The grantee must insure that sufficient funds are available to meet any non-Federal share of the cost of construction of the facility;

(3) The grantee must complete the project within a reasonable time;

(4) The grantee must insure that the construction is:

(i) Functional;

(ii) Economical;

(iii) Representative of excellence of architecture and design; and

(iv) Not elaborate in design or extravagant in the use of materials, compared with facilities of a similar type constructed in the State or other applicable geographic area;

(5) The grantee must comply with the requirements of the Architectural Barriers Act of 1968 (Pub L. 90–480), including "American National Standard Institute Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," No. A117.1–1961, or other standards prescribed by the Administrator of General Services (41 CFR 101–19.6 et seq.) and other supplemental standards prescribed by the Commissioner and where not consistent, the more stringent standard will prevail;

(6) Plans and specifications must be approved by the Architectural and Transportation Barriers Compliance Board;

(7) The grantee must comply with the provisions of the Davis-Bacon Act (40 U.S.C. 276a et seq.) and with the standards prescribed by Subpart P of Part 74 of this title;

(8) The grantee must assess the impact of the project on the quality of the environment in accordance with section 102(2)(i) of the National Environmental Policy Act of 1969 and Executive Order No. 11514 (34 FR 4247);

(9) The grantee must fully consider the project's relationship to and probably effect on any district, site, building, structure, or object which is included in the National Register of Historic Preservation of the National Park Service;

(10) The grantee must observe nationally recognized safety and health standards and codes, including:

(i) Current National Fire Protection Association standards;

(ii) Standards under the Occupational Safety and Health Act of 1970 (Pub. L. 91–576); and

(iii) State and local codes, to the extent that they are more stringent;

(11) The grantee must evaluate flood hazards in connection with the construction and, as far as practicable, shall avoid uneconomic, hazardous, or unnecessary use of flood plains in accordance with the provisions of Executive Order No. 11296;

(12) The grantee is subject to the regulations on relocation assistance and real property acquisition in Part 15 of this title;

(13) The grantee must ensure that the facility will be used as a public or nonprofit facility for at least 20 years after completion of the project;

(14) The grantee must assure that Federal funds are used only for the purposes for which the funds were provided; and

(15) The grantee must operate and maintain the facility in accordance with applicable Federal, State, and local requirements for the maintenance and operation of facilities.

(b) The construction of a rehabilitation facility may include the construction of residential accommodations for use in connection with the rehabilitation of handicapped individuals if it is necessary to the effective operation of the facility.

(c) Federal financial participation is not available for the costs of offsite improvements or for the construction of any facility used for religious worship or sectarian activity.

§ 1362.9 Wage and hour standards for workshops.

All applicable Federal and State wage and our standards must be observed in projects carried out in workshops.

§ 1362.10 Advisory committee membership.

When an advisory committee is established under a project, its membership must include representatives of handicapped individuals and other individuals to be assisted within the project, providers of services, and other appropriate individuals.

§ 1362.11 Special requirements affecting handicapped individuals with communication problems.

Each project must make necessary arrangements to ensure that personnel are available who are able to communicate with handicapped individuals who rely on special modes of communication, such as manual communication or nonverbal communication devices. Any project must also make necessary arrangements to ensure that personnel are available who are able to communicate in the native language of handicapped individuals with limited English-speaking ability from ethnic groups which represent substantial segments of the population of the communities in which the project activities are being carried out.

§ 1362.12 Accessibility to project activities by handicapped persons.

Any facility or other setting to be used for carrying out any activities assisted under this part must be accessible to, and usable by, handicapped individuals in accordance with the Architectural Barriers Act of 1968, as amended, and its implementing standards, 41 CFR Part 101–19.6 *et seq.* In addition, project activities must be conducted in settings which are free from architectural, communication and other barriers to the participation of handicapped persons in accordance with the requirements of 45 CFR Part 84.

§ 1362.13 Protection, use, and release of personal information.

(a) All personal information about individuals served by any project under this part, including lists of names, addressees, photographs, and records of evaluation, must be held confidential.

(b) The use of information and records concerning individuals must be limited only to purposes directly connected with the project, including project evaluation activities. This information may not be disclosed, directly or indirectly, other than in the administration of the project unless the consent of the agency providing the information and the individual to whom the information applies, or his representative, have been obtained in writing. The Commissioner and other Federal or State officials responsible for enforcing legal requirements have access to this information without written consent being obtained. The final product of the project may not reveal any personal identifying information without written consent of the individual or his or her representative.

§ 1362.14 Collection of data from State agencies.

When the collection of data is necessary from either handicapped individuals being served by two or more State agencies or from employees of two or more of these agencies, the project director must submit requests for the data to appropriate representatives of the affected agencies, as determined by the Commissioner. This requirement also applies to employed project staff and individuals enrolled in courses of study supported under this part.

§ 1362.15 Limitations on joint funding of projects.

The provisions of the Joint Funding Simplification Act (Pub. L. 93–510) and Title V of the Omnibus Territories Bill (Pub. L. 95–134) do not apply to any projects or other activities supported under this part.

§ 1362.16 Other HEW regulations which apply.

Several other HEW regulations apply to grants and, in some instances, other awards under this part. These include:

45 CFR Part 16—Department grant appeals process

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants (except for business opportunities for handicapped individuals under § 1362.117)

45 CFR Part 75—Informal grant appeals procedures (Indirect cost rates and other cost allocations)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health, Education, and Welfare—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedures for hearings under Part 80

45 CFR Part 84—Nondiscrimination on the basis of handicap in Federally assisted programs

45 CFR Part 90—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance

Subpart B—Projects for the Provision of Vocational Rehabilitation Services

§ 1362.40 Special projects and demonstrations; improved services to severely handicapped individuals.

(a) *What is the purpose of this program?* Under section 311(a)(1) of the Act, grants may be made for special projects, concerned with establishing programs and constructing facilities for expanding or otherwise improving vocational rehabilitation services and other rehabilitation services to handicapped individuals, especially those who are the most severly handicapped. Handicapped individuals served under this program include individuals with spinal cord injuries, blind individuals, deaf individuals, and other groups of severely handicapped individuals, irrespective of age or vocational potential, identified each year by the Commissioner.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by States and public and other non-profit agencies and organizations.

(c) *What are the matching requirements?* Grants may be made for paying all or part of the costs of activities covered under this program. Where part of the costs is to be borne by the grantee, the amount of grantee participation is determined at the time of the grant award and is generally not less than 10 percent of the total cost of the project.

(d) *What costs does the Federal assistance cover?* In addition to generally allowable project costs, Federal financial participation may also be available for the costs of construction of a rehabilitation facility.

(e) *Is an evaluative component required?* All projects and demonstrations supported under this program must contain an evaluative component to measure overall project effectiveness in providing vocational rehabilitation services and other rehabilitation services to severly handicapped individuals.

(f) *What are the special considerations in projects and demonstrations providing services to individuals with spinal cord injuries?* Projects in which vocational and other rehabilitation services are provided to individuals with spinal cord injuries, whether administered separately or in coordination with a large program supported in part under Title II of the Act, must:

(1) Establish a multi-disciplinary system of providing rehabilitation services specifically designed to meet the special needs of individuals with spinal cord injuries, including acute care, vocational and other rehabilitation services, community and job placement, and long-term community follow-up and health maintenance. The system must be established on an appropriate geographical basis which reflects patterns of patient flow and must be administered in close coordination with similar programs of the National Institute of Handicapped Research, the Veterans Administration, the National Institute of Health, and other public and private agencies and institutions;

(2) Demonstrate and evaluate both the service and cost benefits of a regional service system to those individuals with spinal cord injuries who might be served within it;

(3) Establish, within the system, a rehabilitation research environment for the achievement of new knowledge leading to the reduction and treatment of complications arising from spinal cord injury and the development of new techniques of medical management and rehabilitation;

(4) Demonstrate and evaluate the development and application of improved methods and equipment essential to the care, management and rehabilitation of individuals with spinal cord injury; and

(5) Demonstrate methods of community outreach and education for individuals with spinal cord injury in areas such as housing, transportation, recreation, employment, and other community activities.

(g) *What are the special considerations in projects and demonstrations providing services to blind individuals?* Projects in which services are provided to blind individuals must:

(1) Demonstrate innovative methods of providing intensive rehabilitation services needed to rehabilitate blind individuals; or

(2) Provide mobility training services or comprehensive counseling services not otherwise available in the locality in which individuals served by the project reside; or

(3) Conduct coordinated rehabilitation service activities with other public or nonprofit agencies serving blind individuals in the same area.

(h) *What are the special considerations in projects and demonstrations providing services to deaf individuals?* Projects in which services are provided to deaf individuals must:

(1) Demonstrate innovative methods of providing the specialized services needed to rehabilitate and make maximum use of the vocational potential of deaf individuals; or

(2) Conduct coordinated activities with other public and nonprofit agencies administering programs for deaf persons in the same area in order to expand or improve rehabilitation services for deaf individuals.

(i) *What are the special considerations in projects which involve constructing facilities?* The acquisition, expansion, remodeling, alteration or renovation of an existing building in connection with a special project or demonstration may not be undertaken unless it has been demonstrated to be essential to expanding or otherwise improving rehabilitation services to handicapped individuals within the related special project or demonstration. Any construction of a rehabilitation facility undertaken under this program is subject to the requirements affecting construction under § 1362.8 of this part.

§ 1362.41 Special projects and demonstrations; new approaches to service delivery.

(a) *What is the purpose of this program?* Under section 311(a)(2) of the Act, grants may be made for special projects and demonstrations, and related research and evaluation concerned with applying new types or patterns of services or devices, including opportunities for new careers for handicapped individuals or other individuals in programs serving handicapped individuals.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by States and public and other non-profit agencies and organizations.

(c) *What are the matching requirements?* Grants may be made for paying all or part of the costs of activities covered under this program. Where part of the costs is to be borne by the grantee, the amount of grantee participation is determined at the time of the grant award and is generally not less than 10 percent of the total cost of the project. In projects and demonstrations providing new career opportunities, grantees are expected to assume an increasing percentage of the new careerist salaries in order to assure that employment commitments will be met.

(d) *What costs does the Federal assistance cover?* In addition to generally allowable project costs, Federal financial participation may also be available for:

(1) New careerist salary and training expenses; and

(2) Necessary supportive services to enable new careerists to secure employment.

(e) *Is and evaluative component required?* All projects and demonstrations supported under this program must contain an evaluative componenet to measure overall program effectiveness.

(f) *What handicapped individuals may participate in new careers training?* Handicapped individuals to be provided new career opportunities and supportive services under this program may be only those individuals who have been determined by the State unit to be handicapped individuals under the State plan for vocational rehabilitation services under Part 1361.

(g) *What are the special consideration in projects and demonstrations providing new career opportunities?* Applicants must assure that the occupations for which training is being provided will offer realistic possibilities for continuing full-time employment and an opportunity for promotion and advancement through structured channels of promotion.

§ 1362.42 Grants for services for handicapped migratory agricultural workers or seasonal farmworkers.

(a) *What do the special terms mean?* For purpose of this section—

(1) "Family members" or "members of the family" means any relative by blood or marriage of a handicapped migratory agricultural worker or seasonal farmworker and other individuals living in the same household with whom the handicapped migratory agricultural worker or the seasonal farmworker has a close interpersonal relationship, and who are with the worker, or have accompanied the worker on his migratory tour to the point in time at which the State agency comes into contact with him.

(2) "Migratory agricultural worker" means a person who occasionally or habitually leaves his place of residence on a seasonal or other temporary basis to engage in ordinary agricultural operations or in services incident to the preparation of farm commodities for the market in another locality in which he resides during the period of such employment (29 CFR Part 11).

(3) "Seasonal farmworker" means a person who on a seasonal or other temporary basis engages in ordinary agricultural operations or in services incident to the preparation of farm commodities for the market within daily commuting distance from his place of normal residence.

(b) *What is the purpose of this program?* Under section 312 of the Act, grants may be made for the support of projects or demonstrations for the provision of vocational rehabilitation services to handicapped individuals who are migratory agricultural workers or seasonal farmworkers and to members of their families (whether or not handicapped) who are with them, where these services are necessary to the vocational rehabilitation of the handicapped migratory agricultural worker or seasonal farmworker.

(c) *Who is eligible to apply for Federal assistance?* Applications may be made by State vocational rehabilitation agencies or local agencies administering a vocational rehabilitation program under written agreements with State agencies.

(d) *May joint projects be developed?* A State agency may, if it chooses, enter into an agreement with the State vocational rehabilitation agencies of one or more other States to develop a cooperative program for the provision of vocational rehabilitation services under this section.

(e) *What costs does the Federal assistance cover?* In addition to generally allowable project costs, Federal financial participation may also be available for:

(1) Staff training necessary to improve the capacity of the State or local agency to serve handicapped migratory agricultural workers or seasonal farmworkers and members of their families when the training is included within a program of services; and

(2) Maintenance payments which will be provided at rates consistent with rates paid to handicapped individuals under Part 1361 of this chapter.

(f) *What are the special project considerations under this program?* Each project must be administered in close cooperation with other public and nonprofit agencies and organizations having special skills and experience in the provision of services to migratory agricultural workers, seasonal farmworkers, or their families, including programs under Title I of the Elementary and Secondary Education Act of 1964, the Migrant Health Act and the Farm Labor Contractor Registration Act of 1963.

§ 1362.43 Projects with industry.

(a) *What is the purpose of this program?* Under section 621 of the Act, agreements may be entered into with individual employers and with other entities to establish jointly financed projects which provide handicapped individuals with training, employment, and supportive services and assistance within business, industry, or other realistic work settings in order to prepare them for competitive employment and permit them to maintain the employment.

(b) *Who is eligible to participate in this program?* (1) Employers and organizations with whom the Commissioner may enter into an agreement include any industrial, business, or commercial enterprise; labor organization; employer, industrial, or community trade association; rehabilitation facility; or other agency or organization with the capacity to arrange, coordinate, or conduct training and other employment programs and provide supportive services and assistance for handicapped individuals in a realistic work setting.

(1) The Commissioner enters into an agreement in consultation with the Secretary of Labor and the Secretary of Commerce and with the designated State unit in the State in which the project is to be carried out, except where the scope of the proposed project extends beyond a single State.

(c) *What are the matching requirements?* The Federal share may not be more than 80 percent of the total cost of the project.

(d) *What costs does the Federal assistance cover?* Federal financial participation under this program may be available for:

(1) The costs of job training and related vocational rehabilitation services and supportive rehabilitation services;

(2) Instruction and supervision of trainees;

(3) Training materials and supplies, including consumable materials;

(4) Instructional aids;

(5) Bonding fees, liability and insurance premiums;

(6) The purchase or modification of equipment of facilities adapted for the use of handicapped individuals and special aids and appliances; and

(7) Minor alteration and renovation necessary to ensure access to and utilization of buildings by handicapped persons.

(e) *What is the required scope of project activities under this program?* Project activities under this program include:

(1) Providing handicapped individuals with training and employment in a realistic work setting in order to prepare them for employment in the competitive market. The training and employment programs shall include a planned and systematic sequence of training and instruction in occupational and employment skills, and provide reasonable assurance of gainful employment at the successful termination of such training and instruction.

(2) Providing handicapped individuals with supportive services which are necessary to permit them to continue to engage in the employment or the type of employment for which they have received training under this program.

(3) To the extent appropriate, expanding job opportunites for handicapped individuals by analyzing job demands and capabilities of the handicapped individuals and providing for:

(i) The development and modification of jobs to accommodate the special needs of the handicapped individuals being trained and employed under this program;

(ii) The purchase and distribution of special aids, appliances, or equipment adapted to the needs of a handicapped individual for use at a job site;

(iii) The modification of any facilities or equipment of the employer which are to be used primarily by handicapped individuals under this program; and

(iv) The establishment of appropriate job placement services.

(f) *What prior assurances are required for agreements?* Before entering into an agreement under this program, the Commissioner consults with the prospective employer or other entity sponsoring the project, and, to the extent possible, with the designated State unit and the handicapped individuals to be trained and employed under the project. On the basis of this consultation, it must be determined that:

(1) The designated State unit will, to the maximum extent practicable, maintain a continuing relationship with the handicapped individuals to be served in the project and will either provide necessary vocational rehabilitation services and related supportive services directly or will otherwise ensure their availability;

(2) The bargaining agent under any applicable collective bargaining agreement concurs with the project;

(3) The trainee wage rates will not tend to create unfair competitive labor cost advantages nor have the effect of impairing or depressing wage or working standards established for experienced workers for work of a comparable character; and

(4) No abnormal labor condition such as a strike, a lockout, or other similar condition exists with respect to the applicant.

(g) *What general provisions are required in agreements?* Any agreement entered into must, in addition to standard provisions:

(1) Provide for adherence to the terms or conditions of employment prescribed by any applicable Federal, State, or local law;

(2) Provide that a determination by competent authority of failure to adhere to the terms or conditions required by paragraph (g)(1) of this section will constitute cause for termination of the contract or agreement;

(3) Provide that the Federal share of the costs will cover only a part of the total costs of the project;

(4) Provide that the recruitment, examination, appointment, training, promotion, retention, or any other personnel action with respect to any handicapped individual receiving training or employment, will be without regard to race, sex, color, creed, age, or national origin, and that violation will constitute grounds for termination of the contract or arrangement and that the United States will have a right to seek judicial enforcement of this provision;

(5) Provide that trainees will be compensated for hours spent in production of any goods or services;

(6) Provide that individuals to receive training or employment services under the contract or arrangement will include only those individuals determined by the appropriate designated State unit to be handicapped individuals suitable for these services;

(7) Provide reasonable assurance that handicapped individuals successfully completing the training program will be employed by the employer or within a similar enterprise;

(8) Specify the duration of the project;

(9) Provide that when funds are given directly to an employer, the Commissioner, together with the designated State unit, has the right to review any termination of employment. In the event that the termination occurs less than three years after the handicapped individual began his or her employment, the Commissioner is entitled to require the repayment of a portion of the funds made available to the employer, if the Commissioner in consultation with the designated State unit determines that there was not a reasonable cause for the termination;

(10) Provide that any handicapped individual placed with an employer under this program will be given terms and benefits of employment equal to those which are given other employees of the employer;

(11) Provide that handicapped employees will not be unreasonably segregated from other employees; and

(12) Contain an agreement to make reports and to keep any records and accounts required by the Commissioner and to make records and accounts available for audit purposes.

(h) *What wage rates are required under agreements?* (1) The agreement must include the rate of compensation to be paid to trainees engaged in the production of any goods or services. The wage rate paid a trainee must be the higher of the following:

(i) The minimum entrance rate for inexperienced workers in the same occupation or if the occupation is new to the establishment, the prevailing entrance rate for the occupation among other establishments in the community or area; or

(ii) The minimum rate required under the Fair Labor Standards Act or the Walsh-Healy Public Contracts Act, to the extent that these acts are applicable to the trainee.

(2) The agreement must further provide for an increasing rate of payment to trainees if the training program is of such duration that periodic increases are reasonable and if the proficiency of the trainee merits the increases.

(i) *What on-the-training is required?* The agreement must:

(1) Provide for methods of instruction, progression of trainees, and size of the training group, including individualized or group training, comparable in duration to other training programs for the particular occupation, and adequate in content to qualify trainees for employment;

(2) Provide adequate and safe facilities and equipment; and

(3) Require that suitable records of attendance, performance and progress of trainees be maintained and that these records be made available to the Commissioner when requested.

§ 1362.44 Projects for vocational training services.

(a) *What do the special terms mean?* For purposes of this section—

(1) "Training in occupational skills" means a planned and systematic sequence of instruction under competent supervision which is designed to impart predetermined skills and knowledge with respect to a specific occupational objective or a job family, and to assist the individual to adjust to a work environment through the development of appropriate patterns of behavior.

(2) "Work evaluation" means the appraisal of the individual's capacity:

(i) To adjust to a work environment;

(ii) To acquire occupational skills; and

(iii) To attain appropriate vocational goals.

(3) "Work testing" means the utilization of work, simulated or real, to assess the individual's productive, physical, and psychological capacity to adapt to a work environment.

(4) "Job tryouts" means work experience, within a rehabilitation facility or in conjunction with outside industry or other community resources to assist the individual to acquire knowledge and develop skills; and to assess his readiness for job placement or fitness to engage in a specific occupation.

(5) "Vocational training services" includes:

(i) Tranining with a view toward career advancement;

(ii) Training in occupational skills;

(iii) Related services including work evaluation, work testing, provision of occupational tools and equipment required by the individual to engage in such training, and job tryouts; and

(iv) Payment of weekly training allowances to individuals receiving such training and related services.

(b) *What is the purpose of this program?* Under section 302(b) of the Act, grants may be made for providing vocational training services to handicapped individuals, especially the most severely handicapped, in public or other nonprofit rehabilitation facilities.

(c) *Who is eligible to apply for Federal assistance?* Applications may be made by States and public and nonprofit organizations and agencies. Any rehabilitation facility involved in providing vocational training sevices, must:

(1) Be public or nonprofit;

(2) Have been in operation at least 1 year;

(3) Provide training courses in occupational skills (with the major portion of each course being provided within the facility) and related services including work evaluation, work testing, and job tryouts, and the major portion of each of these services, except for job tryouts, must be provided within the facility;

(4) Meet occupational health and safety standards prescribed by regulations of the Secretary of Labor;

(5) Meet standards for rehabilitation facilities established by the Commissioner; and

(6) Prepare trainees for gainful employment.

(d) *What costs does the Federal assistance cover?* In addition to generally allowable project costs, Federal financial participation may also be available for the costs of weekly training allowances.

(e) *What are the special project considerations under this program?* Each applicant under this program must provide evidence that:

(1) Weekly training allowances will supplement any wages or other remuneration due to a trainee, and the amount of the payment for the weekly training allowance will be identified and disbursed separately from any payment representing wages or other remuneration due to a trainee;

(2) No trainee will remain in training when it is determined that he or she is no longer making progress (as indicated by regular training progress reports) toward the completion of a training program or in any event for more than 2 years;

(3) If any portion of the vocational training services is performed outside the designated rehabilitation facility, the applicant will retain responsibility for the quality of the services; and

(4) The full range of vocational training services will be made available to each trainee to the extent needed.

(f) *What individuals may participate in this program?* Only individuals who have been determined by the appropriate State unit to be eligible for and in need of vocational training services may receive services under this program. Severely handicapped individuals must be selected for participation in a project prior to other handicapped individuals.

(g) *How much may weekly training allowances be?* (1) A weekly training allowance must be available to each trainee, except that the allowance may not be paid for any period in excess of 2 years and for any week shall not exceed $30 plus $10 for each dependent, or $70, whichever is less. dependents may be included when their relationship to the trainee is that of spouse, parent, child under the age of 21 (including an adopted child or stepchild), or handicapped child whose dependency is related to the handicap, and who are living in the same home with the trainee.

(2) The amount of the weekly training allowance is determined in accordance with paragraphs (h) and (i) of this section. The adjusted weekly training allowance available to a trainee may not be less than $20 per week. When a weekly training allowance is paid for dependents, the amount is $10 per week for each dependent.

(3) The State unit shall determine the amount of the weekly training allowance and any adjustment to it, after consultation with the facility and in accordance with the training services plan.

(h) *What factors are considered in determining the amount of weekly training allowances?* The following factors must be considered:

(1) The extent of the need for an allowance including any expenses reasonably attributable to receipt of training services;

(2) The extent to which the allowance will help ensure entry into and satisfactory completion of training; and

(3) The extent to which the allowance will motivate the trainee to achieve an improved standard of living.

(i) *What factors are considered in adjustment of weekly training allowances?* (1) Adjustment in the weekly training allowance may be made at any time during the individual's training period and the amount of the allowance shall be reviewed periodically. The facility may propose the adjustment, but the final determination is made by the State unit.

(2) In considering whether an adjustment is appropriate the following factors are considered:

(i) Whether the trainee is earning a wage;

(ii) The relationship of the amount of wages, if any, to the amount of the allowance;

(iii) Any other material change in the economic condition of the individual or his family; and

(iv) The effect of any adjustment on the incentive of the trainee.

§ 1362.45 Projects for American Indian vocational rehabilitation services.

(a) *What do the special terms mean?* For the purpose of this section—

(1) "American Indian" means a person who is a member of an Indian tribe.

(2) "Governing bodies of Indian tribes" means those duly elected or appointed representatives of an Indian tribe or of an Alaskan native village. These representatives must have the authority to enter into contracts, agreements, and grants on behalf of their constituency.

(3) "Indian tribe" means any Federal or State Indian band, rancheria, pueblo, colony, or community, including any Alaska Native village or regional village corporation (as defined in or established pursuant to the Alaska Native Claims Settlement Act).

(4) "Reservation" means a Federal or State Indian reservation, public domain Indian allotment, former Indian reservation in Oklahoma, and land held by incorporated Native groups, regional corporations and village corporations under the provisions of the Alaska Native Claims Settlement Act.

(b) *What is the purpose of this program?* Under section 130 of the Act, grants may be made to provide vocational rehabilitation services to handicapped American Indians who reside on Federal or State reservations in order to prepare them for suitable employment.

(c) *Who is eligible to apply for Federal assistance?* Applications may be made only by the governing bodies of Indian tribes located on Federal and State reservations. A governing body is required to consult with the designated State unit or the appropriate designated State units in the development of an application.

(d) *How are the services to be administered?* A governing body may provide the vocational rehabilitation

services directly or it may contract or otherwise enter in an agreement with a designated State unit, a rehabilitation facility, or another agency to assist in the implementation of the vocational rehabilitation service program for handicapped American Indians. A governing body may also enter into an inter-tribal arrangement with governing bodies of other Indian tribes for carrying out a project which serves more than one Indian tribe. In any case, to the maximum extent feasible, the vocational rehabilitation service program must be comparable in type and quality to that provided by the State unit or units in the State or States in which the program is being carried out and each tribal program must be administered by a special tribal organizational unit for vocational rehabilitation.

(e) *What costs does the Federal assistance cover?* Federal financial participation may be available in expenditures for the provision of vocational rehabilitation services and for the administration, including staff development, of a program of vocational rehabilitation services. Federal financial participation may also be available in expenditures for services reflecting the cultural background of the American Indians being served, including treatment provided by native healing practitioners who are recognized as such by the tribal vocational rehabilitation program.

(f) *What are the special requirements under this program related to the State plan program?* Each applicant under this program must provide evidence that:

(1) Effort will be made to provide a broad scope of vocational rehabilitation services in a manner and at a level of quality at least comparable to those services provided by the designated State unit under Part 1361;

(2) There has been consultation in the preparation of the application with the designated State unit or designated State units of the State or States in which vocational rehabilitation services are to be provided under the proposed project;

(3) All decisions affecting eligibility for and the nature and scope of vocational rehabilitation services to be provided, and the provision of these services, will be made by the tribal vocational rehabilitation program through its vocational rehabilitation unit and will not be delegated to another agency or idividual;

(4) Priority in the delivery of vocational rehabilitation services will be given to those handicapped American Indians who are the most severely handicapped;

(5) An order of selection of handicapped individuals to be served under the program will be specified if services cannot be provided to all eligible handicapped American Indians who apply;

(6) All vocational rehabilitation services will be provided according to an individualized written rehabilitation program which has been developed jointly by the representative of the service providing organization and each handicapped American Indian being served;

(7) Handicapped American Indians living on Federal or State reservations where service programs are being carried out under this section will have an opportunity to participate in matters of general policy development and implementation affecting vocational rehabilitation service delivery on the reservation;

(8) Cooperative working arrangements will be developed with the designated State unit, or designated State units, as appropriate, which are providing vocational rehabilitation services to other handicapped individuals who reside in the State or States being served;

(9) Any similar benefits available to handicapped American Indians under any other public program which might meet in whole or in part the cost of any vocational rehabilitation service will be full considered in the provision of vocational rehabilitation services in accordance with § 1361.47 unless this consideration would significantly delay the delivery of service;

(10) Any handicapped American Indian applicant or recipient of services who is dissatisfied with any action with regard to the provision or denial of a vocational rehabilitation service under this section may file a request for an administrative review of the action by a member of the supervisory staff of the organization administering the program. If the client is still dissatisfied, he or she may request a fair hearing before the project administrator, or the next higher level in the administrative structure of the tribal organization;

(11) Minum standards will be established for facilities and providers of service which will be comparable to the standards set by the designated State unit or designated State units in the State or States in which the program is to be provided; and

(12) Maximum use will be made of public or other vocational or technical training facilities or other appropriate community resources.

(g) *What are the special project considerations under this program?* (1) Grants may not be made under this program to cover the costs of providing vocational rehabilitation services to handicapped individuals not residing on Federal or State reservations.

(2) Any handicapped American Indian who is eligible for services under this program but who wishes to be provided service by the designated State unit must be referred to the State unit for such services.

(3) Preference in employment in connection with the provision of vocational rehabilitation services under this section must be given to American Indians, with a special priority being given to handicapped American Indians.

(4) The provisions of sections 5, 6, 7, and 102(a) of the Indian Self-Determination and Education Assistance Act also apply under this program. These provisions relate to grant reporting and audit requirements, maintenance of records, access to records, availability of required reports and information to Indian people served or represented, repayment of unexpended Federal funds, criminal activities involving grants, penalties, wage and labor standards, preference requirements for American Indians in the conduct and administration of the grant, and requirements affecting requests of tribal organizations to enter into contracts. For purposes of applying these requirements to this program, the Commissioner is authorized to carry out those responsibilities assigned to the Secretary of Interior.

(5) To the extent that funds have been appropriated under this section, the Commissioner approves all applications which meet acceptable standards of program quality. If the Commissioner does not approve any application because of deficiencies in proposed program standards, he provides technical assistance to the applicant Indian tribe with respect to any areas of the proposal which were judged to be deficient.

Subpart C—Assistance for Rehabilitation Facilities

§ 1362.50 Project development grants.

(a) *What is the purpose of this program?* Under section 301(d) of the Act, grants may be made for the purpose of assisting in planning the development of a rehabilitation facility as well as the services to be provided by the facility.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by public or other nonprofit agencies, institutions, or organizations which are either operating or are studying the feasibility of operating a rehabilitation facility.

(c) *What costs does the Federal assistance cover?* In addition to generally allowable project costs, Federal financial participation may also be available for:

(1) Expenses associated with the use of volunteers; and

(2) Architectural planning incidental to program planning but not including working drawings.

(d) *How long may the Federal assistance be available?* A project may be approved for a maximum project period of 12 months.

§ 1362.51 Grants for construction of rehabilitation facilities.

(a) *What is the purpose of this program?* Under section 301(b) of the Act, grants may be made for the construction of rehabilitation facilities.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by State vocational rehabilitation agencies or other public or nonprofit organizations or agencies which operate or propose to operate a public or other nonprofit rehabilitation facility.

(c) *What are the matching requirements under this program?* The Federal share may not be more than 50 percent of the total project cost.

(d) *What costs may the Federal assistance cover?* Federal financial participation may be available for:

(1) Acquisition of land in connection with construction of a rehabilitation facility;

(2) Acquisition of existing buildings;

(3) Remodeling, alteration, renovation, or expansion of existing buildings;

(4) Construction of new buildings;

(5) Architect's services;

(6) Site survey and soil investigation;

(7) Fixed or movable equipment;

(8) Works of art in an amount not to exceed 1 percent of the total cost of the project; and

(9) Other activities specifically provided for in the application.

(e) *How long may the Federal assistance be available?* Grants are awarded for that period of time necessary for the completion of the approved construction project. Any project in which the construction has not begun during the 18-month period immediately following the date of notice of the grant award may be terminated at the end of that time period by the Commissioner.

(f) *What are the special requirements under this program?* (1) Applicants must assure that they will comply with the requirements specified under § 1362.8 and with any other requirements of the Department in effect concerning Federally assisted building design and construction activities.

(2) The Commissioner may approve exceptions to these requirements where he finds that such exceptions are not inconsistent with the Act and the purpose of this program.

§ 1362.52 Rehabilitation facility staffing grants.

(a) *What is the purpose of this program?* Under section 301(c) of the Act, grants may be made for the compensation of rehabilitation facility professional and technical staff.

(b) *Who is eligible to apply for Federal assistance?* (1) Applications may be made only by public or other nonprofit rehabilitation facilities constructed after September 26, 1973.

(2) Rehabilitation facility staffing grants may be made only with respect to the operation of a rehabilitation facility following construction. Where the construction consists of expansion, remodeling, alteration, or renovation of an existing rehabilitation facility, the expansion, remodeling, alteration, or renovation is required to be extensive enough to result in the addition of new services or the extension of existing services to a substantially increased number of handicapped individuals. If the rehabilitation facility was in operation prior to the construction activity, a staffing grant may be made only for the additional staff necessary for the facility to provide new services or extend existing services to a substantially increased number of clients.

(c) *What are the matching requirements?* The amount of Federal share under a rehabilitation facility staffing grant is based on either the date on which the first client is admitted for services after completion of the related construction project or on that earlier date after completion of the construction project which is specified in the approved application. The Federal share may not be more than 75 percent of total project costs for the period ending with the last day of the 15th month following the month in which the operation of the rehabilitation facility began; 60 percent of costs for the first year after that, and 45 percent of costs for the third year after that.

(d) *What costs may the Federal assistance cover?* Federal financial participation may be available for personnel costs (including fringe benefits) of rehabilitation facility staff, as set forth in the approved application.

(e) *How long may the Federal assistance be available?* A project may be approved for a maximum project period of 4 years and 3 months.

§ 1362.53 Rehabilitation facility improvement grants.

(a) *What is the purpose of this program?* Under section 302(c) of the Act, grants may be made for activities designed to analyze, improve, and increase the professional services provided to handicapped individuals by rehabilitation facilities, the management effectiveness of facilities or any other part of their capacity to provide employment and services for handicapped individuals.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by public or nonprofit rehabilitation facilities or organizations, or by a combination of such rehabilitation facilities.

(c) *What are the matching requirements?* The Federal share may not be more than 80 percent of the total project cost.

§ 1362.54 Grants for establishing or operating comprehensive rehabilitation centers.

(a) *What do the special terms mean?* (1) "Comprehensive rehabilitation center" means a facility or group of facilities which serves as a focal point within a community for the development and delivery of services for handicapped persons and other persons. A comprehensive rehabilitation center functions as a community information and referral resource center for handicapped persons and for other public and other nonprofit agencies in the community which serve handicapped persons. A comprehensive center may, in addition, directly provide a broad range of vocational rehabilitation, health, educational, social, and recreational services to handicapped persons.

(2) "Handicapped person" means an individual of any age who has a physical or mental disability.

(b) *What is the purpose of this program?* Under section 305 of the Act, grants or contracts may be made to establish or operate comprehensive rehabilitation centers. These comprehensive rehabilitation centers serve primarily as centers for the development, delivery, and coordination of vocational rehabilitation services and other services needed by handicapped persons in the community.

(c) *Who is eligible to apply for assistance?* (1) Applications may be made by designated State units.

(2) A designated State unit which has been awarded a grant under this program may award a subgrant to a unit of general purpose local government or to any other public or nonprofit private agency or organization or enter into a

contract with agencies or organizations in the community.

(d) *What are the matching requirements?* (1) The Federal share of any grant awarded to a designated State unit may not be more than 80 percent of the total costs of the project.

(2) No subgrant or contract awarded by a State unit to a general purpose local government unit, a public or other nonprofit agency or organization, or other agencies or organizations may pay more than 80 percent of the total cost of establishing or operating a comprehensive rehabilitation center under this program.

(e) *What costs does the assistance cover?* In addition to generally allowable project costs, Federal financial participation may also be available for:

(1) Salaries of additional professional and technical personnel required to operate a comprehensive rehabilitation center;

(2) Acquisition of equipment necessary for operating a center;

(3) Expansion, remodeling or alteration of an existing building when necesary to adapt it or increase its effectiveness for use as a comprehensive rehabilitation center;

(4) Leasing of a facility to serve as a comprehensive rehabilitation center; and

(5) Works of art in an amount not to exceed one percent of the total cost of the project when the expansion, remodeling or alteration of an exising building is involved.

(f) *What are the special project considerations under this program?* (1) Services may be provided within the comprehensive rehabilitation center directly by the agency or organization or the group of agencies or organizations which is operating the center or they may be provided by other agencies or organizations using either their own facilities or the facilities of the center;

(2) The facilities of the center must be made available for recreational activities for handicapped persons;

(3) To the maximum extent possible, the center must provide upon request to other public and other nonprofit agencies, organizations, facilities and other entities in the community information services and technical assistance necessary to assist them in complying with the requirements of this Act, with special reference to the requirements under section 504 of the Act. Technical assistance includes both the maintenance of rosters of special support personnel available within the community such as interpreters for the deaf, readers for the blind, attendants, legal aid and advocacy personnel, and the coordination of referrals of these personnel;

(4) Any center established or operated under this program must be located in close proximity to the majority of the handicapped persons in the commuity to be served;

(5) The need for the establishment of a comprehensive rehabilitation center under this program must be identified in the State planning for rehabilitation facilities under § 1361.22;

(6) Information and referral services provided by a center must be fully coordinated with information and referral services provided by the State unit under § 1361.20 or by any other public or other nonprofit agency or organization in the community;

(7) Priority is given to establishing or operating comprehensive rehabilitation centers at facilities which are already in operation; and

(8) New facilities are established through the expansion, remodeling, or alteration of an existing building only after it has been fully demonstrated that there are no existing facilities in the community with the potential for developing and delivering adequate services under this program. If the expansion, remodeling, or alteration of an existing building is involved, each facility must comply with the requirements specified under § 1361.8, and with any other requirements of the Department in effect concerning Federally assisted building design and construction activities.

§ 1362.55 Loan guarantees for rehabilitation facilities.

(a) *What is the purpose of this program?* Under section 303 of the Act, the Commissioner may guarantee the payment of prinicpal and interest on loans made by non-Federal lenders and by the Federal Financing Bank to private nonprofit entities for the construction (including equipment) of rehabilitation facilities.

(b) *What special assurances are required from applicants?* Each applicant under this program must assure that:

(1) The construction of the rehabilitation facility will be carried out in accordance with the requirements specified under § 1362.8 and with any other requirements of the Department in effect concerning Federally assisted building design and construction activities;

(2) The need for the rehabilitation facility and the construction activity for which the loan is sought have been identified by the State unit within the State planning for rehabilitation facilities under § 1361.22;

(3) Sufficient financial resources are available to enable compliance with the terms and conditions of the loan for which the guarantee is sought;

(4) There is legal authority to finance, construct, and maintain the proposed project, to apply for and receive the loan for which the guarantee is sought, and to pledge or mortgage any assets or revenues to be given as security for the loan or against other satisfactory security;

(5) The loan will be secured by a first loan lien against the facility to be constructed or against other security satisfactory to the Commissioner;

(6) The rate of interest on the loan does not exceed the annual percentage determined by the Commissioner to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States;

(7) The loan would not be available on reasonable terms and conditions without the guarantee; and

(8) Any additional determination found necessary by the Commissioner with respect to particular applications in order to protect the financial interests of the United States.

(c) *How is the evidence of indebtedness to be presented?* The evidence of indebtedness with respect to direct loans must be in the form and detail required by the Commissioner.

(d) *How are loans to be secured?* All loans must be secured in a manner which the Commissioner finds reasonably sufficient to insure repayment. The security may be one or a combination of the following:

(1) A first mortgage on the facility and its site;

(2) Negotiable stocks or bonds of a quality and value acceptable to the Commissioner;

(3) A pledge of unrestricted and unencumbered income from an endowment or other trust funds acceptable to the Commissioner;

(4) A pledge of a specific portion of annual general or special revenues of the applicant, acceptable to the Commissioner;

(5) Full faith and credit (tax supported) obligations of a State of local public body; or

(6) Such other security as the Commissioner may find acceptable in specific instances.

(e) *What is the repayment period?* The repayment period is limited to 25 years; provided, that:

(1) The Commissioner may, in particular cases where he determines that a repayment period of less than 25 years is more appropriate to an

applicant's total financial plan, approve the shorter repayment period; and

(2) In no case may a loan repayment period exceed the estimated useful life of the facility to be constructed with the assistance of the loan.

(f) *How are loans repaid?* Unless otherwise specifically authorized by the Commissioner, each loan is repayable in substantially level total annual installments of principal and interest, sufficient to amortize the loan through the final year of the life of the loan.

(g) *What is the loan guarantee agreement?*

(1) When an application for a loan guarantee is approved by the Commissioner, an offer of a loan guarantee is sent to the applicant, setting forth the pertinent terms and conditions. The loan guarantee is conditioned upon the fulfillment of these terms and conditions. The accepted loan guarantee offer constitutes the Loan Guarantee Agreement between the Commissioner and the applicant.

(2) Each Loan Guarantee Agreement must provide:

(i) That the loan guarantee evidenced by the agreement is incontestable:

(A) In the hands of the applicant on whose behalf the loan guarantee is made except for fraud or misrepresentation on the applicant's part in securing the guarantee;

(B) As to any person (or successor in interest) who makes or contracts to make a loan to the applicant in reliance on the loan guarantee, except for fraud or misrepresentation on the part of this other person in making or contracting to make the loan;

(ii) That if the applicant defaults in making payment, when due, of the principal and interest on the loan for which the guarantee is made, and this default is not cured within 90 days of its occurrence, the holder of the loan has the right to make demand in writing upon the Commissioner for the purchase of the loan by the Commissioner.

(iii) That each holder of a loan to an applicant on whose behalf the loan guarantee is made under the Agreement has a contractual right to receive from the United States interest payments in an amount sufficient to reduce by 2 percent per year the net effective interest rate determined by the Commissioner to be otherwise payable on the loan;

(iv) That payments of interest under paragraph (g)(2)(iii) of this section are made by the Commissioner, in accordance with the terms of the loan directly to the holder of the loan or to a trustee or agent designated in writing to the Commissioner by the holder until the Commissioner is notified in writing by the holder that the loan has been transferred. Under such a written notification of transfer the Commissioner makes interest payments directly to the new holder of the loan;

(v) That the applicant is permitted to repay up to 15 percent of the original principal amount of the loan in any calendar year without additional charge; and

(vi) Any other provisions found necessary by the Commissioner to protect the financial interests of the United States.

(h) *When is a loan guarantee closed?* Closing for any loan is accomplished at the time agreed upon by the parties to the loan and found acceptable by the Commissioner.

(i) *May the right of recovery be waived?* In determining whether there is good cause for waiver of any right of recovery, the Commissioner takes into consideration the extent to which:

(1) The facility with respect to which the loan guarantee or direct loan was made will continue to be devoted by the applicant or other owner to use for the purpose for which it was constructed or another public or nonprofit purpose which will promote the purposes of the Act;

(2) There are reasonable assurances that for the remainder of the repayment period of the loan, other public or nonprofit facilities not previously utilized for the purpose for which the facility was constructed will be so utilized and are substantially equivalent in nature and extent for such purposes; and

(3) Recovery would seriously curtail the provisions of vocational rehabilitation services to handicapped individuals in need of these services in the geographical area.

Subpart D—[Reserved]

Subpart E—Rehabilitation Training

§ 1362.70 Rehabilitation long-term training.

(a) *What is the purpose of this program?* Under section 304 of the Act, grants or contracts may be made for the continuing support of training projects designed to assist in increasing the numbers of personnel trained in providing vocational, medical, social, and psychological rehabilitation services to handicapped individuals and in demonstrating experimental and innovative methodologies for the training of skilled rehabilitation personnel.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by State agencies and by other public or nonprofit agencies and organizations, including institutions of higher education.

(c) *What are the matching requirements?* No minimum share is routinely required of applicants but the applicant is expected to furnish as large a part of the total project cost as possible. In the case of academic training projects with a multi-year project period, the applicant's share of the teaching costs is expected to increase progressively in each succeeding year so that total personnel costs are fully absorbed by the grantee at the termination of the project period.

(d) *What costs does the Federal assistance cover?* (1) In addition to generally allowable project costs, Federal financial participation may also be available for:

(i) Student stipends;

(ii) Tuition and fees; and

(iii) Student travel in conjunction with training assignments.

(2) Except in the case of State vocational rehabilitation agencies, other agencies of a State, or agencies of local governments, reimbursement of indirect costs will not exceed 8 percent of the amount allowed for direct costs, exclusive of permanent equipment, rental of space, building alteration or renovation, subagreements (except for procurements), tuition, fees, and training allowances for postdoctoral trainees).

(e) *What is the scope of this program?* Awards are made to provide a balanced program of assistance to meet the medical, vocational, and other personnel training needs of both public and private rehabilitation programs, rehabilitation facilities, and other institutions. The balanced program of assistance includes academic and non-academic training activities in rehabilitation medicine, rehabilitation nursing, rehabilitation counseling, rehabilitation social work, rehabilitation psychiatry, rehabilitation psychology, physical therapy, occupational therapy, speech-language pathology and audiology, rehabilitation facility administration, vocational evaluation and work adjustment, prosthetics and orthotics, specialized personnel in providing services to blind and deaf individuals, rehabilitation job placement and job development, and therapeutic recreation for handicapped individuals, including homebound and institutionalized individuals. The balanced program also includes projects to train individuals to work more effectively with handicapped individuals with limited English-speaking ability, projects to train new types of rehabilitation manpower, experimental projects concerned with the training of rehabilitation personnel,

and projects to demonstrate innovative models and techniques for the training of rehabilitation workers.

(f) *What are the special considerations in the review of applications?* The Commissioner arranges for any new or competing continuation application submitted under this program to receive a review in a group meeting of consultants who are not regular Federal employees and who are qualified by virtue of training and experience in the field of rehabilitation in which the application is submitted. The review is conducted in coordination with similar peer review groups established within such Federal agencies as the National Institute of Handicapped Research and the National Institutes of Health when these groups have expertise in matters pertaining to training related to the treatment and rehabilitation of handicapped individuals. The peer groups:

(1) Make recommendations concerning the merit of new and competing continuation applications prior to the awarding of funds; and

(2) Provide guidance in the dissemination of findings resulting from rehabilitation training activities.

(g) *What are the special considerations in awarding traineeships?* (1) Traineeships may provide fianancial support to students with a career interest in a rehabilitation field at any level of training. (2) No training or instruction may be provided to an individual for any one course of study extending for a period in excess of four years. (3) Each trainee:

(i) Must be a United States citizen or a foreign national lawfully admitted to the United States for permanent residence;

(ii) Must take the training only at the educational institution or agency designated in the traineeship award or under the auspices of that institution or agency;

(iii) Must not be an employee of the Federal Government; and

(iv) Must not concurrently receive educational allowances from any other Federal, State, or local public or voluntary agency when that allowance is conditioned on a conflicting employment obligation incurred by the trainee. Excepted are Federally assisted student loans, or educational allowances or benefits payable under chapters 34, 35, and 36 of Title 38, U.S.C. as limited by section 213 of the Veterans' Educational and Training Amendments Act of 1972, or educational allowances or benefits for veterans payable under any State or local program; and

(v) Must apply to the institution or agency which has been awarded a grant for traineeships under this program since the selection of all trainees is made by the institution or agency conducting the training.

§ 1362.71 State vocational rehabilitation unit in-service training.

(a) *What is the purpose of this program?* Under section 304 of the Act, grants may be made for the support of special projects for training State vocational rehabilitation unit personnel in program areas essential to the effective management of the unit's program of vocational rehabilitation services or in skill areas which will enable staff personnel to improve their ability to provide services to severely handicapped individuals.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made only by State vocational rehabilitation units.

§ 1362.72 Rehabilitation continuing education programs.

(a) *What is the purpose of this program?* Under section 304 of the Act, grants may be made for the support of programs which:

(1) Develop and conduct training for State unit staff at the administrative, supervisory, professional, subprofessional, or clerical levels in order to develop and upgrade needed knowledge and skills for effective agency performance and to develop mastery of new program developments dealing with significant issues, priorities and legislative thrusts of the State-Federal vocational rehabilitation program; and

(2) Develop and conduct training programs for staff of public and other nonprofit rehabilitation agencies and facilities which cooperate with State units in the delivery of rehabilitation services.

(b) *What are the matching requirements?* No minimum share is routinely required of applicants but the applicant is expected to furnish as large a part of the total project cost as possible.

(c) *What are the special project considerations under this program?* A rehabilitation continuing education program must provide for:

(1) A broad integrated sequence of training activities; and

(2) Training which focuses on meeting recurrent training needs common throughout a multi-State geographical area.

§ 1362.73 Rehabilitation short-term training.

(a) *What is the purpose of this program?* Under section 304 and section 12(a)(2) of the Act, short-term training and technical instruction may be provided in areas of special significance to the delivery of vocational, medical, social, and psychological rehabilitation services.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by State agencies and public or nonprofit agencies and organizations, including institutions of higher education.

(c) *What are the matching requirements?* (1) Under section 304 of the Act, grants and contracts may pay only part of the project costs and the applicant is expected to furnish as large a part of the total project cost as possible.

(2) Although no matching share is required of applicants under section 12(a)(2) of the Act, they may be expected to share in the costs of the project. In such cases, the amount of participation is a matter of negotiation.

(d) *What costs does the Federal assistance cover?* (1) In addition to generally allowable project costs, Federal financial participation may also be available for:

(i) Trainee per diem costs; and

(ii) Trainee travel.

(2) Except in the case of State vocational rehabilitation agencies, other agencies of a State, or agencies of local government, reimbursement of indirect costs will not exceed 8 percent of the amount allowed for direct costs.

(e) *How long may the Federal assistance be available?* A project may be approved for a maximum project period of 12 months.

(f) *What are the special project considerations under this program?* (1) Short-term training projects include special seminars, institutes, workshops, and other courses of short duration which meet non-recurring training needs and which have been identified by the Commissioner in cooperation with representatives and organizations with an interest in the short-term training of rehabilitation personnel;

(2) Conferences and meeting in which training is not the primary focus may not be supported;

(3) The preparation of training materials may not be supported under a grant unless the materials are essential for the conduct of the seminar, institute, workshop or other short course for which the grant support has been requested; and

(4) The Commissioner arranges for any application for a short-term training project with a national scope to receive a review in a group meeting of consultants who are not regular Federal employees and who are experienced in the training of vocational, medical,

social, or psychological rehabilitation service personnel.

§ 1362.74 Rehabilitation research fellowships.

(a) *What is the purpose of this program?* Under section 12(a)(2) of the Act, rehabilitation research fellowships may be awarded to individuals who wish to conduct an advanced research study in the rehabilitation of handicapped individuals or who wish to prepare for professional careers in the field of rehabilitation research.

(b) *Who is eligible to apply for Federal assistance?* Any individual currently employed in a rehabilitation program or activity and any individual who wishes to enter employment in rehabilitation research may apply for assistance.

(c) *What costs does the Federal assistance cover?* A rehabilitation research fellowship may cover:

(1) Student or special stipends;

(2) Tuition and fees;

(3) Travel essential to the conduct of the research study; and

(4) Other costs essential for the completion of the study.

(d) *How long may the Federal assistance be available?* No training or instruction (including a combination of traineeships and research fellowship awards) may be provided to an individual for any course of study extending for a period of more than 4 years.

(e) *What are the special considerations in awarding fellowships?* An individual awarded a rehabilitation research fellowship must meet all requirements specified in § 1362.70(g)(3).

Subpart F—Helen Keller National Center for Deaf-Blind Youths and Adults

§ 1362.80 Terms.

For the purpose of this subpart—

(a) "Center" means the Helen Keller National Center for Deaf-Blind Youths and Adults, including its field offices;

(b) "Deaf-blind individuals" means persons who are blind within the meaning of the law relating to vocational rehabilitation in each State and have a chronic hearing impairment so severe that most speech cannot be understood with optimum amplification. The combination of the two disabilities causes extreme difficulty for the person to attain independence in activities of daily living, psychosocial adjustment, or in the pursuit of a vocational objective; and

(c) "Grantee" means the public or nonprofit agency or organization selected as the party to the agreement to receive funds for the construction and operation of the Helen Keller National Center for Deaf-Blind Youths and Adults.

§ 1362.81 Purpose.

Under section 313 of the Act, the Commissioner may enter into an agreement with any public or nonprofit agency or organization for payment of all or part of the costs of the establishment and operation, including construction and equipment, of a center for the vocational rehabilitation of deaf-blind individuals. The center shall be known as the Helen Keller National Center for Deaf-Blind Youths and Adults.

§ 1362.82 Scope of activity.

The scope of the agreement must cover the following areas of activity:

(a) The construction of a facility for the vocational rehabilitation of deaf-blind individuals which will be especially adapted to the needs of the deaf-blind individuals;

(b) The demonstration of methods which provide the specialized intensive vocational rehabilitation services, independent living services and other services, needed to rehabilitate deaf-blind individuals;

(c) The training of professional and allied personnel needed to staff facilities specifically designed to provide rehabilitation services and the training of personnel for serving deaf-blind individuals and for training other personnel who serve deaf-blind individuals;

(d) The conduct of research related to the problems of deaf-blind individuals and their rehabilitation, which shall be conducted in full coordination with any similar research supported under the Act;

(e) The conduct of related activities which will expand or improve the services for deaf-blind individuals; and

(f) The improvement of public understanding concerning the needs of deaf-blind individuals.

§ 1362.83 Agreement.

In addition to other provisions, the agreement shall provide that, to the extent feasible, the Center shall seek to recover from States, private insurers, and other participating public and private agencies the costs of services provided to individuals by the Center.

§ 1362.84 Selection of grantee.

The selection of the grantee will be made by the Commissioner with preference given to the application that promises:

(a) Maximum effectiveness in the organization and operation of the Center; and

(b) The most substantial staff skill, experience and capability in providing a broad program of service, research, training and related activities in the field of rehabilitation of deaf-blind individuals.

Subpart G [Reserved]

Subpart H—Projects and Other Assistance for the Provision of Special Rehabilitation Services and Assistance

§ 1362.100 Projects for the establishment and operation of centers for independent living.

(a) *What is the purpose of this program?* Under section 711 of the Act, grants may be made for the planning, establishment and continuing operation of centers for independent living.

(b) *What is a center for independent living?* A center for independent living is a facility which offers severely handicapped individuals a combination of independent living services such as:

(1) Intake counseling to determine the severely handicapped individual's need for specific independent living services;

(2) Referral and counseling services with respect to attendant care;

(3) Attendant care and the training of personnel to provide attendant care;

(4) Counseling and advocacy services with respect to legal and economic rights and benefits;

(5) Peer counseling;

(6) Independent living skills, counseling and training, including training in the maintenance of necessary equipment, training in job seeking skills, counseling on therapy needs and programs, and special independent living skill training for blind individuals or deaf individuals;

(7) Housing and transportation referral and assistance;

(8) Surveys, directories, and other activities to identify appropriate housing and accessible transportation and other support services;

(9) Health maintenance programs;

(10) Community group living arrangements;

(11) Education and training necessary for living in the community and participating in community activities;

(12) Individual and group social and recreational activities; and

(13) Other programs and services, necessary to provide resources, training, counseling, services or other assistance of substantial benefit in promoting the independence, productivity and quality of life of severely handicapped individuals.

(c) *Who is eligible to apply for Federal assistance?* (1) Applications may be made by designated State units. The State unit may either directly operate a center for independent living or it may award a contract to another public or nonprofit agency or organization in the State for the purpose of operating a center or a group of centers.

(2) If a State unit has failed to submit an application within six months of the deadline date established by the Commissioner for application submittal under this program, or if a State unit has indicated at any time prior to the deadline date that it does not intend to submit an application, applications for Federal assistance may be made by local public agencies and by private nonprofit organizations within the State.

(d) *What are the matching requirements?* No minimum share is routinely required of applicants but each applicant is expected to furnish as large a part of the total project costs as possible.

(e) *What are the special project considerations under this program?* Any center for independent living established or operated under this program must:

(1) Assure that severely handicapped individuals will be substantially involved in policy direction and management of the center and, to the greatest extent possible, will be employed by the center; and

(2) Make effort to provide as many of the services identified in paragraph (b) of this section as possible.

§ 1362.101 Grants for independent living rehabilitation services for older blind individuals.

(a) *What do the special terms mean?* For purposes of this section—

(1) "Blind individual" means a person whose central visual acuity does not exceed 20/200 in the better eye with correcting lenses or whose visual acuity, if better than 20/200 is accompanied by a limit to the field of vision in the better eye to such a degree that its widest diameter subtends an angle no greater than 20 degrees.

(2) "Independent living rehabilitation services" when provided to older blind individuals under this program means:

(i) Services to help correct blindness such as outreach services, visual screening, surgical or therapeutic treatment to prevent, correct, or modify disabling eye conditions and hospitalization related to these services;

(ii) The provision of eyeglasses and other visual aids;

(iii) The provision of services and equipment to assist an older blind individual to become more mobile and more able to care for himself;

(iv) Mobility training, braille instructions, and other services and equipment to help an older blind individual adjust to blindness;

(v) Guide services, reading services, and transportation;

(vi) Supportive services or rehabilitation teaching services, in such areas as home mechanics, personal management, home economics and communication skills, in order to assist an individual in adjusting to blindness and improving independent living skills; and

(vii) Any other services designed to assist an older blind individual in adjusting to blindness and coping with daily living activities within family or community.

(3) "Older blind individual" means a blind individual aged fifty-five or older whose severe visual impairment makes gainful employment extremely difficult to attain or retain but for whom the achievement of independent living rehabilitation goals is possible.

(b) *What is the purpose of this program?* Under section 721 of the Act, grants may be made to provide special programs of independent living rehabilitation services to assist in meeting immediate needs of older blind individuals in adjusting to their blindness. The design of the independent living rehabilitation services shall be sufficiently flexible to assist older blind individuals to adjust to their blindness by becoming more able to care for their individual needs.

(c) *Who is eligible to apply for assistance?* Applications for Federal grants may be made only by designated State units. Applications may be made by public or private nonprofit agencies or organizations to those designated State units which have been awarded Federal grants under this program.

(d) *What are the matching requirements?* The Federal share may not be more than 90 percent of the total project costs. In the case of a subgrant made by a designated State unit, the subgrant may not pay more than 90 percent of the total project costs.

(e) *What special assurances are required from applicants?* A designated State unit must assure that any new methods and approaches to the provision of independent living services demonstrated under this program which are determined by the Commissioner to be effective will be incorporated into the delivery of services under the State plan for independent living rehabilitation services under Part 1363.

(f) *What are the special project considerations under this program?* When funds are used by the designated State units to make subgrants to public or private nonprofit agencies or organizations, the project must include activities which:

(1) Provide independent living rehabilitation services to older blind individuals;

(2) Improve or expand independent living rehabilitation services for older blind individuals and public understanding of the problems of older blind individuals; and

(3) Utilize service resources available in the geographical area under any related programs which are supported under authority of the Older Americans Act.

§ 1362.102 Grants for the protection and advocacy of the rights of severely handicapped individuals.

(a) *What is the purpose of this program?* Under section 731 of the Act, grants may be made to establish systems to protect and advocate the rights of severely handicapped individuals receiving independent living rehabilitation services under a program or project supported under Part 1363 of this chapter or under § 1362.100 or § 1362.101 of this part.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by any unit of State government which does not provide treatment, vocational rehabilitation services, or other services (other than protection and advocacy services) to handicapped individuals. The project may either be directly administered by the applicant agency or may be administered through another public or nonprofit agency or organization.l

(c) *What are the matching requirements?* No minimum share is routinely required of applicants.

(d) *What are the special considerations under this program?* (1) Any system established under this program must have the authority and capacity to pursue legal, administrative, and other appropriate remedies to ensure the rights of all severely handicapped individuals receiving independent living rehabilitation services under Part 1363 of this chapter or under § 1362.100 or § 1362.101 of this part.

(2) Any system established under this program must be administratively and financially independent of any public or private nonprofit agency or organization administering an independent living rehabilitation service program for severely handicapped individuals or providing any similar treatment or rehabilitation services to such individuals.

(3) Any system established under this program must ensure and demonstrate full coordination with protection and advocacy programs established in the State under the Developmental Disabilities Assistance and Bill of Rights Act and may be administered by the same agency administering this program. The system must also ensure and demonstrate full coordination with any client assistance program established uner § 1362.103 of this part.

§ 1362.103 Client assistance projects.

(a) *What do the special terms mean?* For purposes of this section—

(1) "Client or client applicant" means an individual who:

(i) Is seeking vocational rehabilitation services from the State agency; or

(ii) Is receiving vocational rehabilitation services from the State agency; or

(iii) Has been receiving vocational rehabilitation services from the State agency, but the provision of such services has been terminated and he or she is seeking assistance in connection with the termination of such services.

(2) "Counselor" means a client assistance worker who functions as an ombudsman.

(3) "Project area" means the geographical or administrative area served by project counselors and designed in a manner to facilitate client or client applicant accessibility to the project. A project area may be a rehabilitation facility, a State agency district office, or a special unit for a specific disability, and in some cases, may be Statewide.

(b) *What is the purpose of this program?* Under section 112 of the Act, grants may be made for the purpose of establishing client assistance projects to provide counselors to inform and advise all clients and client applicants in the project area of all available benefits and their rights in seeking these benefits under the Act. Upon request of the clients or client applicants, project counselors assist clients and client applicants in their relationships with the projects, programs, and facilities providing services to them under the Act and help them to pursue legal, administrative, and other appropriate remedies available to ensure the protection of their rights under the Act.

(c) *Who is eligible to apply for Federal assistance?* Applications must be submitted only by State agencies. The State agency may directly administer the project or it may administer the project through public or nonprofit agency or organization.

(d) *What are the matching requirements?* No minimum share is routinely required of applicants.

(e) *What costs does the Federal assistance cover?* In addition to generally allowable project costs, Federal financial participation may also be available for costs of client, client applicant, or attendant travel in connection with the provision of assistance under a project.

(f) *What are responsibilities of counselors employed in these projects?* Counselors employed within projects under this section are responsible for:

(1) Helping clients or client applicants to understand the vocational rehabilitation services program;

(2) Advising clients or client applicants of benefits available to them under the vocational rehabilitation program and related Federal and State assistance programs, and their rights and responsibilities in connection with these benefits;

(3) Otherwise assisting clients and client applicants in their relationships with projects, programs, and facilities providing vocational rehabilitation services under the Act;

(4) Referring clients or client applicants for assistance in pursuing legal, administrative and other remedies available to insure the protection of the rights of handicapped individuals under the Act; and

(5) Advising State agencies of identified problem areas in the delivery of vocational rehabilitation services to handicapped individuals and suggesting methods and means of improving State agency performance.

(g) *What are the special project considerations under this program.* Each applicant must assure that:

(1) No project employee may be a person who is presently serving as staff or consultant, or who is receiving benefits of any kind directly or indirectly from any rehabilitation project, program, or facility assisted under the Act in the project area, except for individuals receiving traineeships under Subpart E of this part;

(2) The project director will have direct access to the director of the designated State unit of the State agency and shall report directly to the director or his designate if the project is administered directly by the State agency. The project director shall be expected to participate in all policy and program development activities affecting the conduct of the project and shall be assured of access to any field office affected by the project;

(3) All clients or client applicants within the project area will have the opportunity to receive adequate client assistance services under the project;

(4) Project activities will be fully coordinated with other programs and activities carried out under this Act and under the Developmental Disabilities Assistance and Bill of Rights Act related to the protection and advocacy of the rights of handicapped persons and there shall be written agreements with these other programs in order to define the extent of the coordinated effort;

(5) Maximum effort will be made to enter into cooperative arrangements with institutions of higher education to secure the services of graduate students who are undergoing clinical training in rehabilitation related fields, and in fields related to the protection and advocacy of handicapped individuals, except that no compensation with funds appropriated under the Act will be provided to such students in connection with their participation in a project under this program;

(6) A counselor under this program will be able to participate in any administrative review of agency action, or any fair hearing conducted in connection with a client or client applicant being assisted under this program; and

(7) The project will contain an evaluative component to measure its effectiveness.

§ 1362.104 Project grants for interpreter services for deaf individuals.

(a) *What is the purpose of this program?* Under section 315 of the Act grants may be made to establish within each State a program of interpreter services for deaf individuals which may include a resource for the referral of such services. These services may be made available directly to deaf individuals and to any public agency or private nonprofit organization which is involved in providing assistance or services to deaf individuals.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by designated State units.

(c) *What costs does the Federal assistance cover?* (1) In addition to generally allowable project costs, Federal financial participation may also be available for the purchase or rental of special telephone amplification, and other devices for deaf persons.

(2) Federal financial participation may not be available for any administrative or related costs incurred by a designated State unit in the administration of the State's vocational rehabilitation program. Funds may also not be used for the provision of interpreter services to a deaf individual who is receiving vocational rehabilitation services under

Part 1361 of this chapter or independent living services under Part 1363 of this chapter unless the interpreter services are in connection with an essential activity not directly involved in the individual's rehabilitation or are provided in connection with providing access to other agencies or organizations which serve deaf individuals.

(d) *What are the special project considerations under this program?* (1) Each program must be operated in areas within the State which are specifically selected to provide convenient access to services by the maximum number of deaf individuals;

(2) Each program must include a plan for coordinating all interpreter referral services with the information and referral programs carried out by the State unit under § 1361.20 under the State plan for vocational rehabilitation services;

(3) Each program must seek to the greatest extent possible to enter into contractual or other arrangements with private nonprofit organizations comprised primarily of deaf or hearing impaired individuals, or private nonprofit organizations which have the primary purpose of providing assistance or services to deaf or hearing impaired individuals, for the operation of the program;

(4) All interpreters participating in the program must be individuals knowledgeable in the basic principles and the code of ethics of interpreting for deaf persons and who have been certified by a national organization recognized by the Commissioner, who meet standards for interpreters which have been established by a recognized State agency or organization, or who are currently undertaking training in order to meet these established standards;

(5) No deaf individual who is being provided interpreter services will be required to pay for these services;

(6) Any State unit operating a program under this section may provide interpreter services without cost for a maximum period of one year to any public or private nonprofit organization which provides assistance to deaf individuals. After that time, however, those agencies or organizations receiving services must be required to pay the designated State unit for the costs of any additional interpreter services which are provided;

(7) To the extent possible and needed, a program will provided tactile interpretation for deaf individuals who are also blind.

§ 1362.105 Special projects for the training of interpreters for the deaf.

(a) *What is the purpose of the program?* Under section 304(d) of the Act, the Secretary, through the Office of Information and Resources for the Handicapped, may make grants to establish additional training programs for interpreters for the deaf or to assist in the support of existing training programs for interpreters for the deaf. No more than twelve programs may be established or assisted under the this program.

(b) *Who is eligible to apply for a grant?* Applications may be made by any public or private nonprofit agency or organization or post secondary institution.

(c) *What costs does the Federal grant cover?*

(1) In addition to generally allowable project costs, Federal financial participation may also be available for:

(i) Student stipends;

(ii) Tuition and fees; and

(iii) Student travel.

(2) Reimbursement of indirect costs will not exceed 8 percent of the amount allowed for direct costs, exclusive of permanent equipment, rental of space, building alteration or renovation, subagreements (except for procurements), tuition and fees.

(d) *What are the special project considerations under this program?*

(1) All training supported under this program must be directed towards enabling individuals to be trained or retrained to meet the standards for manual or oral interpreting for deaf individuals, which have been established by the Secretary.

(2) Where appropriate, special training activities supported under this program must be coordinated with related training projects which may contribute to the overall success of the program. The training or retraining of teachers who work with deaf students, but who are not certified teachers of the deaf, may be provided in the area of special communication skills for use with deaf students, through short-term training or in-service training but, if provided through in-service training, it must be supported only through funds appropriated under the Education for All Handicapped Children Act.

(3) Priority in the awarding of grants is given to public or private nonprofit agencies or organizations which are currently operating effective training programs for interpreters for the deaf and which have the potential for training in a multi-State geographical area.

§ 1362.106 Projects for reading services for blind individuals.

(a) *What do the special terms mean?* For purposes of this section—

(1) "Blind individual" means a person whose central visual acuity does not exceed 20/200 in the better eye with correcting lenses or whose visual acuity, if better than 20/200, is accomplished by a limit to the field of vision in the better eye to such a degree that its widest diameter subtends an angle of no greater than 20 degrees. For purposes of this program, an individual who is both deaf and blind shall be considered to be a blind individual.

(2) "Agency or organization of national scope" means an agency or organization which conducts its programs of activity throughout the country.

(b) *What is the purpose of this program?* Under section 314 of the Act grants may be made for the purpose of:

(1) Providing reading services to blind individuals who are not otherwise eligible or potentially eligible for those reading services which are available through other State or Federal programs;

(2) Expanding the quality and scope of reading services available to blind individuals without regard to financial need; and

(3) Assuring to the maximum extent possible that adequate reading services are provided to blind individuals who are enrolled in educational institutions at all levels and who require reading services to enter employment and to continue in employment.

(c) *Who is eligible to apply for Federal assistance?* Applications may be made by States and by private nonprofit agencies or organizations of national scope. Any State conducting a reading service program under this section shall administer the program through the designated State unit.

(d) *What is the scope of reading services which may be provided?* Reading services for blind individuals may include:

(1) The employment of persons to read aloud to blind individuals from printed materials;

(2) The transcription of printed information into braille or sound recordings at the special request of a blind individual;

(3) The acquisition, storage, retrieval, and distribution of braille materials and sound recordings;

(4) The purpose, storage, and distribution of equipment and materials necessary for the production, duplication, and reproduction of braille materials and sound recordings;

(5) The purpose, storage, and distribution of equipment to blind

individuals in order to provide them with individual access to printed materials in auditory or tactual modes by mechanical or electronic means;

(6) Radio reading services for educational and rehabilitation purposes for blind individuals; and

(7) The employment of persons to read tactually from printed materials to blind individuals who are also deaf.

(e) *What are the special project considerations under this program?* (1) When the full scope of reading services cannot be provided under a project, priority is expected to be given to those reading services directly related to preparing for and retaining employment;

(2) To the maximum extent possible, project activities must be coordinated with related ongoing programs being undertaken in the project service area;

(3) No blind individual who is being provided reading services will be required to pay for these services; and

(4) Any blind individual provided services under this program will be given the opportunity to select any person to be hired to read directly to him or her.

§ 1362.107 Business opportunities for handicapped individuals.

(a) *What is the purpose of this program?* Under section 622 of the Act, grants may be made, or contracts may be awarded, to enable handicapped individuals to establish or operate commercial or other enterprises which develop, manufacture, produce, or market specified products or services.

(b) *Who is eligible to apply for Federal assistance?* Any handicapped individual who has been certified as eligible by a State unit may be awarded a grant or a contract under this program. If two or more handicapped individuals wish to receive assistance in order to establish or operate an enterprise jointly or under a cooperative arrangement, they must all be certified by the State unit.

(c) *What costs does the Federal assistance cover?* Federal financial participation may be available only for those costs specified and approved in each grant or contract award. These costs may cover any investment in either fixed or moveable property, including equipment and machinery, stocks nd supplies, necessary working capital, services of individuals needed in connection with the preparation of the business plan, technical and consultative assistance intended to improve the capability of the handicapped individual or individuals to establish or operate the enterprise, and the purchase of any additional goods or services necessary to establish or operate the enterprise. The total amount of assistance which may be provided to establish or operate any enterprise may not be more than $100,000 during the entire period of Federal support.

(d) *What types of enterprises are included?* A handicapped individual may be assisted under this program to establish or operate any type of commercial or other enterprise, including a cooperative enterprise, which appears to offer promise of profitable operation. The enterprise may be in any sector of the economy such as construction, manufacturing, retail or wholesale sales, services, transportation, or agriculture. For purposes of this program, "enterprise" means any commercial, industrial, agricultural, service, or other business activity which is 100 percent owned, established, organized and operated by a handicapped individual or a group of handicapped individuals for the purpose of profit.

(e) *How is an individual certified as eligible by a State unit for vocational rehabilitation?* (1) To participate in this program an individual must contact the State unit of the State vocational rehabilitation agency to indicate interest in being certified as eligible. The individual must advise the State unit of the general type of enterprise which he or she wishes to establish or operate.

(2) When certification is requested by a handicapped individual who is currently being provided vocational rehabilitation services, the State unit reviews his or her record to determine the individual's potential capacity to establish or operate an enterprise of the general type being considered. If the individual has not been provided vocational rehabilitation services by a designated State unit in the past, or if previous vocational rehabilitation services cannot be considered fully relevant to the request for certification, the State unit reviews any related material available from its own files or from the files of other agencies or other sources. If additional information is needed, the State unit performs any diagnostic studies necessary to determine whether the individual is in fact a handicapped individual and to assess his or her overall capacity for establishing or operating an enterprise of the general type proposed.

(3) When the State unit determines that the handicapped individual has the potential capacity to establish or operate an enterprise of the general type proposed, it certifies the individual as eligible and advises the individual in writing within 60 days of the request for certification. The State unit also advises the handicapped individual of the availability of its staff to assist in preparing and submitting an application for Federal assistance, including any application for loan assistance being submitted to the Small Business Administration.

(4) When the State unit determines that any handicapped individual does not have the capacity to establish or operate an enterprise, the State unit advises the individual in writing within 60 days of the request for certification and will inform the individual of the reasons for this determination. In such a case, the State unit also advises the individual of the opportunity available for an administrative review of agency action and, if necessary, a fair hearing under § 1361.48.

(5) The State unit continues to provide vocational rehabilitation services to any handicapped individual currently receiving services under an individualized written rehabilitation program. In the case of a handicapped individual not previously provided rehabilitation services, the State unit will provide an opportunity for initiating these services within State policies governing the order of selection of handicapped individuals to receive vocational rehabilitation services.

(f) *How does an individual apply for Federal assistance?* (1) A handicapped individual who has been certified as eligible for participation in this program and wishes to request Federal assistance must submit an application in the form and detail required by the Commissioner. The application must include the comprehensive business plan for the enterprise which specifies the costs expected to be incurred the period for which the Federal assistance is being requested. The application must also indicate whether a loan has been requested from the Small Business Administration or from other capital sources, the purpose and amount of any requested loan, and what action was taken on each request.

(2) The handicapped individual must attach to the application a copy of the certification of eligibility from the State unit.

(g) *Is the handicapped individual required to invest in the cost of the enterprise?* A handicapped individual receiving assistance will not routinely be required to contribute any specific proportion of the cost of establishing or operating the enterprise. As determined to be appropriate in each case, however, the Commissioner may refer the individual to the Small Business Administration if an application for a loan from that office has not already been submitted; or he may require the handicapped individual to contribute to

the establishment or operation of the enterprise from personal assets; or he may request the individual to use personal funds and anticipated Federal funds to attract other capital. The specific amount expected to be contributed by any handicapped individual will be negotiated at the time of the award.

(h) *How are awards made?* The Commissioner makes awards under this program in consultation with the Secretary of Labor and the Secretary of Commerce. The Commissioner may also arrange for the Small Business Administration, another Federal agency, a State or local agency or organization, or a qualified individual to advise on the soundness of the business plan and the likelihood of its successful establishment or operation.

(i) *What factors will be considered in making awards?* In making awards under this program, the Commissioner considers such factors as:

(1) The qualifications and experience of the applicant;

(2) The merit of the comprehensive business plan submitted by the handicapped individual;

(3) The availability of funds from other private and public resources and the extent to which these other funds are being used;

(4) The prevailing business and market conditions affecting the type of enterprise to be established or operated in the geographical area and the potential market for its products or services;

(5) The severity of the disability of the handicapped individual requesting assistance;

(6) The financial need of the handicapped individual requesting assistance;

(7) The extent to which handicapped individuals might benefit from the planned enterprise;

(8) The extent to which handicapped individuals might be employed within the planned enterprise;

(9) The extent to which the planned enterprise might offer an opportunity for replication by other handicapped individuals in other parts of the country; and

(10) The geographical distribution of enterprises assisted under this program throughout the country.

(j) *Do the funds have to be repaid?* There is no requirement that funds awarded under this program be repaid to the Federal Government. If the handicapped individual should cease to operate the enterprise for any reason during the period of Federal support, any funds or real assets remaining after all outstanding debts have been paid are returned to the Commissioner in an amount proportional to the Federal investment in the total costs of the establishment or operation of the enterprise.

(k) *Will any report be required?* The Commissioner requires progress reports from time to time from a handicapped individual establishing or operating an enterprise under this program. A final report, including an independent audit of the enterprise, is required 90 days after the completion of the period of Federal support.

§ 1362.108 Special projects and demonstrations for making recreation activities accessible to handicapped individuals.

(a) *What is the purpose of this program?* Under section 311(a)(3) of the Act, grants may be made for special projects and demonstrations, and related research and evaluation concerned with operating programs to demonstrate methods of making recreation activities fully accessible to handicapped individuals, including the renovation and construction of facilities where appropriate.

(b) *Who is eligible to apply for assistance?* Applications may be made by States and public and other nonprofit agencies and oranizations.

(c) *What are the matching requirements.* Grants may be made for paying all or part of the costs of activities covered under this program. Where part of the costs is to be borne by the grantee, the amount of grantee participation is determined at the time of the grant award and is generally not less than 10 percent of the total cost of the project.

(d) *What costs does the Federal assistance cover?* In addition to generally allowable project costs, Federal financial participation may also be available for those costs specified in § 1362.51(d) in the case of any project which involves the renovation or construction of a facility.

(e) *Is an evaluative component required?* All projects and demonstrations supported under this program must contain an evaluative component to measure overall project effectiveness.

(f) *What are the special project considerations under this program?* Approved projects must:

(1) Demonstrate innovative ways in which recreation services and activities can be made fully accessible to handicapped individuals, with special emphasis on those who are the most severely handicapped;

(2) Focus on as broad a range of recreation activities as is appropriate to the geographical area, including indoor and outdoor recreation activities; competitive, active, and quiet recreation activities; social activities; and recreation activities related to the fine arts. These activities may include but are not limited to, arts, camping, dance, drama, fitness, 4–H, scouting, sports, travel and other related recreation activities;

(3) Provide for a schedule of recreation activities which does not interfere with a handicapped individual's attendance at work or school;

(4) Utilize existing facilities for the provision of recreation activities to the greatest extent possible; and

(5) Ensure that any renovation or construction of facilities shall conform with the requirements specified under § 1362.8 and with any other requirements of the Department in effect concerning Federally assisted building design and construction activities.

§ 1362.109 Project grants for the initiation of special recreation programs for handicapped individuals.

(a) *What is the purpose of this program?* Under section 316 of the Act, grants may be made for the initiation of special programs to provide handicapped individuals with recreation activities which can be expected to aid in their mobility and socialization.

(b) *Who is eligible to apply for Federal assistance?* Applications may be made by States and other public nonprofit agencies and organizations.

(c) *What are the matching requirements?* Although there is no minimum share required of applications under this program, the applicant is expected to furnish as large a part of the total project cost as possible and to furnish an increasing share of the project costs in each succeeding year of the project period.

(d) *How long may the Federal assistance be available?* A project may be approved for a maximum project period of 5 years. The project period may not be extended beyond the initial 5 year period.

(e) *What are the special project considerations under this program?* (1) Activities carried out under this program must include as broad a range of recreation activities as is appropriate to the geographical area, including indoor and outdoor recreation activities; competitive, active, and quiet recreation activities; social activities; and recreation activities related to the fine arts. These activities may include, but are not limited to, arts camping, dance, drama, 4–H, fitness, scouting, sports,

travel and related recreation activities designed;

(i) To promote personal satisfaction;

(ii) To provide equal recreation opportunity;

(iii) To provide normalization experiences;

(iv) To foster social interaction and physical and mental health; and

(v) To provide individualized rehabilitation and therapeutic activities to alleviate the effects of disabilities.

(2) The scedule of recreation activities must be arranged so as not to interfere with a handicapped individual's attendance at work or school.

(3) To the greatest extent possible, existing facilities and resources must be used to provide the recreation activities and must utilize existing community recreation programs or service resources available under any related programs in the geographical area which are supported or authorized under the Development Disabilities Assistance and Bill of Rights Act, the Education for all Handicapped Children Act, the National Endowment of the Arts and Humanities Act of 1965, Title XX of the Social Security Act, the Community Education Act, and the Historic Preservation Fund and Land and Water Conservation Fund.

(4) Recreation services provided under this program must be provided in a manner consistent with the provisions of similar services under Part 1361 of this chapter.

§ 1362.110 Technical assistance.

(a) Under section 12 and section 506 of the Act, the Commissioner may provide, directly or by contract with State vocational rehabilitation agencies or experts or consultants or groups thereof, technical assistance and consultation:

(1) To a public or other, nonprofit rehabilitation facility in matters of professional or business practice within the facility; or

(2) With the concurrence of the Architectural and Transportation Barriers Compliance Board, to a public or other nonprofit agency, institution, organization, or facility in matters concerning the removal of architectural, transportation, or communication barriers.

(b) *What types of reports are required?* A rehabilitation facility or public or nonprofit agency, institution, organization or facility which receives technical assistance consultations must be furnished with the recommendations of the consultant. A copy of the recommendations must also be furnished to the appropriate State agency. The rehabilitation facility or public or nonprofit agency, institution, organization or facility receiving the technical assistance will be expected to provide a prompt report to the Commissioner concerning the consultation and a report 6 months afterwards as to what has been done about the recommendations.

3. A new Part 1363 is added to Chapter XIII to read as follows:

PART 1363—THE STATE INDEPENDENT LIVING REHABILITATION SERVICES PROGRAM

Subpart A—Definitions

Sec.
1363.1 Terms

Subpart B—State Plans for Independent Living Rehabilitation Services

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1363.37 Scope of State unit program; independent living rehabilitation services for individuals.
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1363.41 Scope of State unit program: Establishment and construction of rehabilitation facilities.
1363.42 Scope of State unit program: Facilities and services for groups of severely handicapped individuals.
1363.43 Scope of State unit program: Telecommunications systems and special materials for blind individuals and deaf individuals.

Subpart C—Allotment and Payment

1363.44 Allotment of Federal funds for independent living services.
1363.45 Payments from allotments for independent living services.

Authority: Section 12(c) of the Rehabilitation Act of 1973, (29 U.S.C. 711(c)).

Subpart A—Definitions

§ 1363.1 Terms.

The following terms were defined in § 1361.1 of this Chapter:

"Act"
"Blind"
"Commissioner"
"Construction of a rehabilitation facility"
"Designated State unit"
"Establishment of a rehabilitation facility"
"Nonprofit"
"Physical and mental restoration services"
"Physical or mental disability"
"Rehabilitation facility"
"Secretary"
"State"
"State unit"
"Vocational rehabilitation services"

The following new terms are used in this part:

"Attendant care" means the assistance provided to a severely handicapped individual in performing a variety of tasks required to meet essential personal needs in such areas as bathing, communicating, cooking, dressing, eating, homemaking, toileting, and transportation.

"Health mainteance" means the provision of those health care services which are necessary for a severely handicapped individual to maintain or improve his or her functional capabilities and those services which might contribute to avoiding complications or reactivations of the severely handicapped impairment or the development of additional impairments.

"Independent living rehabilitation services," or "independent living services," when provided to a severely handicapped individual, means those services listed in § 1363.37.

"Independent living rehabilitation services," or "independent living services" when provided for the benefit of groups of severely handicapped individuals, includes:

(a) The establishment or construction of a rehabilitation facility which provides independent living services to individuals;

(b) The provision of other facilities and services which promise to

contribute substantially to the independent living rehabilitation of a group of severely handicapped individuals but which are not related directly to the individualized written rehabilitation program of any one severely handicapped individual;

(c) The use of existing telecommunications systems; and

(d) The use of services providing recorded materials for blind individuals and captioned films or videocassettes for deaf individuals.

"Severely handicapped individual" means an individual whose ability to function independently in family or community, or whose ability to engage or continue in employment is so limited by the severity of his or her physical or mental disability that independent living rehabilitation services appreciably more costly and of appreciably greater duration than vocational rehabilitation services which might be provided under Part 1361 are required in order to enable achieving a greater level of independence in functioning in family or community or engaging or continuing in employment.

"State plan" means the State plan for independent living rehabilitation services.

"Transportation" means necessary travel in connection with a severely handicapped individual's engaging or maintaining employment or improving his or her ability to carry out independent living activities within family or community.

Subpart B—State Plans for Independent Living Rehabilitation Services

State Plan Content: Administration

§ 1363.2 The State plan: General requirements.

(a) *Purpose.* In order for a State to be eligible for grants from the allotment of funds under Title VII of the Act, it must submit an approvable State plan for providing independent living rehabilitation services to severely handicapped individuals.

(b) *Form and content.* The State plan must contain, in the form prescribed by the Commissioner, a description of the State's independent living rehabilitation program, the plans and policies to be followed in carrying out the program, and other information requested by the Commissioner.

(c) *Consolidated rehabilitation plan.* The State may choose to submit a consolidated rehabilitation plan which includes both the State plan for vocational rehabilitation services and the State plan for independent living rehabilitation services. The State may also choose to submit a consolidated plan which includes either or both of the State's rehabilitation plans and the State's plan for services for persons with developmental disabilities developed under the Developmental Disabilities Assistance and Bill of Rights Act.

(d) *Duration.* The State plan must cover a three-year period and must be amended whenever necessary to reflect any material change in any applicable phase of State law, organization, policy or agency operations which affects the administration of the State plan.

§ 1363.3 Review of State plan by Governor.

The State unit must submit the State plan to the State Governor for review and comments. The Governor is given an opportunity to review and comment on all State plan amendments and on long-range program planning projections or other periodic reports, except for periodic statistical or budget and other fiscal reports. The Office of the Governor has 45 days to review this material. The State submits any comments to the Commissioner with the documents.

§ 1363.4 State plan approval and disapproval.

(a) *State plan approval.* Except in the case of the first State plan submitted under Title VII, the State plan must be submitted for approval no later than July 1 of the year preceding the first fiscal year of the three-year period for which the State plan is submitted. The Commissioner approves any State plan or amendment meeting the requirements of the Act and of this part.

(b) *State plan disapproval.* The Commissioner does not disapprove any State plan or modification, until reasonable effort has been made to resolve any problem and the State has been given reasonable notice and opportunity for a hearing.

§ 1363.5 Withholding of funds.

(a) *When withheld.* Payments under section 704 of the Act may be withheld, suspended, or limited as provided by section 101(c) of the Act, when after a reasonable notice and opportunity for hearing has been given to the designated State unit, the Commissioner finds that:

(1) The State plan has been so changed that it no longer conforms with the requirements of section 705 of the Act, or

(2) In the administration of the State plan, there is a failure to comply substantially with any provision of such plan.

(b) *Notification of State unit.* The designated State unit is notified of the decision.

(c) *Judicial review.* The decision to withhold, suspend, or limit payments described in paragraph (a) of this section may be appealed to the United States Court of Appeals for the Circuit in which the State is located in accordance with section 101(d)(1) of the Act.

(d) *Informal discussions.* Hearings meeting the requirements of § 1361.5(d) of this chapter are not called until after reasonable effort has been made to resolve the questions involved by conference and discussion with State officials.

§ 1363.6 State unit for administration.

(a) *Designation of State unit.* The State plan must provide that the designated State unit administers the State's independent living rehabilitation service program conducted under this part.

(b) *Designation of State unit for the blind.* The State plan may designate a State commission for the blind or another agency of the State which is authorized under State law to provide vocational rehabilitation services to blind individuals under a State plan for vocational rehabilitation services, as the State unit to administer that part of the plan under which independent living services are provided to blind individuals.

(c) *Responsibility for administration.* The State plan must assure that all decisions affecting eligibility for, the nature and scope of available independent living rehabilitation services and the provision of these services are made by the designated State unit, and that this responsibility may not be delegated to any other agency, facility, or individual.

§ 1363.7 Staffing of designated State unit.

(a) *General staffing requirement.* The State plan must assure that the staff of the designated State unit includes specialist personnel skilled in the coordination and provision of independent living services and similar services to severely handicapped individuals.

(b) *Special communication needs staffing.* The State plan must also assure that the State unit makes available personnel able to communicate with severely handicapped individuals who rely on special modes of communication, such as manual communication or nonverbal communication devices, and personnel able to communicate in the native languages of severely handicapped individuals with limited

English-speaking ability from ethnic groups which represent substantial segments of the population of the communities in which the services are being provided.

§ 1363.8 Staff development.

The State plan must assure a program of staff development for all classes of positions involved in providing independent living services within the designated State unit. The staff development program must emphasize improving the skills of staff directly responsible for the provision of independent living services.

§ 1363.9 State unit studies and evaluations.

(a) *Scope of studies.* The State plan must assure that the State conducts studies of the independent living rehabilitation service needs of severely handicapped individuals within the State, including comparative studies of the different methods for providing these services, such as regional and community centers, centers for independent living, halfway houses, and patient-release programs. The State plan must also assure that the State conducts studies to determine effective alternatives to institutionalization. Any studies carried out under the plan must fully utilize findings from relevant studies which have been conducted in the past.

(b) *Evaluations.* The State plan must assure that the State conducts evaluations of the effectiveness of the State unit's independent living rehabilitation program in meeting the service needs of severely handicapped individuals in the State. These evaluations must measure the adequacy of State unit performance in providing independent living services to severely handicapped individuals, in the light of program and financial resources available in the State.

(c) *Use of findings.* The State plan must also assure that findings from the State's studies and evaluations are utilized in planning for and improving future independent living services.

(d) *Availability of reports.* Reports of studies and evaluations must be available to the public for review and inspection.

§ 1363.10 State plan and policy development consultation.

(a) *Advisory committee.* The State plan must assure that the State unit organizes a committee of severely physically and mentally handicapped persons, which may include parents or guardians of severely handicapped persons as necessary, to consult on a continuing basis in the initial development and periodic revision of the State plan. The members of the advisory committee must serve on a rotating basis after severely handicapped persons in the State have been provided an opportunity to suggest those individuals considered by them to be best qualified to represent severely handicapped individuals in need of independent living services. The State plan must assure that this committee periodically consults with the State unit in matters of policy and program development and implementation which affect the overall administration of the State's independent living rehabilitation service program. The committee must also participate actively in the periodic evaluations of the State's independent living rehabilitation service program.

(b) *Other consultations.* The State plan must also assure that that is a procedure for taking into account the views of providers of independent living services and other individuals interested in services for severely handicapped individuals.

§ 1363.11 Provision of technical assistance in poverty areas.

The State plan must assure that the State unit undertakes special efforts to provide technical assistance to public and other nonprofit agencies and organizations located in areas of urban or rural poverty which are interested in developing capability for providing independent living services. The State must annually report those special efforts which have been undertaken in this regard.

§ 1363.12 Cooperation with other public agencies.

The State plan must assure that, to the greatest extent possible, the designated State unit enters into cooperative arrangements with, and utilize the services and facilities of, other public agencies which provide services to severely handicapped individuals, including those agencies administering the State's special education, vocational education, and developmental disabilities service programs, public health, mental health, and mental retardation programs, housing, and transportation programs. Veterans Administration programs, and the programs authorized under Title XIX and Title XX of the Social Security Act.

§ 1363.13 Utilization of local public and private nonprofit agencies, organizations, and facilities.

(a) *General provisions.* The State plan must assure that the State unit utilizes local public and private nonprofit agencies, organizations, and facilities, as appropriate, to provide independent living services. The State plan must describe the methods and criteria to be used to ensure the appropriate use by the State unit of these local agencies, organizations, and facilities, including entering into agreements with them or making direct grants to them for providing independent living services.

(b) *Special requirements for State unit grantees.* Any agency, organization, or facility awarded a grant by the State unit must assure that severely handicapped individuals are fully involved in policy and program development activities affecting the provision of independent living rehabilitation services. Any agency, organization, or facility awarded a grant by a State unit must also assure that any services provided under the grant are at least of the same quality as services provided directly by the State unit.

(c) *Grants from State units.* At least 20 per cent of the funds received by a State under this part must be used to make grants to local public agencies and private nonprofit organizations for the conduct of independent living service programs. The State plan must assure that the State unit makes the availability of funds known to potential applicants within the State and identifies the criteria against which applications for grant funds are evaluated. These criteria must provide priority in the awarding of funds to those agencies and organizations which are directed and managed to a substantial degree by severely handicapped individuals.

(d) *Waiver of grants by State units.* The designated State unit may request from the Commissioner a waiver of the requirement that grants in the amount required under paragraph (c) of this section be made for any fiscal year when there is sufficient evidence to determine that the local agencies and organizations cannot use the funds effectively. In waiving this requirement, the Commissioner considers such factors as the number of agencies and organizations which have indicated an interest in applying for funds, the capability of these agencies and organizations, and the efforts which have been made by the State unit to improve the capacity of the agencies and organizations for conducting independent living rehabilitaion service programs.

(e) *Priority for State unit clients.* When a program of independent living rehabilitation services is conducted by a local public agency or a private nonprofit organization, the program must be designed primarily to serve those severely handicapped individuals who have been determined by the State

unit to be eligible for independent living services under the State plan.

(f) *State unit plans under related funding programs.* The State plan must specify the State's goals and plans with respect to the distribution of any Federal funds received for the establishment and operation of independent living centers under § 1362.110 of this chapter. The State plan must further indicate whether the State unit will directly apply for independent living center grants or whether local public agencies or private nonprofit organizations in the State will have the opportunity to apply for Federal funds under § 1362.110 of this chapter.

§ 1363.14 Independent living services for older blind individuals.

The State plan must assure that the State unit seeks to incorporate within its program of services any new methods or approaches to the provision of independent living rehabilitation services to older blind individuals which have been demonstrated to be effective under a special project under § 1362.111 (Grants for independent living services for older blind individuals) or § 1362.40 (Special projects and demonstrations; improved services to severely handicapped individuals) of this chapter. The Commissioner advises the State unit when the results of a special project have been found to be effective and requires that they be integrated within the State program to the extent feasible.

§ 1363.15 Reports.

The State plan must assure that the State unit submits reports in the form and detail and at the time required by the Commissioner, and complies with any requirements necessary to assure the correctness and verification of these reports.

§ 1363.16 Other administrative and fiscal requirements.

(a) *Applicability of vocational rehabilitation regulations.* Certain regulations covering the State plan for vocational rehabilitation services also apply under this part for purposes of the State plan for independent living rehabilitation services. These regulations include:

§ 1361.11 Methods of administration.
§ 1361.16 Standards of personnel administration
§ 1361.25 General administrative and fiscal requirements (except as provided in paragraph (b) of this section relative to Part 74).
§ 1361.44 Authorization of services.
§ 1361.47 Participation by handicapped individuals in the costs of vocational rehabilitation services.
§ 1361.48 Administrative review of agency action, and fair hearing; review by Secretary.
§ 1361.49 Protection, use, and disclosure of personal information.
§ 1361.76 State and local funds.

Subpart G—Procedures for Hearings on State Plan Conformity and Compliance.

(b) *Applicability of Part 74.* The provisions of Part 74 of this title, establishing uniform administrative requirements and cost principles, also apply to all grants made under this part.

(c) *Program administration.* Federal financial participation is available in expenditures under the State plan for the provision of services and for program planning, development, evaluation, and control; research; advocacy; interpretation of the program to the public; personnel administration, including the administration of affirmative action plans; use of advisory committees; the removal of architectural barriers in State agency offices and facilities; program accreditation; and training and staff development for State unit personnel. All expenditures in which Federal financial participation is claimed under the State plan must be subject to the administrative or supervisory control of the designated State unit.

State Plan Content: Provision and Scope of Service

§ 1363.30 Processing referrals and applications.

The State plan must assure that the State unit establishes and maintains written standards and procedures to assure expeditious and equitable handling of referrals and applications from severely handicapped individuals for independent living services.

§ 1363.31 Eligibility.

(a) *General provisions.* (1) The State plan must assure that eligibility requirements are be applied by the designated State unit without regard to sex, race, creed, color, or national origin of the individual applying for service. The State plan must specify that no group of individuals is excluded from service solely on the basis of the type of disability or on the basis of age.

(2) The State plan must assure that no residence requirement is imposed which excludes from services under the plan any individual who is present in the State.

(b) *Basic conditions.* The State plan must assure that eligibility is based only upon:

(1) The presence of a severe physical or mental disability;

(2) The presence of a severe limitation in ability to function independently in family or community or to engage or continue in employment; and

(3) There is a reasonable expectation that independent living rehabilitiation services will significantly assist the individual to improve his or her ability to function independently in family or community or to engage or continue in employment. For purposes of determining an individual's eligibility for independent living services, improvement in ability to function independently in family or community refers to a demonstration in functional and behavioral terms of an individual's greater independence or maintenance of independence in such areas as self-care, activities of daily living, driving, using public transportation, shopping, housekeeping, communicating, or living more independently.

§ 1363.32 Determination of eligibility for independent living rehabilitation services.

(a) *General provisions.* The State plan must assure that the State unit conducts an evaluation of each severely handicapped individual who applies for independent living services. This evaluation is limited to that information necessary to determine whether the individual is eligible to be provided independent living services and takes into consideration any relevant case record materials available from files of the designated State unit or from the files of other agencies. A special diagnostic study is conducted specifically for purposes of determining eligibility for independent living services only if already available information is not complete, relevant, or current.

(b) *Scope of evaluation.* The State plan must also assure that the evaluation is sufficient in scope to determine which services will best meet the current and future needs of the individual for fuctioning more independently in family or community or engaging or continuing in employment.

§ 1363.33 Certification of eligibility or ineligibility.

(a) *Certification of eligibility.* The State plan must assure that, before or at the same time as acceptance of a severely handicapped individual for independent living rehabilitation services, there must be a certification that the individual has met the basic requirements specified in § 1363.31. The State plan must also assure that the certification is dated and signed by an appropriate staff member of the designated State unit.

(b) *Certification of ineligibility.*

(1) The State plan must assure that whenever it is determined that

independent living services cannot be expected to assist an individual to engage or continue in employment or to function more independently in family or community, there must be a certification dated and signed by an appropriate staff member of the State unit.

(2) The State plan must also assure that the certification indicates the reasons for the ineligibility determination and is made only after full consultation with the individual or, as appropriate, his or her parent, guardian, or other representative, or after giving a clear opportunity for this consultation. In this case, the State unit notifies the individual in writing of the action taken and informs the individual of his or her rights and the means by which he or she may express and seek remedy for any dissatisfactions, including procedures for administrative review and fair hearings. When appropriate, the individual is provided a detailed explanation of the availability of the resources within a protection and advocacy project established within the State under § 1362.102 and referral is made to other agencies and facilities, including the State's vocational rehabilitation program under Part 1361 of this chapter.

(3) The State plan must also assure that when an applicant for independent living services has been certified as ineligible because of a determination that these services cannot be expected to assist the individual to engage or continue in employment or to function more independently in family or community, the individual's current status will be reviewed no later than 12 months after the determination has been made. The review need not be conducted in situations where the individual has refused the review, the individual is no longer present in the State, or the individual's whereabouts are unknown.

§ 1363.34 Order of selection for services.

The State plan must show the order to be followed in selecting groups of severely handicapped individuals eligible to be provided independent living rehabilitation services when these services cannot be provided to all persons who apply. The State plan must assure that first priority is given to those severely handicapped individuals, including homebound individuals, who are not presently receiving vocational rehabilitation services under the State vocational rehabilitation service program under Part 1361 because of the severity of their physical or mental disability, and those severely handicapped individuals who are institutionalized, have been institutionalized in the past, or are at risk of becoming institutionalized. The State plan must also assure that priority is given to other groups of severely handicapped individuals identified by the Commissioner from time to time.

§ 1363.35 The case record for the individual.

The State plan must assure that the State unit maintains for each applicant for independent living services and for each individual receiving these services, a case record which includes documentation concerning the individual's eligibility for service and the provision and payment for services. The State plan must assure that a review of the progress of each severely handicapped individual being served is carried out at least annually to determine whether services should be continued, modified, or discontinued, or whether the individual should be referred to a program of vocational rehabilitation services under Part 1361 or to any other program of assistance. The case record must indicate the findings of these periodic reviews.

§ 1363.36 The individualized written rehabilitation program for independent living rehabilitation services.

(a) *General provision.* The State plan must assure that an individualized written rehabilitation program is initiated and periodically updated for each severely handicapped individual provided independent living rehabilitation services. The State plan must also assure that each independent living service is provided in accordance with the written program. The individualized written rehabilitation program must be developed jointly by the appropriate staff member of the State unit and the severely handicapped individual or, as appropriate his or her parent, guardian or other representative. A copy of the written program, and any amendments, must be provided to the severely handicapped individual or, as appropriate, his or her parent, guardian or other representative.

(b) *Initiation of program.* The individualized written rehabilitation program must be initiated after certification of eligibility under § 1363.33 and must indicate the goals established for each individual, the services to be provided, and the anticipated duration of the service program and each component service.

(c) *Review.* The State plan must assure that the individualized written program will be reviewed as often as necessary but at least on an annual basis. Each severely handicapped individual, or, as appropriate, his or her parent, guardian or other representative must be given an opportunity to review the program and, if necessary, jointly redevelop and agree by signature to its terms.

(d) *Review of ineligibility determination.* The State plan must assure that if services are to be terminated under a written program for any reason, the following conditions and procedures must be met or carried out:

(1) This decision is made only with the full participation of the individual, or, as appropriate, his or her parent, guardian, or other representative, unless the individual has refused to participate, the individual is no longer present in the State, or his or her whereabouts are unknown. When the full participation of the individual or a representative of the individual has been secured in making this decision, the views of the individual are recorded in the individualized written rehabilitation program;

(2) The rationale for the ineligibility decision is recorded as an amendment to the individualized written rehabilitation program certifying that the provision of independent living services has demonstrated that the individual is not capable of functioning more independently in family or community or engaging or continuing in employment. A certification of ineligibility under § 1363.33 is then executed;

(3) There is a periodic review, at least annually of the ineligibility decision in which the individual is given opportunity for full consultation in the reconsideration of the decision, except in situations where a periodic review would be precluded because the individual has refused services or has refused a periodic review, the individual is no longer present in the State, or his or her whereabouts are unknown; and

(4) There is a periodic review of determinations made by the designated State unit, in addition to those concerning eligibility, at the request of the severely handicapped individual, his or her parent, guardian, or other representative.

(e) *Coordination with vocational rehabilitation, developmental disabilities and education programs.* The development of the individualized written rehabilitation program for independent living services and the provision of these services must be coordinated to the maximum extent possible with the individualized written rehabilitation program for vocational rehabilitation services for that individual, if there is such a written program. This must also be coordinated with any individualized written

rehabilitation program for the individual prepared under the Developmental Disabilities Assistance and Bill of Rights Act or with any individualized written education program for the individual prepared under Part B of the Education for Handicapped Children Act.

§ 1363.37 Scope of State unit program; independent living rehabilitation services for individuals.

(a) *Scope of services.* The State plan must assure that, as appropriate to meeting the independent living rehabilitation service needs of any severely handicapped individual, the following independent living rehabilitation services may be available:

(1) Counseling services, including psychological counseling, psychotherapeutic counseling, peer counseling, and related services;

(2) Housing incidental to the provision of any independent living rehabilitation service, and including appropriate accommodations to, and modifications of, any space utilized to serve severely handicapped individuals;

(3) Physical and mental restoration services, including;

(i) Physical and mental medical rehabilitation services;

(ii) Dentistry services;

(iii) Nursing services;

(iv) Therapeutic treatment, such as physical therapy, occupational therapy, speech, language and hearing therapy, therapeutic recreation, drama therapy, music therapy and art therapy;

(v) Health maintenance;

(vi) Eyeglasses and visual services; and

(vii) Prosthetic, orthotic and other assistive appliances and devices.

(4) Attendant care;

(5) Transportation;

(6) Interpreter services for deaf individuals, including tactile interpretation for deaf-blind individuals;

(7) Reading services, rehabilitation teaching services, and orientation and mobility services for blind individuals;

(8) Recreational activities;

(9) Services to members of a severely handicapped individual's family when necessary for improving the individual's ability to live and function more independently, or the individual's ability to engage or continue in employment;

(10) Vocational and other training services, including personal and vocational adjustment when necessary for improving a severely handicapped individual's ability to live and function more independently, or his or her ability to engage or continue in employment;

(11) Job placement services;

(12) Referral services;

(13) Telecommunications, sensory and other technological aids and devices;

(14) Services for children of pre-school age including physical therapy, development of language and communication skills, and child development services;

(15) Any other vocational rehabilitation services available under the State plan for vocational rehabilitation services under Part 1361 of this chapter, which are appropriate to the independent living rehabilitation needs of a severely handicapped individual; and

(16) Any appropriate preventive services necessary to decrease the future needs of a severely handicapped individual assisted under this program for similar services.

(b) *Written policies.* The State plan must also assure that the State unit establishes and maintains written policies covering the quality, scope, and extent of each of the independent living services listed in paragraph (a) of this section which is to be provided under the State program, and the conditions, criteria, and procedures under which the service is to be provided. These policies must assure that when services are being provided to assist a severely handicapped individual to continue or engage in employment, the services must be provided under Part 1361 if the individual is also eligible for vocational rehabilitation services.

§ 1363.38 Case closure.

The State plan must assure that when the objectives of the individualized written rehabilitation program are achieved, there is a record describing the way in which the severely handicapped individual has benefited from independent living rehabilitation services and has significantly improved his ability to engage or continue in employment or his ability to function independently in his family or community.

§ 1363.39 Duration.

The State plan must assure that no uniform durational requirement is imposed. The estimated duration of each service must be recorded for each individual under an individualized written rehabilitation program.

§ 1363.40 Standards for facilities and providers of services.

The State plan must assure that the State unit maintains written standards for the various types of facilities and providers of services utilized by the State unit in providing independent living services to severely handicapped individuals. The designated State unit must assure that providers of service meet all licensure or certification requirements in the State. The State unit must also assure that any facilities used in connection with the delivery of services under this program meet the standards specified in the Architectural Barriers Act of 1968 and, the "American Standard Specification for Making Buildings and Facilities Accessible to, and Usable by the Physically Handicapped," No A117.1–1961, as amended, and its implementation standards, 41 CFR Part 101–19.6 et seq.

§ 1363.41 Scope of State unit program: Establishment and construction of rehabilitation facilities.

If the State plan provides for the establishment and construction of rehabilitation facilities which provide independent living services, it must further assure that the primary purpose of the establishment or construction of any facility is to provide independent living rehabilitation services to severely handicapped individuals under this part. The provisions of § 1361.51 and § 1361.52 concerning the establishment and construction of rehabilitation facilities under the State plan for vocational rehabilitation services also apply.

§ 1363.42 Scope of State unit program: Facilities and services for groups of severely handicapped individuals.

The State plan may provide for facilities and services which may be expected to contribute substantially to the rehabilitation of a group of severely handicapped individuals but which are not related directly to the individualized rehabilitation program of any one individual. If the State plan includes these facilities and services, it must further assure that the State unit establishes and maintains written policies covering their provision.

§ 1363.43 Scope of State unit program: Telecommunications systems and special materials for blind individuals and deaf individuals.

The State plan may provide for the use of existing telecommunications systems which have the potential for substantially improving independent living rehabilitation service delivery methods and the delivery of appropriate programming to meet the particular needs of severely handicapped individuals. The State plan may also provide for the use of special services available to provide recorded material for blind individuals and captioned television, films or video cassettes for deaf individuals. If the State plan includes these services, it must further assure that the States unit shall

establish and maintain written policies covering their provision.

Subpart C—Allotment and Payment

§ 1363.44 Allotment of Federal funds for independent living services.

(a) The allotment of Federal funds for independent living services for each State is computed in accordance with the requirements of section 703 of the Act.

(b) Where the State plan designates separate agencies to administer the part of the plan under which independent living rehabilitation services are provided for blind individuals, and the rest of the plan, respectively, the division of the State's allotment is a matter for State determination.

§ 1363.45 Payments from allotments for independent living services.

The Commissioner pays to each State an amount computed accordance with the requirements of section 704 of the Act. The Federal share is 90 percent except for the cost of construction of rehabilitation facilities where the Federal share may be no more than 50 percent.

PART 1370 [DELETED]

4. Part 1370 of Chapter XIII is deleted.

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Thursday
November 29, 1979

Part III

Environmental Protection Agency

National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[FRL 1312-2]

National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This amendment to the National Interim Primary Drinking Water Regulations establishes a Maximum Contaminant Level (MCL) of 0.10 mg/l and associated monitoring and reporting requirements for total trihalomethanes (TTHMs), including chloroform, that are introduced into drinking water by the reaction of naturally occurring substances with chlorine in the course of water treatment. The proposed requirement to utilize granular activated carbon (GAC) or equivalent technology in those public water systems subject to significant contamination by synthetic organic chemicals has been separated from this promulgation and will be reproposed for additional public comment in the near future.

EFFECTIVE DATES: For community water systems serving 75,000 or more persons, monitoring must begin 1 year following promulgation and the effective date of the MCL is 2 years following promulgation. For community water systems serving 10,000 to 75,000 persons, monitoring must begin within 3 years from the date of promulgation and the effective date of the MCL is 4 years from the date of promulgation. Effective immediately, systems that plan to make significant modifications to their treatment processes for the purpose of complying with the TTHM MCL are required to seek and obtain State approval of their treatment modification plans.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Director, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. (202-472-5016).

SUPPLEMENTARY INFORMATION:

History of Rulemaking

On July 14, 1976, EPA published an Advance Notice of Proposed Rulemaking (ANPRM), entitled "Control Options for Organic Chemicals in Drinking Water" (41 FR 28991 *et seq.*). The ANPRM summarized the many facets of the issue of organic chemicals in drinking water including the legislative background, health effects data, the state of available control technology and costs. Advantages and disadvantages of various regulatory and non-regulatory options were examined, and the ANPRM solicited comments and information regarding the problem and options presented. On February 9, 1978, the EPA published a proposed rule (43 FR 5756, *et seq.*) To amend the National Interim Primary Drinking Water Regulations to include an MCL and associated monitoring and reporting requirements for TTHMs. At the same time, a requirement for the use of GAC or equivalent technology was proposed for application to those drinking water sources subject to significant contamination by synthetic organic chemicals of industrial origin. Subsequently, on July 6, 1978, EPA published a Supplemental Notice of Proposed Rulemaking (43 FR 29135, *et seq.*) soliciting comment on EPA's reassessment of the economic impact analysis for the proposal, providing additional documentation in support of the proposal, clarifying certain aspects concerning the effects of organic chemicals in drinking water, and extending the public comment period from July 31, 1978, to September 1, 1978.

The two **Federal Register** Notice preambles and the supporting documentation cited therein provided a detailed discussion of EPA's rationale for proposing controls on organic chemicals in drinking water. The subjects covered included: assessments of the sources and occurrences of, and human exposure to, THMs and other organic chemicals in drinking water; discussion of the toxicology and epidemiology studies that relate to possible human health risks; rationale for the selection of the MCL for TTHMs and associated requirements; and a discussion of the control technology, economic impact and air pollution and energy impacts of the proposal. EPA's analyses of these subjects have been revised to incorporate information gained during the public comment period.

A total of 598 written comments were received in response to the proposed regulations of which 391 addressed the subject of THMs. In a number of cases the commenters confused the two different regulations being proposed for organic chemical control. For example, some commenters incorrectly assumed that GAC was proposed as the requirement for control of THMs and objected accordingly.

Public hearings were held between March and July, 1978, in Miami, Florida; New Orleans, Louisiana; Boston, Massachusetts; Los Angeles, California; St. Louis, Missouri; Louisville, Kentucky; Washington, D.C. and Dallas, Texas. A total of 259 witnesses testified at the public hearings, and of these, 157 commented on the proposed regulations for THMs. Commenters included water utilities, state and local officials, public interest groups, federal health regulatory and research agencies, engineering consulting firms and individual citizens and scientists. In addition, there were 496 communications from members of Congress, and both the House and Senate Appropriations Committees, and the Council on Wage and Price Stability offered comments on the proposed regulations. The National Drinking Water Advisory Council was also consulted for their comments on the regulations. A number of the comments were duplicative, in that often the same persons or organizations submitted both written and oral comments and such comments often induced inquiries from members of Congress on the same subject. EPA has thoroughly considered all comments received in formulating the final regulations. A detailed breakdown of the comments and the Agency's responses to them are attached as Appendices.

Legal Authority

These final regulations are issued under the authority of the Safe Drinking Water Act, as amended (SDWA), 42 U.S.C. 300f *et seq.*, specifically, sections 1401, 1412, 1445 and 1450. They constitute amendments to the National Interim Primary Drinking Water Regulations (NIPDWR), 40 CFR Part 141, as authorized by Section 1412(a)(1).

As noted in the preamble to the proposed regulations (43 FR at 5759), EPA considered establishing these regulations as Revised Primary Drinking Water Regulations but concluded that they would be more appropriate as amendments to the NIPDWR. This means that the feasibility of control measures under the NIPDWR must be adjudged to have been available as of December, 1974, when the SDWA was enacted. As prescribed by Section 1412(a)(2), these Interim Regulations protect health to the extent feasible, using technology, treatment techniques, and other means which the Administrator determines are generally available (taking costs into consideration) on the date of enactment (of the SDWA).

Although Congress clearly contemplated the comprehensive control of organic chemical contaminants in the

Revised Regulations, the statute nowhere precludes EPA from establishing requirements as amendments to the Interim regulations even after the issuance of the report of the National Academy of Sciences under Section 1412(e). The statute does not require that all regulations subsequent to the NAS report be issued as Revised Regulations. All that is required is that the applicable statutory criteria be met. Given Congress' early concern with the presence of organic chemicals in drinking water, the availability of control measures to reduce the level of TTHMs to 0.10 mg/l since 1974, and EPA's finding that THMs "may have an adverse effect on the health of persons," amending the Interim Regulations to include these requirements as a first step toward controlling organic chemical contaminants in drinking water is clearly authorized at this time.

On February 10, 1978, one day after the publication of EPA's proposal in this rulemaking in the **Federal Register**, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in *Environmental Defense Fund* v. *Costle*, No. 75–2224, 578 F.2d 337. In that case, EDF sought more comprehensive control by EPA of organic chemicals in the NIPDWR that were promulgated in December 1975. Following a review of the statutory provisions and the legislative history regarding the scope of the Interim Regulations, the Court found that EPA could exercise a degree of administrative discretion in deciding whether to control organic chemical contaminants under the NIPDWR. The Court also stated:

> As we have indicated above, we believe the legislature contemplated that the interim regulations would, where feasible, control every contaminant that may prove injurious to health. The failure of the challenged regulations to do so thus becomes suspect. In light of the clear language of the legislative history, the incomplete state of our knowledge regarding the health effects of certain contaminants and the imperfect nature of the available measurement and treatment techniques cannot serve as justification for delay in controlling contaminants that may be harmful. (578 F.2d at 345).

The Court deferred final resolution of the issue by remanding the record to EPA for a report regarding "significant changes that have occurred, since the promulgation of the interim regulations, in (EPA's) assessment of the problem of controlling organic contaminants in drinking water," and to advise the Court "as to whether it plans to propose *amended interim regulations* in light of newly acquired data" (emphasis added) (578 F.2d at 346). This evidenced the Court's recognition that amendments to the Interim Regulations were not restricted to mere modifications to existing requirements, as argued by one commenter. Following EPA's submission of its February 9, 1978, proposed regulations, the Court affirmed EPA's earlier rulemaking action without prejudice to the filing by EDF of a petition to review any action or inaction of the EPA concerning proposed regulations dealing with organic contaminants and without prejudice to the filing by EDF of a motion to recall the mandate should circumstances warrant such action. (Court's order, dated July 14, 1978). These final regulations directly address the Court's concerns as they were set forth in that opinion.

Summary of the Regulations

Section 141.12 of the Interim Regulations has been amended to add a new maximum contaminant level of 0.10 mg/l for TTHMs. TTHMs in § 141.2 are defined as the arithmetic sum of the concentrations of the THM compounds (trichloromethane (chloroform), dibromochloromethane, bromodichloromethane and tribromomethane (bromoform)) rounded to two significant figures. This MCL is applicable to all community water systems serving 10,000 or more persons that add a disinfectant to their treatment process. The effective dates of the MCL are specified at § 141.6 as two years from the date of promulgation for those systems serving a population of 75,000 persons or more and four years from the date of promulgation for those systems serving a population of 10,000 to 75,000. At this time, systems serving fewer than 10,000 persons are not covered by these regulations unless States exercise their discretion and expand their coverage to these smallest systems.

Under new Section 141.30, systems serving 75,000 or more persons are required to begin monitoring within one year from the date of promulgation of this regulation and systems serving from 10,000 to 75,000 persons are required to begin monitoring within three years from the date of promulgation. No monitoring is required for systems serving fewer than 10,000 persons under the federal regulations, but the States may extend coverage at their discretion.

The minimum total number of samples required to be taken by the system is required to be determined on a per plant basis, with the exception that wells drawing raw water from a single aquifer may, with State approval, be considered on treatment plant. Thus, if a system has only one treatment plant, the minimum number of samples is four samples per quarter; if it has two treatment plants, the minimum is eight samples per quarter; if it has three treatment plants, the minimum is twelve samples per quarter. All samples taken at the established frequency (e.g., quarterly, annually) must be collected on the same day.

Community water systems using surface sources and systems using ground water sources are, at a minimum, required to monitor for TTHMs at quarterly intervals, with a minimum of four samples each quarter for each treatment plant used by the system. Each quarter, the system's sampling scheme must insure that at least 25% of the samples are taken at locations within the distribution system reflecting maximum residence time of the water in the system, and that no more than 75% of the samples are taken at other representative locations within the distribution system. In selecting representative sampling locations for TTHM monitoring, the regulations provide that the system shall take into account the number of persons served, source of raw water and treatment methods used. To the extent possible, representative sampling for systems with more than one treatment plant should reflect the distributed water from each plant separately.

Systems are further required to average the results of all analyses performed per quarter and to report the results to the State, and to EPA if such monitoring requirements have not yet been adopted by the State with primary enforcement responsibility. All samples collected must be used in computing the average, unless the analytical results are invalidated for technical reasons by a responsible official. Compliance will then be determined based upon a running annual average of the quarterly samples.

The regulations also provide that this sampling frequency of four samples for TTHMs per quarter per year may be reduced by the State to a minimum of one sample for TTHMs per quarter per year (for each plant used by the system) if, after the system has monitored for at least one full year in accordance with the original schedule, it can demonstrate to the State that the water it serves is consistently below the TTHM MCL of 0.10 mg/l. This minimum single TTHM sample must be taken at a point in the distribution system that reflects maximum residence time to insure adequate protection. The system would be required to immediately revert back to the "four samples per quarter" sampling frequency if the single TTHM

sample exceeds the standard and such results have been confirmed by at least one check sample, or in the event of any significant change in its source of water or treatment program. The system must continue such program for at least one year before it could be eligible for reduced monitoring again. The regulations also authorize the States (and EPA, where the State does not have primary enforcement responsibility) to increase the monitoring frequencies at their discretion where such is deemed necessary and appropriate to insure consistent compliance with the MCL throughout the distribution system.

Special consideration is given in the regulations to community water systems which draw their water exclusively from groundwater sources by allowing them to have their monitoring requirements reduced by the State at the outset based upon a judgment by the State that such systems are not likely to be subject to TTHM contamination. The regulations require that such a system must demonstrate to the satisfaction of the State based on at least one sample for each treatment plant used by the system that it has a maximum total trihalomethane potential (MTP) of less than 0.10 mg/l. Thus, if the results from at least one MTP sample are less than 0.10 mg/l and after an examination of local conditions, the State may reduce the monitoring requirements of such a ground water system to not less than one sample for MTP per year. "Maximum total trihalomethane potential" is defined under new § 141.2(s). Any system using exclusively groundwater sources whose MTP is equal to or greater than 0.10 mg/l, which results have been confirmed by a check sample, must comply with the four TTHM samples per quarter per year requirement for at least one full year. Thereafter, the monitoring may be reduced by the State to one TTHM sample per quarter if the TTHM levels are consistently less than 0.10 mg/l, or to one MTP sample per year if the MTP is shown to be less than 0.10 mg/l.

Systems are required to report to the State (and EPA until the State adopts these regulations) the results of each quarterly sampling within 30 days of receipt of such results. Once the MCL takes effect, public notification as well as reporting to the State is required whenever the running average of quarterly samples during the previous 12 months indicates that the MCL of 0.10 mg/l has been exceeded.

To ensure the continued microbiological quality of the drinking water as TTHM levels are being reduced, water systems are required to seek and receive State approval of their plans to make significant modifications to their treatment processes. State approval shall be conditional upon inclusion of additional monitoring and other requirements prescribed by the State to assure microbiological quality in accordance with the guidance provided by EPA. Finally, analyses must be performed by approved laboratories and in accordance with EPA specified methods.

Trihalomethanes

As explained in the preamble to the proposed regulations, the THMs found in drinking water are members of the family of organohalogen compounds which are named as derivatives of methane, where three of the four hydrogen atoms have been replaced by three atoms of chlorine, bromine or iodine. Ten distinct compounds are possible by various combinations of three halogenated atoms, one hydrogen and carbon atom. Current analytical methodology applied to drinking has thus far detected chloroform (trichloromethane), bromodichloromethane, dibromochloromethane, bromoform (tribromomethane) and dichloroiodomethane and monitoring methods are currently available for the brominated and chlorinated THMs but not the iodinated THMs because of chemical instability.

The principal source of chloroform and other trihalomethanes in drinking water is the chemical interaction of the chlorine added for disinfection and other purposes with the commonly present natural humic and fulvic substances and other precursors. The actual levels of TTHMs in drinking water, however, will vary depending upon the season, chlorine contact time, water temperature, pH, type and chemical composition of raw water and treatment methodology. Since the natural organic precursors are more commonly found in surface waters, water taken from a surface source is more likely than ground water (with notable exceptions) to produce high THM levels.

Generally, the THM producing reaction is as follows:

Chlorine + (Bromide ion or iodide ion) + Precursors = Trihalomethanes and other Halogenated Compounds

Chloroform is the most common THM found in drinking water and it is also usually present in the highest concentration. In a number of cases, the concentrations of the brominated THMs were found to far exceed the chloroform concentrations. The mixed THMs appear to form by way of an initial oxidation of bromide ion in solution by added chlorine, followed by rapid bromination of the organic precursors. Bromine and chloroform may also be introduced as contaminants of chlorine.

Chloroform and other THMs were first reported in drinking water in late 1974. EPA initiated the National Organics Reconnaissance Survey (NORS) of 80 water utilities, which confirmed that THMs were being formed during chlorination in drinking water treatment process. Concentrations in finished water appeared to be roughly related to the amounts of natural chemicals present in the water.

In late 1975, EPA initiated the National Organics Monitoring Survey (NOMS) in 113 cities. The NOMS demonstrated that considerable amounts of THMs could form in the water after it has entered the distribution systems on the way to the consumer's tap. It also showed that THMs far exceeded the concentrations of other synthetic organic contaminants in finished drinking water, and that brominated THMs could also exceed the chloroform concentrations. Other studies have shown that the TTHMs are only a portion of the chlorinated chemicals generated in water after chlorination. Additional information is contained in EPA's "Statement of Basis and Purpose" accompanying this regulation.

Review of Major Issues

During this rule-making, EPA specifically solicited and received comments on the following major issues: The rationale for setting an MCL for TTHMs and the magnitude of the MCL; the feasibility of and timing for phased reduction of the MCL; the concept of phasing the application of the MCL based upon system size; an alternative of making the MCL applicable to all public water systems and to phase the implementation by a deferred monitoring schedule linked to population size; the method for determining compliance, including the number, frequency and location of sampling sites and the averaging of results; the availability of technology to achieve compliance, and the need for restrictions to assure that biologically safe water would be maintained in the course of achieving TTHM reduction; and the costs incurred by public water systems to achieve compliance with the MCL.

Magnitude and Rationale for the MCL

These final regulations adopt unchanged EPA's proposed MCL for

TTHMs of 0.10 mg/l. The majority of commenters responding to this issue felt that setting an MCL of 0.10 mg/l for TTHMs lacked supporting justification, both in terms of establishment of the need for a regulation to protect public health and also the numerical value that was proposed, while others supported the proposed MCL and some recommended that a lower MCL be selected. Many argued that an unenforceable goal instead of an MCL should be established, or that the MCL should be higher than 0.10 mg/l.

The Coalition for Safe Drinking Water (CSDW), a member organization of both municipal and investor-owned water utilities formed specifically to comment on EPA's proposed regulations, recommended that an MCL be established only for chloroform and that the MCL should be no lower than 0.3 mg/l. The CSDW presented a number of witnesses at the various public hearings and submitted voluminous written comments on the THM regulation. Among the arguments presented were: That chloroform is not known to be a human carcinogen; that other THMs are not known to be animal carcinogens; that the bioassy of chloroform conducted by the National Cancer Institute was flawed; that a threshold level could be established for carcinogenic risk; that the epidemiological studies purporting to indicate human risk were flawed or misinterpreted; that the cancer risks from chloroform could be considerably lower than those computed using the conservative linear or multi-stage models. One (Roe) stated that chloroform might be beneficial. EPA evaluated the CSDW's comments but found their arguments unpersuasive. A detailed analysis of the CSDW's comments is contained in EPA's response to comments, Appendix A. A summary of their specific comments is presented in Appendix B.

Comments from the National Cancer Institute (NCI), National Academy of Sciences (NAS), the National Drinking Water Advisory Council (NDWAC), the National Institute of Environmental Health Sciences (NIEHS) and federal regulatory agencies such as the Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC), generally supported EPA's proposal. A summary of their specific comments is presented in Appendix B. They stated that sufficient scientific evidence had been accumulated to conclude that chloroform is an animal carcinogen as shown from a properly conducted bioassay and should be presumed to be a risk to humans and that, as such, prudent public health policy warrants reasonable measures to reduce human exposure. The NDWAC also specifically concurred with the 0.10 mg/l MCL proposal for TTHM. The Environmental Defense Fund (EDF) suggested that a lower MCL would be feasible.

EPA's decision to regulate THM levels in drinking water is based on a number of factors which were extensively discussed in the preambles to its proposal notices of February 9 and July 6, 1978. They include, in summary, the potential human health risks of chloroform and other THMs; the fact that drinking water is the major source of human exposure to THMs; the fact that THMs are the most ubiquitous synthetic organic chemicals found in drinking water in the U.S. and are generally found at the highest concentrations of any such chemicals; the fact that THMs are introduced in the course of water treatment as by-products of the chlorination process and thus are readily controllable; that low cost and feasible means have been generally available since 1974 to reduce their concentrations in drinking water; that monitoring is feasible; and that the THMs are also indicative of the presence of a host of other halogenated and oxidized, potentially harmful by-products of the chlorination process that are concurrently formed in even larger quantities but which cannot be readily characterized chemically.

In concluding that exposure to THMs in drinking water poses a human health risk, EPA followed the four principles on human risk assessment set forth in the 1977 report of the National Academy of Sciences, "Drinking Water and Health," which EPA feels are representative of the consensus of scientific opinion. As stated in the proposal, they are as follows:

1. Effects in animals, properly qualified, are applicable to man.
2. Methods do not now exist to establish a threshold for long-term effects of toxic agents.
3. Exposure of experimental animals to toxic agents in high doses is a necessary and valid method of discovering possible carcinogenic hazards in man.
4. Material should be assessed in terms of human risk, rather than as "safe" or "unsafe."

In the specific case of chloroform and other THMs, EPA has relied primarily on animal studies demonstrating the toxicology of chloroform. These are described in the NAS report, "Drinking Water and Health", and in the "Statement of Basis and Purpose" accompanying this regulation. The bioassay results from studies conducted by the NCI have demonstrated the carcinogenicity of chloroform in both rats and mice. Dr. Arthur Upton, Director of NCI, concluded in his comments that chloroform and other chemicals have been "proven as carcinogens in bioassays." Mechanisms for the metabolism and toxicity of chloroform are being investigated and include information demonstrating covalent binding of chloroform metabolites to DNA and the probable intermediate formation of phosgene as a metabolite.

EPA has also concluded that the available epidemiological evidence relative to THM concentrations or other drinking water quality factors and cancer morbidity/mortality has not been conclusive but is hypothesis generating and at least suggestive of a health risk. The NAS in its review of 13 preliminary epidemiological studies affirmed EPA's interpretation and concluded that the risks were probably small but that important confounding factors could not be distinguished in indirect ecological studies to allow a precise evaluation of the contributions from THMs. They pointed out the lack of sensitivity of epidemiological procedures due to lack of exposure data for individuals, population diversity and mobility, inability to control for all known contributing variables such as smoking, occupational exposures, diet, alcohol consumption, socio-economic and urbanization factors, and the usual 20–40 year latency period required for most cancers. The NAS also pointed out that sufficient evidence was available from animal toxicology studies to conclude that exposure to chloroform did pose a risk to human health. Additional studies are underway. Since epidemiology *per se* cannot "prove" causality, and because it may well be impossible to epidemiologically establish a strong causal association that THMs and related chemicals in drinking water contribute to higher cancer rates, EPA has extrapolated from the results of animal studies to assess the risk posed by THMs to humans.

EPA has also concluded that it would be inappropriate at this time to distinguish between an MCL for chloroform and other THMs. As a family of compounds, the THMs are similar in chemical composition and nature and are formed concurrently during the chlorination of drinking water. Brominated THM levels greater than 0.6 mg/l have been detected in some drinking waters. Their relative distribution in finished water is a

function of the organic and halide precursor concentrations which can be highly variable and unpredictable. The other THMs are under further study in the NCI bioassay program because of human exposure and structural similarity to chloroform. Mutagenicity studies in *Salmonella typhimurium* bacterial test systems have shown that brominated and iodinated THMs are more mutagenic than chloroform. The gas chromatographic analytical method concurrently analyses all four THMs, and treatment methods that would be employed would simultaneously reduce all of the THMs.

Excluding brominated THMs from these regulations would permit a substantial number of communities with low chloroform levels, but otherwise high THM and other by-product contamination, to avoid any improvement of treatment practice and, by implication, water quality.

Even though the toxicology of each of the other THMs has not at this time been as thoroughly studied by the scientific community as chloroform, the available toxicological information, their structural similarities to chloroform, and the fact that effective treatment is generally available to reduce public exposure to these potentially harmful contaminants as well as for chloroform, leads EPA to conclude that it would be inappropriate to exclude them from regulation.

Commenters had suggested that an MCL of 0.30 mg/l for chloroform could be computed as a "safe" level for human consumption by incorporating an uncertainty factor of 2,000 into Roe's "no observed effect dose." EPA has concluded that such an approach is totally inappropriate when dealing with human risk from chronic exposure to a potential carcinogen. That approach assumes the existence of a threshold level for carcinogens below which no risk would exist. It is thus inconsistent with the principles stated by the NAS in "Drinking Water and Health." In addition, 0.30 mg/l is well above the levels that are currently achievable in the large majority of public water systems by generally available methods that are technically and economically feasible. The comment was rejected. These comments and the Agency responses are detailed in Appendix A.

Because of the technical inability to determine a "safe" level for a carcinogen and the conclusion, therefore, that some risk must be assumed at any dose, regulatory agencies have attempted to minimize human exposure to carcinogens to the extent feasible. This approach was endorsed in the comments received from the National Cancer Institute, National Institute of Environmental Health Science, National Academy of Sciences, Consumer Product Safety Commission, National Institute of Environmental Health Sciences, Food and Drug Administration, Occupational Safety and Health Administration, as well as the National Drinking Water Advisory Council. See Appendix B.

EPA's selection of an interim MCL of 0.10 mg/l was based on a balancing of public health considerations and the feasibility of achieving such levels in public water systems in the United States. This balancing reflects the existing and generally available technology for water treatment which relies heavily on the proven use of chlorine to produce biologically safe water. It includes the existence of monitoring methods and trained personnel, economic considerations, and the limited amount of technical assistance available from EPA and the States, but primarily the risks that may be introduced in some cases from possibly inadvisable and improperly managed fundamental changes in disinfection practice.

Thus, the interim MCL should not be construed as an absolutely "safe" level, but rather a feasible level achievable with water treatment technology available since 1974. The preponderance of the current scientific thought on human exposure to substances that have been demonstrated to be carcinogens in animals in appropriate tests is that they be considered potential carcinogenic risks to humans. The presumptions are that human health risk is related to the extent of exposure and that no threshold level without risk can be experimentally demonstrated for a genetically diverse population. Translated into regulatory policy, exposure should be minimized so as to minimize unnecessary risks. Therefore, public water systems should strive to reduce TTHMs and related contaminant concentrations to levels as low as is economically and technologically feasible without compromising protection against the transmission of pathogenic microorganisms via drinking water.

The latest comprehensive information on concentrations of TTHMs in the U.S. drinking water was obtained from the National Organics Monitoring Survey (NOMS) of 113 communities sampled 3 times in 1975–77. This represented a wide range of water types including both surface and ground waters, and waters with minimal and substantial TTHM formation potentials. Mean levels of TTHM for Phase II and Phase III were 0.12 mg/l and 0.10 mg/l, respectively, in samples allowed to react to completion (terminal). Averages of both dechlorinated and terminal samples could be considered estimates of likely concentrations to be found at the tap of the average consumer. These were 0.09 mg/l and 0.08 mg/l, respectively, in Phase II and Phase III. However, maximum TTHM levels ranged as high as 0.70 mg/l and 0.78 mg/l in terminal samples. Therefore, an interim MCL of 0.10 mg/l will result in substantial reductions of TTHM concentrations in many water systems now exceeding the MCL.

Many commenters conceded that TTHMs were undesirable constituents of drinking waters, but preferred that a goal rather than an enforceable MCL should be established. In other words, it was suggested that compliance with a TTHM limit should be optional. However, neither the SDWA nor the facts at hand support such a course of action at this time. The SDWA provides for goals only in the case of the Administrator's list of recommended MCLs (Section 1412(b)(1)(B)), and, even then, the goal is to be selected as the value that would result in no known or anticipated adverse health effects and would allow an adequate margin of safety. Revised regulations must specify MCLs that come as close to the recommended levels as is feasible using the best technology, treatment techniques and other means which the Administrator finds are generally available (taking costs into consideration) (section 1412(b)(3)).

The SDWA clearly requires that EPA take regulatory action by establishing enforceable standards, not merely health goals. Since the issuance of EPA's ANPRM and proposal in this rulemaking, only a limited number of systems have voluntarily reduced the levels of TTHMs in their water supplies. Only in the presence of a mandatory requirement can EPA expect the full commitment in time and resources by community water systems and the oversight by State regulatory agencies necessary to achieve compliance nationally.

MCL Summary

Thus, based on the foregoing considerations set forth in the rulemaking record, the Administrator believes that an MCL for TTHMs of 0.10 mg/l in the Interim Regulations will protect human health to the extent feasible as prescribed by Section 1412(a)(2) of the SDWA. Since the optimum and only totally "safe" dose for any carcinogen would be zero, EPA strongly encourages all public water systems, not only those that exceed the

interim MCL, to implement measures to minimize the amounts of TTHMs and related by-products in finished water. TTHM levels in finished water are a function of the raw water quality (precursor content) and the sequence of treatments applied. Based upon the performance of developing technologies, it appears that ulitmately many public water supplies with currently high TTHM levels may be able to achieve TTHM concentrations as low as 0.010 to 0.025 mg/l and EPA suggests those values as future goals. The MCL will be reconsidered in the Revised National Primary Drinking Water Regulations based upon an updated assessment of technological and economic feasibility, implementation experience and additional toxicological information.

Population Coverage and Phase-In of the MCL and Monitoring Requirements

The proposed regulations would have initially applied the MCL only to those community water systems serving 75,000 or more people, and would have only required that monitoring data be collected for one year in communities serving between 10,000 and 75,000 people. Systems smaller than 10,000 would not be initially covered. The proposed effective date of the MCL was 18 months after promulgation.

EPA solicited comments on alternative approaches for coverage and implementation, for example by applying the MCL to all systems and phasing-in implementation through a deferred monitoring schedule (i.e., systems larger than 75,000 required to begin monitoring within one year of promulgation, 10,000–75,000 within three years of promulgation, and all other communities within five years).

The majority of commenters felt that the regulations should not be limited to the larger than 75,000 population community water systems, although some agreed that some phasing mechanism would be appropriate. The NDWAC suggested that utilities serving 10,000 to 75,000 should be included beginning three years after implementation of regulations in the larger than 75,000 group. The NDWAC also recommended in its initial comments that implementation in communities smaller than 10,000 should be at the option of the State.

EPA has concluded that the coverage of these regulations should be expanded to include community water systems serving 10,000 or more persons. Systems serving 75,000 or more people are required to comply within two years of promulgation, and systems serving between 10,000 and 75,000 are required to comply within four years of promulgation.

This still means that systems serving fewer than 10,000 people are not required to comply with the TTHM MCL. However, EPA does not believe that this approach will result in those persons served by the smallest systems being afforded reduced health protection. This is because the great majority (about 80%) of these smallest systems are served by groundwater sources that are low in THM precursor content. The proportion of small community water systems that utilize chlorine is less than that of large systems and transport time within the distribution system, which increases the extent of TTHM formation, is generally shorter in small systems. Therefore, their drinking water is less likely to be subject to TTHM contamination.

Moreover, the smallest systems incur a greater risk of adversely affecting the microbiological quality of their drinking water when steps are taken to reduce TTHMs. The majority of waterborne disease outbreaks attributable to inadequate treatment practice still occur in the smallest systems. Such systems also have limited or no access to the resources and professional expertise needed for TTHM control. Thus, EPA believes that it would be premature to divert their already sparse resources away from improving their disinfection practices by requiring compliance with a TTHM MCL at this time.

It is imperative that any changes in current treatment practice must be carefully supervised and supported by technical assistance from the States or EPA. However, it is not administratively feasible for the States and EPA to adequately supervise the approximately 57,000 systems which each serves communities of fewer than 10,000 people.

The approximately 60,000 community water systems in the U.S. range in size from 25 persons to several million and serve a total of about 213 million people. The 390 systems exceeding 75,000 population serve about 101 million people, and the 2,300 systems between 10,000 and 75,000 serve an additional 66 million people. Thus, the final regulations cover approximately 80% of the U.S. population served by community water systems. Most of these larger systems have at least potential access to the technical personnel needed to safely and successfully carry out any fundamental changes in disinfection practice. The smallest systems serve only 20% of the population but comprise a sufficiently large number of systems to make careful supervision effectively impossible in the short-term. Nevertheless, EPA does not intend that these smallest systems be excluded from coverage of the TTHM regulations indefinitely.

EPA considered specifying monitoring requirements for these smallest systems and/or making the MCL applicable to such systems with an extended timeframe for compliance. However, considerable additional time would have been necessary to insure availability of laboratory capability to handle the increased number of TTHM analyses and adequate State and EPA technical assistance. Therefore, it did not seem prudent to specify requirements now for which compliance would be required so far in the future. The considerable experience that will be gained from the efforts of the larger systems to comply with the TTHM MCL will serve to make compliance by the smaller systems more feasible. For that reason, EPA expects that small systems will be subject to a TTHM MCL under the Revised Primary Drinking Water Regulations when they are established. In those States which choose to exercise their discretion to extend coverage to the small systems, EPA expects that additional phasing may be appropriate within this size category based on greatest likelihood of TTHM contamination, such as by first including those systems with surface water supplies.

Implementation Timing

The majority of commenters on the question of the timing of the effective date of the MCL felt that 18 months after promulgation was inadequate to allow for design and implementation of the most cost-effective treatment system for compliance. They stated that eighteen months would only be adequate if minor modifications were needed. EPA has reevaluated the treatment methods most likely to be used and has concluded that in most cases relatively minor technical modifications will be sufficient to substantially reduce TTHM levels below the MCL. Therefore, a delay in the effective date would not have been justified on this ground.

Other commenters pointed out that insufficient laboratories were available to analyze TTHM samples and that a quality assurance program would need to be developed; some suggested that monitoring should be delayed for those reasons. EPA agrees with those commenters concerned about the availability of sufficient numbers of laboratories capable of providing acceptable analytical data. At this time, only relatively few laboratories have demonstrated the capability of

consistently producing data with the required accuracy and precision.

EPA has, therefore, decided to extend the time frame for initiation of the monitoring requirement for systems serving 75,000 or more persons from the proposed three months after promulgation to one year after promulgation. This will allow additional time for State and private laboratories to develop their capabilities and to become certified to provide data in support of compliance determinations. Since the effective date for initiation of monitoring is one year after promulgation and one year of monitoring results is required to determine compliance, the effective date of the MCL for those systems is established as 2 years after promulgation. To accommodate the large incremental monitoring load, application of the monitoring requirements to the approximately 2,300 systems serving 10,000 to 75,000 persons is established at 3 years following promulgation and the effective date of the MCL in this population range is 4 years after promulgation. Despite these extended deadlines, EPA encourages water systems to initiate monitoring and corrective measures sooner than this schedule whenever it is feasible to do so, especially where high TTHM levels are suspected.

EPA will immediately initiate an interim certification program for State laboratories (and others if appropriate) that will be based on their ability to analyze Performance Evaluation samples which will be provided by EPA's Environmental Monitoring and Support Laboratory (EMSL). Two analytical methods (Purge and Trap and Liquid-Liquid Extraction) have been approved under § 141.30(e) of the regulations and the written procedures are available on request from EPA's EMSL, 26 W. St. Clair Street, Cincinnati, Ohio 45268.

To qualify for Interim Certification, laboratories will be required to demonstrate their ability to analyze the Performance Evaluation samples provided to them to within 20% of the "true value" for each of the THMs as well as for the total of the THMs in the samples, using at least one of the approved methods. As the certification program develops and more laboratories gain expertise, it is likely that the precision and accuracy requirements will become more stringent. A quality assurance program will be established to insure that continued certification is dependent upon the laboratories' continued ability to perform quality analyses.

State Primacy and Exemptions

The time frame of these amendments to the NIPDWR will significantly affect two other statutory provisions of the SDWA: continuation of State primary enforcement responsibility (or primacy) under Section 1413 and the issuance of exemptions from MCLs under Section 1416.

With respect to State primacy, the Agency will shortly be proposing amendments to its State implementation regulations, 40 CFR Part 142, which will provide primacy States adequate time to amend their regulations without jeopardizing primacy while more stringent federal regulations take effect. States are encouraged to begin the process of amending their regulations as quickly as possible. However, no action to withdraw primacy will be taken pending the establishment of new EPA regulations under Part 142.

Under Section 1416(b)(2)(B) of the SDWA, schedules attendant to exemptions from the NIPDWR must require compliance by no later than January 1, 1981 (or January 1, 1983, for systems that enter into enforceable agreements to become part of a regional water system). This will, in most cases, preclude the issuance of exemptions from the requirements promulgated today. Since the issuance of exemptions is discretionary with the State, or EPA where the State does not have primary enforcement responsibility, the unavailability of exemptions *per se* is not believed to be a fatal deficiency in the regulations. Nevertheless, EPA recognizes that some systems may not achieve compliance by the effective dates despite their best efforts. EPA is planning to seek from Congress an extension of the exemption deadlines as they may apply to these regulations when the Agency's implementation of the Act is the subject of oversight hearings. The States and EPA may also exercise their enforcement discretion in those cases where compliance with the MCL for TTHMs is not achieved before the applicable effective date despite the system's good faith efforts to comply.

Summary

Therefore, EPA has accepted the recommendation of the NDWAC and many other commenters to broaden the coverage of the THM regulations and to phase-in its implementation as follows:

Water systems serving more than 75,000 are required to be in compliance by two years from the date of promulgation of these regulations. Systems serving between 10,000 and 75,000 are required to be in compliance by four years from the date of promulgation.

Monitoring must be initiated no later than one year from the promulgation date by those water systems 75,000 or larger, and three years from promulgation by those systems in the 10,000 to 75,000 population range. However, EPA urges that compliance and monitoring be accelerated in those water systems where this is feasible and where assistance is available from the primacy authority, especially where high TTHM levels are suspected.

Compliance with the MCL and monitoring in communities smaller than 10,000 would only be required if the primacy State adopts regulations that are more expansive than these federal regulations. EPA will consider expanding the coverage of THM regulations to include smaller systems when it establishes Revised Primary Drinking Water Regulations.

Monitoring Requirements

The proposed monitoring requirements for systems exceeding 75,000 population included quarterly sampling consisting of at least five water samples collected on the same day. The sampling locations were to be representative of TTHM concentrations at the consumer's tap; no more than 20% to be collected at the entry point of the distribution system, no less than 20% at the extremes of the system and the remaining 60% representative of population density throughout the distribution system. Compliance would be determined by averaging the quarterly values from the preceding 12 months. Surveillance monitoring only for one year was proposed for systems between 10,000 and 75,000 population. This consisted of two samples per quarter to be collected at the entry to the distribution system. One sample would be dechlorinated and the other stored for seven days to permit completion of the chlorination reaction. These final regulations eliminate any distinction (except for timing) between the largest and medium size systems and modify the requirement somewhat.

The majority of the comments on this issue were in agreement with the concept of determining compliance by an annual average of quarterly samples. Others disagreed, arguing that averaging might mask fluctuations, and some felt that averaging results in the distribution system would result in higher exposures to those populations residing in the extremes of the system. A few felt that the extreme values rather than averages should be used to compute compliance. Some commenters suggested that systems using deep ground water should

be exempted because of probable low THM formation potential. Others disagreed with a continued monitoring requirement, even at a reduced frequency, after it had been established that TTHM concentrations were unlikely to approach or exceed the MCL. A number agreed with monitoring requirements but objected to public notification of results.

The intent of the monitoring requirements is to provide a reasonable representation of the normal concentrations of TTHMs and related chemicals at the tap of the typical consumer. Data has shown that there can be wide variation of TTHM concentrations particularly in surface waters and groundwaters with high precursor levels on a day to day basis and that levels at various points in a distribution system can differ markedly. The variations can be due to a number of factors that include seasonal or other changes in precursor concentrations in the raw water, the amount of precipitation and surface run-off, the treatment method, the presence of combined or free residual chlorine, chlorine contact time, pH, temperature and transit time during distribution.

EPA feels that it would be unreasonable at this time to demand the kind of pinpoint control that would be necessary to maintain TTHM levels below a particular figure at all times and at all locations in the distribution system of every water system. This Interim Regulation is intended to reduce the extremes of TTHM concentrations that have been found in some of the nation's public water systems, and thus, to reduce the variability that may occur within a given distribution system. TTHMs in drinking water do not present acute or short-term risks but rather chronic or lifetime risks that increase with long-term exposure. Therefore some variations are tolerable and probably do not contribute to a change in overall risk. Thus, EPA has concluded that an averaging approach is appropriate and the use of a 12 month running average for computing compliance is retained in the regulations.

The frequency of monitoring must be based upon its usefulness for determining the concentrations of TTHMs in finished water. It should also reflect the potential for variability of the contaminant concentration, and this is highly dependent upon site-specific factors such as distance from the treatment plant, source water quality and treatment methods used. These factors are particularly important in selecting sampling locations which will be truly representative of water served to consumers regardless of their location within the distribution system, especially when a system uses more than one treatment plant.

The consensus of the comments was that quarterly monitoring was adequate in most cases but many argued for more samples. Quarterly monitoring has been retained in the regulation because EPA considers this to be the minimum acceptable frequency in those places where the water has a potential for seasonal variability in TTHM levels. EPA strongly urges that States review each water system's monitoring program to insure that the monitoring is reflective of seasonal and other variation factors. More frequent monitoring should be required where this is necessary for adequate consistent year-round control of TTHM levels below the MCL. Such discretion to require more frequent monitoring is provided for in these regulations.

In further response to those comments encouraging more frequent monitoring to reflect variations of water quality in the distribution system, EPA agrees that some conditions lead to a greater potential for wide variations of TTHM levels. For example, if a community water system uses more than one treatment plant to provide water, different water sources may be used as well as different treatment processes, leading to the possibility of widely differing TTHM levels in parts of the distribution system. For this reason, the proposed sampling scheme has been changed to increase the weighting of distribution system samples. Samples taken at the entry point to the distribution system can no longer be included in the quarterly or annual averages. No less than 25% of the samples shall be collected at locations within the distribution system reflecting maximum residence time of the water in the system and no more than 75% from representative locations within the distribution system taking into account number of people served, source of water and treatment methods used. Thus, the required number of samples is reduced by 20% yet the results should be more representative of tap levels throughout the system, because the deleted entry point sample would not have reflected TTHM levels for a substantial portion of the population served. Of course, these compliance monitoring requirements do not preclude water systems from utilizing plant samplings for process control.

Moreover, a minimum of four compliance samples is required each quarter for each treatment plant used by the system, except that wells drawing raw water from a single aquifer may, with State approval, be considered one treatment plant for the purpose of determining the minimum number of samples required to be taken by the system. By determining the minimum number of samples per system based upon the number of separate treatment plants used by the system, sampling locations should be selected to reflect water quality in identifiable portions of the distribution systems associated with each plant to the extent possible. Larger systems are those most likely to have more than one treatment plant, and therefore more samples are both desirable in insuring consistent water quality throughout the distribution system and not likely to significantly increase the per capita cost of monitoring. However, it would not be reasonable to increase the number of samples to be taken proportionate to the number of wells drawn from a single aquifer even though each well might literally be considered a single treatment plant; water quality is likely to be consistent throughout the aquifer and many systems have a large number of wells. Therefore, with State approval, wells drawing raw water from a single aquifer may be deemed to be a single treatment plant for purposes of determining the minimum number of samples required to be taken by the system. The regulations do not provide for similar flexibility for systems drawing water from a single surface source due to the likelihood of much greater variability in raw water quality and treatment methods at different plants.

The sampling locations are important because TTHM levels will likely be higher in those parts of the distribution system where residence time of the water is longest, which is served by surface water sources, and where chlorination, as opposed to other disinfection practices, is used. Even though the samples will be averaged for determining compliance with the MCL, EPA expects that sampling will be conducted in such a way so as to insure that all parts of the distribution system are serving water to consumers in compliance with the MCL. Thus, where a system draws its raw water from multiple sources, or has more than one treatment plant utilizing different treatment methods, high THM levels in specific parts of the distribution system should be identified where possible, and such levels reduced to the extent feasible. EPA intends to address more comprehensively the problems of systems with multiple source waters and

multiple plants with differing treatment programs, when it proposes Revised Primary Drinking Water Regulations in the future.

EPA also recognizes that there are a number of public water systems, such as those utilizing ground waters and some surface water supplies, where, because of the consistent quality of the source water and the treatment method employed, the probability that finished water would approach or exceed the MCL is remote. After a satisfactory record has been established, through one year of monitoring at a frequency of four TTHM samples per quarter, a water system may request that the State allow a reduction of the monitoring frequency. Upon the State's examination of at least one year of compliance data and a finding by the State that local conditions are such that TTHM concentrations are consistently below the maximum contaminant level, the system's monitoring frequency may be reduced to a minimum of one TTHM sample per quarter taken at a point in the distribution system that reflects the maximum residence time of the water served. Should the system experience a significant change in either its source of water or its treatment program, it must immediately reinstitute the four samples per quarter monitoring program initially required and continue on that program for at least another year before its sampling frequency could be reduced again so that the data baseline can be re-established. The original sampling requirements must also be reinstated immediately if the results from any analysis for TTHMs are found to exceed 0.10 mg/l and such results are confirmed by at least one check sample taken promptly after the results of the first analysis are received.

The State's decision to reduce a system's monitoring frequency must be made on a case-by-case basis taking into account such factors as the monitoring data, the quality and stability of the source of raw water, low total organic carbon (TOC) values, low maximum TTHM potential (MTP) during the time period when THM formation would most likely be at a maximum and the type of treatment employed. Except in certain ground water cases, monitoring cannot be reduced to less than one TTHM sample per quarter. This minimum monitoring is deemed necessary and is sufficient to demonstrate that conditions have not changed to the extent that the MCL might be exceeded. Intermittent use of another water source may also require additional monitoring at the discretion of the State. This flexibility is included in the regulations to allow States to modify the generally applicable monitoring requirements where appropriate only on a case-by-case basis to insure adequate public health protection. Figure 1 presents the basic steps to be followed by those systems (other than special ground water cases discussed below) that seek State approval to have their monitoring requirements reduced from four samples to one sample of TTHMs per quarter per year. "Maximum total trihalomethane potential (MTP)" is defined as the maximum concentration of TTHMs produced in a given water containing excess free chlorine after seven days at a temperature of 25° C. Determination of maximum TTHM potential should not be confused with measurement of terminal TTHM concentrations. The latter is measured under the ambient conditions of the distribution system with regard to temperature and storage time.

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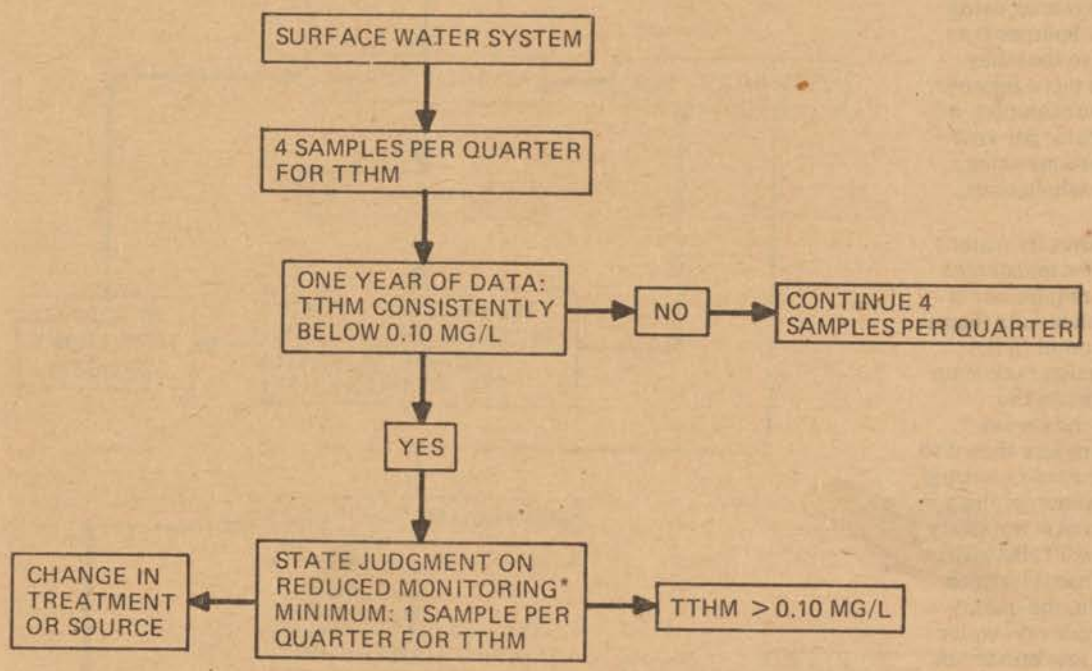
FIGURE 1
CONSIDERATIONS FOR REDUCED MONITORING REQUIREMENTS SURFACE WATER SYSTEMS

THE MINIMUM MONITORING REQUIREMENT IS FOUR SAMPLES PER QUARTER PER PLANT. REDUCED MONITORING REQUIREMENTS MAY BE APPROPRIATE IN CERTAIN CASES; UPON WRITTEN REQUEST FROM THE PUBLIC WATER SYSTEM, STATES MAY REDUCE THE REQUIREMENTS THROUGH CONSIDERATION OF APPROPRIATE DATA AS FOLLOWS:



*FACTORS FOR CONSIDERATION:
- MONITORING DATA, MTP, TTHM, TOC
- QUALITY AND STABILITY OF SOURCE WATER
- TYPE OF TREATMENT

BILLING CODE 6560-01-C

Ground Water Sources

As several commenters suggested and EPA agrees, many, if not most, ground waters contain such small amounts of precursor organic compounds (as demonstrated by low total organic carbon levels and low measured maximum TTHM potential) and are so stable, as to virtually preclude the possibility of generating TTHM levels approaching or exceeding 0.10 mg/l even when free chlorine is employed as a disinfectant. For this reason, the regulations provide that the monitoring frequency applicable to systems using exclusively ground water sources may be reduced at the outset so that they may be relieved from the more rigorous monitoring program of four samples, or even one sample, per quarter per year which is applicable to systems using surface water sources in whole or in part.

Thus, a system that draws its water exclusively from ground water sources may have its monitoring requirements reduced by the State if the results from a single sample taken at a point in the distribution system reflecting maximum residence time of the water in the system and analyzed for maximum TTHM potential (MTP) are less than 0.10 mg/l and the State determines in writing that, based on an examination of the local conditions, the system is not likely to approach or exceed the TTHM MCL. The State is expected to consider such factors as monitoring data, the quality and stability of the system's raw water source, low TOC values, low maximum TTHM potential during the time period when THM formation would most likely be at a maximum and the type of treatment employed. Such sampling frequency cannot be reduced to less than one sample for MTP per year. If such a system experiences a significant change in its source of water or treatment program, it must immediately take an additional sample for MTP analysis to determine whether it should be authorized to continue on the reduced monitoring program following the change. If the MTP is ever greater than 0.10 mg/l and such results are confirmed by a check sample taken promptly after the results of the original sample are received, the system must immediately begin taking and analyzing four samples per quarter per year for one full year. The year's results would then be averaged for determining whether the system was in compliance with the TTHM MCL. "Maximum total trihalomethane potential" is defined in the regulations at new § 141.2(s).

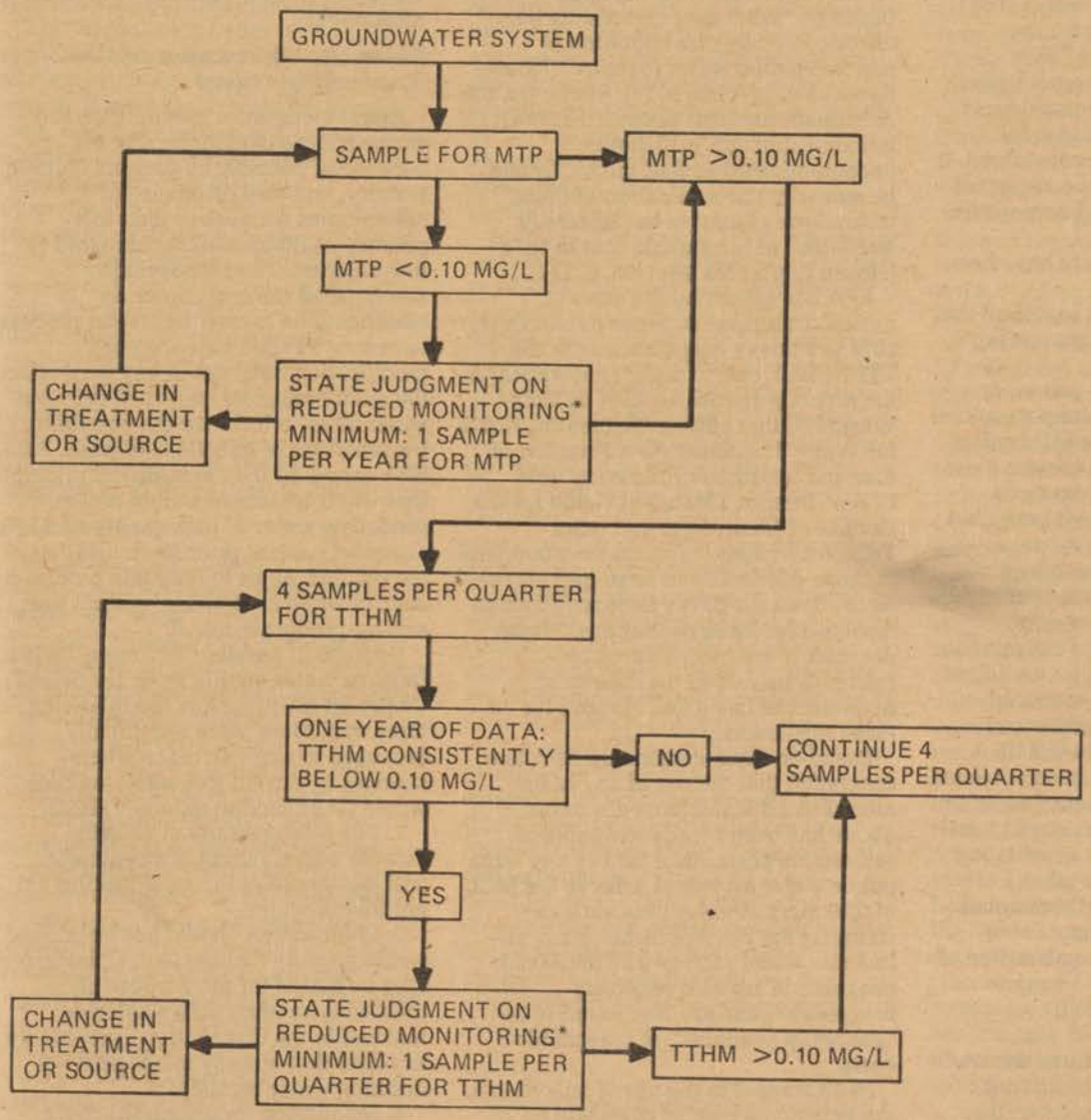
Figure 2 presents the basic steps to be followed by those systems using exclusively ground water sources that seek to have their monitoring frequency reduced at the outset to one sample analyzed for MTP per year, as opposed to the four samples for TTHMs per quarter per year otherwise applicable.

BILLING CODE 6560-01-M

FIGURE 2

CONSIDERATIONS FOR REDUCED MONITORING REQUIREMENTS GROUNDWATER SYSTEMS

THE MINIMUM MONITORING REQUIREMENT IS FOUR SAMPLES PER QUARTER PER PLANT; SYSTEMS USING MULTIPLE WELLS DRAWING RAW WATER FROM A SINGLE AQUIFER MAY WITH STATE APPROVAL BE CONSIDERED AS ONE TREATMENT PLANT. REDUCED MONITORING REQUIREMENTS MAY BE APPROPRIATE IN CERTAIN CASES; UPON WRITTEN REQUEST FROM THE PUBLIC WATER SYSTEM, STATES MAY REDUCE THE REQUIREMENTS THROUGH CONSIDERATION OF APPROPRIATE DATA AS FOLLOWS:



*FACTORS FOR CONSIDERATION:

- MONITORING DATA, MTP, TTHM, TOC
- QUALITY AND STABILITY OF SOURCE WATER
- TYPE OF TREATMENT

BILLING CODE 6560-01-C

Technical Feasibility of TTHM Reduction

In establishing an MCL for TTHMs, EPA is not required to specify any particular method to achieve that standard. However, in establishing Interim Regulations, EPA must find that technology was generally available in 1974 to achieve the MCL. Thus, the preamble to the proposal did discuss a number of approaches that could be utilized to achieve the MCL depending on the individual circumstances. The "Interim Treatment Guide for the Control of Chloroform and Other Trihalomethanes" was also published and made available to commenters to provide information on successful techniques that should be considered. It is incorporated by reference as part of the Statement of Basis and Purpose for these regulations.

Three general alternatives have been presented:

(1) Use of a disinfectant (oxidant) that does not generate (or produces less) THMs in water;

(2) Treatment to reduce precursor concentrations prior to chlorination; and

(3) Treatment to remove THMs after formation. Many possible choices exist within each category. For example, alternate disinfectants or oxidants that might be considered include ozone, chlorine dioxide, and chloramines (combined chlorine). Precursor reduction processes include off-line raw water storage, aeration, improved coagulation, ion exchange resins, granular activated carbon (GAC), powdered activated carbon (PAC), and ozone enhanced biological activated carbon (BAC). TTHM reduction has also been achieved by merely moving the chlorine addition point to later stages in the conventional treatment process, and by substituting prechlorination with some other preoxidation process. TTHM removal processes include GAC, aeration or macroreticular resins. A combination of these methods may be necessary to comply with the TTHM MCL.

Few comments discussed the feasibility of the available treatments, and three suggested that additional research should be performed on the subject. EPA has concluded that many methods have been shown to be effective for meeting the 0.10 mg/l MCL for TTHMs and it remains only for the individual water systems to select the one or more procedures that are optimal for their particular water characteristics.

Which treatment method (or combination of treatment methods) is ultimately selected by a water supplier to achieve compliance with the MCL must be based upon a case-by-case assessment of the system's entire treatment process, and an evaluation of the precursor content of its raw water source and TTHM formation potential as well as the need to assure optimal biological quality of drinking water derived from contaminated sources.

In determining what technologies were "generally available" in 1974 for achieving the standard, EPA has taken cost into consideration. The legislative history of the SDWA clearly requires that the reasonableness of costs must be based on "what may reasonably be afforded by large metropolitan or regional public water systems" (House Report No. 93–1185, p. 18). Moreover, the Administrator must assume that most intake waters are sufficiently uncontaminated so that the MCLs can be met with the application of those technologies found to be "generally available" at reasonable cost in 1974 (House Report No. 93–1185, p. 13).

EPA has estimated the costs of various treatment methods available in 1974 to achieve compliance with the TTHM MCL of 0.10 mg/l. They appear in the report prepared for EPA by Culp/Wesner/Culp entitled, "Estimating Costs for Water Treatment As a Function of Size and Treatment Efficiency" and EPA's "Interim Treatment Guide for the Control of Chloroform and other Trihalomethanes." The cost assumptions in those documents in large part serve as the basis for EPA's Economic Impact Analysis for these regulations. These documents are incorporated by reference as part of the Agency's Statement of Basis and Purpose for these regulations.

Based on these documents, EPA has concluded that the use of any of the alternative disinfectants discussed above has been clearly available at reasonable costs since 1974 to any large public water system to achieve the MCL of 0.10 mg/l. Alternatives, such as changing the point of disinfection, off-line raw water storage and improved coagulation are also relatively inexpensive and are also found to be "generally available" at reasonable costs.

With respect to the use of adsorbants, the reasonableness of costs will be dependent upon the particular operational parameters that are employed. For purposes of establishing these regulations, EPA assessed the costs that would be incurred by systems utilizing GAC as a replacement for their existing filter media, with a regeneration frequency of one year. Although most systems are expected to select the less expensive treatment methods where they are effective in achieving compliance with the MCL, the use of GAC under these operating conditions has also been found to be "generally available" at reasonable cost since 1974 for achieving the standard. Systems with very high raw water TOC may need to use GAC with more stringent operating parameters or additional treatment methods to achieve the MCL. For this reason, EPA has also assessed the cost of using biological activated carbon (ozone plus GAC) with a regeneration frequency for the carbon of two years; this cost has also been found to be reasonable.

Disinfectant Restrictions and the Standard Plate Count

Restrictions were proposed on the excessive use of chlorine dioxide because of possible by-product chlorite toxicity, and also on misuse of chloramines because of their low-potency as disinfectants compared to free chlorine. The proposal also admonished those considering modifications to their treatment process to reduce TTHMs that any such modification must not in any way affect the microbiological quality of drinking water so as to increase the possibility of transmission of infectious disease. Also, EPA espoused the fundamental principle that water treatment should aim at producing water of high quality and low chemical content prior to application of the oxidant, so as to maintain pathogen control while minimizing oxidant use and by-product demand.

Because of possible adverse effects on finished water quality from ill-advised treatment modification, the following three conditions were specifically proposed to apply in cases where changes to current treatment practice would be utilized to reduce TTHMs:

1. The total quantity of chlorine dioxide added during the treatment process should not exceed 1 milligram per liter of water.

2. Chloramines should not be utilized as the primary disinfectant. Chloramines may be added for the purpose of maintenance of an active chlorine residual in the distribution system only to water that already meets primary drinking water regulations.

3. Monitoring for general bacteria populations (Standard Plate Count) should be performed as determined by the State but at least daily for at least one month prior to and six months subsequent to the modifications.

These restrictions have been deleted from the final regulations to provide the States with greater discretion to prescribe requirements as necessary on a case-by-case basis. This should not be construed to reflect EPA's lack of concern regarding microbiological

quality. As described below, EPA is requiring that water systems obtain State approval of any proposed significant modifications to their treatment process. Once a system's plan is approved, the system must follow the plan. Moreover, these regulations prescribe those minimum conditions which must be satisfied by the plan before State approval can be granted. EPA will also publish guidance for the States that will serve as a useful reference in approval of system plans.

This approach is believed to be more reasonable than the inclusion of specific nationally applicable restrictions which may or may not be applicable in every case. Because systems will begin making modifications to their disinfection processes immediately upon promulgation of this regulation (and in fact, some systems have already begun to make such changes), EPA has determined that good cause exists to make the requirements of § 141.30(f) (approval of system treatment modification plans) effective immediately upon promulgation. This is necessary to ensure that all system treatment modifications are made subject to close State and EPA supervision at the earliest possible time.

Chlorine Dioxide

Oxidation/reduction reactions of chlorine dioxide in water produce chlorite and some chlorate and ultimately chloride ions. Preliminary studies with cats and rats had indicated that excessive exposures (above 10 mg/l) to chlorite had resulted in deleterious effects on red blood cells in some animals. A limit on applied chlorine dioxide of 1 mg/l was proposed to provide a margin of safety from the possible effects of ingested chlorine dioxide and chlorite and chlorate, and assumed that a portion of the chlorine dioxide would be spontaneously reduced to chloride which is not toxic. In a more recent study in a human population using drinking water treated seasonally with chlorine dioxide, statistically significant blood effects were not found at concentrations of approximately 5 mg/l of oxidant in water; however, this was a short duration test that terminated earlier than expected. One individual shown to be deficient in glucose 6-phosphate dehydrogenase, a genetic defect that is present in a small percent of the U.S. population that would possibly be sensitive to oxidants, showed an effect, but, it was within the range of effects of some of the normal population.

Only ten comments were received on the proposed chlorine dioxide restriction and nine were opposed claiming insufficient evidence of adverse health risk. Several suggested acceptable levels as high as 2 or 3 mg/l, but did not submit supporting data.

EPA has concluded that while there is evidence that exposure to chlorine dioxide by-products can result in detectable if not clinically significant blood effects, restrictions should be more appropriately placed on the residual oxidants (ClO_2, ClO_{-2} and ClO_{-3}) in the water rather than on the amount of ClO_2 added. The extent of the oxidation/reduction of the added ClO_2 and the formation of the intermediate chlorite and chlorate would be a function of the reducing agents present in the water, and the chlorine dioxide that would be completely reduced to chloride is of no toxicological significance.

In the 1979 update of "Drinking Water and Health", the NAS reviewed the data as of 1978 and estimated acceptable exposure values of 0.38 mg/l and 0.21 mg/l for chlorine dioxide and chlorite respectively. These were computed from data in rats and cats and incorporated an uncertainty factor of 100. The NAS also noted that the computed value for chlorine dioxide was consistent with EPA's proposal limiting the amount added to 1 mg/l assuming 50% conversion to chloride. Very recent incomplete data obtained from controlled studies with normal male volunteers detected slight but not clinically significant effects at higher than normal doses. These experiments are continuing and will produce more definitive results within the next year.

Therefore, although the restriction on chlorine dioxide addition has been deleted from the regulation, EPA feels that whenever chlorine dioxide is used residual oxidants should be monitored and kept below 0.5 mg/l. EPA will consider establishing an MCL for chlorine dioxide, chlorite and chlorate or the aggregate as total oxidant for inclusion in the Revised Regulations after further studies have been fully evaluated.

Chloramines

Chloramine (combined chlorine) has been shown to be a simple and readily available means of reducing the formation of THMs in many water supplies in those cases where raw water quality and treatment methods permit.

The proposal to restrict the use of chloramines in THM control in inappropriate circumstances was based upon the well known fact that chloramines, in themselves, are very weak disinfectants for bacteria, virus and protozoa compared to free chlorine as HOCl, ozone and chlorine dioxide. Thus, the use of chloramines as a primary disinfectant, (i.e., to kill or inactivate pathogens in raw water), may increase the risk of pathogens reaching the consumer. The proposed restriction would not have affected the use of chloramines for disinfection maintenance in distribution systems.

Opponents of the restriction argued that chloramines had been effectively used in many systems. Other commenters agreed with the proposal that chloramines should be restricted from use as a primary disinfectant. Those opposed to the restriction did not distinguish between the common use of chloramines to maintain an active combined chlorine residual (as a secondary disinfectant by EPA's definition) and total reliance on chloramines (as a primary disinfectant). None of the commenters contradicted the experimental fact that chloramines are much less efficient bacteriocides and virocides than chlorine (HOCl), ozone, and chlorine dioxide. The NDWAC felt that the proposed limitation was unduly restrictive.

Providing the necessary barrier against waterborne disease transmissions is the function of the total process of providing water to the consumer. This process begins with selection of the best available source, and its protection from contamination and is followed by the treatment train, that may consist of off-line storage, coagulation, sedimentation and filtration and/or lime treatment and pH adjustment, along with several increments of oxidant (disinfectant). It concludes with protecting the finished water in transit by maintenance of the integrity of the distribution system. EPA recognizes the use history as well as the risks inherent in misuse of chloramines and has concluded that the decision is best made on a case-by-case basis by the State or primacy authority in its review and approval of a water system's plan under § 141.30(f) to provide the necessary supervision. This subject is also included in EPA's guidance to the States for approval of system treatment modification plans.

Standard Plate Count

The presence of coliform bacteria is considered to be the most reliable indicator of possible fecal contamination and associated enteric microorganism. Current National Interim Primary Drinking Water Regulations (40 CFR 141.21, 40 FR 59556) require monitoring for coliforms on a frequency based upon population served in the community water system and include an MCL of 1 coliform per liter as determined by the membrane filter

technique. Nevertheless, certain bacteria, viruses and cysts are more resistant to disinfectants and are capable of surviving in water longer than the coliform indicator organisms.

Because of the possibility that, in the course of applying treatment modifications to reduce TTHMs, some water systems might be tempted to utilize less efficient disinfectants such as chloramines or shorter contact times with free chlorine, the proposal contained a requirement to utilize the Standard Plate County (SPC) analysis during transition periods when current treatment practice was being modified. This was intended to be applied as a more sensitive indicator of general biological quality to signal the possibility of a deterioration of treatment effectiveness and therefore increased potential of undetected pathogens.

Of the comments on this issue, more than half opposed or questioned the significance of the SPC as an indicator of water quality. However, somewhat less than half of the commenters agreed with the proposal that SPC should be required during treatment modification. A few suggested that SPC should be required only for those water sources receiving discharges of municipal waste. Others felt that SPC should be used at the discretion of the State. The NEWAC recommended that the SPC should not be a regulatory requirement but rather a matter of State discretion.

In "Drinking Water and Health," the Safe Drinking Water Committee of the NAS underscored the usefulness of SPC applied in conjuction with total coliform tests to measure the sanitary quality of drinking water. The Committee recommended use of SPC to:

1. Provide a method for monitoring for changes in the microbiological quality of finished water;

2. Determine whether the normal flora of a water supply may be interfering with coliform detection; and

3. Monitor the effectiveness of a disinfectant or treatment practice within the plant and distribution system and provide an indication of filter-effluent quality deterioration and the occurrence of the breakthrough of microorganisms.

EPA remains convinced that the SPC is an appropriate adjunct to coliform monitoring and a sensitive indicator of process performance and distribution system integrity, and that it should be employed particularly during periods when treatment modifications are being introduced. Many public water systems have extensively used the test as a routine quality monitor. Its application is particularly essential in drinking water drawn from raw water sources contaminated by sewage effluent. SPC has been deleted as a requirement from these regulations, but should be a condition for State approval of system plans where disinfection process modifications are contemplated. SPCs are therefore included in the guidance to States for approval of system treatment modification plans.

Microbiological Considerations—State Approval of System Treatment Modification Plans to Reduce TTHMs

Historically, the States have had the responsibility of ensuring that drinking water in public water systems has received adequate treatment before it is distributed. When systems alter traditional treatment practices to reduce TTHMs, States must continue to exercise control to assure that water is provided to the consumer by public water systems that is microbiologically and chemically safe and of optimal quality. Where States lack primacy enforcement responsibility, that responsibility falls to the EPA Regional Office.

The goal of disinfection has been and still is to produce water that is biologically safe to drink; this goal is attained by killing pathogens in the water. However, potentially harmful chemicals are now known to be produced during disinfection. Quality control thus necessitates careful consideration of all appropriate factors for each public water system modifying disinfection processes to control production of those chemicals, and States should exercise their full authority to see that the public is protected.

The National Academy of Sciences' reports, "Drinking Water and Health" and "The Disinfection of Drinking Water" and the Office of Drinking Water (EPA) Report, EPA-570/9-78-002, "Evaluation of the Microbiology Standards for Drinking Water" address the principles of drinking water disinfection and their effect on microbial problems. These documents, along with the guidance accompanying this regulation, should be consulted early in the development of the public water supply's program to reduce TTHM formation.

The basic principle in achieving compliance with the TTHM MCL is that as TTHM control practices are conceived and put into practice, the water supplied to the consumer must be of optimal quality. Systems must be carefully supervised to ensure that water quality is not allowed to deteriorate as a result of changes in treatment practice, thereby creating risks to the public health from particular chemicals or infectious agents. The integrity of the bacteriological quality of the drinking water must not be compromised.

EPA is therefore requiring that public water systems contemplating significant changes in treatment practice to control TTHMs submit an action plan to the State for approval and after approval has been received, to follow the conditions set forth in the approved plan, that will be based upon the guidance provided by EPA.

The following summarizes the major principles set forth in the EPA guidance to the States:

1. Prior to any significant modification, the entire system should be evaluated to detect the presence of sanitary defects and to determine the risks from breakthrough of microbiological contaminants in the source water, through treatment and in the distribution system. Virus studies are essential where source waters are heavily contaminated with sewage effluents.

2. A comprehensive evaluation of existing treatment practices and available options should be conducted to determine the most effective treatment modifications that would result in optimum finished water biological quality and TTHM control. Any system deficiencies that are found during the examination should be promptly corrected.

3. A baseline water quality survey of source water, water undergoing treatment prior to disinfection and water within the distribution system particularly in the extremes of the system and in deadends should be conducted prior to the initiation of the TTHM control practices at a sufficient frequency and time span to establish an understanding of the water quality. Measured parameters should include coliform and fecal coliform bacteria, fecal streptococci, standard plate count incubated at 35° C and 20° C, phosphate, ammonia nitrogen, TOC and others directed by the State based on the particular characteristics of local water quality. In systems using poor quality source water, for example, a weekly or more frequent sampling frequency may be necessary.

4. Following modification, the water quality survey (in item 3 above) should be continued for one year to determine the performance of the treatment system for all seasons. The parameters in the baseline study should continue to be examined using samples from the same locations.

5. Treatment practices for THM control should also provide effective post disinfection to control microbial

populations, and an active disinfectant residual should be maintained in all parts of the distribution system.

6. If the present point of chlorination is altered, the supply should maintain proper pH control and allow sufficient contact time for optimal disinfection.

7. Monitoring for chlorate, chlorite and chlorine dioxide should be performed when chlorine dioxide is used as a disinfectant. Residual concentrations of total residual oxidants (except for HOCl derivatives) in the water should not exceed 0.5 mg/l in the interim until further EPA studies are completed.

8. Chloramines are less efficient as disinfectants particularly for virus and protozoans as compared to chlorine, chlorine dioxide and ozone. If chloramines are used with contaminated source water, the total treatment process should be capable of compensating for any potential reduction in disinfection efficiency.

9. Ozone is not an appropriate disinfectant for high TOC containing waters unless the potential for post treatment biological growth can be controlled such as by the use of processes that control biodegradable chemicals in the source water and the finished water.

10. Systems presently utilizing pre-chlorination for disinfection purposes must be certain that alternative pretreatment practices are sufficient to protect the public if changes are introduced.

11. Any oxidant (disinfectant) used to treat drinking water will interact with chemicals already in the water to form undesirable by-products in the finished water. Therefore the basic principle should be to maximize precursor removal prior to the addition of the oxidant so as to minimize a disinfectant demand and by-product formation. Otherwise, an excessive disinfectant demand could reduce the efficiency of any disinfectant practice and add, in the process, substantial amounts of undesirable and perhaps toxic compounds.

12. Varied and extensive modification of existing treatment processes often result in changes in the chemical and microbial quality of treated water. Increased monitoring of coliform bacteria and the use of other indicators of the sanitary quality of water (e.g., SPC) are advisable.

Individual system plans for TTHM control should include the design of the vulnerability and baseline data surveys and the additional surveillance monitoring to assure maintenance of biological quality with the altered treatment system and must be approved by the State prior to their implementation. The plan should also include information on current treatment practices and their performance and other information as directed by the State. EPA believes that if States and public water systems follow the guidance and technical assistance is provided as needed, TTHM control will be safely achieved.

Economic Impact Assessment

The economic impact of these regulations was projected based on the three principal control options available to the approximately 2,700 community water systems serving more than 10,000 people required to comply with the regulatory requirements—modifying chlorination or associated treatment procedures, changing disinfectants, using an adsorbent, or some combination of the above. The calculation of total national cost projections for the TTHM regulation required an estimate of the number of systems choosing each control option and the incremental costs associated with each option considered. An incremental expense will accrue to all systems covered, whether or not treatment is required, to cover monitoring expenses. These expenses for all systems covered are included in the following estimates of total costs for the TTHM regulation.

This analysis employed a probabilistic and structured approach for determining the choice of control options that each public water system would make since no empirical method exists for predetermining that choice. A logical sequence of decision points was designed to distribute the systems anticipated to be covered by the regulation according to the most likely path they would follow. The decision made at each point is consistent with the following criteria:

1. The treatments currently used: If a system does not add chlorine it will not be affected by a THM regulation, and therefore will require no new treatment.

2. Water source used: If a system uses surface water (except the Great Lakes and some high quality mountain water) as its primary source, it is more likely to exceed a given level of THM contamination. Hence the number of water systems using water from ground or surface sources affects the number of systems which will exceed the MCL and will therefore require treatment.

3. Degree to which water quality exceeds MCL: If the presence of TTHMs is only slightly in excess of the initial MCL, then minimal modifications to current treatment procedures may be adequate for compliance. As the level of contamination increases, a system must consider more significant (and costly) treatment techniques.

4. Economic considerations: The presumption was that systems would adopt the least costly treatment strategy that satisfies the regulations.

5. Treatment effectiveness: Many systems with TTHM concentrations only slightly above the MCL can comply by modifying treatment procedures. Others may need to change disinfectants. Finally, precursor concentrations resulting in very high THM formation potentials can probably be best controlled by the use of adsorbents. This is because of the likelihood that high disinfectant demand waters cannot be disinfected adequately without generating considerable amounts of by-products of unknown hazard or without exceeding the MCL. Consequently, some of those systems with very high levels of TTHMs are projected to use adsorbents.

Based on all information available to EPA of the 390 public water systems that serve more than 75,000 people, 61 purchase the majority of their water from other systems that are presumed to provide treatment. Thus, a total of 329 systems would be initially affected although 7 of these were excluded because they do not presently add a disinfectant. Of the remaining 322, some 95 systems were estimated to have TTHM levels above 0.10 mg/l and hence would require changes in their treatment processes.

Since the final regulation phases in coverage to include systems serving between 10,000 and 75,000 people, the economic analysis has also included the costs these systems will bear in achieving compliance. Of the 2,295 public water systems that serve between 10,000 and 75,000 people, 355 are known to purchase the majority of their water from other systems that are presumed to provide treatment. Thus a total of 1,940 systems between 10,000 and 75,000 population would be initially affected, although 281 of these are excluded because they do not presently add a disinfectant. Of the remaining 1,659, some 420 systems were estimated to have TTHM levels above 0.10 mg/l and hence would require changes in their treatment processes to comply by the applicable effective date in the regulation.

The following projections were made based upon information presented during the comment period primarily from the water utilities and consultants. Of the systems estimated to be in the range of 1 to 1.5 times the MCL, 60 percent were expected to modify their chlorination procedures and 40 percent were expected to change disinfectants. Of the systems with TTHM levels in the

range of 1.5 to 2.5 times the MCL, 25 percent were expected to change their chlorination procedures with 75 percent changing disinfectants. Finally, of the systems exceeding 2.5 times the MCL, 80 percent were anticipated to change disinfectants and the remaining 20 percent would likely use an adsorbent. On the basis of the above assumptions, national cost estimates for compliance with these final regulations are as follows:

Summary of Estimated Total Costs for an MCL Regulation With the Trihalomethane Concentration of 0.10 mg/l

[In millions of 1980 dollars]

	Categories according to population served by average system		
	10,000–75,000	Over 75,000	Total
Capital Expenditures	$40	$45	$85
Operation and Maintenance	5	5	10
Revenue Requirements	9	10	19
Annual per Caita Costs of Treatment [1] (dollars)	0.60	0.90	0.70
Increase in Annual Residential Bill [1] (dollars)	1.20	1.80	1.40

[1] Includes only systems projected to incur treatment costs associated with the THM regulations.

Per capita costs will vary depending upon the type of treatment selected, the system size, and many other factors. Given an MCL of 0.10 mg/l, the range of annual residential bill increases for a typical family of 3 would be from $0.32 to $1.89 for systems using an alternative disinfectant and $4.44 to $11.18 for systems using an adsorbent in combination with ozonation assuming a 720 day regeneration cycle.

The costs presented in this final analysis are considerably lower than EPA's previous national cost estimates for the TTHM regulations as set forth in the February 9, 1978, notice and later revised in the July 6, 1978, supplemental notice, even though they are now stated in 1980 dollars while the August 1977 report accompanying the proposed regulations used 1976 dollars. The differences causing this reduction result from numerous changes in the underlying data, based on information received during the comment period, including: (a) Revised estimates of the number of systems using disinfectants; (b) revised estimates of the level of TTHMs in a given ground or surface system; (c) changes in the probabilities assigned to branches of the decision tree used to select among control options with more systems using chloramines and many fewer using GAC; (d) revisions of unit cost data to reflect inflation to 1980 dollars and increases in assumed levels of professional fees (resulting in an approximate 28 percent increase in costs); (e) changes in the GAC costs to reflect longer projected regeneration cycles (from 60 days to 360 days for GAC alone and 720 days for GAC and ozone), more off-site regeneration at regional facilities and use of GAC in existing filter beds. Detailed analysis of the costs of various options and the underlying data are contained in the "Economic Impact Analysis of a Promulgated Trihalomethane Regulation for Drinking Water," available on request, and incorporated by reference as part of the Statement of Basis and Purpose for this regulation.

Although the typical economic impacts appear to be reasonable, it is possible that some utilities will have unique problems which lead to financial hardships. This would take the form of an inability to raise capital needs for improvements in treatment necessary to comply with the TTHM regulation. Should a situation arise, opportunities exist which can ease these financing difficulties. The Office of Drinking Water provides technical assistance in this area, and interested parties should contact: Victor J. Kimm, Deputy Assistant Administrator for Drinking Water (WH–550), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460 for additional information.

Energy Impact Assessments

The TTHM regulation will have a negligible impact on annual domestic energy consumption. The total energy requirements associated with the regulation are 508×10^9 BTU's, or 0.0007 percent of 1977 U.S. energy consumption. The *annual* energy requirements of the various treatment alternatives selected by utilities to meet the MCL for TTHMs are as follows: Electric power, 39.9 million kilowatt-hours; diesel fuel, 64,000 gallons; and natural gas, 76.4 million cubic feet. In 1980 dollars these total annual energy requirements are estimated to cost $2.3 million per year. The annual electric power demand of 39.9 kwhr is approximately 0.002 percent of 1977 total domestic electric power sales. The annual diesel fuel demand represents only 0.00002 percent of the 1977 total domestic demand for refined oil products. At 76.4 million cubic feet, the annual natural gas demand represents less than 0.004 percent of the 1977 domestic natural gas demand.

Approximately 87 percent of the electric power demand is due to ozone disinfection processes. GAC treatment and ozonation together represent 96 percent of the total electric power demand.

The diesel fuel and natural gas requirements are created by the GAC regeneration process. For those water utilities without on-site GAC regeneration, transport of GAC to remote processing sites will require diesel fuel. The regeneration process itself requires either oil or natural gas as an energy source. In preparing these energy demand estimates, EPA assumed that only natural gas would be used in GAC regeneration furnaces. The energy impacts of this regulation are reduced from those associated with the proposal because fewer systems are expected to resort to the more energy intensive treatment methods to achieve compliance with the MCL.

Evaluation Plan

As noted previously, these regulations are considered to be an initial step in controlling disinfection by-products, with TTHMs being a surrogate. As the regulations are implemented, an extensive data collection effort will begin through the self-monitoring programs at the applicable public water systems. These data will include levels of TTHMs associated with disinfection of various types of raw water sources and the specific technologies utilized for control of TTHMs.

Compliance with the regulations will be determined by State program staffs and the compliance data will be included in the Model State Information System and Federal Data Reporting Systems (computer systems). This will allow easy access to evaluation of national compliance with the regulations.

The compliance data will be evaluated along with results of ongoing research and development efforts which are examining the toxicology of disinfection by-products and available treatment alternatives for control. The evaluation will be used to determine the appropriateness of the level of the MCL and will be the basis of further regulatory actions controlling disinfection by-products. These evaluations will be conducted no later than three years after the promulgation of the regulations. The Director, Criteria and Standards Division, Office of Drinking water, should be contacted if further information is desired.

Under Executive Order 12044, EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized." I have reviewed this regulation and determined that it is a specialized

regulation not subject to the procedural requirements of Executive Order 12044.

Dated: November 5, 1979.

Douglas M. Costle,

Administrator.

Accordingly, Part 141, Title 40 of the Code of Federal Regulations is hereby amended as follows:

1. By amending § 141.2 to include the following new paragraphs (p) through (t):

§ 141.2 Definitions.

* * * * *

(p) "Halogen" means one of the chemical elements chlorine, bromine or iodine.

(q) "Trihalomethane" (THM) means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

(r) "Total trihalomethanes" (TTHM) means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane [chloroform], dibromochloromethane, bromodichloromethane and tribromomethane [bromoform]), rounded to two significant figures.

(s) "Maximum Total Trihalomethane Potential (MTP)" means the maximum concentration of total trihalomethanes produced in a given water containing a disinfectant residual after 7 days at a temperature of 25° C or above.

(t) "Disinfectant" means any oxidant, including but not limited to chlorine, chlorine dioxide, chloramines, and ozone added to water in any part of the treatment or distribution process, that is intended to kill or inactivate pathogenic microorganisms.

2. By revising § 141.6 to read as follows:

§ 141.6 Effective dates.

(a) Except as provided in paragraph (b) of this section, the regulations set forth in this part shall take effect on June 24, 1977.

(b) The regulations for total trihalomethanes set forth in § 141.12(c) shall take effect 2 years after the date of promulgation of these regulations for community water systems serving 75,000 or more individuals, and 4 years after the date of promulgation for communities serving 10,000 to 74,999 individuals.

3. By revising the introductory paragraph and adding a new paragraph (c) in § 141.12 to read as follows:

§ 141.12 Maximum contaminant levels for organic chemicals.

The following are the maximum contaminant levels for organic chemicals. The maximum contaminant levels for organic chemicals in paragraphs (a) and (b) of this section apply to all community water systems. Compliance with the maximum contaminant levels in paragraphs (a) and (b) is calculated pursuant to § 141.24. The maximum comtaminant level for total trihalomethanes in paragraph (c) of this section applies only to community water systems which serve a population of 10,000 or more individuals and which add a disinfectant (oxidant) to the water in any part of the drinking water treatment process. Compliance with the maximum contaminant level for total trihalomethanes is calculated pursuant to § 141.30.

* * * * *

(c) Total trihalomethanes (the sum of the concentrations of bromodichloromethane, dibromochloromethane, tribromomethane (bromoform) and trichloromethane (chloroform)) 0.10 mg/l.

4. By revising the title, the introductory text of paragraph (a) and paragraph (b) of § 141.24 to read as follows:

§ 141.24 Organic chemicals other than total trihalomethanes, sampling and analytical requirements.

(a) An analysis of substances for the purpose of determining compliance with § 141.12(a) and § 141.12(b) shall be made as follows:

(b) If the result of an analysis made pursuant to paragraph (a) of this section indicates that the level of any contaminant listed in § 141.24 (a) and (b) exceeds the maximum contaminant level, the supplier of water shall report to the State within 7 days and initiate three additional analyses within one month.

5. By adding a new § 141.30 tc read as follows:

§ 141.30 Total trihalomethanes sampling, analytical and other requirements.

(a) Community water system which serve a population of 10,000 or more individuals and which add a disinfectant (oxidant) to the water in any part of the drinking water treatment process shall analyze for total trihalomethanes in accordance with this section. For systems serving 75,000 or more individuals, sampling and analyses shall begin not later than 1 year after the date of promulgation of this regulation. For systems serving 10,000 to 74,999 individuals, sampling and analyses shall begin not later than 3 years after the date of promulgation of this regulation. For the purpose of this section, the minimum number of samples required to be taken by the system shall be based on the number of treatment plants used by the system, except that multiple wells drawing raw water from a single aquifer may, with the State approval, be considered one treatment plant for determining the minimum number of samples. All samples taken within an established frequency shall be collected within a 24-hour period.

(b)(1) For all community water systems utilizing surface water sources in whole or in part, and for all community water systems utilizing only ground water sources that have not been determined by the State to qualify for the monitoring requirements of paragraph (c) of this section, analyses for total trihalomethanes shall be performed at quarterly intervals on at least four water samples for each treatment plant used by the system. At least 25 percent of the samples shall be taken at locations within the distribution system reflecting the maximum residence time of the water in the system. The remaining 75 percent shall be taken at representative locations in the distribution system, taking into account number of persons served, different sources of water and different treatment methods employed. The results of all analyses per quarter shall be arithmetically averaged and reported to the State within 30 days of the system's receipt of such results. Results shall also be reported to EPA until such monitoring requirements have been adopted by the State. All samples collected shall be used in the computation of the average, unless the analytical results are invalidated for technical reasons. Sampling and analyses shall be conducted in accordance with the methods listed in paragraph (e) of this section.

(2) Upon the written request of a community water system, the monitoring frequency required by paragraph (b)(1) of this section may be reduced by the State to a minimum of one sample analyzed for TTHMs per quarter taken at a point in the distribution system reflecting the maximum residence time of the water in the system, upon a written determination by the State that the data from at least 1 year of monitoring in accordance with paragraph (b)(1) of this section and local conditions demonstrate that total trihalomethane concentrations will be consistently below the maximum contaminant level.

(3) If at any time during which the reduced monitoring frequency prescribed under this paragraph applies, the results from any analysis exceed 0.10 mg/l of TTHMs and such results are confirmed by at least one check sample taken promptly after such results are received, or if the system makes any significant change to its source of water or treatment program, the system shall immediately begin monitoring in accordance with the requirements of paragraph (b)(1) of this section, which monitoring shall continue for at least 1 year before the frequency may be reduced again. At the option of the State, a system's monitoring frequency may and should be increased above the minimum in those cases where it is necessary to detect variations of TTHM levels within the distribution system.

(c)(1) Upon written request to the State, a community water system utilizing only ground water sources may seek to have the monitoring frequency required by subparagraph (1) of paragraph (b) of this section reduced to a minimum of one sample for maximum TTHM potential per year for each treatment plant used by the system taken at a point in the distribution system reflecting maximum residence time of the water in the system. The system shall submit to the State the results of at least one sample analyzed for maximum TTHM potential for each treatment plant used by the system taken at a point in the distribution system reflecting the maximum residence time of the water in the system. The system's monitoring frequency may only be reduced upon a written determination by the State that, based upon the data submitted by the system, the system has a maximum TTHM potential of less than 0.10 mg/l and that, based upon an assessment of the local conditions of the system, the system is not likely to approach or exceed the maximum contaminant level for total TTHMs. The results of all analyses shall be reported to the State within 30 days of the system's receipt of such results. Results shall also be reported to EPA until such monitoring requirements have been adopted by the State. All samples collected shall be used for determining whether the system must comply with the monitoring requirements of paragraph (b) of this section, unless the analytical results are invalidated for technical reasons. Sampling and analyses shall be conducted in accordance with the methods listed in paragraph (e) of this section.

(2) If at any time during which the reduced monitoring frequency prescribed under paragraph (c)(1) of this section applies, the results from any analysis taken by the system for maximum TTHM potential are equal to or greater than 0.10 mg/l, and such results are confirmed by at least one check sample taken promptly after such results are received, the system shall immediately begin monitoring in accordance with the requirements of paragraph (b) of this section and such monitoring shall continue for at least one year before the frequency may be reduced again. In the event of any significant change to the system's raw water or treatment program, the system shall immediately analyze an additional sample for maximum TTHM potential taken at a point in the distribution system reflecting maximum residence time of the water in the system for the purpose of determining whether the system must comply with the monitoring requirements of paragraph (b) of this section. At the option of the State, monitoring frequencies may and should be increased above the minimum in those cases where this is necessary to detect variation of TTHM levels within the distribution system.

(d) Compliance with § 141.12(c) shall be determined based on a running annual average of quarterly samples collected by the system as prescribed in subparagraphs (1) or (2) of paragraph (b) of this section, If the average of samples covering any 12 month period exceeds the Maximum Contaminant Level, the supplier of water shall report to the State pursuant to § 141.31 and notify the public pursuant to § 141.32. Monitoring after public notification shall be at a frequency designated by the State and shall continue until a monitoring schedule as a condition to a variance, exemption or enforcement action shall become effective.

(e) Sampling and analyses made pursuant to this section shall be conducted by one of the following EPA approved methods:

(1) "The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method," Method 501.1, EMSL, EPA Cincinnati, Ohio.

(2) "The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction,"Method 501.2, EMSL, EPA Cincinnati, Ohio.

Samples for TTHM shall be dechlorinated upon collection to prevent further production of Trihalomethanes, according to the procedures described in the above two methods. Samples for maximum TTHM potential should not be dechlorinated, and should be held for seven days at 25° C prior to analysis, according to the procedures described in the above two methods.

(f) Before a community water system makes any significant modifications to its existing treatment process for the purposes of achieving compliance with § 141.12(c), such system must submit and obtain State approval of a detailed plan setting forth its proposed modification and those safeguards that it will implement to ensure that the bacteriological quality of the drinking water served by such system will not be adversely affected by such modification. Each system shall comply with the provisions set forth in the State-approved plan. At a minimum, A State approved plan shall require the system modifying its disinfection practice to:

(1) Evaluate the water system for sanitary defects and evaluate the source water for biological quality;

(2) Evaluate its existing treatment practices and consider improvements that will minimize disinfectant demand and optimize finished water quality throughout the distribution system;

(3) Provide baseline water quality survey data of the distribution system. Such data should include the results from monitoring for coliform and fecal coliform bacteria, fecal streptococci, standard plate counts at 35° C and 20° C, phosphate, ammonia nitrogen and total organic carbon. Virus studies should be required where source waters are heavily contaminated with sewage effluent;

(4) Conduct additional monitoring to assure continued maintenance of optimal biological quality in finished water, for example, when chloramines are introduced as disinfectants or when pre-chlorination is being discontinued. Additional monitoring should also be required by the State for chlorate, chlorite and chlorine dioxide when chlorine dioxide is used as a disinfectant. Standard plate count analyses should also be required by the State as appropriate before and after any modifications;

(5) Demonstrate an active disinfectant residual throughout the distribution system at all times during and after the modification.

This paragraph (f) shall become effective on the date of its promulgation.

Appendix A—Summary of Public Comments and EPA Responses on Proposed Amendments to the National Interim Primary Drinking Water Regulations for Control of Trihalomethanes in Drinking Water

The following is a summary and discussion of the principal public comments to EPA's proposed regulations for the control of

trihalomethanes (THMs) in drinking water and EPA's responses to them. Many comments have already been addressed in the preamble which should be referred to for additional explanation of the agency's responses. In its February 9, 1978, notice of proposed rulemaking, EPA specifically solicited comments on the following six questions:

1. The reasonableness of the concept of phasing the application of the regulation by making the MCL mandatory initially only for large water systems and for the time being requiring monitoring only in others, and no requirements in the smallest systems. Should the regulations differentiate in their application between ground and surface water supplies? Are monitoring frequencies sufficient to identify locations with high TTHM levels?

An alternative approach on which public comments are solicited would be to make the MCL applicable to all public water systems and affect phasing of implementation by establishing a deferred monitoring schedule. Systems serving more than 75,000 people would be required to begin monitoring within one year of promulgation, systems serving between 10,000 and 75,000 would be required to begin monitoring within three years and all other communities within five years.

2. The magnitude of the MCL at 0.10 mg/l. Does the current information warrant more restrictive regulations at this time, for example, 0.050 mg/l or less? How rapidly can the MCL be reduced to lower feasible levels?

3. The feasibility and timing of the treatment modifications that will be necessary to achieve compliance. Will 18 months provide adequate time for most impacted systems to take steps to come into compliance?

4. The economic impact on large, medium, and small water systems either for the proposed regulation or for more restrictive regulations. Are EPA's estimates of the cost of compliance reasonable?

5. The concept of averaging the concentrations of the TTHMs for compliance—both the annual averaging of quarterly samples, and the averaging of representative samples within the distribution system.

6. The use of the Standard Plate Count as a more sensitive indicator of microbiological quality while treatment modifications are being introduced and the limitations on chlorine dioxide and chloramines.

In addition, the proposed regulations generated comments on other issues, including such issues as whether the States with primary enforcement responsibility had been provided sufficient time to make State regulations consistent with the federal regulations by the effective date. The majority of commenters did not address all of the issues that were posed by EPA; many commented on just a few issues or only on a single issue.

In all, EPA received 598 written comments and 259 oral statements were presented in the eight public hearings. The total of 857 comments came from various interested parties, including 390 from water utilities, 32 from private industries, 28 from consulting engineers, 95 from special interest groups, 80 from private individuals, 33 from educational institutions, 13 from Federal government agencies, 98 from local governments, 75 from local and State health and environmental departments, and 13 from other groups including some members of Congress. An additional 496 communications from members of Congress were received and responded to directly. Many of the comments were duplicative; some commenters presented both written and oral comments, or the comments were repeated in substance by many commenters, including members of Congress. In a number of cases, commenters simply endorsed the official position taken by a particular organization. For example, 124 water utilities and local governments responded by endorsing the position of the American Water Works Association (AWWA) which recommended an alternative program for the control of organic chemical contamination in drinking water. Comprehensive comments were also received from the Coalition for Safe Drinking Water (CSDW), a member organization of both municipal and investor-owned water utilities formed specifically to comment on EPA's proposed regulations, Calgon Corporation, a large manufacturer of carbon, and the National Drinking Water Advisory Council. These and other major comments are summarized in Appendix B. The following discussion summarizes comments received on the proposed regulations and the Agency's responses to those comments.

1. A majority of public comments disagreed with EPA's proposal to limit the applicability of the TTHM MCL to systems serving greater than 75,000 people. Most commenters preferred to have all water systems included under the regulation if control of chloroform was indeed deemed necessary (many of them did not feel any regulation was necessary). Phasing-in the applicability of the regulation to smaller systems in time was also opposed by some commenters, but a large number thought such a phasing approach to be logical.

The population cut-off of 75,000 received a total of 158 comments. Among the commenters, 132 felt that the regulations should be applied to all systems regardless of size; 22 commenters thought the population cut-off and phasing approach were reasonable. The main reason given by those who opposed the population cut-off was that they felt such an approach was contradictory to the intent of the SDWA which was to protect all persons served by community water systems. Therefore, these commenters said that if there was a health concern, all systems should be required to comply with the TTHM MCL, not just those who are served by a large water system. The commenters who thought that the population cut-off and phasing approach were reasonable cited as their reasons economic and technical feasibility, realizing that the larger water utilities would be better financed and staffed.

In response to the comments, EPA has accepted the recommendation of the National Drinking Water Advisory Council and many other commenters to broaden the coverage of the TTHM regulations to include those systems serving as few as 10,000 people and to phase-in the effective dates of the MCL by system size as follows:

- Water systems serving 75,000 or more people are required to be in compliance with the TTHM MCL within two years from the date of promulgation of the regulations.
- Systems serving between 10,000 and 75,000 people are required to be in compliance by four years from the date of promulgation.

This still means systems serving fewer than 10,000 persons are not covered by these regulations. EPA does not believe that this approach violates the intent of the SDWA to protect all persons served by community water systems. The great majority of smallest systems are served by ground water sources that are low in THM precursor content. Therefore, their drinking water is less likely to be subject to significant THM contamination. EPA is also concerned that measures taken by the smallest systems to reduce THM levels are more likely to result in drinking water of poor microbiological quality since they generally lack the expertise and access to technical assistance necessary for careful supervision of alterations in disinfection practice. Commenters are referred to the preamble to these regulations for a more complete discussion of EPA's rationale for excluding these smallest systems from

the coverage of these amendments to the Interim Regulations.

As discussed in the preamble, EPA's decision to phase-in the effective date of the MCL by system size has been based in part on the present limited laboratory capability available for TTHM analyses and the need for careful supervision of any alterations to the disinfection process. The systems in the 10,000 to 75,000 population range will be able to draw upon the experience gained by the first group of largest systems who must achieve compliance in the shortest feasible time-frame. By that time, laboratory resources and technical assistance from the States and EPA will be available to handle the increased number of systems. It was believed to be unreasonable to make the regulations effective for all systems at once for these reasons.

2. Thirty-seven comments were received on whether the regulations should differentiate between surface and ground water sources. Twenty-five opposed the idea of differentiation and said that the regulations should be based on water quality rather than water sources. Nine believed differentiation between sources was a good approach because in general ground water contains relatively less precursor material than surface water and therefore has less chance to produce TTHMs during chlorination practice. Three thought that the States should make the decision whether to distinguish between surface and ground water.

In response to these comments, the TTHM MCL applies equally to ground and surface water supplies within the population range covered. Water quality serves as the basic distinguishing factor to the extent that only those systems that exceed the MCL will be required to take steps to reduce TTHM levels in the finished drinking water. However, the monitoring requirements have been modified from the proposal to accommodate the valid concerns of some commenters that systems with relatively stable groundwater sources should not be required to incur the expense of regular monitoring where it is demonstrated that TTHM levels are not likely to approach or exceed the MCL. As discussed more fully in the preamble, the States have been accorded some flexibility to modify the monitoring requirements on a case-by-case basis under such circumstances.

3. Four comments were received on the monitoring and compliance timeframes established in the proposal. One of these commenters asked what would happen at the end of one year of monitoring for systems serving 10,000 to 75,000 people. He questioned why no action would be required if the TTHM levels exceeded the MCL. One commenter suggested that monitoring requirements be extended to systems which serve less than 10,000 population and report the results to customers as well as authorities. One commenter suggested that water systems serving more than 75,000 should start monitoring within 6 months, systems serving 10,000–75,000 should start monitoring within 1 year while the rest of the communities should begin monitoring within 3 years. One commenter felt that more discretion should be left to the States to determine which systems should be brought into compliance first.

EPA has responded to the comment concerning compliance by those systems serving between 10,000 and 75,000 persons by applying the TTHM MCL to those systems within 4 years of the promulgation of these regulations. Thus, systems in that size category that exceed the MCL would be required to take measures to reduce TTHM levels in their drinking water.

The monitoring requirements have not been extended to systems serving fewer than 10,000 people in the final regulations. Monitoring and public notification of the results were not believed to be warranted unless and until those smallest systems were also going to be required to reduce TTHM levels when the monitoring results showed that the MCL was exceeded. EPA was also concerned about the availability of laboratories for conducting TTHM analyses for the approximately 57,000 systems that fall within this size category. EPA's rationale for excluding these systems from the coverage of the MCL has already been addressed in response to other comments and in the preamble to these regulations.

The alternative monitoring timeframe suggested by one commenter was presumably intended to lengthen the timeframe that EPA had originally proposed as well as to require monitoring by the smallest size systems within a definite timeframe. In these final regulations, EPA has expanded the timeframe it originally proposed by requiring the largest systems to begin monitoring within one year from the promulgation of these regulations and the next size category within 3 years. EPA found that requiring the largest systems to begin monitoring within three to six months would not have provided adequate time for sufficient numbers of laboratories to become properly certified to perform quality TTHM analyses. An additional two years was believed to be necessary to insure the existence of quality laboratory capability to accommodate the approximately 2,300 more systems in the next size category. EPA's reasons for not requiring monitoring by the smallest size systems have already been discussed.

With respect to the comment suggesting that the States should have more discretion to determine which systems should be brought into compliance first, this regulation does not impair the State's prerogative to give highest enforcement priority to those systems with, for example, the highest TTHM levels. However, applying a uniform effective date for the MCL to the largest size systems first insures a fair application of the regulation among systems and achieves public health protection for the most people in the shortest timeframe. While it is the State's responsibility to enforce compliance with the MCL, it is each system's responsibility to achieve compliance by the applicable date.

4. Other monitoring-related issues submitted by commenters included: Seven commenters said that the proposed timing for monitoring was inadequate; several commenters said that it was premature at this time to require the water utilities to monitor for TTHMs while other commenters urged EPA to establish a deferred monitoring schedule; and two commenters felt that the monitoring requirement and the setting of a MCL should be a two-step action including initial monitoring followed by setting the MCL. One commenter believed that it was necessary to establish an occurrence data base prior to setting a MCL and recommended that monitoring must span at least a 2 to 3 year period in order to determine the varying concentrations of these contaminants.

As noted previously, the effective date of the monitoring requirements has been extended to one year and three years for the two size categories, respectively. This extension will allow adequate time for development of laboratory capabilities. In regard to the two step approach suggested by two commenters and the establishment of an occurrence data base prior to setting an MCL, the EPA agrees with the commenter's concept and has included both steps in the regulations: monitoring followed by compliance with the MCL. A sufficient data base has been established for setting the MCL and monitoring for one year prior to the effective date of the MCL will provide more precise information on variations in TTHM levels. Of course, systems may, at their

option, begin monitoring prior to the effective date.

5. With regard to EPA's proposed monitoring frequencies for TTHMs of five analyses per quarter, 37 comments were received. Eleven comments said that the proposed monitoring frequencies were reasonable. Twenty-two felt that quarterly sampling was insufficient, and some suggested more frequent sampling, such as one sample every month. Two commenters thought the proposed frequencies were too frequent and suggested that monitoring be conducted twice a year. Two commenters suggested that the frequency should be proportionate to the population served and at regular intervals.

EPA has retained the quarterly sampling requirements of the proposal as the minimum acceptable frequency for determining the effect of differing treatment practices and seasonal variations in raw water quality on TTHM concentrations in the finished drinking water. Four instead of five samples per quarter are required based on the number of treatment plants used by the system. Thus, more samples must be taken by those larger systems most likely to utilize more than one plant. This also allows for more representative sampling since TTHM levels may vary depending upon the system's raw water source or treatment program at a particular plant. Systems may seek State approval to have multiple wells drawing raw water from a single aquifer considered as a single treatment plant for the purpose of determining the minimum number of samples.

In response to those comments seeking more frequent sampling, generally, the final regulations provide that the States may require more frequent sampling where it is necessary to insure adequate and consistent control of TTHM levels below the MCL in the water served to all consumers of the system. EPA also recognizes that, in some situations, quarterly sampling should not reasonably be required because the maximum TTHM potential in some ground waters is consistently well below the TTHM MCL. Thus, the final regulations also allow the States to exercise their discretion to reduce the monitoring frequency in those situations. The requirements of these regulations have thus been fashioned to establish a minimum regular monitoring frequency while providing for case-by-case flexibility, recognizing that the optimal monitoring frequency for TTHM control will depend largely on site-specific circumstances.

6. Many comments were received charging that EPA's action of setting a TTHM MCL of 0.10 mg/l was arbitrary, premature and lacking in supporting data. 243 comments suggested that EPA adopt 0.10 mg/l TTHM as a goal rather than a regulation while additional data were being collected and more research on the health effects of the TTHMs was being conducted.

EPA believes that a TTHM MCL of 0.10 mg/l is adequately supported by the evidence in the rulemaking record demonstrating that THMs "may cause any adverse effect on the health of persons" (Section 1401) and that such a standard "shall protect health to the extent feasible, using technology, treatment techniques, and other means, which the Administrator determines are generally available (taking costs into consideration) on the date of enactment" of the SDWA, as required by Section 1412. Although new information will always be forthcoming on any regulatory subject, EPA must make the critical decision of when a sufficient basis is established to support regulatory action in order to comply with the protective intent of the SDWA. Citing the House Report accompanying the Act, the United States Court of Appeals for the District of Columbia Circuit has noted that "controls were not to be delayed pending the development of more refined data on health effects and more efficient detection and treatment technology" (*EDF v. Costle*, 578 F.2d 337, 344 (D.C. Cir. 1978). As discussed in the preamble to these regulations, EPA's mandate to protect the public health to the extent feasible does not contemplate the mere establishment of "goals" which utilities may choose to ignore when the evidence demonstrates that protective action is warranted.

7. Ten comments suggested that if a MCL were to be set for TTHMs, the MCL should be 0.30 mg/l. Other comments suggested higher TTHM MCLs than EPA's 0.10 mg/l ranging from 0.25 mg/l to 15 mg/l. Although most of these suggested MCLs were offered without supporting data, two commenters submitted suggested MCLs based upon their own studies or formulas. One commenter suggested a MCL of 0.3 mg/l for chloroform based upon his studies on dogs, rats and mice in the laboratory while another commenter calculated an MCL for chloroform in drinking water of 0.429 mg/l. Thirty-four comments supported the proposed MCL of 0.10 mg/l for TTHM while 11 comments said that a MCL of 0.10 mg/l should be lower but did not provide supporting data.

In establishing a TTHM MCL of 0.10 mg/l as an Interim Regulation, EPA has struck a reasonable balance between requiring the reduction of TTHM levels in drinking water to protect the public health and what public water systems could reasonably have been expected to achieve in 1974, taking into account technological and economic feasibility. EPA has also been mindful of the fact that corrective measures taken to comply with a TTHM MCL have the potential for adversely impacting the microbiological quality of a system's drinking water. Although technologies are available to reduce TTHM levels below 0.10 mg/l, EPA believes that a more stringent standard at this time would unnecessarily jeopardize the overriding need for quality disinfection. Moreover, EPA expects that many systems striving to comply with the standard of 0.10 mg/l will, in fact, achieve lower TTHM levels as well as a reduction in other potentially harmful disinfection by-products. Thus, EPA's approach to the regulation of THMs, as discussed more fully in the preamble to the regulations, has been both deliberate and cautious.

EPA does not believe that a less stringent MCL is warranted. Based upon EPA's occurrence data, if a less stringent standard were established, very few systems would be required to reduce the TTHM levels in their drinking water, resulting in no improvement of water quality served to their consumers. While this would relieve many systems from any costs, it would clearly not further the protective intent of the SDWA. EPA has determined that treatment methods have been generally available since 1974 at reasonable cost to reduce TTHM levels to 0.10 mg/l, and therefore, a higher standard would not be justified.

As to those commenters who suggested that an MCL of 0.3 mg/l for chloroform could be computed as a "safe" level for human consumption by incorporating an uncertainty factor of 2,000 into Roe's "no observed effect dose." EPA has concluded that such an approach is inappropriate when dealing with human risk from chronic exposure to a potential carcinogen. That approach assumes the existence of a threshold level below which no risk would exist. It is thus inconsistent with the principles stated by the NAS in its report, "Drinking Water and Health". In addition, 0.3 mg/l is well above the levels that are currently achievable in the large majority of public water systems by generally available methods that are technically and economically feasible. Roe's study has been specifically addressed elsewhere in this Appendix.

8. Sixteen comments responded specifically to the question of whether the current information warrants more restrictive regulations at this time and how rapidly the MCL could be reduced to lower feasible levels. Except for one commenter who said that a TTHM MCL of 0.05 mg/l would be technically feasible today at reasonable cost, the other 15 commenters all said that a more restrictive regulation was unnecessary due to questions regarding the health basis of 0.10 mg/l. Further, they expressed serious doubts that a much lower MCL could be met without extensive modification in treatment processes. Several comments disapproved of the agency's intention to make the MCL more stringent in the future, noting that it might be difficult for water utilities to cope with a moving target since the economics of system improvements frequently depend upon the level of control sought. State activities would be seriously disrupted because utilities would have to re-modify their treatment processes whenever new standards were set (modifications would require State approval), and the States would have to change their regulations to retain primary enforcement responsibility.

EPA has already explained its rationale for not imposing a more restrictive standard for TTHMs at this time in its response to other comments and in the preamble to these regulations. EPA's health basis for these regulations is also discussed elsewhere in the preamble and in this Appendix. EPA agrees that reducing TTHM levels to 0.05 mg/l would necessarly result in increased costs greater than those estimated to achieve EPA's MCL of 0.10 mg/l; it is, however, EPA's concern for the potential adverse impact on disinfection practices and microbiological quality rather than the increased cost that has let EPA to conclude that a more stringent standard is not justified at this time.

When EPA establishes Revised Primary Drinking Water Regulations, the Act clearly authorizes and indeed requires, more stringent and more comprehensive regulations of those contaminants which may have an adverse effect on human health, including TTHMs. Congress contemplated that, as new technologies were developed to reduce the level of contaminants in drinking water, EPA's regulations would be reevaluated accordingly. Since new information regarding health effects and treatment technology will continue to be generated, it would be unrealistic to expect that EPA's requirements would remain static. However, EPA recognizes the increased burden placed on water utilities and the States when more stringent regulations are promulgated; when this occurs, adequate opportunity for public comment and time for compliance with any more stringent regulation will be provided.

9. On the question of feasibility of compliance with EPA's proposed TTHM MCL, three commenters said that more research is needed to study the feasibilities of different treatment processes for the removal of TTHMs. One expressed the need for EPA's assistance in evaluating the appropriate treatment for his system. One suggested that ozone in combination with a chlorine residual, when the two are properly used together as part of a total treatment scheme, often results in a significant reduction in the ultimate TTHM levels. One said that granular activated carbon (GAC) is good for TTHM removal as well as taste and odor control. One stated that the type of treatment modification used for compliance with the MCL should be determined by the water utility.

EPA believes that despite the ongoing research being conducted on control of THMs in drinking water, sufficient evidence exists to demonstrate that technology and treatment methods were generally available in 1974 at reasonable cost for water systems to achieve TTHM levels of 0.10 mg/l. Such methods include both relatively inexpensive alterations of a system's disinfecton practices, which will be sufficient in most cases to reduce TTHM levels to below the standard, as well as more complex treatment modifications, such as those suggested by two commenters. EPA's findings regarding the feasibility of TTHM control are fully set forth in the report "Interim Treatment Guide for the Control of Chloroform and Other Trihalomethanes," which has been incorporated by reference as part of the Agency's Statement of Basis and Purpose for these regulations.

A 1978 report prepared by J. S. Zagorski, G. D. Allgeier and R. L. Mullins, Jr., "Removal of Chloroform from Drinking Water," studying the reduction of chloroform formation upon subsequent chlorination, reported that various common treatment processes including sedimentation; sedimentation followed by chemical coagulation and precipitative softening; sedimentation, chemical coagulation, precipitative softening and rapid sand filtration; and sedimentation followed by chemical coagulation, precipitative softening, rapid sand filtration and GAC adsorption resulted in substantial reductions of the chloroform formation potential. They also reported that both alum and polymers at moderately large dosages were capable of reducing the potential of Ohio River water to form chloroform and other THMs. Both ozonation and powdered carbon at high doses also reduced THM formation potential. In the plant-scale studies, the same investigators also reported that moving the point of chlorination from the head of pre-sedimentation reservoirs to the head of the coagulation process significantly reduced the concentration of $CHCl_3$ in finished water, and that ammoniation at the head of precipitative softening ceased the THM formation reaction and markedly reduced the level of THMs in softened water. Aeration also was able to reduce chloroform in finished water.

As explained in EPA's response to other comments and in the preamble, in light of currently available information, EPA need not wait for the results of additional research before establishing regulations to control TTHMs. Rather, any new information will be considered by EPA when it develops Revised Primary Drinking Water Regulations.

EPA agrees with the comment that the type of treatment modification used to comply with the TTHM MCL must be determined by the water utility that has the ultimate responsibility to select a method for achieving compliance. Many commenters appeared to erroneously confuse the TTHM regulation with EPA's proposal of a specific treatment technique for control of pollution-related synthetic organic chemicals in drinking water. Nevertheless, technical assistance will be provided by EPA and the States on a case-by-case basis. Systems that modify their treatment processes to comply with the TTHM MCL are also required to obtain State approval of their plans prior to implementation to insure proper supervision of alterations in disinfection practice.

Significant reductions in THMs can normally be achieved by making relatively minor modifications to existing water treatment systems, such as maximizing the efficiency of precursor removal during coagulation/filtration or changing the point of chlorination. Where minor modifications to existing treatment methods prove insufficient to bring the system into compliance with the MCL, the system may need to use an adsorbent technology, such as GAC, to reduce precursors and thereby achieve compliance with the MCL. Thus, each system will probably be using a

combination of the available treatment options that will be most effective for its situation. Because of these treatment alternatives, total reliance upon an adsorbent for reduction of the THMs to below the MCL will not likely occur. The EPA has estimated that of the approximately 2,700 systems serving more than 10,000 people required to comply with the MCL, approximately 25 systems may ultimately need to install adsorbent technology to control THMs.

10. One commenter stated that GAC has never been tested or proven in full-scale operation in the United States and therefore constitutes a nationwide experiment in water treatment.

The availability and efficacy of GAC technology has been clearly demonstrated by the large extent of use by numerous facilities in the United States as well as overseas. GAC technology has been used for many years in the water treatment industry, and today over 60 drinking water plants presently use GAC in their treatment facilities. Extensive use of GAC is practiced in the food and beverage industry for removal of organic contaminants from process waters and in the treatment of industrial and municipal waste waters prior to discharge to receiving waters. GAC for removal of organic chemical contaminants has been in use by numerous European municipal drinking water plants since the 1960's and as industrial activity continues to increase, more facilities using GAC are being installed.

Most drinking water plants in the U.S. have been using GAC as a replacement for the media in their existing filters for the stated purpose of removal of taste and odors. However, with the development of more sophisticated analytical procedures which are capable of detecting and measuring levels of organic chemicals (including THMs and THM precursors) in drinking water, EPA now knows that such chemicals are actually being removed by GAC and that their presence, previously undetectable by analytical measurement, was being manifested through taste and odor problems.

Commenters nevertheless question the availability of means for the regeneration of GAC and use of GAC in post contactors for removal of organic compounds. Regeneration of GAC has been demonstrated in numerous locations including a full scale operation at a drinking water facility in the late 1960's in the U.S. Some European drinking water plants have also been regenerating GAC for several years. The frequency at which drinking water plants in the U.S. replace the GAC ranges from less than six months to two to three years. The GAC is usually removed from the facility and replaced by virgin carbon.

In addition to its use by numerous and varied types of drinking water systems in the U.S. and overseas, GAC has been widely and successfully used for the treatment of municipal waste waters for removal of organic chemical pollutants. For example, since the mid-1960's, the municipality of Lake Tahoe has used GAC in contactors with on-site regeneration. Thus, regeneration technology has been applied both on site and at central furnace facilities. Frequency of regeneration will necessarily be dependent upon TTHM reduction needed on a case-by-case basis. Numerous drinking water treatment plants are presently operating modules of full scale GAC systems or pilot plants to more fully correlate GAC performance with various regeneration frequencies.

11. One commenter stated that the GAC treatment process may result in serious problems and these may outweigh the alleged environmental benefits associated with GAC treatment. These problems include potential air pollution from regeneration and the waste water associated with air pollution scrubbers as well as waste water from backwash and drainage from carbon slurries.

GAC is normally regenerated at furnace temperatures of 750° C to 900° C and at these temperatures, data do not show that most pollutants are oxidized to other than harmless compounds. EPA has considered potential waste disposal problems including air and water pollution relating to GAC reactivation and has found that techniques are available to control wastes from these facilities.

In regard to discharge of backwash water or drainage from carbon slurries (if at the water treatment plant), no additional water is expected to be necessary. In fact, less water is normally used in backwashing with GAC than with conventional media in the filter. Any drainage from carbon slurries at the off-site GAC regeneration facility is not large in volume and normally is discharged to municipal treatment plants.

12. Several commenters were concerned that the use of GAC may constitute a larger health hazard than means for improvement of water quality. The alleged health hazards associated with GAC included desorption, chromatographic effect (competitive displacement), resorption (leaching) of heavy metals and polycyclic aromatic hydrocarbons contained in the virgin or regenerated carbon, release of carbon fines, promotion (catalytic reactions) on the carbon itself of hazardous compounds due to chemical reactions between chlorine and organic compounds, bacterial growth on the carbon and air pollution from regeneration facilities. Commenters also noted that indirect hazards were associated with GAC usage through the manufacture of GAC and the production of energy necessary to operate GAC facilities. They said these industries, such as the coal industry, pose a high risk of morbidity and mortality to the workers. Because of these concerns, they urged that additional research and testing should be conducted prior to implementation of GAC in this country's major waterworks. It was suggested that toxicological evaluations be conducted using concentrated effluents from GAC to assess these potential hazards.

EPA has evaluated the potential hazards associated with the use of GAC. The items listed can be shown to occur under specific laboratory conditions directed at obtaining a specific reaction, such as the promotion reaction or the chromatographic effect, but no significant hazard is expected under actual use conditions so long as proper operating procedures are followed. For example, use of GAC for THM control will not result in desorption of TTHM to levels above the MCL since the GAC would be regenerated at the point where THM levels in the effluent approached those in the influent. Also, bacterial growth on GAC is common, is frequently encouraged by adding oxygen to the influent waters, and assists in reduction of precursor compounds. Control of bacteria in the finished drinking water is effectively accomplished by disinfection and the alleged slugs of bacteria breaking through the GAC do not occur with proper operation; in any event, proper disinfection with a residual throughout the distribution system would eliminate this potential hazard.

In addition, present data have not shown a health hazard associated with the use of GAC in its many applications in drinking water treatment. Nevertheless, EPA is continuing to conduct research on these questions. For example, short term bioassay studies are being conducted with animals using concentrated raw and finished waters to assess the toxicological significance of various disinfectants, such as chlorine and ozone, and the use of various treatment technologies, including GAC. However, the methodologies used in these studies are only now being developed and must be verified by more established methods.

13. Twenty-seven comments were received discussing the proposed effective date of the TTHM regulations. In general, the commenters thought that the compliance dates for either the monitoring requirement or the MCL were unreasonable. A number of these commenters had apparently confused the effective date for the TTHM regulations with that for the treatment technique requirement and commented accordingly.

Specifically, 11 commenters said the allowed time for compliance with the proposed regulations was unreasonable without specifically referring to whether the comment was addressed to the monitoring schedule or the MCL. Nine commenters, however, submitted specific time-tables that they felt would be required for compliance with the proposed TTHM regulations ranging from monitoring beginning 3 months after promulgation of the regulations to as long as 8 years for the completion of plant modifications.

One commenter submitted his suggestion of a specific time-table including the following: (1) Request for variance or exemption should be submitted no later than the effective date, (2) design specifications should be submitted to States for approval no later than 18 months after the effective date, (3) by no later than 24 months after the effective date, final design plans and specifications should be submitted to States for approval, (4) construction should be completed and operation should begin no later than 4 years after effective date, and (5) operational data should then be submitted to States for evaluation. One commenter suggested postponement of the regulations and instead conducting a two-year comprehensive monitoring program. One commenter felt that the proposed time-table of the TTHM regulation was adequate.

Thirty-four commenters said that EPA's proposed effective date, allowing 18 months for compliance, was unreasonable and that it was technically impossible for systems to design the most cost-effective treatment system within that timeframe. These comments suggested allowing additional time for compliance, ranging from 3 to 7 years. Four thought the allowed time of 18 months was adequate. Three said the regulation should be more flexible with regard to the time for compliance and the type of treatment modification used and suggested that the States make these decisions. One commenter said that the allowed 18 months was adequate if only minor modifications were needed but that additional time would be required if major changes to the treatment plant were needed. Another commenter said that whether the allowed timing was adequate would depend upon whether the particular water system would need to use GAC to remove TTHMs. One stated that the primacy States should have a minimum of two years to revise their regulations to be consistent with the regulations finally adopted by EPA before they became effective requirements for the water supplies. One commenter said that although the proposed timing was feasible, in most cases, the final regulations should provide for a delay in the effective date for systems that could show the need for additional time. One commenter said that the proposed compliance schedule was appropriate if the MCL were established at 0.30 mg/l.

EPA has responded to the comment seeking more time to achieve compliance by extending the effective date of the TTHM MCL for systems serving more than 75,000 people to two years after the promulgation of these regulations. Systems serving between 10,000 and 75,000 people have been given four years to achieve compliance with the MCL. Both dates take into account the need for one year of monitoring data to be established and the need for adequate time to develop quality laboratory capability for TTHM analyses. The two-year effective date of the MCL for the first size category also serves to provide primacy States with sufficient time to amend their regulations before the MCL takes effect. In the meantime, EPA will not allow State primacy to be needlessly jeopardized. The Agency will be proposing regulations shortly as amendments to 40 CFR Part 142 which will allow for a reasonable amount of time for States to conform their regulations to the federal requirements.

The extended timeframes suggested by some commenters do not appear to be warranted for applicability to all systems. It appears that these commenters may have been erroneously assuming that GAC was being required for control of TTHMs in all cases. On the contrary, EPA believes that most systems will be able to achieve compliance with the TTHM MCL of 0.10 mg/l with relatively minor changes to their existing treatment processes. Therefore, the timeframe provided in the final regulations should provide ample time for compliance measures to be implemented. However, EPA recognizes that additional time may be needed by those few systems that will need to institute more complex treatment modifications to comply with the TTHM MCL. In such cases, Section 1416 normally provides for the issuance of exemptions. Due to the belated issuance of these amendments to the Interim Regulations, an extension of the compliance deadlines presently established in Section 1416 will be needed to authorize exemptions from the TTHM MCL. EPA will seek a legislative extension of the exemption deadline. So long as good faith efforts are being taken by systems to comply with the TTHM MCL, EPA and the States may exercise their enforcement discretion to insure compliance as expeditiously as practicable.

14. Seventy comments addressed the specific cost estimates for installation of the technologies as well as the projected national cost impacts of the regulations. The majority said that EPA's estimates were not reasonable and that the actual costs would be considerably higher. A few comments felt that the costs were reasonable or "in the ball park."

Of these comments, 32 stated that the costs for installation of the technologies were low while five thought that the estimates were reasonable. Some of these felt that the EPA estimates in most cases did not conform to local economic conditions. Other commenters said the EPA's costs were underestimated and submitted cost estimates for their particular utilities in support of their argument. They indicated that compliance with the MCL would require far larger investments by the utility than those estimated by EPA. In addition, one commenter provided data showing that the cost impacts would be higher because his public water system used 225 gallons per capita per day (gpcd) as compared to the 179 gallons per capita per day used by EPA in the estimates. The commenter also used maximum daily and hourly flows of 240 percent and 390 percent of average daily flows, respectively, and 65 percent of the total year's flow occurred during the four summer months.

EPA's analysis of the cost and economic impact of the final regulation is discussed in the preamble and described in detail in the "Economic Impact Analysis for a Promulgated Regulation for Trihalomethanes in Drinking Water". The costs of treatment are based upon average national costs and were determined from an analysis of the costs of materials and labor rates in various parts of the United States. The costs of treatment represent those of an average size utility in each of several size categories, and serve as the basis for assessment of the national cost impacts. It is expected that some utilities would experience costs that are

higher than the average system in its size category, while others would be lower. In order to reflect site-specific factors for a utility, contingency factors are incorporated into the treatment cost estimates.

The base flows used in the cost analysis are values representing the average flow conditions for a certain size range of systems. The values are based upon a recent survey of 1,000 water systems in the United States during which it was determined that larger systems have higher water usage per capita than do smaller systems. This is a result of commercial and industrial customers. Thus, a different flow base was used for each size category ranging from 155 to 210 gpcd for systems serving one million persons or more. Capital costs were based upon capacity flows and O&M costs were based upon average daily flows. The exception was that capital costs of GAC were based upon the average day in the peak month which was less than the capacity flow. Commenters are referred to EPA's document "Economic Analysis" for further details.

15. One comment noted that it was difficult to determine whether EPA's estimates of the cost for compliance were reasonable. He felt that debt service, the additional water treatment plant personnel laboratory assistance and control, and more sophisticated monitoring equipment, were not adequately considered. One commenter stated that it would cost $20,000 to $30,000 per year to conduct monitoring for his utility. Four said that the compliance cost for TTHM analyses estimated by EPA at $25 per sample was low and that the current rate for commercial TTHM analyses was approximately $100 per sample exclusive of sampling and delivery costs. Two other commenters suggested that prices of $75 and $120 per sample, respectively, were appropriate. Three commenters agreed with the EPA's estimation of monitoring costs.

EPA's analysis of the costs of treatment specifically considered each of the items of concern to the commenter. Debt service is included in the annual costs (revenue requirements) and includes interest rates on capital of 8% and 10% for public and privately-owned utilities, respectively. The rate for privately-owned utilities was revised from the 9% rate used in the cost estimates supporting the proposed regulations to take into account the current and projected cost of capital. Additional plant personnel were included in the O&M costs and thereby in the annual costs.

In regard to monitoring costs, the total required monitoring costs were estimated to be $800 per year per system based upon four samples per quarter. As noted in the preamble, monitoring costs for some systems will be higher than $800 per year because these systems have more than one plant, thereby necessitating (in some cases) additional sampling. This cost estimate included costs of analysis at $50 per sample. The cost of sampling and mailing samples to an outside laboratory was not considered to be significant. No additional sophisticated monitoring equipment was included in the estimate; however, it was anticipated that many systems would purchase analytical equipment to perform their own analyses. While commercial rates for TTHM analyses varied from $25 per sample to more than $100 per sample, $50 was used as a reasonable estimate and this was increased from the value of $25 per sample used in the proposed regulations. However, it is expected that the cost per sample will likely be lower, since increased availability of analytical services, competition between laboratories and the increased number of samples for analyses will provide opportunities for cost-savings.

In addition to the costs associated with the required monitoring, additional costs will be incurred by some systems in the monitoring conducted to assure that the bacteriological quality of the drinking water will be maintained during and after treatment modifications for the purpose of reducing THM levels. Costs of this monitoring will vary between systems but will not likely exceed approximately $5,000 at systems with the most extensive monitoring program. This estimate was based upon use of outside contract laboratories, and it is expected that most water systems will conduct some of the analyses in their own laboratories, thereby reducing the costs. Nevertheless, this cost is considered reasonable for those systems which will need the most extensive monitoring (e.g., for systems serving 10,000 people, this cost would be $0.50 per person), and is a one-time expense (as opposed to continued requirements for quarterly TTHM monitoring).

16. One commenter said that the use of a forty-year amortization period to determine the yearly cost for capital improvements was unreasonable in that the life of the water treatment facility would be considerably less than 40 years.

Forty years was used as representative of the average expected life of equipment in public water systems. While some equipment may require replacement sooner than 40 years, other equipment has a life greater than 40 years. While privately-owned utilities often depreciate equipment at a 20-year rate, this is primarily for tax advantages and does not represent the true life of the equipment. Publicly owned utilities most often use rates of approximately 40 years since no tax advantages are available. Since over 80% of water systems are covered by this regulation and are publicly-owned, it is reasonable to use the 40-year amortization period as the basis of annual costs.

17. One commenter said that EPA's use of $5.58 per hour for labor in its EPA cost estimates was too low, stating $7.00 per hour for labor cost would be more appropriate. The cost estimates have been revised and now include labor costs at $11.75 per hour including fringe benefits. In addition, it should be noted that contrary to the commenter's statement, the proposed regulations were based upon an average labor cost of $7.50 per hour.

18. A number of commenters argued that the costs were underestimated because of specific factors in the analysis. For example, one commenter stated, based upon the use of GAC, that the difference between his potential national cost estimates and EPA's estimates could be explained primarily by four factors. It was not clear to what extent these comments differentiated between costs for GAC for TTHM control and costs for GAC to control other synthetic organic chemicals in the separate treatment technique requirement. The four specific areas of difference noted by this commenter and EPA's responses are as follows:

(a) EPA determined its estimated capital costs for a system based upon the capacity of the entire system; whereas, the commenter estimated the system capital costs as equal to the sum of the capital costs for each treatment plant based on the capacity of each plant.

The EPA recognizes that several large public water systems use more than one treatment plant and thereby might be required to install necessary treatment at each plant if they utilize the same or similar source waters. Due to the limitations of available data, the cost estimates were based upon installation of treatment for the total flow capacity of each water system, rather than separate flows from each plant. EPA does not believe that per plant costs would significantly affect the national cost estimates. Treatment costs depend upon flow capacity whether apportioned per plant or taking the system as a whole. In some cases, costs could be

reduced if only the flow from a single plant required treatment to reduce TTHMs. These effects have been taken into account by including contingencies in the cost estimates. Moreover, since it is generally the larger systems that have multiple plants, additional costs of treatment will be borne by a greater number of customers, reducing the per capita impact.

(b) EPA's estimates were based upon the system capacity on the average day of the peak month; whereas, the commenter's estimates were based upon the actual capacity of each treatment plant.

As presented in the cost analysis and discussed above, costs were determined based upon system capacity except for the use of GAC which was based upon the average day in the peak month. This was determined to be an appropriate cost base rather than total plant capacity because compliance with the MCL will be based upon a running annual average of average quarterly monitoring results and not a peak value.

(c) EPA assumed that some of the affected systems would design facilities for a 9-minute empty bed contact time (EBCT); whereas, the commenter assumed that all GAC facilities would be designed for an 18-minute EBCT.

It is anticipated that for most systems, 9 minutes EBCT will be adequate to achieve the MCL. It is possible that certain systems may require additional contact time but use of an average condition is entirely appropriate in the development of a national cost estimate. Use of 18 minutes EBCT as the base of the national cost estimate would have inflated the costs unrealistically.

(d) The commenter's estimates for specific systems, based on the costing out of the individual components, were 30–80% higher than EPA's proposed estimates.

As stated previously, EPA's cost estimates have been substantially revised to take into account many of the commenter's concerns. The cost estimates have been based upon the most accurate and recent sources of information and cost data available and that have been reviewed within the industry. Differences between the commenter's costs and EPA's proposed cost estimates were primarily due to differences in the base year for the estimates (EPA was 1976 dollars and the commenter was 1978) and differences in EBCT (9 minutes vs. 18 minutes). In any event, the commenter's detailed estimates have been evaluated and the EPA estimates have been revised appropriately.

The commenter's O&M cost estimates were higher than EPA's primarily because they were based on expenses at multiple treatment plants. Certain specific costs, such as the price of GAC and fuel costs, also account for portions of the differences and have been revised in the final cost analysis. EPA's GAC costs were based upon current and projected costs and ranged from $0.65 to $0.84 per pound of GAC depending upon the size of the public water system. Fuel costs were also projected and included estimates for 1980 of $0.84 per gallon for diesel fuel, $0.0038 per cubic feet for natural gas, and $0.038 per kilowatt-hour for electricity. The commenter's revenue requirement estimates were higher than EPA's primarily because of the higher estimates of capital and O&M costs.

19. Two comments stated that the costs were understated because the increased demand for materials required to comply with the regulations would cause costs to rise beyond normal inflation rates. This concern has been evaluated and, as shown in the economic analysis, no single chemical or component of any of the available treatment technologies is expected to experience a sufficiently large demand so as to affect its price. For example, the initial demand for GAC (to meet these regulations) is estimated to be four million pounds whereas the industry has excess GAC capacity of more than 100 million pounds per year.

20. One commenter stated that the EPA estimates did not include costs for land that would be necessary for installation of the GAC facilities. As shown in the economic analysis, costs of land acquisition were included in the capital cost estimates.

21. One commenter indicated that the EPA's estimates were based upon 1976 costs. He felt that approximately 20 percent increase was needed just due to elapsed time to date (1978) and that at the time of construction of needed facilities, another 50 percent inflationary increase would be applicable.

EPA's costs have been revised to reflect anticipated use of 1980 dollars to meet the regulations. The estimates were increased to 1980 dollars through the use of the available cost indices which included separate indices for labor, steel, excavation, concrete, manufactured equipment, pipes and valves, electrical and instrumentation, housing, and producer prices. These indices took into account anticipated inflation to 1980 and the precise index values are presented in the economic analysis and supporting documents. Overall, unit costs have been increased by approximately 36% as a result of this change from 1976 to 1980 dollars.

22. A number of commenters stated that the use of GAC will have substantial financial impact upon water supplies and that actual costs are very difficult to predict and are understated. For example, the average capital cost for a system serving over one million people was alleged to exceed $106 million with annual costs of more than $23 million. These commenters estimated that rate increases for residential customers would be in the range of 40–70% and that these rates could double where there were site-specific problems, such as land acquisition. The commenters claimed that these costs may result in insurmountable problems at some utilities in obtaining financing for GAC treatment facilities. They charged that EPA's assessment of the feasibility of financing the GAC treatment facilities was totally out of step with the realities of both the financing markets and operating needs of the public utilities.

Costs for GAC treatment are highly dependent on the substances being removed and the target level in finished water. The use of GAC to control THM precursors would not require the most stringent design and operating characteristics in most cases. Thus, the cost for this application would likely be very much less than the cost for using GAC to control synthetic organic chemicals. As noted in the preamble, EPA's cost estimates for using GAC for TTHM control were revised from those costs supporting the proposed regulations. For purposes of the economic analysis supporting this final THM regulation, EPA estimated the costs for a system using GAC by replacing its existing filter media with GAC and regenerating its carbon no more frequently than once every 12 months. Only systems with severely contaminated raw water sources will require the extent of GAC usage that the estimates accompanying the original proposal were based upon (post-filtration contractors with two month regeneration cycles). The data indicate that in most cases the raw waters were relatively uncontaminated and this was used in determining feasibility of treatment and reasonableness of costs for purposes of establishing the MCL. Thus, the revised costs are significantly lower than those in the economic analysis of the proposed regulations. Of course, the economic impact analysis is based upon a specific model system and costs will vary depending upon specific details at each site. To a reasonable extent, site-specific factors were included in the revised analysis and EPA's supporting economic document should be consulted for details. The document also examined the feasibility

of financing and found that financing is available.

23. Nine commenters said that the cost estimation should be more realistically based upon results from controlled experiments such as field studies. As the commenters suggested, one of the primary factors considered by EPA in developing the cost estimates has been the engineering application of the available treatment technologies. EPA has revised its cost estimates to reflect the engineering costs developed by Culp, Wesner, and Culp, consulting engineers with extensive experience in water treatment technology.

24. One commenter stated that the costs for GAC did not include the investment necessary for disposal of the concentrated organics removed from the off-gases by either landfill or underground injection. The cost estimates for use of GAC are based upon off-site regeneration, and all aspects of regeneration of GAC, including disposal of scrubber waters and other waste products were taken into account.

25. Two commenters stated that the cost estimates were low because EPA did not include the costs of installation of conventional treatment (coagulation, sedimentation, filtration) followed by THM control. The commenters indicated that some water supplies use sources from such places as the Adirondacks which do not necessitate conventional filtration but have TTHM levels at 150 to 250 mg/l. One of the commenters stated that for his system, which serves 140,000 people, to meet the MCL filtration would have to be installed at a capital cost of $12 million, an annual cost of $1.3 million, and a rate increase of 60 percent.

Most public water systems use conventional treatment technology and thus EPA's cost estimates included only those treatment technologies that are additions or adjustments to such conventional treatment. It would not be appropriate to include the costs of conventional technology in these regulations since, in most cases, compliance with other requirements of the NIPDWR (e.g., turbidity) necessitate use of conventional treatment. Therefore, the cost of conventional treatment should not be directly attributable to this regulation. Nevertheless, many of these systems are expected to be able to comply with the regulations through adjustment of chlorination procedures or use of an alternate disinfectant.

26. One commenter stated that the economic impact assessment did not take into account the costs of treating waste water from GAC operations, such as backwash waters, wet scrubbers and drainage from carbon slurries. It was estimated that 50,000 gallons of waste water will be generated for every one million gallons of drinking water treated and half of that amount would need to be discharged. This commenter concluded that this would result in increased flows and an approximate 4% increase in operation and maintenance costs at municipal waste water treatment facilities.

EPA's estimates did take into account disposal of any additional waste waters from the use of GAC. For example, the cost estimates were based upon regeneration of carbon at an off-site, privately owned, regeneration facility. The costs of regenerated carbon utilized in the estimates were based upon actual manufacturer's estimates and operating rates. Overall rates included costs of GAC regeneration and all ancillary activities such as air pollution control and disposal of waste waters.

27. Several commenters stated that the estimates were low because EPA did not include the administrative, environmental, overhead, and political costs of implementing the regulations. Two of these commenters felt that additional dollars would be required for such items as cost of processing variances, public hearings, research costs into health and treatment aspects of the regulations, monitoring compliance, laboratory instrumentation and facilities, and laboratory certification programs.

The Agency agrees that each of the above items has some degree of costs associated with it and has taken appropriate costs into account in the revised cost estimates. Systems would not be expected to conduct research into the health aspects of the regulations, and only research into treatment aspects to the extent necessary to determine which treatment would be most effective in meeting the MCL. Costs attributable to administrative or legal (or political) factors, processing variances, and public hearings are difficult to precisely estimate. They have been included in appropriate parts of the estimate. Thus, administrative and legal costs have been included in the engineering costs at a rate of 12% of the total treatment cost. Some of the overhead costs have been included in the O&M costs which include labor rates with fringe benefits. Further, costs associated with monitoring have been included in the monitoring costs; environmental costs have been considered in GAC regeneration costs which would take into account such items as air pollution control equipment and disposal of by-products; finally, any other costs not included in those components of the total cost have been included in the contingency added to the costs.

28. One commenter said that the costs associated with the treatment cost analysis were inflated. He stated that the cost analysis was based upon NOMS data which averaged values of THM concentrations measured in over 100 finished water supplies across the United States. The commenter believed that the cost analysis should have been done in two phases: one for summer conditions and one for winter, using quenched values for all 117 cities, and measured at the point in the distribution system most distant from the source to accurately measure the THM concentration reaching the consumer.

EPA's national cost estimate has been based upon NOMS which is the most recent available data base with regard to the levels of THMs in finished drinking water supplies. Certainly a more refined and extensive survey would provide a higher degree of confidence for its estimates; however, for the purposes of assessing the national cost impact of these regulations, the NOMS data base was felt to be a reasonable representation of THM occurrence.

29. One commenter estimated that the cost to the consumers in his system could increase 50 to 75 cents per 1,000 gallons and the needed treatment modifications would also result in reducing his filter capacity up to 70 percent. Other estimated rate increases reported by several commenters reached as high as 120 percent, while it was stated by one commenter that a 5.4% increase would be necessary for his utility.

EPA's projected national capital expenditures total $85 million in 1980 dollars resulting in a overall rate increase of 2% which is a considerable reduction from EPA's original estimates. EPA's original estimates were $154 million (1976 dollars), equivalent to $210 million in 1980 dollars, and included only those impacted communities larger than 75,000 population. EPA's revised cost estimates now include those communities between 10,000 and 75,000 population, and assume that a total of 515 water systems would be required to institute some type of change in current processes. Fewer systems are expected to use the more expensive treatment technologies. Available technologies range from no-cost or very low cost changes such as improving coagulation or moving the point of chlorination (172 systems estimated), to low to moderate cost changes, such as modification of

the disinfectant (319 systems estimated), to high cost changes, such as use of an adsorbent like GAC (24 systems estimated).

EPA restructured its decision tree based upon several factors regarding the treatment technology alternatives that are available to meet the MCL and the number of systems by size that would be likely to modify or install treatment because they exceeded the MCL. It is not anticipated that the existing filter capacity, as suggested by the commenter, would be reduced by application of these technologies. These projections have been derived based to a large degree upon information received during the comment period. For example, considerably wider use of chloramines and less usage of GAC is expected to be selected to reduce THMs. Primarily, for those reasons, the cost estimates have significantly changed, and the typical costs per family (i.e. residential bill increase) are expected in the range of $1.40 per year. In those few cases (24) where GAC is necessary, costs per family have been estimated to be up to $11.20 per year, less than $1.00 per month. After review of existing rates, rates for other utilities, and the specific costs involved, EPA does not believe that such increases will have an unreasonable impact on a family budget.

30. Twenty commenters thought that the monitoring costs were excessive for the water utilities to pay and they felt that the federal government or EPA should conduct or fund the monitoring program. One questioned whether Federal funds would be available to assist in the additional financial burden of the regulations. However, another stated that no federal grants should be issued to public water systems because of their prior record of providing services and supporting themselves from their own resources.

Monitoring costs required by these regulations amount to approximately $800 per system per year. These costs are not considered to be excessive; for example, minimum cost per capita for monitoring for systems serving 10,000 people will be $0.08 per year and for systems serving one million people, $0.0008 per year. As noted above, the costs associated with this regulation generally are not significant and federal financial assistance should not be needed in the size range covered by this regulation. If it is needed, federal financial assistance programs are available for public water system improvements. It is also probable that in many cases the States may provide analytical services for their communities.

31. One commenter was concerned that compliance with the regulations by systems that will require major modifications would be difficult because of the economic and social burden; the commenters also questioned how the regulations relate to the President's urban policy. Several commenters were concerned that the burdens of increased water rates would be difficult for those least able to afford it; that is, low income and high unemployment groups, minorities, and retirees. One felt that the required rate increases for both normal system maintenance and to meet the regulations might not be supported by the customers, concluding that this could eventually result in deterioration of the water supply facilities because the cost of meeting the regulations would take needed capital away from maintenance type programs. One felt that the cost of the regulations would take money away from the needy and could result in poorer and less nutritious diets.

Because of the relatively low costs associated with these regulations, the impact on consumers' other needs are not considered to be significant. EPA believes that providing healthful drinking water must be a high national priority and that these regulations do not conflict with the President's urban policy.

32. A commenter said that it was not clear that GAC would effectively reduce TTHM concentrations more than movement of the chlorination point or changing disinfectants; the choice of installing GAC filtration by water treatment plant managers might produce only slight reduction in TTHM concentrations at a very high cost and therefore might not be a feasible alternative.

EPA estimates that GAC will only be used by about 25 systems to comply with the MCL because less expensive technology alternatives are available, such as changing the point of chlorination or using an alternate disinfectant. For these 25 systems, it is expected that a comprehensive evaluation of the existing treatment will be made to determine the most cost-effective technique for compliance with the MCL. These systems will most likely use a combination of the alternative treatments, such as changing the point of chlorination or maximizing coagulation/filtration efficiencies. Use of GAC for TTHM control has been found to be effective for not only reducing precursor compounds which contribute to TTHM formation, but also to some degree for removing THMs once they are formed.

33. One commenter felt that increases in State program grants would be necessary for States to implement these regulations.

These requirements are not expected to be an undue burden upon State programs. Implementation of these regulations will require State review and approval of proposed plans for treatment modifications for approximately 515 systems. Because of the relatively small number of systems within each State, the phasing-in of the two population segments, and the fact that, for the most part, minor modifications will be necessary, this is expected to be accomplished with minimal disruption to existing State programs. Further, many States already review system plans for any modifications to existing treatment. Compliance monitoring will also be required but this will only be a minor addition to the system already in use by State programs for checking compliance with the NIPDWR in effect.

34. One commenter stated that EPA underestimated the costs of implementing the regulation by underestimating the number of impacted systems. This commenter disagreed with EPA's use of a specific model for the water supply industry, assumptions regarding the number of systems that purchase water and use alternate disinfectants, and assumptions and predictions based upon NOMS for determining the level of THMs and if systems would be impacted. Instead, they said EPA should have conducted sampling at all systems and based its estimates upon those results. They further commented that EPA's estimate of 390 systems serving greater than 75,000 persons was not derived from EPA's Inventory of Systems but was based upon a policy testing model which left out numerous systems including all Federal Systems (e.g. District of Columbia) and the States of Hawaii and Alaska. They criticized EPA for not confirming the hypothetical results of the model with empirical data. Finally, they said EPA's assumptions regarding the number of systems using specific treatment systems such as GAC or no-cost modifications were arbitrary.

EPA has based its assumptions regarding the number of public water systems upon the actual inventory of water supply systems in the U.S. as ascertained in the Federal Reporting Data System (FRDS), and thus the number of systems is as accurate as possible. Certainly, surveys at every plant in the U.S. as suggested by the commenter would provide actual results rather than an estimate of TTHM levels, but NOMS is considered to be a valid representation of national exposure

levels. NOMS is the most recent and extensive data base and is adequate for estimating national cost impacts. In regard to disinfectant use, EPA based its estimates upon an EPA national survey in 1976 of drinking water plant operations. The determination of the number of systems that are expected to use specific types of treatment was discussed in the preamble and are reasonable estimates based upon the TTHM levels and available technologies. Finally, the commenter was unfamiliar with the policy testing model which the Agency uses to support economic and financial analysis. A description of this model is presented in Appendix A of the economic analysis document. It is used only to generate the aggregated costs and financial impacts, based upon inputs from treatment cost data, water supply inventory data, and water supply operating characteristics data.

35. One commenter stated that the EPA should provide a cost estimate of the stated goal of lowering the MCL at a later time to 50 ppb or 10 ppb.

Prior to lowering the MCL to any level, a full economic impact analysis would have to be conducted and available for public comment as part of an entire rulemaking proceeding. The 0.010 to 0.025 mg/l was merely stated as an indication of future technological performance potential.

36. One commenter was concerned that EPA had underestimated the financial implications of the TTHM regulations on water utilities, for example, by assuming that the rate increase required to finance the necessary revenue requirements would be easily obtained. This commenter noted that projections of future capital requirements in addition to the cost of the GAC process for various water systems had not been factored into the analysis. Another commenter stated that in order to install GAC, water utilities would need to raise capital through large rate increases. They noted that there were substantial regulatory barriers which could preclude water utilities from obtaining the necessary rate increases. Even if utilities were able to raise the capital funds, the quality of their credit and the attractiveness of their common stock would be severely reduced; this would reduce their ability to obtain external financing for normal water supply activities.

EPA believes that the estimated costs will not result in an undue burden upon water utilities and therefore, revenue requirements will be reasonably obtained in most cases. Further, EPA did not factor in capital requirements for such items as system maintenance or expansion into the analysis since these are not directly related to the regulations. Since implementation of these regulations will improve drinking water quality, utilities should be in a favorable position to obtain rate increases. Further, it is not expected that bond rating of the utilities will be significantly affected or that regulatory barriers will seriously prevent systems to obtain financing for complying with these regulations.

37. Two commenters stated that EPA was required to prepare an Environmental Impact Statement (EIS) in conjunction with these regulations. They noted that EPA had not addressed the significant primary and secondary environmental problems associated with the use of GAC treatment facilities and that EPA's assessment had not evaluated the full environmental impact potential of the regulations so as to be functionally equivalent to an EIS.

EPA is not required to prepare a formal EIS for these regulations. Section 102(2)(C) of the National Environmental Policy Act (NEPA) requires the preparation of an EIS for "major Federal actions significantly affecting the quality of the human environment." However, the courts have exempted EPA rulemaking from this requirement where the Agency's action in carrying out its statutory obligations is designed to protect the environment and amounts to the "functional equivalent" of the requirements of NEPA. Although the courts have not specifically addressed the applicability of NEPA under the SDWA, the "functional equivalent" standard is equally appropriate and clearly satisfied here. This rulemaking has involved extensive efforts by EPA, including public participation, for evaluating the primary environmental impacts related to the control of TTHMs in drinking water. The potential negative impacts included air and water pollution impacts of GAC and its attendant regeneration furnaces, waste disposal issues related to such furnaces, adverse effects on the microbiological quality of drinking water, as well as risks associated with the use of GAC. Many other environmental impacts will be positive since human exposure to harmful chemicals will clearly be reduced. Moreover, the legislative history of the SDWA indicates that proposed provisions that would have required literal compliance with NEPA for actions taken under the SDWA were rejected by Congress. The secondary impacts were found to be too remote for consideration in EPA's analysis but are also believed to be negligible.

38. Two commenters stated that EPA was required to prepare an Inflationary Impact Statement (IIS) in conjunction with these regulations.

EPA does not believe that it was required to prepare an IIS for these regulations. Under Executive Orders Nos. 11821 and 12044, only major regulatory actions which may have a significant impact on inflation require the preparation of such statements. A major or significant regulation is one which has associated annual costs of greater than $100 million, causes an increase in price of greater than five percent, or is so designated by the Agency's Administrator. For the TTHM regulation, annual costs are estimated at $19 million, and average increases in the price of water are less than one percent. The Administrator has not designated this regulation as significant. Nevertheless, EPA has conducted a full economic and financial impact analysis of these regulations which is reported in the economic analysis document.

39. Comments were received concerning the air pollution and energy impacts associated with the use of regeneration furnaces for GAC. These commenters were concerned that the regulations would promote substantial new consumption of energy through use of GAC as well as in secondary energy consumption such as in the production of the energy that will be used in GAC regeneration, or the energy usage associated with the manufacture and transportation of GAC. One commenter stated that the Agency did not address the cost and environmental impact of such furnaces. One commenter was concerned about the availability and costs of energy for on-site regeneration of GAC as well as increased energy consumption.

EPA issued a supplemental notice of proposed rulemaking on July 6, 1979 (43 FR 29135 at 29147) which addressed precisely these concerns. EPA has concluded that the air pollution and energy impact of these regulations will be negligible. Air pollution associated with GAC furnaces will be minimized by the use of scrubbers whose cost have been included in EPA's estimated cost of compliance for those systems that will be required to use GAC for meeting the TTHM MCL. Since fewer systems are expected to have to install GAC than EPA originally proposed, these impacts have further been reduced. Secondary energy impacts, such as transportation costs, are too tangential to be estimated with any degree of accuracy, but are also considered to be insignificant. Energy consumption will increase consumption by an estimated 508×10^9

BTU's per year or 0.0007 percent of present U.S. energy consumption. These figures do include a number of secondary energy impacts. Commenters are referred to the preamble and EPA's economic impact analysis accompanying these regulations for further details on these issues.

40. One commenter noted that EPA was required to analyze the costs of its actions in terms of the benefits hoped to be obtained and had failed to do so.

EPA has conducted a thorough analysis of the costs of this regulation and has examined in a qualitative source the perceived benefits from reducing levels of human exposure to THMs. It has been determined that the costs of this regulation are reasonable and therefore risks associated with exposure to THMs should be reduced accordingly. However, EPA is not required under the SDWA to perform a quantitative cost/benefit analysis nor to base regulatory decisions solely on the basis of such an analysis. Rather EPA is directed to establish an MCL which requires contaminants which may have any adverse effect on human health, including carcinogens, to be reduced to the extent feasible and that is the basis of EPA's establishment of the TTHM MCL at 0.10 mg/l TTHMs. Further reduction was not considered to be feasible at this time because of the potential trade-off of compromising the bacteriological quality of the drinking water due to less effective disinfection practices. Commenters are also referred to the discussion that follows below.

41. Information on the relative benefits related to the costs of the TTHM regulation was provided in an NAS Report, "Non-Fluorinated Halomethanes in the Environment" (1978). Dr. Andelman, using GAC and aeration as the tool to demonstrate a methodology of evaluating cost and benefits, concluded that in the absence of any other perspective, it was not cost-beneficial to use GAC or aeration simply to reduce chloroform concentrations in drinking water.

The report stated:

> From the viewpoint of economics, the central policy issue in controlling human exposure to any toxic substance is whether the benefits of reducing deaths, suffering, illness, and other losses outweigh the costs of controls. This involves identification of population exposure levels and a determination of when the costs of additional controls exceed the benefits of a further reduction in exposures.

The report applied four concepts and principles including: (1) The discounted value of an individual's production, (2) extrapolations from risk premiums, (3) costs of illness and human suffering, and (4) the Pareto Improvement principle, and applied the empirical estimates of values of reducing the probability of death to develop his benefit-cost evaluation. The report concluded that:

> Depending on the methodology that is used to compute costs, from these examples, the most reasonableness estimates of the per capita value associated with reducing the probability of death by 100 percent range from $100,000 to $1,000,000.

EPA has reviewed this NAS report and believes that the cost side of a benefit-cost equation that is used in the control of toxic substances should have been calculated for each specific control technique because the costs per person benefited may vary greatly among the available control options. The NAS report selected only aeration and GAC adsorption process for the control of THM concentration in drinking water and failed to consider other less expensive treatment methods which will, in fact, be used by most systems to comply with the TTHM MCL.

The report assumed that the most significant effect of human exposure to chloroform in drinking water was cancer and that all of these cancers result in death; effects other than cancer mortality were presumed to be negligible. Therefore, the report said the benefits of reducing human exposure to chloroform in drinking water could be estimated by multiplying data on lifetime risk of cancer by the economic value of reducing the risk of death from cancer in a population. The benefits also could be calculated by multiplying the daily per capita uptakes of chloroform by the risk of a cancer death over an average lifetime from a given daily dose of the carcinogen by the economic value of reducing the risk of a cancer death.

Based upon the above principles and other assumptions, the report found that:

> Very high concentrations of chloroform in drinking water are associated with enough risk of cancer to justify the costs, on economic grounds alone, of treatment processes for removal of this compound. The potential magnitude of the problem is even greater if allowance is made for the upper limit of risk. Furthermore, justification for treatment rises with the value imputed to avoiding a death. However, the current cost of treatment to remove chloroform from drinking water is sufficiently high that the economic justification for removing chloroform from drinking water in the United States, assuming the most probable risk, exists only in those cases where maximum initial concentrations of chloroform are found in drinking water, there is maximum fluid intake, and the risk of death is valued at $1,000,000 or more. Using a more typical and more statistically justifiable value of reducing the risk of death, i.e., $300,000, the high cost of removing chloroform alone cannot be justified on economic grounds for the most probable risk conditions, even when there are maximum concentrations and intake.

EPA believes the analysis in this NAS report has everal serious shortcomings which obviates its conclusions. As is stated in the report itself, the analysis was designed primarily "to demonstrate a methodology," rather than to draw strong conclusions about the particular example used. In EPA's view, the following assumptions made in the analysis bias it against regulation of THM: (1) The risk extrapolation used for chloroform is lower by a factor of 8.5 from that derived by the NAS in *Drinking Water and Health* (the existence of so large a discrepancy in an estimate by the same organization using the same model illustrates the difficulties in making a fine-grained comparison of risks and costs), (2) no account is taken of the benefits of GAC other than removal of THM, such as removal of other disinfection by-products, synthetic organic chemicals present in the raw water, and substances with objectionable taste and odor, and (3) it does not take into account much cheaper technologies for THM control. In spite of these biasing assumptions, the analysis still concludes that, for an assumed value per cancer case avoided of $500,000, a community would be justified in installing GAC for TTHM control if its TTHM level exceeded 164 ug/l, a conclusion which is not at all inconsistent with an MCL of 100 ug/l.

EPA agrees that the costs and benefits of alternative regulations should be examined in deciding whether and how stringently to regulate, where the statutory framework does not prohibit such examination. While no such prohibitions are contained in the SDWA, EPA believes that the uncertainties in quantifying the health benefits of regulatory actions, particularly given the great scientific uncertainties about the effects of low levels of carcinogens, make formal cost-benefit analysis of limited usefulness in regulatory decision making.

The quantification of risk is sorely limited by the lack of demonstrable accuracy and precision of any statistical model, the inability to identify more than a portion of the substances that would be generated by chlorination in water, the inability to predict the toxic potency of those chemicals individually let alone as a variable complex mixture, the inability to quantify the contributions of these chemicals to and their interactions with the mass of toxic chemicals that are part of human body burdens, and the inability to identify

particularly susceptible high risk segments of the population.

The costs that were used in the NAS analysis dwelled on GAC and aeration which are among the most expensive options and which only a small number of water systems would need to use. Prevention or reduction of THM formation potential prior to introduction of chlorine is much less costly than removal after formation. The NAS estimate of benefits associated with the THM regulation considered removal only of chloroform and none of the other by-products, and also did not consider any other water quality improvements. The study's cost of not controlling THMs in public water systems did not include the considerable offset of increased cost to consumers and society by increased reliance on bottled water or home devices that ostensibly reduce organic chemicals at the tap. Morbidity costs, lost wages and health treatment costs were also not considered. Thus, risks and benefits can easily be underestimated, and costs overestimated. Considering costs, risks and benefits is of course an essential part of any regulatory process, but the judgment of an acceptable societal cost for a human life is a matter of policy that requires many more complex and subtle factors that are not within the current state-of-the-art for these types of quantitative analyses. Additional discussion of cost-benefit analyses is provided below in the reponse to the comments submitted by the Council on Wage and Price Stability.

42. The Council on Wage and Price Stability (CWPS) said that the EPA studies contain:

(a) No analysis of the benefits of alternative performance standards or of alternative population-size cut-offs, and

(b) No analysis of either the costs or the benefits of alternative design standards.

Consequently, CWPS believed that the EPA analyses shed no light on the reasonableness (i.e., the cost-effectiveness) of these decisions. They said that EPA provided no information about the consistency of these regulatory decisions with each other or with other EPA regulations. CWPC believed that because the resources available for health-related programs are limited, it is important that those resources be allocated in a way that maximizes the benefits (in terms of lives saved or cases of illness or injury avoided). This in turn would require that the incremental cost per cancer case avoided be at least approximately equated for different regulations or different adopted standards. CWPS felt that it was incumbent upon EPA to support its proposed regulations with careful risk-assessment and cost-benefit analyses, employing the best estimates available regarding uncertain variables, parameters, and relationships. CWPS made some preliminary calculations and suggested that more lives could be saved with no increase in costs by tightening up on the performance standard for THM (i.e., lowering the allowable concentration below 100 ug/l and concomitantly relaxing the population cut-off (higher than 75,000)). CWPS said that:

(a) The incremental cost of lowering the population cut-off from 100,000 to 75,000 (given a 100 ug/l standard) is $12.2 million per additional cancer case avoided.

(b) The incremental cost of strengthening the performance standard from 100 ug/l to 50 ug/l (given a population cut-off of 75,000) is $6.3 million per additional cancer case avoided.

(c) Thus, the cost of avoiding cancer cases by applying the MCL to communities with populations of 75,000 and above, which EPA had done, is double the cost of avoiding cancer cases by strengthening the standards to 50 ug/l, which EPA did not propose.

(d) CWPS also said, "These calculations do not necessarily mean that the performance standard should be tightened to 50 ug/l, but they do suggest that the (two) proposed regulations are internally inconsistent."

The CWPS comments raise two separate types of issues with respect to the THM regulation. The first concerns the use of cost-benefit analysis to determine whether a regulation is justified and what its overall level of stringency should be. The second concerns whether, *given* that a regulation limiting THM levels is to be implemented, the proposal would be the most cost-effective way of using a given level of social resources to reduce the population's exposure to THMs.

On the first issue, CWPS did not draw any conclusions as to whether the regulation was justified, but recommended that cost-benefit analyses be an integral part of the Agency's decision process.

EPA has reviewed the subject of using cost-benefit analysis in regulatory decision-making under the SDWA and reached the following conclusions. First, benefit-cost analysis is most useful to decision-makers when benefits can be specified with the same degree of certainty as the costs. However, when dealing with long-term health risks, such as cancer-causing contaminants like THMs, while it is possible to establish the existence of a risk, it is beyond the state-of-the-art of current scientific knowledge to establish the exact degree of risk. Crude indications of risk can be made, and these can be used to develop a range of health benefits associated with a regulation, however, the range is so broad that its use in benefit cost analysis overwhelms these elegant and sensitive analytical procedures. In addition, there is little agreement on the dollar value which should be ascribed to the avoidance of a case of cancer. Past estimates have ranged from $10,000 to $158 million. Therefore, due to these two fatal deficiencies, it is not possible to place excessive significance on cost-benefit analysis for the long-term health risks related to this regulation.

Despite these inherent difficulties, EPA conducted an analysis of regulation alternatives. Constraints to decisionmaking involving technical and administrative issues tended to limit the range of alternatives. Within this framework, however, it was possible to establish that for the regulation the marginal cost of a case of cancer avoided is approximately $200,000 (counting only the benefits of THM reduction). This is similar to that suggested in the NAS report cited by Dr. Andelman. Further discussion is included in the Statement of Basis and Purpose.

On the second issue, EPA agrees that any regulation should make the most efficient possible use of the social resources devoted to compliance, to the extent that it is possible to predict. CWPS presented an analysis which purported to show that, for the same total cost, a greater reduction in THM exposure might be obtained by reducing the MCL and increasing the population cut-off figure. However, the assumption had been made that systems exceeding the MCL would reduce their THM levels precisely to the MCL; in fact, many of the control technologies would actually reduce THM levels to much lower levels in practice. When account is taken of this fact, the analysis shows that EPA's proposed regulation is more cost-effective than the CWPS' suggested alternative. After staff-level discussion, CWPS recognized this and other technical deficiencies in its analysis in a letter to EPA dated January 31, 1979.

43. Sixty-nine comments were received on the proposed concept of averaging concentrations of TTHMs for compliance. A majority of the commenters approved of both the annual averaging of TTHM values from quarterly samples, and the averaging of TTHM values of representative samples within the distribution system. However, fourteen commenters thought that

averaging the quarterly results would mask fluctuations in TTHM levels as affected by seasonal and other site-specific factors. One said that quarterly averaging would be justified if EPA were concerned about the chronic but not acute effects of THMs. One said that flexibility should be retained in the regulation for later reconsideration of this averaging concept. Two commenters said that compliance should be determined by averaging all of the results of samples taken in the preceding 12 months. One suggested that a geometric mean should be used in compiling and averaging the sampling results. One felt that there was not enough information to determine whether the concept of averaging was reasonable.

On the question of averaging results of samples in the distribution system, several commenters felt that averaging values could mask high TTHM concentrations and fail to protect those individuals receiving maximum doses. Because flow patterns in the distribution system are likely to be relatively constant, these commenters believed that some residents could be unduly exposed to consistently high levels of TTHMs over a long period of time. One commenter opposed averaging the high values of TTHM analyses from samples taken at the extremes of a distribution system, with the lower results from other areas of the distribution system because it would result in uneven population exposure. Three others suggested that all samples should be taken at the extremes of the distribution system instead of averaging all sample results. One suggested that all samples should be incubated to obtain terminal TTHM and hence uniform results. One commenter said that all samples should be taken from the same point every time to avoid misrepresentation. One commenter thought that selection of sampling locations should be based upon results of a sanitary survey for each system.

EPA's proposal to determine compliance with the TTHM MCL based upon an annual average of the sampling results per quarter has been retained in the final regulations. EPA recognizes that TTHM levels may fluctuate depending upon seasonal and other site-specific factors. However, the MCL for TTHMs has been established primarily to protect the public from the adverse effects attributable to chronic exposure to these contaminants, rather than from any acute effects. EPA nevertheless retains the flexibility to amend these regulations should new information indicate that annual averaging of quarterly results is not adequately protective. On the other hand, EPA believes that it would not be reasonable to determine compliance by an annual average of all samples taken since this could clearly allow systems to mask fluctuations in TTHM levels over the year. In regards to use of a geometric mean as the basis of the MCL, the arithmetic mean is considered to be more appropriate because it is a more accurate representation of typical human exposure.

With regard to those commenters who expressed concern about EPA's proposed sampling program, it is noted that it would have required systems to average a minimum of five samples per quarter, no more than 20% of the samples to be taken at the entry point to the distribution system, no less than 20% at the extremes of the distribution system and the remaining 60% at representative points in the system relative to population density. In response, these final regulations have reduced to four the minimum number of samples to be taken per quarter, but no longer allow any samples to be taken at the entry point to the distribution system, where TTHM levels would have likely been lowest, and where few consumers would have actually been exposed to such levels. EPA believes that this sampling program will better reflect the average TTHM levels in the drinking water served to most consumers.

However, EPA rejected the suggestions to require all samples to be taken either at the extremes of the distribution system, or at the same point in the distribution system each time. Such sampling schemes would not fairly represent the water system as a whole. However, EPA is concerned that very high levels of TTHMs at the extreme ends of a distribution system be reduced. EPA believes that by requiring extreme sampling results to form a larger percentage of the quarterly average (25% as opposed to the proposed 20%), any great differences in TTHM concentrations in such locations may be detected and corrected.

In response to the remaining comments on EPA's proposed sampling program, EPA has not required all samples to be incubated to obtain terminal results because this would probably overestimate actual concentrations at the taps of most consumers. EPA agrees with the comment that sampling locations must be selected by the system on a case-by-case basis, preferably after a sanitary survey, depending upon the particular configuration of its distribution system. Systems are encouraged to work with the States and EPA in the selection of truly representative sampling points. EPA has required that the number of samples taken be commensurate with the number of treatment plants used by each system to allow sampling to detect differences in TTHM levels within each system attributable to different source waters and different treatment methods. Once problems are detected, systems should reduce extreme differences of TTHM levels within their distribution system.

44. Twenty-three commenters supported EPA's proposal to require use of the Standard Plate Count (SPC) as a more sensitive indicator (than the coliform test) of microbiological quality during treatment modifications. Thirty-seven commenters felt that the SPC was of questionable value or unreliable, and that the SPC requirement would impose an unnecessary administrative burden on water utilities. Five commenters suggested that the SPC should only be required for those systems whose water sources receive municipal point source discharges, and should not be required for all treatment modifications. Four commenters also felt that the SPC should only be used to confirm a questionable microbiological count and that the decision to use the SPC should be left to the discretion of the State regulatory agency.

In response to these comments, EPA has decided to delete from these regulations the SPC as a mandatory requirement for all systems that make treatment modifications to comply with the TTHM MCL. However, EPA still believes that compliance with the TTHM MCL should not be achieved at the expense of the microbiological integrity of the water and that the SPC can be a reliable and useful tool as an overall indicator of water quality. Therefore, in order to insure that disinfection is not compromised, while affording maximum flexibility to the States to address case-by-case situations, these final regulations have included a requirement whereby systems must seek and obtain State approval of any planned significant modifications to their treatment process made to comply with the TTHM MCL that could affect biological quality. The States (or EPA in non-primacy States) must therefore exercise careful supervision over system treatment changes by prescribing specific measures (which would include the SPC in appropriate cases) to insure the continued microbiological quality of the drinking water. The usefulness of the SPC and other biological tests are

discussed in greater detail in the preamble to these regulations and will be discussed in EPA's guidance to the States concerning approval of system treatment modification plans.

45. Ten comments were received on EPA's proposed restriction on the use of chlorine dioxide as an alternative disinfectant to free chlorine. Nine opposed the restriction of using chlorine dioxide at a maximum dose of 1 mg/l but provided no supporting data. One felt that EPA should encourage the testing and use of alternative disinfectants while others felt that the limit of 1 mg/l for chlorine dioxide was arbitrarily set and that up to 2 to 3 mg/l chlorine dioxide should be allowed. One commenter reported that chlorine dioxide was effective in reducing the TTHM concentration in his system from 284 mg/l to 16 mg/l.

In response to these comments, EPA has deleted from the final regulations its proposed restriction on the amount of added chlorine dioxide. EPA is nevertheless concerned about the uncertain state of knowledge concerning the potential for adverse effects associated with chlorite, chlorate and chlorite ion, which are produced from oxidation/reduction reactions of chlorine dioxide in water. EPA will be considering proposing limitations on the residual oxidants (ClO_2, ClO^-_2, and ClO^-_3) in the finished drinking water rather than on the amount of chlorine dioxide added. In the meantime, additional research on the health effects of alternative disinfectants will continue. MCLs may be developed for inclusion in the Revised Regulations after further studies have been fully evaluated.

By requiring all systems significantly modifying their treatment process to comply with the TTHM MCL to obtain State approval of their modification plan, EPA expects that where restrictions on chlorine dioxide are necessary, the States will impose such restrictions as appropriate in accordance with EPA guidance including monitoring for residual oxidants and maintaining their concentration at a low level. Where chlorine dioxide is completely reduced to chloride, no restrictions would be necessary since by-products are believed to be of no toxicological significance. Case-by-case judgments can also be made to impose restrictions when the presence of reducing agents in the raw water of a particular system would result in excess formation of chlorite and chlorate. Additional discussion on the use of chlorine dioxide as an alternative disinfectant is contained in the preamble to these regulations and will be contained in additional EPA guidance to the States for approval of system treatment modification plans.

46. Fifty-five commenters opposed EPA's proposed limitation on the use of chloramines as a primary disinfectant. They argued that chloramines would solve some of the problems of using chlorine for drinking water treatment because chloramines do not react with precursors to produce TTHMs, and chloramines have been in use in many water systems for many years without any problems. Eleven commenters agreed that chloramines should be restricted from use as a primary disinfectant. One of these commenters reported that preliminary data had indicated that chloramines may not be effective in neutralizing viruses and amoebic or Giardia cysts. One commenter suggested that chloramines may be used after the primary disinfection step for the purpose of maintaining an active disinfectant residual. The NDWAC felt that the proposed limitation was unduly restrictive.

EPA found that most of the commenters opposed to the imposition of restrictions on the use of chloramines failed to recognize that EPA's proposed restriction was limited to prohibiting its use as a primary disinfectant. EPA does not disagree with those commenters who endorsed the use of chloramines as an effective secondary disinfectant (to maintain an active combined chlorine residual). Nevertheless, in response to these comments, EPA has decided to delete the chloramine restriction from the final regulations, allowing appropriate restrictions to be imposed in necessary situations by the States in approving system treatment modification plans. Use of chloramines instead of free chlorine has been shown to be a simple and readily available means for reducing the formation of TTHMs in many examples. However, they are also known to be weak disinfectants for certain bacteria, viruses and protozoa, compared to free chlorine as HOCl, ozone and chlorine dioxide. Therefore, where such contamination is suspected, appropriate restrictions should be imposed. Additional information on the use of chloramines as an alternative disinfectant is contained in the preamble to these regulations and in additional EPA guidance to the States on approval of system treatment modification plans.

47. Eleven comments were received opposing the concept of setting an MCL to control TTHMs in drinking water. Two commenters said that EPA lacked legal authority to regulate the TTHMs under the Amendments to the National Interim Primary Drinking Water Regulations (NIPDWR). One commenter noted that the feasibility of control measures under the NIPDWR must be adjudged to have been available as of December 1974, when the SDWA was enacted. Three commenters said the NAS report, "Drinking Water and Health" fell far short of providing the needed scientific definition and did not recommend EPA to set MCLs for TTHMs. One commenter said that the EPA should not yield to the pressure from some public interest groups to set a MCL for TTHMs before the health risks have been established. Four commenters believed that the main reason EPA proposed an MCL for TTHMs was because EPA was anti-chlorination and was trying to abolish chlorination practice in water treatment. One of the four suggested that instead of an MCL, EPA should tighten chlorine specifications so that no contamination of the water will result during chlorination practice. Three others recommended that the regulations provide guidance on the proper use of chlorine as a disinfectant, either free or combined, for case-by-case applications.

EPA's response to those comments addressing the Agency's authority to establish these regulations as Interim Primary Drinking Water Regulations is contained in the preamble, and commenters are referred thereto. EPA agrees that the feasibility of control measures under the NIPDWR must be based on technology generally available as of 1974 and has found that these regulations satisfy the statutory test.

With respect to those commenters that cited the NAS Report "Drinking Water and Health" to support their position that regulation of TTHMs is premature, EPA disagrees with their interpretation that the NAS only recommended further research. In fact, the NAS concluded that: "strict criteria be applied when limits for chloroform in drinking water are established to protect the public health." Moreover, Dr. Riley Housewright of the NAS Safe Drinking Water Committee, stated that: "chloroform and other THMs present a health hazard and that steps should be taken to prevent their formation or to remove them from drinking water." As noted in the preamble and EPA's responses to other comments in this Appendix, EPA believes that sufficient information is known about the potential for adverse health effects from the presence of THMs in drinking water

to warrant regulation at this time. Although further research will continue to be forthcoming, EPA need not wait for definitive proof of harm before it takes regulatory action under the SDWA.

With respect to those commenters who charged that EPA's establishment of a TTHM MCL evidenced EPA's intent to abolish chlorination as a drinking water treatment practice, EPA disavows such an intent. However, EPA does believe that improper or careless use of chlorine, as well as any other disinfectant, can result in the unnecessary formation of potentially harmful by-product chemicals in the finished drinking water. EPA acknowledges that chlorine is currently the most widely used, highly effective drinking water disinfectant and expects that use to continue. However, control of TTHMs should lead to a more judicious use of chlorine and will serve to minimize human health risks from exposure to other disinfection by-products. EPA also agrees that better quality control in the manufacture of chlorine for drinking water treatment is necessary to avoid harmful contaminants contained therein and will address such concerns in conjunction with its overall review of water treatment additives. EPA's guidance to the States for approval of system treatment modification plans will contain additional information on proper chlorine use.

48. A total of 306 comments were received expressing a concern for the basis of health effects data that support the proposed TTHM regulations. The majority of the commenters felt that the proposed MCL was not based upon incontrovertible health effects information and urged that additional health effects research and epidemiological studies should be conducted. Only a few commenters said the supporting health effects data for the proposed THM regulations were adequate and that the regulatory action was justified now.

Specifically, 292 comments said that the available health effects data, both epidemiological studies and laboratory animal tests, were not conclusive and were disputed by many scientists. These commenters, therefore, believed that the setting of an MCL for TTHMs was not warranted at this time. They suggested that more research should be conducted specifically on the toxicological assessment procedures and the health effects of long term exposure to low dosage of THMs.

EPA has reviewed these comments in light of all available health effects information and has concluded that long term low level exposure to TTHMs may be harmful to human health. EPA's conclusions are supported by comments and statements of policy by representatives of the National Cancer Institute, National Academy of Sciences, National Drinking Water Advisory Council, National Institute of Environmental Health Sciences, Food and Drug Administration, Occupational Safety and Health Administration, and the Consumer Product Safety Commission. These commenters emphatically stated that EPA should not wait for additional evidence to proceed with regulatory action to control chloroform and trihalomethanes in drinking water which was warranted now. These comments are summarized in Appendix B.

The following discussion summarizes the specific concerns expressed by commenters regarding the health basis of the regulations and presents the Agency's responses.

49. Comments were received that argued that chloroform poses no potential cancer risk and there are no available data that support the premise of a causal relationship between the concentrations of THMs normally found in drinking water and cancer in humans. They noted that the epidemiological studies that have been conducted concerning drinking water and a possible connection with cancer risk in humans were inconclusive.

EPA reviewed the available 18 epidemiological studies concerning the relationship between cancer morbidity/mortality and constituent concentration in drinking water supplies. In summary, many but not all of the preliminary studies have found positive correlations between some drinking water quality factors and some cancer mortality and morbidity statistics such that the general hypothesis is supported. Further evaluations are necessary due to the confounding factors inherent in epidemiological studies of this nature. Therefore, EPA has relied primarily on the results of animals studies in concluding that TTHMs in drinking water pose a risk to humans. Thus, EPA does not disagree with the comment that data do not exist to demonstrate a causal relationship between the concentrations of synthetic organic chemicals including THMs in drinking water and cancer in humans. However, the positive correlation of cancer morbidity/mortality and contaminants in drinking water are suggestive and are not inconsistent with the carcinogenic potential of chloroform as demonstrated by well conducted animal experiments at high doses.

50. Some commenters opposed EPA's reliance on animal studies for its finding that TTHMs in drinking water pose a health risk on the grounds that extrapolation of results in animal cancer studies to humans is fraught with problems and uncertainties.

EPA recognizes the problems of extrapolating animal data to man. The state-of-the-art in toxicology as illustrated by the NAS in the report "Drinking Water and Health" is that the effects in animals, properly qualified, are applicable to man. Chloroform has been shown to be carcinogenic in experimental animals; its metabolic pattern in animals is similar to that in humans; EPA therefore believes that the carcinogenic effect of chloroform as observed in animals do indicate risks from human exposure to TTHMs in drinking water.

51. Some commenters argued that the study (by National Cancer Institute (NCI)) cited by EPA to support the carcinogenicity of chloroform was "a preliminary screening test and not a definitive study." They said that the study was not intended to be used to extrapolate health effects of chloroform to drinking water levels and that the NCI study was inadequately controlled and did not follow proper scientific protocols. Since a new EPA/NCI study is underway it was recommended that the implementation of any regulations be delayed until this study was completed. They claimed that the NCI study was not intended to be used to extrapolate the adverse health effects of the tested animals to the potential human health risk posed by the low levels of chemicals that are found in drinking water, since many researchers believe that the high morbidity rates in the animal experiments suggested acute toxicity rather than chronic toxicity.

Based on the NAS review and the NCI report, EPA has concluded that the NCI chloroform-carcinogen bioassay with all its short-comings is a valid test. It has been accepted by the other federal agencies for regulatory purposes. The morbidity noted took months or years to develop and would not be an acute effect by definition which would occur in 3–7 days. In addition, the studies performed as early as 1945 by Eschenbrenner and Miller pointed out the carcinogenic potential of chloroform and the metabolic similarity of chloroform in humans and animals. The NCI study on the carcinogenic potential of chloroform has been used by the NAS as well as by the EPA's Cancer Assessment Group (CAG) for risk estimation. Additional refining studies are continuing, but sufficient evidence

exists to indicate potential human risk and, therefore, to reduce human exposure.

52. Several commenters stated that Dr. Roe's studies with chloroform on dogs, rats and four strains of mice at low dose levels did not produce tumors in animals. Dr. Roe recommended a level of 300 ppb THM in drinking water based upon his results. It was claimed that Roe's studies showed a no observed effect at 595,000 (drinking water equivalent) ppb of chloroform in drinking water. Therefore, he argued that 300 ppb would provide margin of safety of 2,000. It was argued that EPA had used 500 as a margin of safety in other regulations. Based upon his chosen statistical extrapolation model, he found that a THM MCL of no lower than 0.30 mg/l (300 ppb) would provide a more than adequate margin of safety. however, it was also stated that this level is still too low to be justified on a cost-benefit basis if GAC were required.

EPA has concluded that Dr. Roe's studies with chloroform on dogs, rats and four strains of mice at low dose levels further strengthens the hypothesis of chloroform carcinogenicity. In one study, the mice fed 17 mg/kg/day chloroform showed no incidence of renal carcinoma, but an excess of tumors of the renal cortex were observed in the male ICI—Swiss mice, at a dose level of 60 mg/kg/day. The negative results observed in the dog experiment may be attributed to the fact that either the animals were not exposed for a suitable length of time (i.e., duration of life span) or that an insufficient number of animals were tested. The negative results of the rat study may be attributed to the lack of strain sensitivity.

Using a no-observed-effect-level for chloroform of 17 mg/kg/day, Dr. Roe recommended 300 ppb chloroform in drinking water as an acceptable level. According to his calculation this would provide a margin of safety of 2000 for a standard person drinking two liters of water per day. The NAS Safe Drinking Water Committee and many other scientists now believe that the methods at present do not exist to establish a threshold for long-term effects of carcinogens; thus, the safety factor of 2000 referred to in Roe's recommendation of 300 ppb THM does not apply to carcinogens since no exposure can be considered to be absolutely "safe". EPA is directed by the SDWA to reduce human exposure to harmful contaminants in drinking water to the extent feasible. EPA's THM MCL of 0.10 mg/l can be feasibly achieved. The comment regarding the costs vs. the benefits of the use of GAC is discussed elsewhere in this Appendix.

54. Some commenters said that EPA's proposed MCL of 100 ppb was needlessly low and will require costly additions or changes to water treatment facilities without achieving any corresponding benefit in water quality.

EPA has found that exposure to TTHMs should be minimized. The level of the MCL at 0.10 mg/l TTHMs was determined to be a feasible level for achievement under the interim regulations. Systems are encouraged to reduce the level of TTHMs below the MCL if technically feasible. EPA expects that compliance with the MCL will benefit drinking water consumers in reduced exposure to THMs as well as reduced exposure to other disinfection by-products which may have adverse health effects. For some systems the aesthetic quality of the water will also improve because taste and odor producing compounds will be reduced along with reductions in TTHM levels. As discussed in the preamble and in EPA's Economic Analysis accompanying this final regulation, costs are not considered to be significant in that most required changes will be relatively minor.

54. It was stated by several commenters that there are a lack of health effects data on THMs other than chloroform and therefore, if an MCL is set, it should only apply to chloroform.

EPA has found that the THMs other than chloroform (bromoform, dibromochloromethane, dichlorobromomethane) are structurally similar to chloroform, and possibly undergo similar metabolic pathways and exert similar bioeffects. Like chloroform, bromoform exposure leads to fatty degeneration and centrilobular necrosis of the liver. Bromoform, dibromochloromethane and dichlorobromomethane have been reported to be mutagenic in Ame's bacterial test system. This test provides information indicative of the potential of genetic damage in biological systems. Thus, because of the chemical similarities in chemical structure and biological activity, EPA's concern regarding potential toxic effects of these chemicals and setting the MCL for TTHMs is reasonable.

55. Several commenters stated that there was no hard evidence that low level exposure to TTHMs produces cancer.

Based on current scientific knowledge, EPA must extrapolate from the results of animal tests using higher dosages to determine potential human health risks from exposure to low levels of particular contaminants. With chemicals such as chloroform that have been shown to be carcinogenic in animals, no level of exposure can be presumed safe. Therefore, EPA has concluded that TTHMs in drinking water must be reduced to the extent feasible as required by the SDWA.

Nevertheless, recent studies using low levels of 2-amino N-acetyl-fluorene (2-AAF) in mice suggest that low level exposure of animals to this compound produces liver tumors when applied. These adequately controlled studies (23,000 animals) showed a no threshold effect (liver cancer) was observed for AAF at the 1% level. In order to be able to measure below the 1% effect somewhere in the order of 100,000 animals would be required.

56. Some commenters claimed that other animal experiments have suggested the existence of definite threshold limits for toxic and carcinogenic effects.

EPA's position is that available data suggest a non-threshold response for carcinogenesis. As an example, the recent Acetyl Amino Fluorene experiments were consistent with a no threshold mechanism for liver tumor induction. This position is supported by the comments of Drs. Upton, Kennedy, Bingham and King from the National Cancer Institute (NCI), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA) and Consumer Products Safety Commission (CPSC), respectively, as noted in the preamble and presented in Appendix B. EPA's position is discussed in both the preamble and the Statement of Basis and Purpose. Also, the National Academy of Sciences addressed this issue in "Drinking Water and Health" (NAS, 1977) as follows:

> Carcinogenic effects may well not have threshold dose-effect relationships. If an effect can be caused by a single hit, a single molecule, or a single unit of exposure, then the effect in question cannot have a threshold in the dose-response relationship, no matter how unlikely it is that the single hit or event will produce the effect. Mutations in prokaryotic and eukaryotic cells can be caused by a single cluster of ion pairs produced by a beam of ionizing radiation. We would expect that mutations can be caused by a single molecule or perhaps group of molecules in proximity of DNA. The necessary conclusion from this result is that the dose-response relationship for radiation and chemical mutagenesis cannot have a threshold and must be linear, at least at low doses.
>
> We therefore conclude that, if there is evidence that a particular carcinogen acts by directly causing a mutation in the DNA, it is likely that the dose response curve for carcinogenicity will not show a threshold and will be linear with dose at low doses (pp. 37–38).

Methods Do Not Now Exist to Establish a Threshold for Long-Term Effects of Toxic Agents

With respect to carcinogenesis, it seems plausible at first thought, and it has often been argued, that a threshold must exist below which even the most toxic substance would be harmless. Unfortunately, a threshold cannot be established experimentally that is applicable to a total population. A time-honored practice of classical toxicology is the establishment of maximum tolerated (no-effect) doses in humans based on finding a no-observed-adverse-effect dose in chronic experiments in animals, and to divide this dose by a "safety factor" of, say, 100, to designate a "safe" dose in humans. There is no scientific basis for such estimations of safe doses in connection with carcinogenesis. For example, even if no tumors are obtained in an assay of 100 animals, this means only that at a 95% confidence level, the true incidence of cancer in this group of animals is less than 3%. Even if we were to carry out the formidable task of using 1,000 animals for the assay and no tumors appeared we could only be 95% sure that the true incidence were less than 0.3%. Obviously, 0.3% is a very high risk for a large human population.

In fact, there are no valid reasons to assume that false-negative results of carcinogenicity tests are much less frequent than false-positive ones. To dismiss all compounds that did not induce tumors in one or two mouse and rat experiments as non-carcinogenic is wrong. Labeling as "carcinogens" all substances that gave rise to increased incidence of tumors is justified only if there is conclusive evidence of a causal relationship. The "relative risk" of compounds that are not found to induce tumors in animal experiments must also be considered. But this requires evaluation of data other than those collected in chronic toxicity studies on rodents.

Experimental procedures of bioassay in which even relatively large numbers of animals are used are likely to detect only strong carcinogens. Even when negative results are obtained in such bioassays, it is not certain that the agent tested is unequivocally safe for man. Therefore, we must accept and use possibly fallible measures of estimating hazard to man.

57. As noted by a number of commenters, the assumption of parallel response between test animals and humans does not hold for many species.

EPA believes that animal experiments that demonstrate a carcinogenic response are indicative of a potential carcinogenic response in the human population. This is supported by Drs. Upton, Kennedy, Bingham, and King from the NCI, FDA, OSHA, CPSC, and NIEHS, respectively, whose testimony is presented in the preamble and Appendix B.

58. Some commenters stated that EPA's extrapolation procedure erroneously utilized two "very consecutive" techniques to determine the MCL for THMs. They said that either technique could probably be justified, but not both.

The level of the MCL is based upon feasibility of available treatment technology and maintenance of biological safety and not on an extrapolation technique from experimental data. The need to limit human exposure is demonstrated by the potential adverse health effects from long term exposure to chloroform from animal studies.

59. Comments were received that alleged that EPA estimates of environmental exposures to chloroform appear to be erroneous and suggested that EPA make every effort to obtain correct values for contributions from air, food and water. Also, they suggested the possibility that *in vivo* formation of chloroform and other THMs in the human body might occur. The commenters felt that the available data suggest that more cost-effective avenues, such as control of chloroform in the work place, may be available for reducing THMs in the environment than by implementing the proposed TTHM MCL.

EPA's estimates of environmental exposure to chloroform were based upon the most recent available data and are considered to be adequate representations of exposure levels. The speculation of *in vivo* formation of chloroform and other THMs in the human body contradicts what is known concerning the fate of chloroform in a mammalian system although this may be occurring from ingestion of chlorine in water. In mammalian systems, chloroform is metabolized to carbon dioxide and other metabolites. The rate of metabolism will be dependent upon the species. Therefore, there is little chance of chloroform being biochemically produced endogenously in the human body.

With regard to the suggestion that there may be more cost-effective means for controlling chloroform in other aspects of the environment, EPA has found that drinking water is a significant contributor to overall human exposure to THMs. Moreover, control of THMs in drinking water is not a significant burden upon water utilities, and will result in reduced human exposure to other potentially harmful disinfection by-products as well. Thus, EPA believes that these regulations are necessary for reducing human exposure to chloroform from a significant source. OSHA and FDA have likewise taken action to reduce human exposure to chloroform under their respective statutory authorities.

60. Some commenters noted that the concentrations of THMs found in public water systems present no mutagenic, teratogenic, acute, subchronic, or chronic toxicological health risk to the public.

Based on the evidence in EPA's rulemaking record, EPA has concluded that THMs pose a carcinogenic risk at the levels found in drinking water. No safe level can be deemed to exist for human exposure to carcinogens and therefore, levels of these contaminants should be reduced to the extent feasible.

61. Some commenters alleged that EPA misconstrued the four general "principles" for risk assessment stated by the NAS in its report "Drinking Water and Health." They argued that EPA did not properly use these principles and ignored the available data. Specifically, with regard to the first NAS principle, EPA was faulted for not taking into account a number of variables in extrapolation of the animal data to humans, including differences between species response to carcinogens, weight, intake of food and water, and routes of exposure. With regard to the second NAS principle, they argued that EPA ignored animal experiment data that showed a threshold level for no-effect responses with respect to a number of suspected carcinogens, as well as experiments involving animals and humans suggesting a no-effect level for chloroform. In support of their claim that threshold levels can be established for carcinogens, they cited the existence of *in vivo* biological processes and human exposure to natural carcinogens without adverse health effects. With regard to the third NAS principle, they claimed EPA did not consider the significance of the detoxification and repair mechanisms operative in animals and humans in its health assessment of THMs. Finally, with regard to the fourth NAS principle, they claimed EPA ignored the guidelines for assessing risk for chloroform as set forth in EPA's "Interim Guideline for Carcinogen Risk Assessment." The comments also faulted EPA for using only the linear model for extrapolating the NCI animal data to humans, while ignoring the data presented by Roe, Eschenbrenner, and Miller, as well as the estimates of risk by Tardiff using the "margin of safety," "probit-log" and "two step" extrapolation models.

The EPA has carefully evaluated all available data and believes it has properly followed the four NAS principles. Each of the commenters' concerns have been thoroughly considered in determining the health

basis of the regulation. EPA has used the present state-of-the-art in toxicology in using the NCI bioassay study on the carcinogenicity of chloroform for assessing cancer risk to humans. The studies by Roe, Eschenbrenner, and Miller were not suited for risk extrapolation because either the dosages were not high enough to observe the response or the experiments were not performed for long enough time periods to observe tumorigenic response.

The question of threshold and/or no threshold for carcinogens is discussed elsewhere in this Appendix, in the preamble and in EPA's Statement of Basis and Purpose accompanying these regulations. The linear non-threshold model is a conservative risk model and consistent with the method used by the NAS. The basis of the regulation is that a human health risk exists even though precise quantification of the risk cannot be made using current toxicological procedures. Therefore, EPA's regulatory approach is to minimize human exposure to these potential carcinogens to as low a level as is feasible.

62. Some commenters said that EPA ignored the relationship between dose and time-to-tumor observation in assessing the health risk of a carcinogenic material.

EPA does recognize the potential relationship between dose and time-to-tumor, but this has not been taken into consideration in the calculation of risk because scientific methods and data are not currently available to adequately perform such a computation.

63. Dr. Timothy DeRouen, representing the Coalition for Safe Drinking Water, critiqued the epidemiological studies cited by EPA in the proposed regulations. He discussed the studies for a possible relationship between chlorinated drinking water and cancer mortality. His principal points and EPA's responses are as follows:

(1) Dr. DeRouen commented that although some consistencies exist to support the premise of a relationship between organic chemicals in drinking water and cancer risk, comparable inconsistencies exist that were not pointed out by EPA.

EPA has concluded that in epidemiological studies, inconsistencies are always present, due to one or more confounding factors. Because of this and as noted in the preamble and EPA's Statement of Basis and Purpose, EPA did not rely upon the epidemiology studies as a basis for the regulations. Rather, they have been found to support the hypothesis, as Dr. DeRouen noted, that some relationship may exist between cancer risk and chloroform in drinking water. EPA's conclusions based on animal studies are justified.

(2) Dr. DeRouen said that correlational studies are the crudest kind of epidemiology investigation and their results should be used to suggest more definite studies. However, they are not considered accurate enough for decision-making.

EPA believes that since several of the individual correlational studies when evaluated collectively suggest that chloroform in water poses a risk, the hypothesis is strengthened. Drs. Upton and Schneiderman of the NCI supported this conclusion and suggested that reducing TTHM concentrations by 100 micrograms per liter could lead to a decrease in cancer rates of up to 7.5% in men and 10% in women for bladder cancer and between 7.5% and 8.5% in large intestinal cancer for women and men, respectively, assuming the validity of one of the studies.

(3) Dr. DeRouen also commented that the epidemiological studies did not adequately adjust the data for confounding variables such as urbanization and industrialization. He noted that in a recent study where additional variables were considered, the statistical significance "dissipated" relative to GI and urinary tract cancers.

As noted previously, taking into account the multitude of interplaying factors in epidemiology studies is a complex problem. EPA has carefully evaluated the available study results, and taken collectively, they generally support the hypothesis of the risk of chloroform in drinking water. The commenter's concerns that the impact of several variables "dissipated" when re-examined may be valid but these issues do not vitiate the basis of the regulations. EPA's finding that chloroform may pose a carcinogenic risk to humans is based primarily upon animal toxicity studies.

(4) Dr. DeRouen noted that the epidemiological studies would have more credence if the health effects were uniformly distributed over all race-sex groups, but that this was usually not the case in the drinking water/organics studies.

EPA believes that it is not necessary to have a uniformly distributed effect over all race-sex groups, although when this is the case conclusions can be more strongly supported. Rarely in even well-controlled experimental studies are the effects uniformly distributed among sex groups even in in-bred strains of test animals.

(5) Dr. DeRouen stated that unexpected and unlikely statistically significant correlations were reported for some cancer sites, and significant relationships were not seen in humans for liver or kidney cancers, which were the effects seen in the animal tests.

EPA believes that site-specific cancers are not necessarily observed across species. This was supported by Drs. Upton and Kennedy of NCI and FDA, respectively.

(6) Dr. DeRouen commented that in many studies, the presence of statistically significant results would change depending upon the statistical or analytical model selected. In general, therefore, the statistical methods are usually specified in the protocol before performing the study.

EPA agrees with this comment and it is supported by Dr. Hoel from NIEHS. The epidemiological studies cited were correlational, preliminary and hypothesis generating, rather than case-control or prospective in nature. It is therefore expected that further studies could be designed based on those already conducted which could be more definitive. EPA has pointed out many of these same problems in its evaluation of the epidemiological studies in the preamble accompanying the February 9, 1978, proposal, and EPA's Statement of Basis and Purpose as did the NAS, Safe Drinking Water Committee, in its review of the studies. The primary basis for the regulations is the animal toxicology studies including the NCI bioassay results demonstrating that chloroform was an animal carcinogen under conditions of the test. EPA has concluded that the epidemiological studies conducted so far are sufficient hypothesis-generating studies, and taken as a whole are supportive of the animal data in pointing out the possible human risk. The pros and cons of the studies are discussed in more detail in the Agency's Statement of Basis and Purpose for these regulations.

64. Dr. F. J. C. Roe, representing the Coalition for Safe Drinking Water, submitted written and oral comments. He also submitted copies of his recent studies on chloroform carcinogenicity. His major points and EPA's responses are as follows:

(1) Dr. Roe stated that regulatory contexts usually do not distinguish between highly dangerous cancer-causing agents and those such as chloroform for which the evidence is equivocal.

EPA has concluded that the SDWA directs EPA to protect the public health from any contaminant which "may have any adverse effect" on human health. Nevertheless, EPA evaluated the risk of exposure to chloroform to the general population based on its toxic effects, cancer potential and exposure potential. Chloroform has been found to be an

animal carcinogen with well known acute and chronic effects. Its presence in treated finished drinking water potentially exposes over 100 million people over their lifetime. EPA believes this to pose a substantial risk.

(2) He stated that the NCI bioassay was faulty because it erroneously used corn oil as the vehicle for administering chloroform to the test animals, not enough control animals were used, and concommitant exposure to other carcinogens occurred. He urged that prior to setting an MCL, the study should be repeated in a wider dose range and under better controlled conditions.

Although additional studies taking into account the above objections may lead to slightly different responses one way or the other, EPA believes that the findings of carcinogenicity would remain unchanged in light of previously reported studies on other carcinogens and the statistically significant results obtained in the NCI chloroform bioassay. EPA is sponsoring a study that takes into account Dr. Roe's suggestions. However, it would not be prudent to delay setting an MCL for TTHMs pending refinement of the data, given the existence of credible data to date demonstrating an adverse health risk.

(3) Dr. Roe stated that the Theiss (pulmonary adenomas) study produced erroneous statistical results.

As stated in the Statement of Basis and Purpose, EPA did not rely on the Theiss study to reach its conclusions. The study was only included as background information to the published positive results.

(4) Dr. Roe said that the four principles of the NAS (1977) and the non-threshold risk concept for carcinogenesis are not scientifically sound.

As discussed previously, EPA relied upon the judgment of the National Cancer Institute who commissioned and evaluated the bioassay of chloroform in rats and mice and concluded that significant rates of chloroform-related tumors were detected in both rats and mice under conditions of the test. The National Academy of Sciences in "Drinking Water and Health" (1977) concluded that chloroform had been shown by those and other studies to be an animal carcinogen and, as such, should be considered a risk to humans. Other studies sponsored by EPA are underway further refining our knowledge of the toxicology and carcinogenicity of chloroform, which may provide more information on dose-response relationships.

Federal health regulatory agencies have carefully considered various approaches for dealing with potential human carcinogens and the possible presence or lack of thresholds for carcinogens. These agencies have concluded as a matter of policy that in the absence of evidence to the contrary it must be assumed that substances that have been shown to be animal carcinogens in properly conducted tests, must be assumed to be potential human carcinogens, and that threshold exposure levels below which there would be no risk have not been demonstrated experimentally.

Drs. Upton, Kennedy, Bingham, King and Bates/Hoel of NCI, FDA, OSHA, CPSC, and NIEHS, respectively, supported EPA and these principles enunciated by the NAS.

(5) Dr. Roe also submitted results of three additional mouse studies that were conducted on chloroform along with his written comments.

In the first of these studies, the mice of an outbred Swiss albino strain (ICI) were given daily (six days per week) oral doses of 17 mg/kg or 60 mg/kg chloroform in tooth paste base for 77–80 weeks. The animals were observed for an additional 16 weeks. Twenty-two percent of the high dose males developed adenomas or hydronephromas of the kidney. In the second study male mice of the same strain responded similarly, with 18% of the high dose having histologically the same tumors.

In the third mouse study, the response of the male mice of four strains were compared. In each of the four strains, 52 male mice were given 60 mg of chloroform per kilogram (six days per week) using the same experimental design as previously outlined. As in the previous experiments, mice of the ICI Swiss strain developed more kidney tumors than did the vehicle control mice. No excess tumors were found in the remaining three strains.

Dr. Cipriano Cueto (representing the National Cancer Institute) stated to the National Drinking Water Advisory Council (1978) that Dr. Roe's results were entirely consistent with the NCI studies. Dr. Cueto also said that the results of other studies relied upon by Roe using rat and Beagle dog study were also not surprising based on the doses administered and the previous NCI results.

(6) Dr. Roe calculated that a 70 kilogram man consuming one liter of water containing 100 ppb of chloroform would have a 7,000 fold safety factor. Dr. Roe assumed that the mouse was the most sensitive animal model and that 10 mg/kg was the "no effect level" for kidney tumor enhancement.

As discussed previously, the EPA has found that thresholds for carcinogens have not been sufficiently demonstrated and that this type of calculation therefore contradicts that policy and does not take into account many of the principles enunciated by the NAS. Thus, EPA has rejected Dr. Roe's approach as unacceptable for regulating carcinogens in drinking water.

(7) Dr. Roe also stated that it was "reasonable to assume that none (of the THMs) is more active than chloroform itself," and, therefore, a level of 300 ppb for chloroform alone would be as protective as a similar limit for all THMs as proposed by EPA. However, Dr. Roe did not present any scientific facts or principles to support his statement that other THMs are less potent than chloroform.

As discussed earlier, EPA has found that *in vitro* mutagenicity data indicate that the other THMs are more active mutagens than chloroform. EPA's regulation of total THMs has also been based upon the similar chemical structures and expected biological activity, of all THMs, the availability of analytical methods that analyze for total THMs, and the fact that all THMs are produced as a result of disinfection practice.

(8) Dr. Roe stated that animal detoxification mechanisms were overwhelmed by the administration of very high doses of chloroform in the animal studies. He based his comment on the following observations:

(1) Females of the species did not appear at risk.

(2) Ames type assays were negative.

(3) Tumor formation was dependent upon an indirect mechanism which involved both sex hormone status and a deviation from normal metabolic breakdown pathways.

In EPA's opinion, there are many experimental conditions under which one sex or the other is more sensitive to the compound under test and therefore this difference in the results is not surprising. The *in vitro* assays of the Ames type have been shown to be insensitive to certain chemical classes; simple chlorinated hydrocarbons appear to be one of these chemical classes. Dr. Roe presented direct evidence to support his third hypothesis; however, other studies have shown a relationship between chloroform toxicity and testosterone levels in animals.

(9) Dr. Roe asserted that consistent increased survival of three different species exposed to chloroform suggested a beneficial effect.

EPA has carefully reviewed the available data and EPA does not believe

the evidence is sufficient to support this contention.

64. Dr. Arthur Furst, representing the Coalition for Safe Drinking Water, submitted comments, many of which are similar to those detailed previously. His comments and EPA's responses are set forth below:

(1) Dr. Furst commented that the NCI chloroform bioassay was not definitive, that results from animal studies using high dosages (100,000 ppb) cannot be extrapolated to predict human health effects at low dosages (100 ppb), and that human risks cannot be extrapolated from animal data. These comments have been responded to elsewhere in this Appendix.

(2) He also faulted EPA's risk assessment for not following the sigmoid curve which he claimed should represent the dose-response that one would expect from biologically active compounds. EPA has found that the dose-response curve for carcinogens would not be expected to be represented by a sigmoid curve. Rather a linear non-threshold curve is believed to be appropriate in assessing a health risk from carcinogens. Carcinogenic, reversible, or non-reversible progressive chronic response are not "all-or-none" responses, nor do they lend themselves to easily definable criteria for categorizing the biological response. Therefore, carcinogenic responses do not satisfy the conditions upon which use of the sigmoid curve is based.

(3) Dr. Furst also claimed that there is a threshold for carcinogens, and that the histological type of tumors produced in the experimental animals was not related to the human tumor response.

As discussed previously, EPA's policy with respect to risk assessment for potential carcinogens is to include the conservative linear-dose response curve and not a carcinogenic response threshold level so as not to underestimate potential risks. With regard to the type of tumors in animals versus human tumor responses, EPA has concluded that the animal toxicity studies can be related to man irrespective to differences in tumor sites. This is supported by Drs. Upton, Kennedy, Bingham, King, Bates and Hoel of NCI, FDA, OSHA, CPSC, and NIEHS, respectively.

(4) Dr. Furst claimed that release of benzo(a)pyrene could be a factor to be considered when GAC treatment is used. He questioned the use of GAC, claiming that the treatment of water by GAC may be replacing THMs with more potent carcinogens such as benzo(a)pyrene.

EPA has evaluated the available studies involving extraction of GAC with distilled water and the total level of PAHs in the effluent were found to be insignificant.

(5) Dr. Furst suggested that a time to tumor experimental design be undertaken using multiple dose levels. EPA is currently proceeding with additional tests. However, regulatory action need not await the outcome to such studies.

(6) Dr. Furst stated that carcinogens in the environment can interact, thus modifying each others' responses. He stated that there is no association between organic chemicals in New Orleans drinking water and cancer rates.

EPA agrees that synergistic interactions between toxic chemicals can occur which is all the more reason to consider approaches that will reduce human exposures where feasible. The association between New Orleans drinking water and increased cancer rates has been suggested by epidemiology studies but is far from conclusive. EPA's discussion of the epidemiological studies is set forth elsewhere in this Appendix, in the preamble, and in EPA's Statement of Basis and Purpose.

(7) Dr. Furst objected to the conditions under which the NCI bioassay was carried out. He felt that a single massive dose by oral gavage does not compare with a minute fraction of the dose ingested throughout the day. The doses used in this bioassay overwhelmed the ability of the liver to detoxify the THMs. EPA has concluded that high dose animal studies are necessary and valid methods of determining risks from human exposure at lower doses.

These questions are more fully addressed elsewhere in this Appendix and in the Statement of Basis and Purpose.

65. Comments submitted by Dr. Frank L. Lyman on behalf of the Coalition for Safe Drinking Water and EPA's responses are as follows:

(1) Dr. Lyman commented that the 100 ppb level for TTHMs is unnecessarily restrictive.

As discussed thoroughly in the Statement of Basis and Purpose, EPA believes that human exposure to carcinogenic chemicals should be minimized to the extent feasible. The level of 0.10 mg/l TTHM in this interim regulation is based upon technological and economical feasibility in that the level is achievable and is consistent with the SDWA mandate to reduce exposure to contaminants in drinking water to the extent feasible, taking into consideration the potential health risks.

(2) Dr. Lyman stated that the possible benefits of GAC are unknown and GAC itself may have harmful effects on water quality.

The questions of benefits and release of harmful chemicals have been addressed previously in this Appendix. Data to date do not support the speculation that there are adverse effects from GAC use.

(3) Dr. Lyman noted that chloroform has been found in tomatoes, grapes and milk and is also produced in food processing. He urged that the total body burden must be considered in regulating chloroform.

As discussed previously in this Appendix and in the Statement of Basis and Purpose, EPA has examined several exposure routes of chloroform and feels that regulations controlling chloroform in drinking water are necessary since water can be the most significant source of exposure under typical conditions.

(4) Dr. Lyman commented that, in spite of wide-spread chronic industrial exposure to chloroform, there is no evidence of human carcinogenesis.

The unavailability of occupational risk data showing a precise relationship between exposure to chloroform in the work place and human carcinogenesis does not mean that chloroform poses no risk to humans. Systematic and scientifically sound studies have not yet been conducted to evaluate the possibility. However, in view of the positive carcinogenic response in the animal studies, EPA feels that regulations are appropriate at this time. This will result in reduced human exposure to many disinfection by-products, not only chloroform and THMs.

(5) Dr. Lyman stated that animal studies are useful in comparing effects on laboratory animals to human toxicity. EPA concurs with the use of animals in evaluating toxic effects of chemicals. EPA believes that carcinogenicity is one of several end points of toxicity and the statement by Dr. Lyman presented below also applies to the carcinogenic effect: "The toxicologist uses lower animals to predict the effects of chemicals on humans. Generally, the toxicity of a compound in lower animals is similar to that in humans on a dose per unit of body weight, particularly if the metabolic pathways and detoxification mechanisms are similar." Thus, EPA believes that cancers produced by chemicals in animals are evidence of human risk. Drs. Upton, Kennedy, Bingham, King, Bates and Hoel of NCI, FDA, OSHA, CPSC, and NIEHS, respectively, support this belief as presented in Appendix B.

(6) Dr. Lyman criticized EPA's use of the results of animal studies exposing them to high dosages to extrapolate

human health risks associated with exposure to low dosages on the grounds that high dose exposures were more likely than low doses to cause tissue damage which he claimed was a prerequisite to cancer introduction by chloroform. In support of his argument, he noted that high doses of liver and kidney toxins cause cancer to develop in those organs. He concluded that because lower dosages were less likely to damage tissue, they were also less likely to result in the development of tumors.

EPA does not agree with Dr. Lyman's hypothesis that tissue damage is necessary for cancer induction. The scientific community has not yet reached a consensus on this point. There are chemcials that cause the kind of tissue damage Dr. Lyman describes that do not go on to cause cancer (i.e., 1,1,1-trichloroethane). Thereby, tissue damage does not invariably lead to a carcinogenic response. Therefore, it is prudent and consistent with current scientific thought to assume that low level exposure to carcinogens, which may or may not cause direct tissue damage poses a human health risk. FDA, CPSC, NIEHS, NCI, and EPA agree that site-specific cancers are not necessarily found across species.

(7) Dr. Lyman also said that thresholds for carcinogens exist.

EPA believes that thresholds for carcinogens have not been experimentally demonstrated to date. This is thoroughly discussed in the preamble and in response to previous comments.

(8) Dr. Lyman commented that in order to produce tumors in people it would require drinking 15,000–30,000 gallons of water daily with a concentration of 311 ppb to produce tumors in humans.

EPA has evaluated this estimate and has concluded that the direct comparison of dosages from animals to humans in this way neither scientifically valid nor relevant.

(9) Dr. Lyman noted that one must differentiate between a real and potential risk.

EPA believes that sufficient information has been presented to demonstrate a risk from THM exposure that reduction of that risk is feasible and regulation is warranted and required by the SDWA.

66. Comments submitted on behalf of the Coalition for Safe Drinking Water by Farrel R. Robinson and EPA's responses are as follows:

(1) Dr. Robinson said that surveys of drinking water in various cities did demonstrate the presence of THMs but there were no realistic historical data with which these levels could be compared; the available epidemiological data are unreliable.

EPA is relying primarily on the animal toxicity data as the basis of the regulation. The correlational epidemiology is not inconsistent with this data, and assuming that similar raw water quality and chlorine dosage have been used over previous years which is a reasonable assumption in most cases, THM levels would not be significantly different.

(2) Dr. Robinson commented that there are significant problems in interpreting animal data and extrapolating their results to humans.

This has been responded to in detail above and in the preamble and Statement of Basis and Purpose.

(3) Dr. Robinson said NCI bioassays are only applicable to that strain of animals under the conditions of testing.

EPA believes that properly conducted studies in test animals do provide evidence of potential human risks from those chemicals. This is thoroughly discussed elsewhere in this Appendix, the preamble and the Statement of Basis and Purpose.

(4) Dr. Robinson commented that there is a threshold for carcinogens. He claimed that threshold cancer response extrapolations are contrary to scientific fact.

EPA believes that thresholds for carcinogens have not been demonstrated at this time. This is discussed in detail in the preamble, this Appendix and in the Statement of Basis and Purpose.

(5) Principles enunciated by the NAS are not principles but opinions.

EPA has relied on the NAS as representing the consensus of scientific opinion on these subjects.

67. Comments submitted by Dr. Alexander Grendon on behalf of the Coalition of Safe Drinking Water were as follow, that:

(1) EPA has not balanced costs against benefits for GAC. He stated that the costs were enormous while the theoretical benefits are minor.

(2) That there is a threshold for carcinogenesis.

(3) That cancer death rates have been declining for 25 years.

(4) That a person would have to live 74 years before a tumor would develop due to chloroform exposure.

(5) A person would have to live 35 lifetimes before dying from chloroform induced cancer.

Most of these comments has been addressed previously in this appendix and in the preamble. In regards to the time-to-tumor question, EPA feels that the state-of-the-art of toxicology does not provide for estimates such as those Dr. Grendon submitted. Rates of some types of cancer have declined but other types have risen in the past 25 years.

68. Comments submitted by Dr. Richard Reitz, representing Dow Chemical Company, and EPA's responses are as follows:

(1) Dr. Reitz commented that the use of GAC for organic chemical removal may release chemicals into treated waters that are carcinogenic. EPA has responded to this comment elsewhere in this Appendix.

(2) Dr. Reitz criticized EPA's use of the most conservative model for assessing human risk which he said greatly overestimated the risk of trace levels of organic chemicals in drinking water. He said that NCI should develop two separate risk extrapolation models, one for direct-acting carcinogens and another for metabolically model activated carcinogens. He commented that the extrapolation developed by Dr. David Rall and used by EPA's Cancer Assessment Group (CAG) was not appropriate for THMs since THMs are not direct-acting carcinogens but are carcinogens generally "involved in the variable drug metabolizing system," for which that model was not designed.

In support of his argument that EPA used an inappropriate risk model, he cited inconsistencies between the mouse and rat data in the NCI study. He noted that although based on the model one would have expected rats to be more sensitive to chloroform than mice, even though metabolism was required to activate chloroform, the opposite results were obtained. He therefore concluded that EPA's model overestimated the risk to rats by eleven-fold and overestimated the risk to humans by an even greater margin. Using pharmakokinetic data, Dr. Reitz predicted that the "chloroform risk" was one order of magnitude lower than that estimated by EPA.

EPA recognizes that other risk estimation models exist. Depending upon various assumptions, the computed levels can be significantly different among models. EPA has relied on the scientific expertise in the area of risk assessment of the NAS and EPA's CAG for its risk models which are considered to be state-of-the-art. While these models may be more conservative than Dr. Reitz's model, EPA believes that this was a reasonable and responsible choice in view of the SDWA's mandate to protect the public health.

EPA further found that the NAS–CAG models were appropriate for use for chloroform based on the best scientific evidence available. The fact that the results from the rat studies showed them to be four times less sensitive to

chloroform than mice does not mean that the data cannot be used for human risk extrapolation. Species variability in cancer inductions mechanisms could be an explanation for this apparent inconsistency.

(3) Dr. Reitz stated that the doses of chloroform used in the NCI study produced gross liver damage long before the production of tumors. Thus, he said it was impossible to determine whether the carcinogenicity of chloroform was due to a genotoxic reaction or simply a secondary reaction to the extensive liver and kidney necrosis (i.e., epigenic).

As discussed previously, EPA feels high dosage tests are necessary and valid. EPA believes that large doses over long periods of time are required to produce effects in relatively small populations of animals and to increase the experimental sensitivity. The NCI, FDA, CPSC and NIEHS have concurred with this conclusion.

Moreover, one cannot conclude that the use of high dosages in animal experiments means that the resulting carcinogenicity is attributable solely to a toxic assault on the organ. Rather, toxic assaults leading to organ damage do not always evoke a carcinogenic response. Therefore, the particular chemical, in this case chloroform, must also be implicated as a factor when a carcinogenic response is found.

(4) Dr. Reitz commented that since chloroform belongs to the class of chemicals which require metabolic activation for toxicity, one would expect the incidence of oncogenicity to be greater in those species with greater capacities to metabolize the chemical. Dr. Reitz assumed that the metabolic capability of rats was greater than mice and that of humans was greater than rats. He also postulated that glutathione availability was the limiting factor in the rate of macromolecular binding (a factor hypothesized as being a critical step in carcinogenicity).

Since more glutathione was expected to be available after lower dose exposures, Dr. Reitz argued that the chemical's carcinogenic potential at low dosages would be lower than if exposure had occurred at higher dosages. Based on these assumptions, he concluded that the human risk for chloroform was 71 times less than that estimated by CAG. Dr. Reitz said his calculations would result in an MCL between 0.01 mg/l and 0.1 mg/l for incremental risk of 10^{-6} and 10^{-5}, respectively.

EPA does not agree to with Dr. Reitz's assumptions. His hypothesis concerning glutathione availability as a limiting factor in cancer induction has been shown not to be valid in tests using other similarly metabolized carcinogens at low exposure levels. Despite the differences between Dr. Reitz's and EPA's risk estimates, no specific risk value served as the basis for EPA's TTHM MCL, which was based upon technical feasibility factors.

(5) Dr. Reitz cited a study whereby chronic industrial exposure (50–125 ppm) of British Confectionary workers to chloroform for up to 10 years twenty years ago did not produce convincing epidemiology to link chloroform with increased cancer risk. EPA recognizes the difficulties involved with conducting epidemiology studies and this subject has been addressed previously.

(6) Dr. Reitz recommended the following changes be incorporated into the proposed THM regulation:

(a) That the MCL should be increased to 1.0–10 mg/l based on health effects data and risk models.

The MCL was based on a positive qualitative findings of carcinogenicity from animal bioassays and not on any quantitative risk extrapolation. The MCL for chloroform is that level which can be achieved given technological and economic feasibility factors.

(b) That definitive interspecies metabolism studies be carried out to allow a rationale species/species extrapolation. EPA agrees that this would provide additional information and has additional studies underway. However, regulatory action need not await the outcome of such studies.

(c) That a complete evaluation of the chloroform carcinogenicity potential below 200 mg/l be conducted. More research can always be conducted. EPA has an ongoing carcinogenicity study to evaluate chloroform at low levels of exposure. Again, regulatory action need not be delayed.

69. Dr. Joseph Schlosser, of Tulane Medical School, stated that:

(1) Bronchiogenic cancer should not be related to the Mississippi River and drinking water.

(2) The petrochemical industry could be the cause of increased cancer in Southern Louisiana.

(3) There is no consistent thinking about what the reason is for the high incidence of cancer in the New Orleans area. EPA's conclusions regarding the human epidemiology data, including that involving New Orleans, has been discussed elsewhere in this Appendix, in the preamble, and in the Statement of Basis and Purpose.

70. Three commenters said that separate MCLs should be set for each THM, such as chloroform, instead of for total THMs. One of these said that MCLs should only be established for those specific contaminants proven to be human or animal carcinogens. It was argued that, while all THMs were included in the proposed standards, only chloroform has been shown to produce a dose-response relationship for epithelia tumors of the kidney and renal pelvis in the rat and for hepatocellular carcinomas in mice. The other commenters felt that if standards were set for the THMs, concentrations of all THMs should be converted to the same base such as milliequivalents because grouping THMs on a weight basis and expressing the total THMs as mg/l was scientifically incorrect.

EPA's rationale for establishing a MCL for total THMs, instead of for only chloroform or for each THM separately, is set forth in greater detail in the preamble to these regulations and commenters are referred thereto. Although less is known about the health effects of the other THMs than about chloroform, EPA believes that carcinogenicity need not be proven before regulatory action may proceed. Based upon the similarity in chemical structure of all the THMs and the best available information on the health effects of the other THMs, EPA believes that they, as well as chloroform, pose adverse health risks which should be minimized to the extent feasible. It is also reasonable to regulate total THMs as a group because the gas chromatographic analytical method concurrently analyzes all four THMs; also treatment methods that would be employed to reduce chloroform would simultaneously reduce all of the THMs, since they are all formed through the use of chlorine in the disinfection process.

On the question of the use of milliequivalents instead of milligrams, EPA does not believe that such an approach would necessarily be meaningful since insufficient information is available to judge the relative potency of the four THMs to warrant that approach. Moreover, milligrams per liter have been used as the standard measurement for other drinking water MCLs in the NIPDWR and this term has become familiar to the water utilities that must comply with such standards.

71. In addition to those comments previously discussed, 136 comments were received discussing other issues related to sampling and monitoring for TTHMs. Of these, 43 commenters said they supported the sampling and monitoring requirements in the proposed regulations and found them to be adequate and reasonable. Many of these commenters, however, felt that EPA or the States should conduct or pay for the analyses. Seven commenters opposed

the monitoring program because of the added cost burden on utilities and noted the lack of laboratory facilities and skilled personnel. Fifty-one comments favored the monitoring requirements but opposed any requirement to notify the public of such results on the grounds that the public notification requirement would create unnecessary, expensive paper work as well as a "bad-feeling" among the public. One commenter felt that the reporting of THM monitoring data to EPA by utilities should apply only to States that are qualified for primacy.

EPA has already responded in this Appendix to those comments addressing the cost of monitoring. Under the SDWA, the cost of compliance with these regulations must be borne by the water utilities and EPA has taken this factor into consideration in determining minimum monitoring frequencies and has found that such costs are reasonable. With respect to public notification of the results of TTHM monitoring, Section 1414(c) of the SDWA requires that systems notify the public of any failure to comply with an applicable MCL as well as any failure to perform required monitoring. EPA does not believe that the costs of such public notification are unreasonable and any public notice may include appropriate explanation so that the public is adequately informed, but not misled.

The results of all monitoring are required to be reported to the States so that compliance with the regulations can be properly enforced and technical assistance can be provided to correct problems at the earliest possible time. Systems are also required to report results to EPA until such requirements are adopted by the States with primacy.

72. Twenty-four additional commenters raised questions regarding laboratory capabilities, quality assurance of results, and sampling and analytical procedures. They commented about the lack of qualified and experienced laboratories in the U.S. to perform TTHM analyses and about the fact that analytical procedures were not very well defined. They urged that the laboratory certification process be expedited and the analytical procedures be defined as soon as possible.

On the issue of the availability of laboratory facilities and analytical procedures, EPA has responded to those commenters concerned about the availability of sufficient numbers of laboratories capable of providing acceptable analytical data by extending the time frame for initiation of monitoring by systems serving more than 75,000 people from the proposed three months after promulgation to one year after promulgation. The 10,000 to 75,000 size category of systems are given 3 years from promulgation to begin monitoring. This will allow additional time for State and private laboratories to develop their capabilities and to become certified by EPA to provide data in support of compliance determinations. A quality assurance and certification program is also being developed by EPA, to determine the capable laboratories and to insure the reliability of data.

73. One commenter noted that EPA had failed to quantify the contribution of industrial and municipal discharges to the total concentrations of THMs and their precursors. EPA was urged to control THMs and precursor materials at their source; much of the THM in drinking water could be eliminated by not permitting any industrial or municipal discharges of THMs or THM precursors.

While THMs do occur in some drinking water sources as a result of municipal and industrial discharges, EPA has found that such levels are generally significantly lower than the levels associated with chlorination by-products in the finished drinking water. Most THMs in drinking water are the result of the reaction between chlorine and natural precursor compounds in the treatment process. Therefore, in most cases, control of THMs or precursor compounds municipal or industrial discharges would not likely have any significant effect upon THM levels in the drinking water.

74. One commenter noted that because of the inaccuracy and imprecision inherent in the analytical procedure for measurement of THMs, the MCL should include an allowance for the variations in analytical results.

Although EPA has established a single numerical value for the TTHM MCL, the variabilities associated with the analytical procedures have been taken into account in determining what laboratories will be deemed qualified for performing TTHM analyses. EPA has determined that 20% of 0.10 mg/l TTHM will be an allowable variation in the analytical results for purposes of laboratory approval and certification. Recent data show variations in properly run procedures of 10% to 20% and it is expected that as more experience is gained, the allowable variation will be reduced. Thus, while it is necessary to establish a single MCL value, quality control of laboratories is believed to be the most appropriate way of taking into account analytical variability.

Appendix B—Summary of Major Comments (for responses, see Appendix A)

I. Coalition for Safe Drinking Water

A. Introduction

The Coalition for Safe Drinking Water is a group of approximately 90 water systems—both investor and municipally owned—formed to present information and comments concerning EPA's proposed regulations.

The Coalition's doubts and disagreements about the substance of the proposed regulation centered upon EPA's conclusions that:

(1) The trace amount of THMs normally found in drinking water may pose a health risk, and,

(2) The GAC treatment technique is, at this time, required to reduce the levels of THMs in drinking water.

The Coalition also doubted EPA's authority to propose these new requirements as "amendments" to the interim primary drinking water regulations.

B. Legal Issues

1. EPA lacks the authority to promulgate the regulations as amendments to the National Interim Primary Drinking Water Regulations. The regulations are entirely new regulations and not modifications and to propose these regulations requires recommendations from NAS. The NAS has not made this recommendation. Further, the GAC technology was not available in December 1974 and all exemptions for water systems to avoid hardship will end on January 1, 1981.

C. Health Issues

1. Chloroform poses no potential cancer risk and there are no available data that support the premise of a causal relationship between the concentrations of THMs normally found in drinking water and cancer in humans.

2. The epidemiological studies that have been conducted concerning drinking water and a possible connection with cancer in humans are inconclusive.

3. EPA has relied upon animal studies for the hypothesis that trace organics pose a health concern. However, extrapolation of results in animal cancer studies to humans is fraught with its own set of problems and uncertainties.

4. The proposed regulations are based upon fear of the unknown using equivocal animal data and extrapolation models and methods which are unreliable.

5. The study cited by EPA to support the carcinogenicity of chloroform was "a preliminary screening test (by the

National Cancer Institute (NCI)) and not a definitive study." The study was not intended to be used to extrapolate health effects of chloroform to drinking water levels. The NCI study was inadequately controlled and did not follow proper scientific protocols. A new EPA/NCI study is underway and corrects deficiencies of the previous study and it is recommended that the implementation of any regulations be delayed until the studies are complete.

6. Dr. Roe's studies showed a no observed effect at 595,000 (drinking water equivalent) ppb chloroform in drinking water. Dr. Roe recommended a level of 300 ppb THM in drinking water based upon his studies of chloroform. Dr. Francis J. Roe's study with chloroform on dogs, rats and four strains of mice at low dose levels does not produce tumors in animals. Three hundred ppb would provide a margin of safety of 2,000. However, EPA uses 500 as a margin of safety.

7. EPA's proposed MCL of 100 ppb is needlessly low and will require costly additions or changes to water treatment facilities without any corresponding benefit being obtained.

8. There are no health effects data which support carcinogenicity of the other THMs.

9. Based upon most appropriate statistical extrapolation model, the level of the THM MCL should be no lower than 0.30 mg l since this provides a more than adequate margin of safety. However, this level is still too low to be justified on a cost-benefit basis if GAC is required.

10. There is no hard evidence that low level exposure to any of the chemicals produces cancer.

11. EPA estimates of environmental exposures to chloroform appear to be erroneous and it is suggested that EPA make every effort to obtain correct values for contributions from air, food and water. Also, there is the possibility that *in vivo* formation of chloroform and other THMs in the human body may occur. At this point, the available data suggest that more cost-effective avenues, such as control of chloroform in the work place, may be available for reducing THMs in the environment than by implementing the proposed THM MCL.

12. The concentrations of THMs detected in water systems present no mutagenic, teratogenic, or acute, subchronic, and chronic toxicological health risk to the public.

13. EPA has misconstrued the four very general "principles" stated by NAS. EPA has not properly used these principles and has ignored the available data. With regard to the first principle, EPA has not taken into account a number of variables in extrapolation of the animal data to humans; some of these variables include differences in such items as species response to carcinogens, weight between animals and man, intake of food and water, and routes of exposure. With regard to the second principle, EPA has ignored existing scientific data that show a threshold for no-effect responses with respect to a number of suspected carcinogens; there are a number of suspected carcinogens for which animal experiments have established a threshold level of effects; experiments involving humans suggest a no-effect level exists for chloroform; *in vivo* biological processes militate in favor of a no-effect level; and human exposure to natural carcinogens without adverse health effects support thresholds. With regard to the third principle, EPA has not considered the significance of the detoxification and repair mechanisms operative in animals and humans in its health assessment of THMs. With regard to the fourth principle, EPA has ignored the guidelines for assessing risk for chloroform as set forth in EPA's "Interim Guidelines for Carcinogen Risk Assessment." EPA used only the linear model for extrapolating the NCI data to humans, ignored the data of Roe, Eschenbrenner, and Miller, and ignored the estimates of risk by Tardiff using the "margin of safety," "probit-log" and "two step" extrapolation models.

14. EPA has ignored the relationship between dose and time-to-tumor observation in assessing the health risk of a carcinogenic material.

D. Treatment Technology and Economic/Energy Assessments

1. GAC has never been tested or proven on a full-scale operation in the United States and therefore constitutes a nationwide experiment for water treatment.

2. The use of GAC will have substantial financial impact upon water supplies and actual costs are very difficult to predict and are understated. For example, the average capital cost for a system serving over one million people will exceed $106 million with annual costs of more than $23 million. Rate increases for residential customers could be in the range of 40–70% and these rates could double where there are specific problems, such as land acquisition. These costs may result in insurmountable problems for some utilities in obtaining financing for GAC treatment facilities. EPA's assessment of the feasibility of financing the GAC treatment facilities is totally out of step with the realities of both the financing markets and operating needs of the public utilities.

3. The regulations will promote substantial new consumption of energy in operation of the treatment technologies as well as in secondary energy consumptions such as energy usage for GAC regeneration or energy associated with the manufacture and transportation of GAC.

4. The economic impact assessment did not take into account the costs of treating wastewater from GAC operations, such as backwash waters, wet scrubbers and drainage from carbon slurries. It is estimated that 50,000 gallons of waste water will be generated for every one million gallons of drinking water treated and half of that amount will need to be discharged. This will result in increased flows and higher O&M costs at municipal waste water treatment facilities on the order of four percent.

5. The costs were underestimated because of specific factors in the analysis. Based upon the use of GAC, the difference between their potential national cost estimates and EPA's estimates could be explained primarily by four factors (It was not clear to what extent these comments differentiated between costs for GAC for TTHM control and costs for GAC to control other synthetic organic chemicals in the separate treatment technique requirement):

(a) EPA determined its estimated capital costs for a system based upon the capacity of the entire system; whereas, the coalition estimated the system capital costs as equal to the sum of the capital costs for each treatment plant based on the capacity of each plant.

(b) EPA's estimates were based upon the system capacity on the average day of the peak month; whereas, the coalition's estimates were based upon the actual capacity of each treatment plant.

(c) EPA assumed that some of the affected systems would design facilities for a 9-minute empty bed contact time (EBCT); whereas, the coalition assumed that all GAC facilities would be designed for an 18-minute EBCT.

(d) The coalition's estimates for specific systems, based on the costing out of the individual components, were 30–80% higher than EPA's proposed estimates.

6. EPA has underestimated the costs of implementing the regulation by underestimating the number of impacted systems. This is the result of basing the analyses upon a model for the water supply industry and using a number of unfounded assumptions regarding the

number of systems that purchase water and use alternate disinfectants. Also, assumptions and predictions based upon NOMS were used to determine the level of THMs and the extent to which systems would be impacted further. Instead, EPA should have conducted sampling at all systems and based its estimates upon those results. The estimate of the 390 systems serving greater than 75,000 persons was not derived from EPA's Inventory of Systems but was based upon the TBS Policy Testing Model which left out numerous systems including all Federal Systems (e.g. District of Columbia) and the States of Hawaii and Alaska. Also, the hypothetical results of the TBS Model were never checked on to compare with reality. Finally, the number of systems using specific treatment systems such as GAC or no cost modifications were arbitrary assumptions.

7. EPA should provide a cost estimate of the stated goal of lowering the MCL at a later time to 50 ppb or 10 ppb.

8. The financial implications on water utilities have been underestimated by EPA. The financial analysis assumed that the rate increase required to finance the necessary revenue requirements would be obtained easily. Also, projections of future capital requirements in addition to the cost of the GAC process for various water systems were not factored into the analysis.

9. In order to install GAC, water utilities will need to raise capital through large rate increases. There are substantial regulatory barriers which could preclude water utilities from obtaining the necessary rate increases. Even if utilities are able to raise the capital funds, the quality of their credit and the attractiveness of their common stock will be severely reduced; this will reduce their ability to obtain external financing for normal water supply activities.

10. The GAC treatment process may result in serious problems and these may outweigh the alleged environmental benefit associated with GAC treatment. These problems include potential air pollution from regeneration and the waste water associated with GAC from contactor disinfection, backwashing, GAC quenching and transport, drainage from carbon slurries, and the regeneration furnace scrubbers. The total volume of waste water resulting from GAC facilities will be approximately 43,000 gallons per million gallons of water treated. Some of the waste water can be recycled but some will require pretreatment prior to disposal.

11. The use of GAC may constitute a larger health hazard than that of the alleged improvement of water quality. The potential health hazards associated with GAC include desorption, chromatographic effect (competitive displacement), resorption (leaching) of heavy metals and polycyclic aromatic hydrocarbons contained in the virgin or regenerated carbon, release of carbon fines, promotion (catalytic reactions) on the carbon itself of hazardous compounds due to chemical reactions between chlorine and organic compounds, bacterial growth on the carbon and air pollution from regeneration facilities. Indirect hazards associated with the GAC usage derive from the manufacture of GAC and the production of energy necessary to operate GAC facilities. These industries, such as the coal industry, pose a high risk of morbidity and mortality to the workers. Because of these concerns, additional research and testing should be conducted prior to implementation of GAC in this country's major waterworks. It is suggested that toxicological evaluations be conducted using concentrated effluents from GAC to assess these potential hazards.

12. EPA is required to analyze the costs of its actions in terms of the benefits hoped to be obtained but EPA has not done that.

E. Other Comments

1. EPA has failed to quantify the contribution of industrial and municipal discharges to the total concentrations of THMs and their precursors. EPA should control the THMs and precursor materials at their source, and much of the THM in drinking water could be eliminated by not permitting any industrial or municipal discharges of THMs or THM precursors.

2. Because of the inaccuracy and imprecision inherent in the analytical procedure for measurement of THMs, the MCL should include an allowance for the variations in analytical results.

3. If there is a necessity for a MCL for THMs, the MCL should apply to all water systems.

4. The EPA has not addressed the significant primary and secondary environmental problems associated with the use of GAC treatment facilities. Such concerns would normally be considered in an Environmental Impact Statement (EIS) prepared in accordance with the National Environmental Policy Act. However, EPA has stated that the supporting documentation for the regulations is the functional equivalent of an EIS. The EPA documents are not the functional equivalent of an EIS as they have not remotely analyzed the full potential environmental impact.

II. American Water Works Association

The AWWA's recommendations were:

1. Expanded and accelerated health-effects research on THM and synthetic organics as recommended by the NAS.

2. Establishment of 100 ppb level of TTHMs as a goal for all public water supply systems.

3. Elimination of EPA's proposed requirement of GAC as a treatment technique. In its place, EPA sponsorship of at least four plant-size research projects to gather financial and operating, as well as scientific data.

4. Adoption of EPA's proposed monitoring program for TTHM, except that public notification should not be required.

5. Establishment of an EPA financed and operated monitoring program for synthetic organic chemicals.

III. Environmental Defense Fund

The scientific evidence supporting the regulations is massive and convincing. A number of epidemiology studies have been conducted and provide strong support for the regulations in that taken as a whole they show a consistent pattern of association between drinking water and cancer mortality rates at certain sites.

Using the NAS model and Dr. Roe's data, the estimated risk of ingesting 200 ppb of chloroform over a lifetime in a community the size of one million would be predicted to result in 20 excess cancer deaths.

In a case study in New York State, it was found that for urban area populations drinking chlorinated water had a relative risk of 2.7 compared to populations in urban areas that do not drink chlorinated water. This would result in 250 excess cancer deaths per year in a population of one million.

The benefits of the regulation far outweigh the costs.

Because chloramines are quite ineffective in killing viruses and because viruses are not monitored for in drinking water supplies, any encouragement of chloramine usage should proceed with great caution.

The overwhelming consensus of the scientific community is that testing animals with high dosages is perfectly adequate for relating to humans.

Any delay in promulgating the regulations would be unconscionable, in view of the health effects data, and improper, in view of the requirements of the SDWA.

It is abundantly clear that the public wants safer drinking water since large

numbers are turning to alternative sources of water (bottled water) or to home water treatment devices. Unfortunately, all of the available evidence indicates that these alternatives are not adequate substitutes for municipally treated drinking water.

A regulation applicable to only half the population is not good enough and is inconsistent with the congressional intent that maximum feasible protection of public health be provided. The coverage should be expanded.

The level of the MCL should be the level achievable by the application of the most effective THM reducing technique applied to a relatively clean water source, such as an average water supply. A level of 50 ppb was suggested as a possible alternative to the proposed MCL.

IV. Supporting Comments on Health Basis of Regulation

A. Dr. Samuel Epstein, from the University of Illinois, endorsed the following principles:

1. There is no safe level of exposure to a carcinogen.
2. Animal carcinogens should be considered as human carcinogens.
3. Chemicals found to be carcinogenic at high doses in animals are carcinogenic at much lower doses in humans.
4. Chloroform is not the only chemical of concern in contaminated drinking water.
5. If the effects of cigarette smoking are eliminated, cancer rates are not in decline for many sites.
6. There have been 13 epidemiological studies which in context demonstrate an association between chlorinated drinking water and gastrointestinal urinary tract cancer.
7. GAC is a proven water treatment technology.

Dr. Epstein summarized the scientific basis for the regulations as follows:

1. Less than 10% of the 700 chemicals identified have been tested "for their toxicologic and carcinogenic effects."
2. NCI lists 23 of these as carcinogens, 30 as mutagens and 11 as promoting agents.
3. Fish and shellfish which live in polluted water have a high incidence of tumors.
4. Organic extracts of drinking water have been shown to be carcinogenic and mutagenic in animal tests.
5. Organic chemicals in drinking water have shown reproductive effects in one preliminary laboratory test.
6. Epidemiologic studies suggest association between drinking water contaminants and cancer.

B. Susan B. King, chairperson of the U.S. Consumer Product Safety Commission (CPSC) testified that CPSC concurred with the four principles for safety and risk assessment set forth by the NAS in its report, "Drinking Water and Health" and that CPSC also utilized them in their regulations of carcinogens. CPSC also concurred in EPA's conclusion that humans are also susceptible to effects observed in animals, as properly qualified. Ms. King noted that thresholds have not been demonstrated at which a "no effect" level for a carcinogen could be presumed and that varying individual susceptibilities must be considered in a heterogenous human population. She endorsed testing of chemicals at high levels in animals for assessing possible human risks. CPSC uses factors such as potency, extent and nature of human exposure and human uptake factors in evaluating risks from carcinogens. CPSC's interim policy for regulating carcinogens consists of prohibiting use if a reasonable substitute exists and prohibiting use in the absence of a reasonable substitute unless this would result in both unacceptable social and economic costs. CPSC's approach is comparable to EPA's in that the extent of the exposure and risk are considered as well as the availability and costs of alternatives.

C. Dr. Donald Kennedy, Commissioner of the Food and Drug Administration (FDA), stated that FDA was in full accord with the objective of protecting public health from organic chemicals in drinking water, and endorsed EPA's efforts to reduce exposure to THMs. FDA's recent actions to remove chloroform from drug and cosmetic products were consistent with this position.

The FDA agreed that feeding high doses of a carcinogen to test animals provides the most practical way to predict whether a chemical may cause cancer in humans. Dr. Kennedy noted that "the NCI study was a good one that provided a clear demonstration that chloroform is carcinogenic in experimental animals." FDA concurred with EPA's assessment that, since one cannot conclude with certainty that cholorform is or is not a human carcinogen, prudent public health policy demands that we assume the potential for carcinogenesis in humans unless there is strong evidence to the contrary.

Dr. Kennedy submitted as part of his written comments a paper entitled "What Animal Research Says About Cancer." In summary, it noted that testing with large doses of a chemical is the usual, and in most instances, the *only* way to determine whether it causes cancer. Epidemiology is fraught with unreasonable confounding factors from retrospective designs, and therefore, the threshold hypothesis has been rejected on the grounds that no threshold has yet been demonstrated for a carcinogen. However, animal testing can be used to confirm a cause-and-effect relationship between dosage and the incidence of cancer—a relationship general enough to be applied confidently to most hazardous chemicals used over long periods. Moreover, the similarities between cancer in animals and human beings, such as the fact that cancer cells are capable of metastasizing—breaking away from the original cancer and seeding themselves elsewhere—as well as the growing evidence that cancer-causing chemicals interfere with the biochemistry of genetic material, are powerful arguments for the appropriateness of using animals as models for people.

Finally, he found persuasive the comparison between the substances known to cause cancer in human beings and their effect on laboratory animals; or 18 such substances, all but two were also found to be carcinogenic in animals.

D. Dr. Eula Bingham, Assistant Secretary of the Department of Labor and head of the Occupational Safety and Health Administration (OSHA), concurred with Dr. Donald Kennedy's testimony. Dr. Bingham stated that trace contaminants may increase the risk of human cancer and produce other chronic effects. Large numbers of people are placed at risk to chemicals if they are present in drinking water.

Dr. Bingham supported limiting exposure to carcinogens to the lowest feasible level. She stated that animal evidence provides the best qualitative test for assessing potential human carcinogenic risk and that there is presently no means for determining a safe exposure level to a carcinogen. Due to the long latency period for chemical carcinogenesis, it would be imprudent to await the results of human epidemiological studies.

Thus, OSHA's generic proposal to regulate carcinogens relies on animal extrapolation for the detection of carcinogenic activity of chemicals. Because of the statistical insensitivity of laboratory bioassays conducted with limited numbers of animals, she stated that positive test results with experimental animals should generally supersede negative results and that it is appropriate to test chemicals at high exposure levels.

E. Dr. Arthur Upton, Director of the National Cancer Institute submitted

comments. Those points not previously included are stated below.

There are currently 32 carcinogens or suspected carcinogens, 30 mutagens or suspected mutagens, and 11 promoters in drinking water identified from a 1976 list of organic compounds.

Two sets of studies have been carried out to explore the relationship in humans between THMs in drinking water and possible increases in cancer. The first set used presumed measures of THM contamination (i.e., surface waters likely to be chlorinated) vs. ground water (likely to not be chlorinated). The second set used actual measures of THM levels. Nine of ten indirect studies showed a number of statistically significant associations between water quality and cancer.

From the three quantitative studies one could tentatively conclude that cancer of the urinary bladder, and perhaps large intestine are correlated, with THMs in water. He noted that a decrease of 100 micrograms per liter of chloroform in water could lead to a decrease in cancer rates of up to 7.5% in men and 10% in women for bladder cancer and between 7.5 and 8.5% in large intestinal cancer for women and men, respectively. Although these studies did not purport to "prove" a cause-effect association between THMs and cancer, Dr. Upton testified that the weight of evidence showed a "high index of suspicion" of such a relationship.

The additive or more than additive effects from multiple exposure to an array of organic carcinogens in drinking water are of such significance as to warrant an appraisal of the opportunity for modification of the total carcinogenic burden which may be traceable or produced by water processing to reduce the levels of total exposure.

The fact that source carcinogens from drinking water may persist in body tissues makes quantification of these effects difficult.

In the absence of conclusive and quantitative empirical evidence, Dr. Upton supported EPA's reliance on the NAS principles set forth in "Drinking Water and Health." He stated that every dose of a demonstrated carcinogen should be regarded as carrying some potential or presumptive risk. Animal studies must be used to evaluate human carcinogenic risk and to predict the safety of environmental chemicals if human victims are to be spared. He endorsed EPA's proposed TTHM MCL of 100 ppb as a "comprehensive public health measure" in the direction of cancer prevention. Measures taken to control large classes of contaminants were deemed useful for reducing levels of material whose carcinogenic or mutagenic potential was still unknown.

F. Dr. Upton was accompanied by Dr. Marvin Schneiderman and Dr. Umberto Saffiotti, from NCI, who explained the difficulties in predicting with any degree of accuracy, human risk posed by carcinogens due to low levels of exposure, variability in such levels, measurement problems, long latency periods and other confounding factors. They also endorsed EPA's approach to regulating THMs. Those points stated by Dr. Marvin Schneiderman of the NCI not covered previously are outlined below.

The experimental conditions to detect cancer in 1 in 100 or 1% of the time requires 20,000 animals. Experiments performed with 100 animals per dose group can detect approximately a 3% incidence. Three percent is an enormously high incidence. After all, breast cancer, the most common human cancer has a lifetime probability of 7.5% and lung cancer is 6%. Therefore, three percent is in line with the most common of cancers that cause the greatest concern.

G. Dr. Riley Housewright, National Academy of Sciences, provided a review of the NAS report, "Drinking Water and Health" and stated the following:

> Drinking Water regulations have not always been based entirely on health considerations even though protection of consumer health is the unqualified logical goal. For various reasons, drinking water standards have historically been set on the basis of: 1. contaminant background levels, 2. analytical detection limits, 3. technological feasibility of treatment processes, 4. aesthetic considerations, 5. health effects, and combinations of the above. In our report we have attempted to summarize the current knowledge of the health effects of contaminants in drinking water with the purpose of providing the scientific information required for establishing regulations based on health effects.

The NAS report did provide a relatively long list of recommendations for research but these recommendations were not be in lieu of establishing a standard for chloroform. He stated, "there appears to be no question but that, first of all, chloroform is found in drinking water, and it is a carcinogen."

Dr. Housewright also stated that the hazards of ingesting chemical pollutants in drinking water can be assessed in two general ways: epidemiology studies and laboratory studies of toxicity. The insidious effects of chronic exposure to low doses of toxic agents are difficult to recognize, because there are few, if any, early warning signs, and, when signs are ultimately observed, they often imply irreversible effects. In evaluating the potential effects on health of organic compounds found in drinking water, the NAS principal concern was to assess their carcinogenicity. The risk associated with the ingestion of compounds that were identified as carcinogenic were calculated by extrapolation from animal data. Chloroform was one of the compounds that produced cancer in both rats and mice. The NAS Safe Drinking Water Committee believed that: "these tests were valid and there is a hazard to man associated with the ingestion of chloroform," and that "chloroform and other THMs present a health hazard and that steps should be taken to prevent their formation or to remove them from drinking water." He stated that "Our committee believed these tests were valid and that there is a hazard to man associated with the ingestion of chloroform."

In addition, Dr. Housewright stated the following:

Some early epidemiological studies suggested an association between THMs and cancer. Our review of ten epidemiological studies concluded that the association was small and that there was a large margin of error. In most of the studies evaluated, the THM exposure and duration levels were inferred and confounding factors known to affect cancer incidence, such as cigarette-smoking, occupation, use of alcohol and drugs, socio-economic status and many others, were inadequately controlled. The failure of these studies to clearly establish a positive or negative cause and effect relationship between THMs and cancer resides to some extent in the complexities inherent in doing such studies.

We believe that THMs in drinking water present a human health hazard. The principal basis for this is that exposure to them results in cancer in two species of experimental animals. This conclusion is neither confirmed nor denied by the results of epidemiological studies now available; confirmation would require more sensitive epidemiological studies than have been conducted thus far. The examination of currently available epidemiological evidence gives no reason to change the conclusion of the study *Drinking Water and Health* which recommends that "strict criteria be applied when limits for chloroform in drinking water are established to protect the public health."

H. Dr. Richard Bates, National Institute of Environmental Health Sciences, and Dr. David Hoel, National Institute of Environmental Health Services and National Academy of Sciences, stated that determination of a quantitative standard for a contaminant in drinking water must be based upon a

judgment of the risk that is socially acceptable and upon a scientific estimation of the actual risk posed by the contaminant. Scientific estimation of risk from carcinogenic chemicals is not yet an exact science and until that time, regulatory agencies will have to act according to the most likely interpretation of scientific information while resolving uncertainties in a way that assures protection of the public health.

The four principles from NAS are consistent with what is now known about chemical carcinogenesis. The first principle is now widely accepted. Because epidemiology studies have problems of sensitivity and specificity and harmful effects can only be noted after the damage is done, experimental studies must be relied upon to judge the potential carcinogenicity of a chemical to humans. This practice is supported by the observation that most known human carcinogens are also carcinogenic in experimental animals, that generally the same kinds of metabolic enzymes that activate and detoxify chemical carcinogens are present in both human tissues and experimental animals, and that the general process of cancer development is similar in humans and experimental in animals.

With regard to the second and third principles, which discuss the inability to establish thresholds for carcinogens and the validity of using high doses, the fundamental reason for testing at high dose levels is to enhance the sensitivity of the experimental bioassay to detect a chemical carcinogen. A study of 100 animals can only detect the induction of cancer in no less than one percent of the animals. In order to detect lower levels of risk, it would be necessary to test much larger numbers of animals or to use mathematical procedures to estimate the level of risk from lower levels of exposure. The former approach is normally economically infeasible. The latter approach is based upon debatable scientific assumptions including that there is no threshold below which exposure to a carcinogen entails no risk. At the present time, it cannot be determined unequivocally whether or not thresholds exist or to determine which individuals in the population may or may not be able to tolerate additional exposure to carcinogenic chemicals.

The methods described in "Drinking Water and Health" are the best available to provide guidance on low level risks. In view of the many uncertainties, the safest action is always to reduce exposure to a chemical carcinogen to the lowest feasible level.

With regard to the numerical values that are produced by the models in terms of human risk per unit of exposure, Dr. Hoel stated that because of the inability to estimate the possible biological errors, biological differences between species and within species, and the experiences with the empirical data, the use of model predictions in ascribing some certain number of deaths in a population is not necessarily appropriate. He stated that the models could be used to rank carcinogens relative to their potency.

V. Calgon Corporation

As an example of comments providing information and data concerning the technical basis of the regulations, comments submitted by Calgon Corporation are summarized below.

1. GAC has been widely used for over 18 years in potable water applications to control taste, odor, and color in the U.S. and presently over 60 plants in the U.S. use GAC. In these applications, GAC has worked effectively with minimal problems without hazard or injury.

2. GAC is used to remove organic chemical contaminants from potable water in 21 cities in Europe and have been operating for up to 10 years. Most of these plants have on-site reactivation and have been operating without any adverse effects or undue difficulties.

3. GAC does not get into the water system from the filter beds. The bulk of the carbon lost is lost during the periodic backwashing of the carbon beds.

4. GAC does not add heavy metals or polynuclear aromatics (PAH) to the finished water. A composite sample of four activated carbons contained 7.36% ash of which 0.08% was soluble in water. Analysis for inorganic compounds showed very low levels but most significant is that the soluble portion of the ash is dissolved and discarded during the backwashing operation. During reactivation, the ash compounds are liberated and driven off in the furnace or the quench tank which contains boiling hot water, extracting any water soluble ash that is present.

Activated carbon is made by a multi-step process which is not conducive to the formation or retention of PAHs. The raw material, coal, is subject to an oxidation step, followed by a devolatilization step, followed by a long term high temperature (up to 2,000° F) activation step during which time the carbon granules are constantly turned in a reducing atmosphere. This process will drive off any materials with boiling points characteristic of PAHs. Experiments by a U.S. FDA laboratory have not been able to extract any PAHs from activated carbon. Activated carbon is such a strong adsorbent that even a small amount of polynuclear aromatics that might exist would be strongly adsorbed by the carbon.

5. GAC adsorbs organics and allow bacteria naturally present in the water to grow within the carbon bed. However, these bacteria are removed during backwashing and any bacteria in the effluent are easily controlled by disinfection following GAC. Bacterial growth has not been a problem at the more than 60 plants in the U.S. or in the systems in Europe.

6. In addition to its effectiveness in removing taste, odor and color from potable waters, GAC provides other advantages to the water treatment plant, such as savings in the amount of backwash water that is needed. Twenty to 40% savings over conventional media has been experienced by plants using GAC. Also, the demand for chlorine was reduced in these plants by 13% to 14% because organic contaminants had been reduced. Finally, use of GAC has extended service life between backwashes because of a reduction in head loss.

7. Energy requirements, based upon actual experiences, with reactivation of GAC used to treat industrial waste waters, are approximately 8,000 BTUs per pound of reactivated carbon. It is reasonable to expect that reactivation of GAC used to treat drinking water would require less energy. While the reactivation process is relatively energy intensive, the consumption of additional energy for reactivation of GAC from drinking water facilities will be insignificant in view of national consumption of energy.

8. Experience with furnaces reactivating GAC from industrial waste water facilities has shown that proper application of air pollution control technologies can be operated to comply with applicable air pollution requirements.

9. Compliance with the MCL is feasible and use of GAC for this purpose would most likely be for precursor removal.

10. The allotted time for compliance with the MCL is adequate. Systems that elect to use GAC to reduce THMs could be modified very quickly. For most applications, replacement of the existing filter media with GAC will be adequate. For greater bed depths, the necessary contact time can probably be achieved with relatively simple modifications of the existing filter systems. A few systems may require greater bed depth and thus additional time will probably be needed for those systems to make the modifications.

11. The utilities' cost estimates for GAC are overstated in that the capital

required for reactivation is based upon a redundant furnace. Based upon actual experience, it has not been necessary to have such substantial stand-by reactivation capacity. A more reasonable approach would be to utilize two furnaces of equal size with a total capacity equal to the peak flow rates and provide for stocking of buffer carbon to meet needs during periods of maintenance. Also, the use of an outside reactivation service could be used during long down times of the furnace. Detailed cost estimates were provided for GAC for two system sizes.

12. In order for the demand for GAC to be spread over a reasonable time frame, it is recommended that the regulations be phased in three segments separated by three months each.

VI. National Drinking Water Advisory Council

It is the opinion of the National Drinking Water Advisory Council (NDWAC) that EPA is justified in establishing an MCL of 100 ppb for THMs in finished drinking water on the basis of health hazard and feasibility. However, the MCL should not be restricted to utilities serving greater than 75,000 persons. The Council recommends that an MCL of 100 ppb THM also apply to utilities serving between 10,000 and 75,000 persons beginning three years after implementation of the regulation covering those utilities serving greater than 75,000 persons.

The Council also recommends that the implementation of the MCL of 100 ppb THM for utilities serving less than 10,000 persons be at the option of the agency having primacy in each state. The agency having primacy will be more familiar with the water supplies in that state and be better able to evaluate the potential for THM formation as a result of chlorine disinfection. This would serve to avoid unnecessary financial burdens on these utilities. The decision for compliance by those utilities should be made within five years.

The Council believes that the THM requirements should initially apply to all water sources (surface and ground). Where no THM problem is determined, the state should have the responsibility to determine the need for future monitoring requirements in order to assure that THMs do not pose a problem in the future.

It is imperative that the EPA publicly clarify its position relative to lowering the MCL for THM below 100 ppb. If the Agency believes the current health effects data supports an MCL lower than 100 ppb a detailed justification should be provided.

It is recommended that the EPA reconsider its restriction on the use of chloramines. Chloramines have been effectively used for disinfection in certain water systems for many years. Consequently, the Council believes that EPA's proposed regulation is unduly restrictive.

As previously expressed, the NDWAC is of the opinion that the standard plate count, although useful to the utility operator, should not be established as a regulatory requirement.

The Council concurs with the averaging method described in the proposed regulation for determining the level of THM in drinking water supplies.

Appendix C—Analysis of Trihalomethanes

Part I: The Analysis of Trihalomethanes in Drinking Water by the Purge and Trap Method

1. *Scope*

1.1 This method (1) is applicable in the determination of four trihalomethanes, i.e. chloroform, dichlorobromomethane, dibromochloromethane, and bromoform in finished drinking water, raw source water, or drinking water in any stage of treatment. The concentration of these four compounds is totaled to determine total trihalomethanes (TTHM).

1.2 For compounds other than the above-mentioned trihalomethanes, or for other sample sources, the analyst must demonstrate the usefulness of the method by collecting precision and accuracy data on actual samples as described (2).

1.3 Although the actual detection limits are highly dependent upon the gas chromatographic column and detector employed, the method can be used over a concentration range of approximately 0.5 to 1500 micrograms per liter.

1.4 Well in excess of 100 different water supplies have been analyzed using this method. Supplementary analyses using gas chromatography mass spectrometry (GC/MS) have shown that there is no evidence of interference in the determination of trihalomethanes (3). For this reason, it is not necessary to analyze the raw source water as is required with the Liquid/Liquid Extraction Method (4).

2. *Summary*

2.2 Trihalomethanes are extracted by an inert gas which is bubbled through the aqueous sample. The trihalomethanes, along with other organic constituents which exhibit low water solubility and a vapor pressure significantly greater than water, are efficiently transferred from the aqueous phase to the gaseous phase. These compounds are swept from the purging device and are trapped in a short column containing a suitable sorbent. After a predetermined period of time, the trapped components are thermally desorbed and backflushed onto the head of a gas chromatographic column and separated under programmed conditions. Measurement is accomplished with a halogen specific detector such as electrolytic conductivity or microcoulometric titration.

2.3 Confirmatory analyses are performed using dissimilar columns, or by mass spectrometry (5).

2.4 Aqueous standards and unknowns are extracted and analyzed under identical conditions in order to compensate for extraction losses.

2.5 The total analysis time, assuming the absence of other organohalides, is approximately 35 minutes per sample.

3. *Interferences*

3.1 Impurities contained in the purge gas and organic compounds outgasing from the plumbing ahead of the trap usually account for the majority of contamination problems. The presence of such inteferences are easily monitored as a part of the quality control program. Sample blanks are normally run between each set of samples. When a positive trihalomethane response is noted in the sample blank, the analyst should analyze a method blank. Method blanks are run by charging the purging device with organic-free water and analyzing in the normal manner.

If any trihalomethane is noted in the method blank in excess of 0.4 $\mu g/l$, the analyst should change the purge gas source and regenerate the molecular sieve purge gas filter. *Subtracting the blank values is not recommended.* The use of non-TFE plastic tubing, non-TFE thread sealants, or flow controllers with rubber components should be avoided since such materials generally out-gas organic compounds which will be concentrated in the trap during the purge operation. Such out-gasing problems are common whenever new equipment is put into service; as time progresses, minor out-gasing problems generally cure themselves.

3.2 Several instances of accidental sample contamination have been noted and attributed to diffusion of volatile organics through the septum seal and into the sample during shipment and storage. The sample blank is used as a monitor for this problem.

3.3 For compounds that are not efficiently purged, such as bromoform, small variations in sample volume, purge time, purge flow rate, or purge temperature can affect the analytical

result. Therefore, samples and standards must be analyzed under identical conditions.

3.4 Cross-contamination can occur whenever high-level and low-level samples are sequentially analyzed. To reduce this likelihood, the purging device and sample syringe should be rinsed twice between samples with organic-free water. Whenever an unusually concentrated sample is encountered, it is highly recommended that it be followed by a sample blank analysis to ensure that sample cross contamination does not occur. For samples containing large amounts of water soluble materials, it may be necessary to wash out the purging device with a soap solution, rinse with distilled water, and then dry in a 105°C oven between analyses.

3.5 Qualitative misidentifications are a problem in using gas chromatographic analysis. Whenever samples whose qualitative nature is unknown are analyzed, the following precautionary measures should be incorporated into the analysis.

3.5.1 Perform duplicate analyses using the two recommended columns (4.2.1 and 4.2.2) which provide different retention order and retention times for the trihalomethanes and other organohalides.

3.5.2 Whenever possible, use GC/MS techniques which provide unequivocal qualitative identifications (5).

4. *Apparatus*

4.1 The purge and trap equipment consists of three separate pieces of apparatus: the purging device, trap, and desorber. Construction details for a purging device and an easily automated trap-desorber hybrid which has proven to be exceptionally efficient and reproducible are shown in Figures 1 through 4 and described in 4.1.1. through 4.1.3. An earlier acceptable version of the above-mentioned equipment is described in (1).

4.1.1 Purging Device—Construction details are given in Figure 1 for an all-glass 5 ml purging device. The glass frit installed at the base of the sample chamber allows finely divided gas bubbles to pass through the sample while the sample is restrained above the frit. Gaseous volumes above the sample are kept to a minimum to eliminate dead volume effects, yet allowing sufficient space for most foams to disperse. The inlet and exit ports are constructed from heavy-walled ¼-inch glass tubing so that leak-free removable connections can be made using "finger-tight" compression fittings containing Teflon ferrules. The removable foam trap is used to control samples that foam.

4.1.2 Trapping Device—The trap (Figure 2) is a short gas chromatographic column which at <35° C retards the flow of the compounds of interest while venting the purge gas and, depending on which sorbent is used, much of the water vapor. The trap should be constructed with a low thermal mass so that it can be heated to 180° C in less than 1 minute for efficient desorption, then rapidly cooled to room temperature for recycling. Variations in the trap ID, wall thickness, sorbents, sorbent packing order, and sorbent mass could adversely affect the trapping and desorption efficiencies for compounds discussed in this text. For this reason, it is important to faithfully reproduce the trap configurations recommended in Figure 2. Traps containing Tenax only, or combinations of Tenax and other sorbents are acceptable for this analysis.

4.1.3 Desorber assembly—Details for the desorber are shown in Figures 3, and 4. With the 6-port valve in the Purge Sorb position (Figure 3), the effluent from the purging device passes through the trap where the flow rate of the organics is retarded. The GC carrier gas also passes through the 6-port valve and is returned to the GC. With the 6-port valve in the Purge-Sorb position, the operation of the GC is in no way impaired; therefore, routine liquid injection analyses can be performed using the gas chromatograph. After the sample has been purged, the 6-port valve is turned to the desorb position (Figure 4). In this configuration the trap is coupled in series with the gas chromatographic column allowing the carrier gas to backflush the trapped materials into the analytical column. Just as the valve is actuated, the power is turned on to the resistance wire wrapped around the trap. The power is supplied by an electronic temperature controller. Using this device, the trap is rapidly heated to 180° C and then maintained at 180° C with minimal temperature overshoot. The trapped compounds are released as a "plug" to the gas chromatograph. Normally, packed columns with theoretical efficiencies near 500 plates/foot under programmed temperature conditions can accept such desorb injections without altering peak geometry. Substituting a non-controlled power supply, such as a manually-operated variable transformer, will provide nonreproductible retention times and poor quantitative data unless Injection Procedure (8.9.2) is used.

4.1.4 Several Purge and Trap Devices are now commercially available. It is recommended that the following be taken into consideration if a unit is to be purchased:

a. Be sure that the unit is completely compatible with the gas chromatograph to be used for the analysis.

b. Use a 5-ml purging device similar to that shown in Figure 1.

c. Be sure the Tenax portion of the trap meets or exceeds the dimensions shown in Figure 2.

d. With the exception of sample introduction, select a unit that has as many of the purge trap functions automated as possible.

4.2 Gas chromatograph—The chromatograph must be temperature programmable and equipped with a halide specific detector.

4.2.1 Column I is an unusually efficient column which provides outstanding separations for a wide variety of organic compounds. Because of its ability to resolve trihalomethanes from other organochlorine compounds, column I should be used as the primary analytical column (see Table 1 for retention data using this column).

4.2.1.1 Column I parameters: Dimensions—8 feet long x 0.1 inch ID stainless steel or glass tubing. Packing—1% SP-1000 on Carbopack-B (60/80) mesh. Carrier Gas—helium at 40 ml/minute. Temperature program sequence: 45° C isothermal for 3 minutes, program at 8° C/minute to 220° C then hold for 15 minutes or until all compounds have eluted.

Note.—It has been found that during handling, packing, and programming, active sites are exposed on the Carbopack-B packing. This results in tailing peak geometry and poor resolution of many constituents. To correct this, pack the first 5 cm of the column with 3% SP-1000 on Chromosorb-W 60/80 followed by the Carbopack-B packing. Condition the precolumn and the Carbopack columns with carrier gas flow at 220° C overnight. Pneumatic shocks and rough treatment of packed columns will cause excessive fracturing of the Carbopack. If pressure in excess of 60 psi is required to obtain 40 ml/minute carrier flow, then the column should be repacked.

4.2.1.2 Acceptable column equivalent to Column I: Dimensions—8 feet long x 0.1 inch ID stainless steel or glass tubing. Packing—0.2% Carbowax 1500 on Carbopack-C (80/100) mesh. Carrier Gas—helium at 40 ml/minute. Temperature program sequence—60° C isothermal for 3 minutes, program at 8° C /minute to 160° C, then hold for 2 minutes or until all compounds have eluted.

Note.—It has been found that during handling, packing, and programming, active sites are exposed on the Carbopack-C packing. This results in poor resolution of constituents and poor peak geometry. To correct this, place a 1 ft. 0.125 in. OD x 0.1 in.

ID stainless steel column packed with 3% Carbowax 1500 on Chromosorb-W 60/80 mesh in series before the Carbopack-C column. Condition the precolumn and the Carbopack columns with carrier gas flow at 190° C overnight. The two columns may be retained in series for routine analyses. Trihalomethane retention times are listed in Table 1.

4.2.2 Column II provides unique organohalide-trihalomethane separations when compared to those obtained from Column I (see Figures 5 and 6). However, since the resolution between various compounds is generally not as good as those with Column I, it is recommended that Column II be used as a qualitative confirmatory column for unknown samples when GC/MS confirmation is not possible.

4.2.2.1 Column II parameters: Dimensions—6 feet long x 0.1 inch ID stainless steel or glass. Packing—n-octane on Porisil-C (100/120 mesh). Carrier Gas—helium at 40 cc/minute. Temperature program sequence—50° C isothermal for 3 minutes, program at 6°/minute to 170° C, then hold for 4 minutes or until all compounds have eluted. Trihalomethane retention times are listed in Table 1.

5.8 Organic-free water is defined as water free of interference when employed in the purge and trap analysis.

5.8.1 Organic-free water is generated by passing tap water through a carbon filter bed containing about 1 lb. of activated carbon. Change the activated carbon bed whenever the concentration of any trihalomethane exceeds 0.4 μg/l.

5.8.2 A Millipore Super-Q Water System or its equivalent may be used to generate organic-free water.

5.8.3 Organic-free water may also be prepared by boiling water for 15 minutes. Subsequently, while maintaining the temperature at 90° C, bubble a contaminant-free inert gas through the water for one hour. While still hot, transfer the water to a narrow-mouth screw-cap bottle with a Teflon seal.

5.8.4 Test organic free water each day it is used by analyzing according to Section 8.

5.9 Standards.[a]

5.9.1 Bromoform—96%—available from Aldrich Chemical Company.

5.9.2 Bromodichloromethane 97%—available from Aldrich Chemical Company.

5.9.3 Chlorodibromomethane—available from Columbia Chemical Inc., Columbia, S.C.

5.9.4 Chloroform—99%—available from Aldrich Chemical Company.

[a] As a precautionary measure, all standards must be checked for purity by boiling point determinations or GC/MS assays (5).

5.10 Standard Stock Solutions

5.10.1 Place about 9.8 ml of methyl alcohol into a ground glass stoppered 10 ml volumetric flask.

5.10.2 Allow the flask to stand unstoppered about 10 minutes or until all alcohol wetted surfaces have dried.

5.10.3 Weigh the flask to the nearest 0.1 mg.

5.10.4 Using a 100 μl syringe, immediately add 2 drops of the reference standard to the flask, then reweigh. *Be sure that the 2 drops fall directly into the alcohol without contacting the neck of the flask.*

5.10.5 Dilute to volume, stopper, then mix by inverting the flask several times.

5.10.6 Transfer the solution to a dated and labeled 15 ml screw cap bottle with a Teflon cap liner.

Note.—Because of the toxicity of trihalomethanes, it is necessary to prepare primary dilutions in a hood. It is further recommended that a NIOSH/MESA approved toxic gas respirator be used when the analyst handles high concentrations of such materials.

5.10.7 Calculate the concentration in micrograms per microliter from the net gain in weight.

5.10.8 Store the solution at 4° C.

Note.—All standard solutions prepared in methyl alcohol are stable up to 4 weeks when stored under these conditions. They should be discarded after that time has elapsed.

5.11 Aqueous Calibration Standard Precautions.

5.11.1 In order to prepare accurate aqueous standard solutions, the following precautions must be observed.

a. Do not inject more than 20 μl of alcoholic standards into 100 ml of organic-free water.

b. Use of 25 μl Hamilton 702N microsyringe or equivalent. (Variations in needle geometry will adversely affect the ability to deliver reproducible volumes of methanolic standards into water.)

c. Rapidly inject the alcoholic standard into the expanded area of the filled volumetric flask. Remove the needle as fast as possible after injection.

d. Mix aqueous standards by inverting the flask three times only.

e. Discard the contents contained in the neck of the flask. Fill the sample syringe from the standard solution contained in the expanded area of the flask as directed in Section 8.5.

f. Never use pipets to dilute or transfer samples or aqueous standards.

g. Aqueous standards when stored with a headspace are not stable and should be discarded after one hour.

h. Aqueous standards can be stored according to Sections 6.4 and 8.6.

5.11.2 Prepare, from the standard stock solutions, secondary dilution mixtures in methyl alcohol so that a 20 μl injection into 100 ml or organic-free water will generate a calibration standard which produces a response close (±10%) to that of the sample (See 9.1).

5.11.3 Purge and analyze the aqueous calibration standards in the same manner as the samples.

5.11.4 Other calibration procedures (3) which require the delivery of less than 20 μl of a methanolic standard into a 5.0 ml volume of water already contained in the sample syringe are acceptable only if the methanolic standard is delivered by the solvent flush technique (6).

5.12 Quality Check Standard (2.0 μg/l)

5.12.1 From the standard stock solutions, prepare a secondary dilution in methyl alcohol containing 10 ng/μl of each trihalomethane (See Section 5.10.8 Note).

5.12.2 Daily, inject 20.0 μl of this mixture into 100.0 ml of organic-free water ana analyze according to Section 8.

6. *Sample Collection and Handling*

6.1. The sample containers should have a total volume of at least 25 ml.

6.1.1 Narrow mouth screw cap bottles with the TFE fluorocarbon face silicone sepata cap liners are strongly recommended.

6.2 Sample Bottle Preparation

6.2.1 Wash all sample bottles and TFE seals in detergent. Rinse with tap water and finally with distilled water.

6.2.2 Allow the bottles and seals to air dry at room temperature, then place in a 105° C oven for one hour, then allow to cool in a area known to be free of organics.

Note.—Do not heat the TFE seals for extended period of time (>1 hour) because the silicone layer slowly degrades at 105° C.

6.2.3 When cool, seal the bottles using the TFE seals that will be used for sealing the samples.

6.3 Sample Stabilization—A chemical reducing agent (Section 5.6) is added to the sample in order to arrest the formation of trihalo-methanes after sample collection (3, 7). *Do not add the reducing agent to samples when data on maximum trihalomethane formation is desired.* If chemical stabilization is employed, the reagent is also added to the blanks. The chemical agent (2.5 to 3 mg/40 ml) is added to the empty sample bottles just prior to shipping to the sampling site.

6.4 Sample Collection

6.4.1 Collect all samples in duplicate.

6.4.2 Fill the sample bottles in such a manner that no air bubbles pass through the sample as the bottle is filled.

6.4.3 Seal the bottles so that no air bubbles are entrapped in it.

6.4.4 Maintain the hermetic seal on the sample bottle until analysis.

6.4.5 Sampling from a water tap.

6.4.5.1 Turn on water and allow the system to flush until the temperature of the water has stabilized. Adjust the flow to about 500 ml/minute and collect duplicate samples from the flowing stream.

6.4.6 Sampling from an open body of water.

6.4.6.1 Fill a 1-quart wide-mouth bottle with sample from a representative area. Carefully fill duplicate sample bottles from the 1-quart bottle as noted in 6.4.2.

6.4.7 If a chemical reducing agent has been added to the sample bottles, fill with sample just to overflowing, seal the bottle, and shake vigorously for 1 minute.

6.4.8 Sealing practice for septum seal screw cap bottles.

6.4.8.1 Open the bottle and fill to overflowing, place on a level surface, position the TFE side of the septum seal upon the convex sample meniscus and seal the bottle by screwing the cap on tightly.

6.4.8.2 Invert the sample and lightly tap the cap on a solid surface. The absence of entrapped air indicates a successful seal. If bubbles are present, open the bottle, add a few additional drops of sample and reseal the bottle as above.

6.4.9 Blanks.

6.4.9.1 Prepare blanks in duplicate at the laboratory by filling and sealing sample bottles with organic-free water just prior to shipping the sample bottles to the sampling site.

6.4.9.2 If the sample is to be stabilized, add an identical amount of stabilization reagent to the blanks.

6.4.9.3 Ship the blanks to and from the sampling site along with the sample bottles.

6.4.9.4 Store the blanks and the samples collected at a given site (sample set) together. A sample set is defined as all the samples collected at a given site (i.e., at a water treatment plant, the duplicate raw source waters, the duplicate finished waters and the duplicate blank samples comprise the sample set).

6.5 When samples have been collected according to Section 6, no measurable loss of trihalomethanes has been detected over extended periods of storage time (3). It is recommended that all samples be analyzed within 14 days of collection.

7. *Conditioning Traps*

7.1 Condition newly packed traps overnight at 180° C with an inert gas flow of at least 20 ml/min.

7.1.1 Vent the trap effluent to the room, not to the analytical column.

7.2 Prior to daily use, condition traps 10 minutes while backflushing at 180° C. It may be beneficial to routinely condition traps overnight while backflushing at 180° C.

7.2.1 The trap may be vented to the analytical column; however, after conditioning, the column must be programmed prior to use.

8. *Extraction and Analysis*

8.1 Adjust the purge gas (nitrogen or helium) flow rate to 40 ml/min.

8.2 Attach the trap inlet to the purging device. Turn the valve to the purge-sorb position (Figure 3).

8.3 Open the syringe valve located on the purging device sample introduction needle.

8.4 Remove the plungers from two 5 ml syringes and attach a closed syringe valve to each.

8.5 Open the sample bottle and carefully pour the sample into one of the syringe barrels until it overflows. Replace the syringe plunger and compress the sample. Open the syringe valve and vent any residual air while adjusting the sample volume to 5.0 ml. Close the valve.

8.6 Fill the second syringe in an identical manner from the same sample bottle. This second syringe is reserved for a duplicate analysis, if necessary (See Sections 9.3 and 9.4).

8.7 Attach the syringe-valve assembly to the syringe valve on the purging device.

8.8 Open the syringe valve and inject the sample into the purging chamber. Close both valves. Purge the sample for 11.0±.05 minutes.

8.9 After the 11-minute purge time, attach the trap to the chromatograph (turn the valve to the desorb position) and introduce the trapped materials to the GC column by rapidly heating the trap to 180°C while backflushing the trap with an inert gas between 20 and 60 ml/min for 4 minutes.

8.9.1 If the trap can be rapidly heated to 180°C and maintained at this temperature, the GC analysis can begin as the sample is desorbed, i.e., the column is at the initial 45°C operating temperature. The equipment described in Figure 4 will perform accordingly.

8.9.2 With other types of equipment (see Section 4.1.4 and Reference 1) where the trap is not rapidly heated or is not heated in a reproducible manner, it may be necessary to transfer the contents of the trap into the analytical column at <30°C where it is once again trapped. Once the transfer is complete (4 minutes), the column is rapidly heated to the initial operating temperature for analysis.

8.9.3 If injection procedure 8.9.1 is used and the early eluting peaks in the resulting chromatogram have poor geometry or variable retention times, then Section 8.9.2 should be used.

8.10 After the extracted sample is introduced into the gas chromatograph, empty the gas purging device using the sample introduction syringe, followed by two 5-ml flushes of organic-free water. When the purging device is emptied, leave the syringe valve open allowing the purge gas to vent through the sample introduction needle.

8.11 Analyze each sample and sample blank from the sample set in an identical manner (see Section 6.4.9.4) on the same day.

8.12 Prepare calibration standards from the standard stock solutions (Section 5.10) in organic-free water that are close to the unknown in trihalomethane composition and concentration (Section 9.1). The concentrations should be such that only 20 μl or less of the secondary dilution need be added to 100 ml of organic-free water to produce a standard at the same level as the unknown.

8.13 As an alternative to Section 8.12, prepare a calibration curve for each trihalomethane containing at least 3 points, two of which must bracket the unknown.

9. *Analytical Quality Control*

9.1 Analyze the 2 μg/l check sample daily before any samples are analyzed. Instrument status checks and lower limit of detection estimations based upon response factor calculations at five times the noise level are obtained from these data. In addition, response factor data obtained from the 2 μg/l check standard can be used to estimate the concentration of the unknowns. From this information, the appropriate standard dilutions can be determined.

9.2 Analyze the sample blank to monitor for potential interferences as described in Sections 3.1, 3.2, and 3.4.

9.3 Spiked Samples

9.3.1 For laboratories analyzing more than 10 samples a day, each 10th sample should be a laboratory generated spike which closely duplicates the average finished drinking water in trihalomethane composition and concentration. Prepare the spiked sample in organic-free water as described in Section 5.11.

9.3.2 For laboratories analyzing less than 10 samples daily, each time the analysis is performed, analyze at least 1 laboratory generated spike sample which closely duplicates the average finished drinking water in

trihalomethane composition and concentration. Prepare the spiked sample in organic-free water as described in Section 5.11.

9.4 Randomly select and analyze 10% of all samples in duplicate.

9.4.1 Analyze all samples in duplicate which appear to deviate more than 30% from any established norm.

9.5 Maintain an up-to-date log on the accuracy and precision data collected in Sections 9.3 and 9.4. If results are significantly different than those cited in Section 11.1, the analyst should check out the entire analyses scheme to determine why the laboratory's precision and accuracy limits are greater.

9.6 Quarterly, spike an EMSL–Cincinnati trihalomethane quality control sample into organic-free water and analyze.

9.6.1 The results of the EMSL trihalomethane quality control sample should agree within 20% of the true value for each trihalomethane. If they do not then the analyst must check each step in the standard generation procedure to solve the problem (Section 5.9, 5.10, and 5.11).

9.7 Maintain a record of the retention times for each trihalomethane using data gathered from spiked samples and standards.

9.7.1 Daily calculate the average retention time for each trihalomethane and the variance encountered for the analyses.

9.7.2 If individual trihalomethane retention time varies by more than 10% over an eight hour period or does not fall with 10% of an established norm, the system is "out of control." The source of retention data variation must be corrected before acceptable data can be generated.

10. *Calculations*

10.1 Locate each trihalomethane in the sample chromatogram by comparing the retention time of the suspect peak to the data gathered in 9.7.1. The retention time of the suspect peak must fall within the limits established in 9.7.1 for single column identification.

10.2 Calculate the concentration of the samples by comparing the peak height or peak areas of the samples to the standard peak height (8.12). Round off the data to the nearest $\mu g/l$ or two significant figures.

$$\mu g/l = \left(\frac{\text{peak height sample}}{\text{peak height standard}}\right) \times (\text{conc. std. } \mu g/l)$$

10.3 Report the results obtained from the lower limit of detection estimates along with the data for the samples.

10.4 Calculate the total trihalomethane concentration (TTHM) by summing the 4 individual trihalomethane concentrations in $\mu g/l$. TTHM ($\mu g/l$) = (Conc. $CHCl_3$) + (Conc. $CHBrCl_2$) + (Conc. $CHBr_2Cl$) + (Conc. CHBr).

10.5 Calculate the limit of detection (LOD) for each trihalomethane not detected using the following criteria:

$$\text{LOD } (\mu g/l) = \left(\frac{A \times ATT}{B \times ATT}\right) (2\ \mu g/l)$$

where B = peak height (mm) of 2 $\mu g/l$ quality check standard

A = 5 times the noise level in (mm) at the exact retention time of the trihalomethane or the baseline displacement in (mm) from the theoretical zero at the exact retention time of the trihalomethane.

ATT = Attenuation factor

11. *Accuracy and Precision*

11.1 One liter of organic-free water was spiked with the trihalomethanes and used to fill septum seal vials which were stored under ambient conditions. The spiked samples were randomly analyzed over a 2-week period of time. The single laboratory data listed in Table II reflect the errors due to the analytical procedure and storage.

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Table I—*Retention Data for Trihalomethanes*

Trihalomethane	Retention time minutes: Column I 1% sp1000 Carbopack B	Acceptable Alternative to column I 0.4% Carbowax Carbopack	Column II n-octane Porasil-C
Chloroform	10.7	8.2	12.2
Bromodichloromethane	13.7	10.8	14.7
Chlorodibromomethane (Dibromochloromethane)	16.5	13.2	16.6
Bromoform	19.2	15.7	19.2

Table II—*Single Laboratory Accuracy and Precision for Trihalomethanes*

Spike $\mu g/l$	Number samples	Mean $\mu g/l$	Precision standard deviation	Accuracy percent recovery
Chloroform				
1.2	12	1.2	0.14	100
12.0	8	11.	0.16	92
119.0	11	105	7.9	88
Bromodichloromethane				
1.6	12	1.5	0.05	94
16.0	8	15.	0.39	94
160.0	11	145.	10.2	91
Chlorodibromomethane				
2.0	12	1.9	0.09	95
20.0	8	19.	0.70	95
196.0	11	185.	10.6	94
Bromoform				
2.3	12	2.3	0.16	100
23.0	8	23.	1.38	100
231.0	11	223	16.3	97

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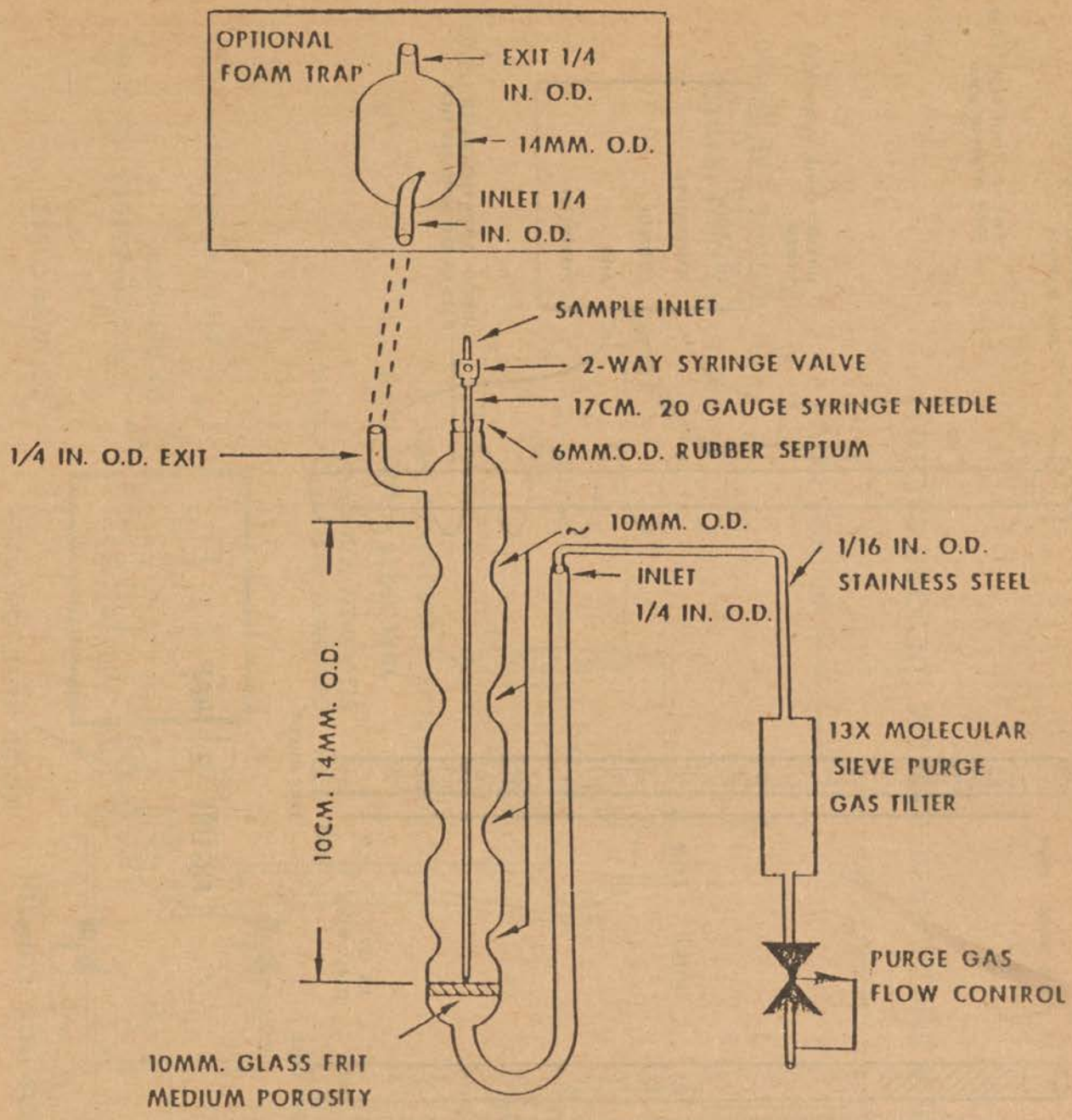

FIGURE 1. PURGING DEVICE

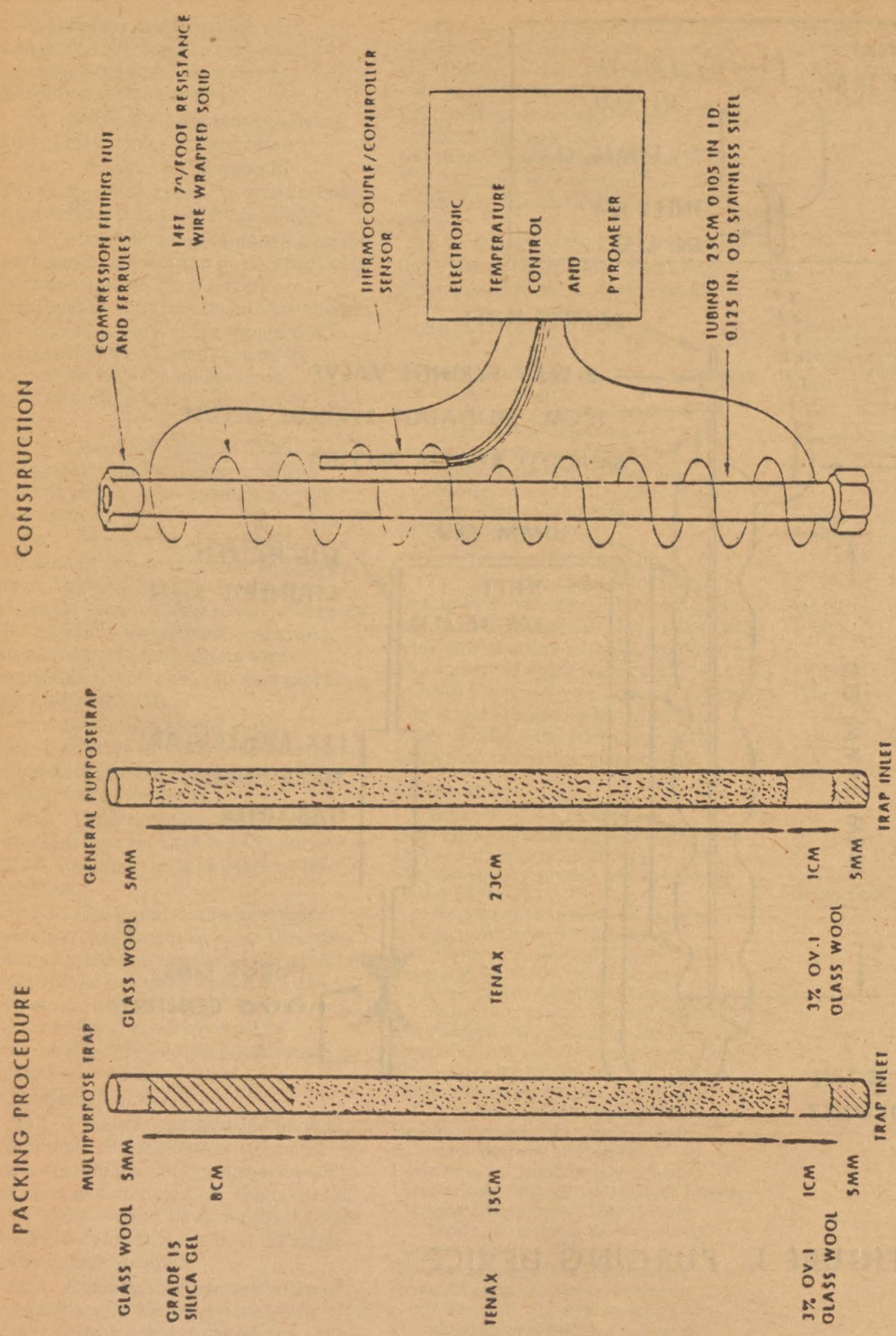

FIGURE 2 TRAP

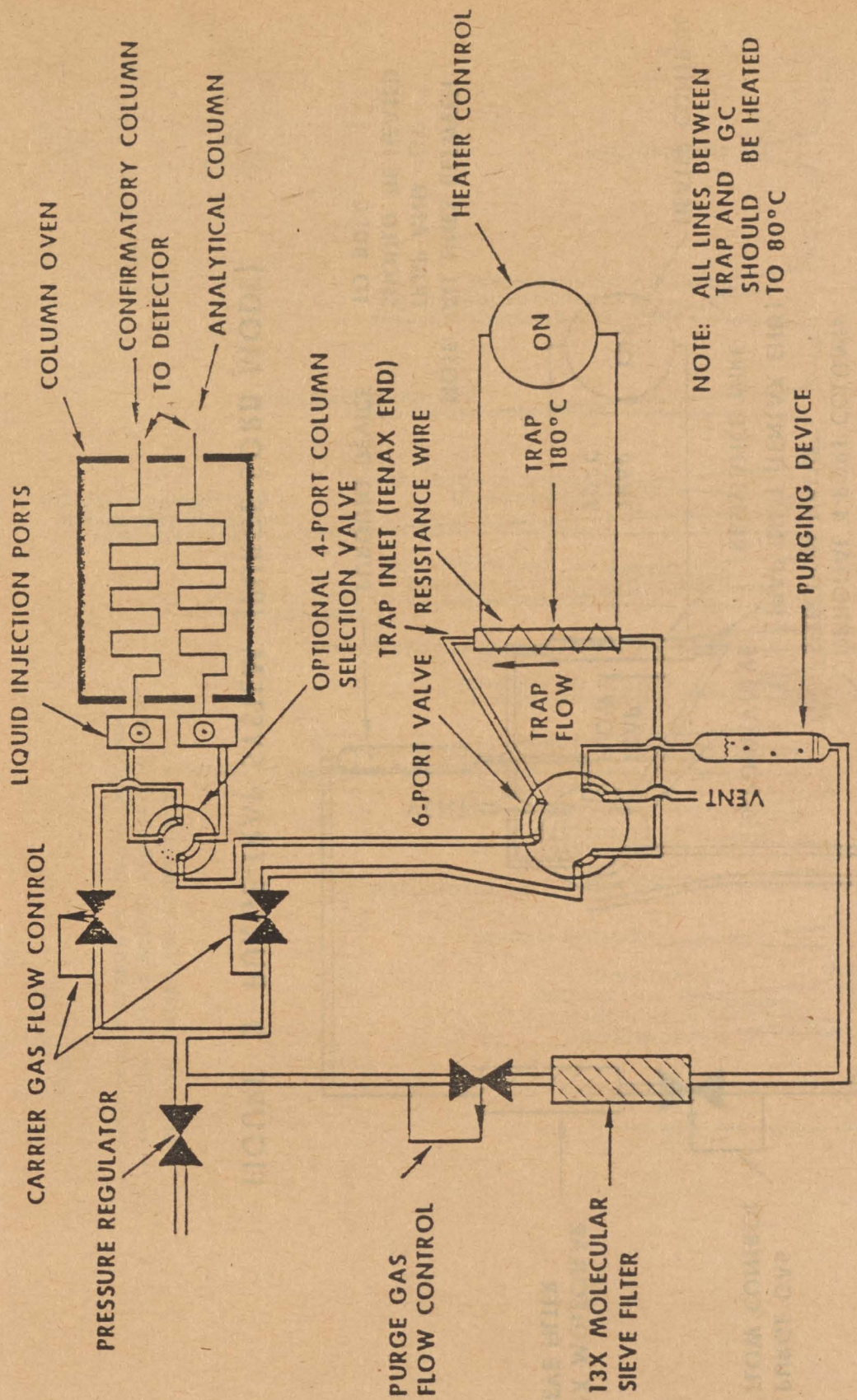

FIGURE 4 PURGE-TRAP SYSTEM (DESORB MODE)

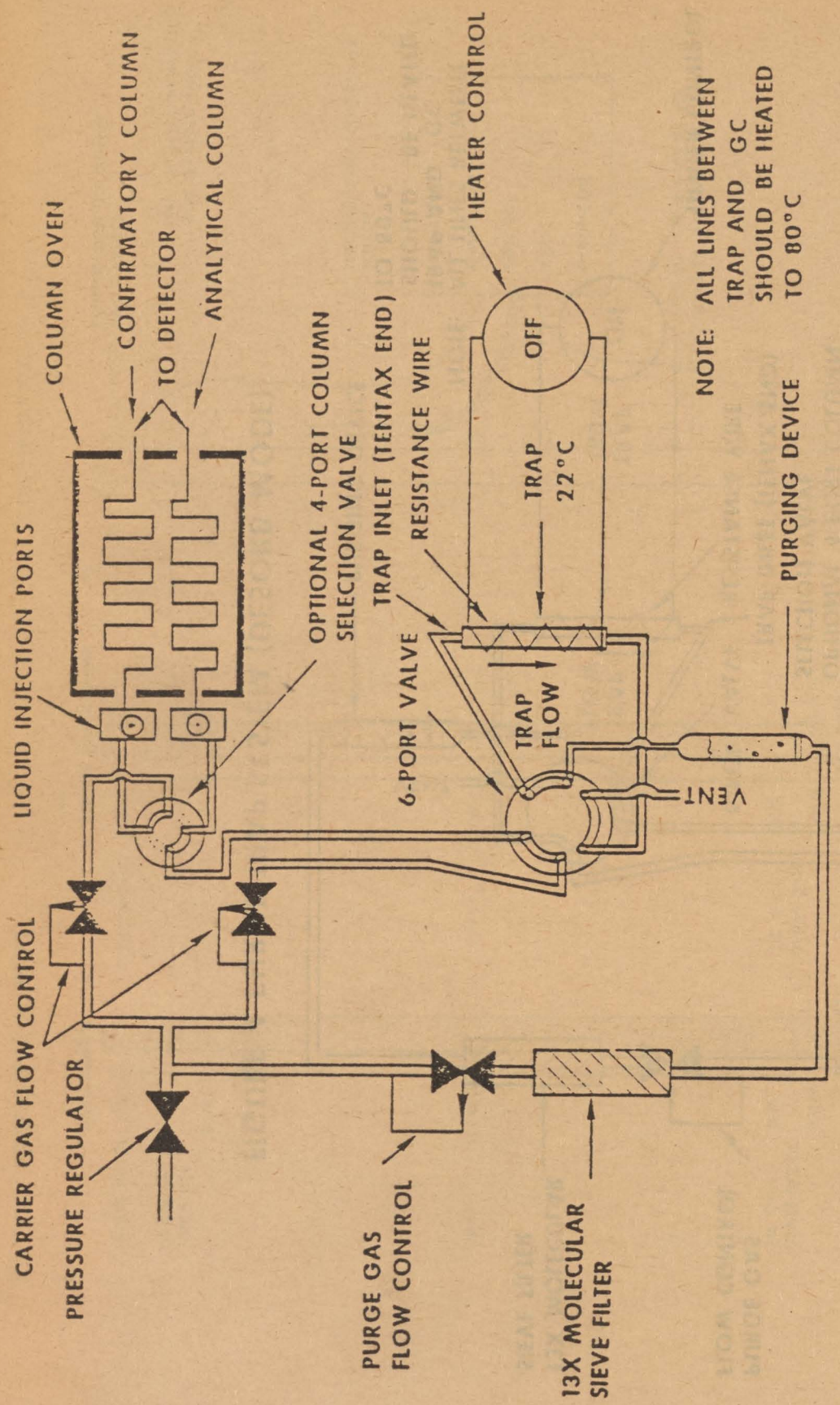

FIGURE 3 PURGE-TRAP SYSTEM (PURGE-SORB MODE)

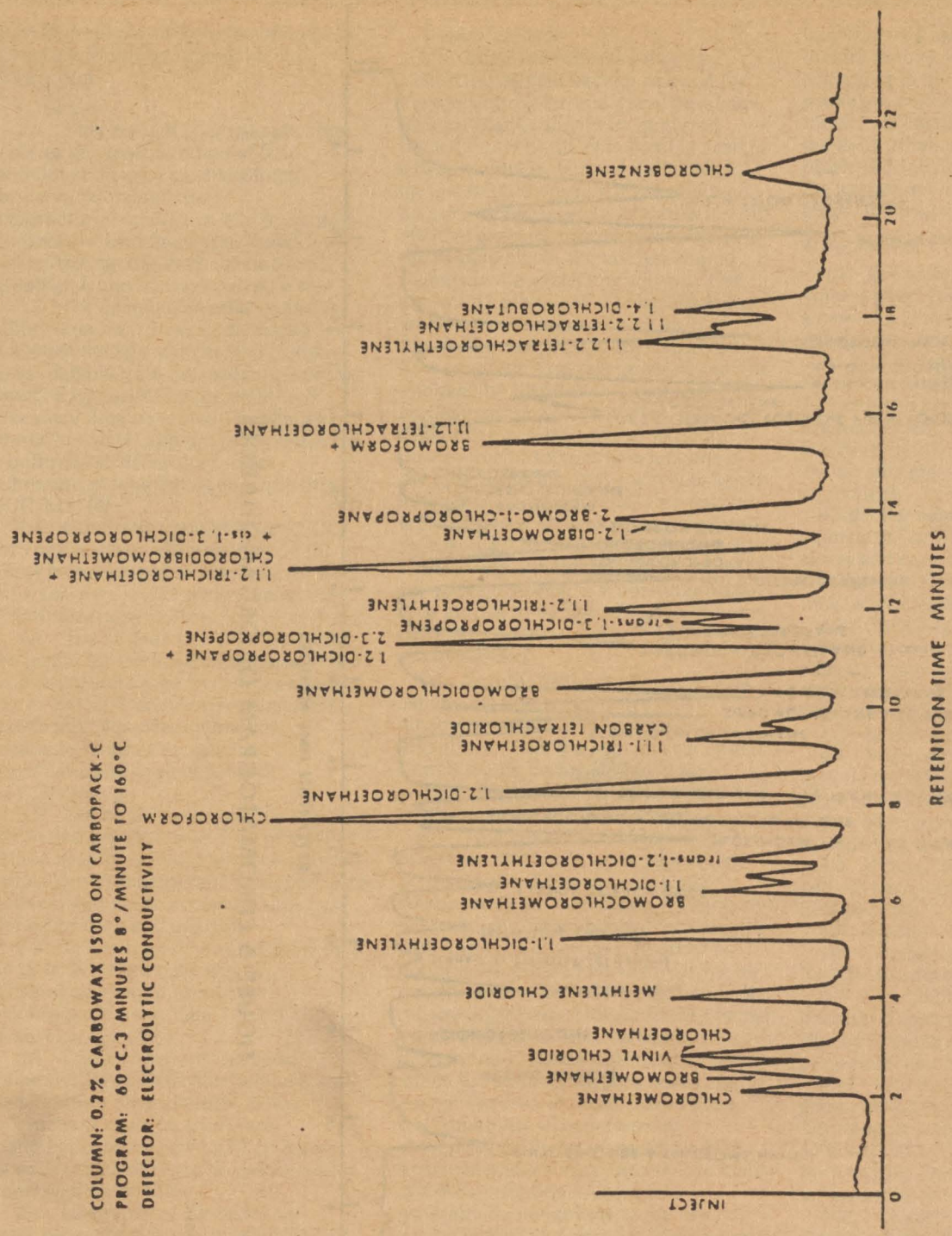

FIGURE 5 CHROMATOGRAM OF ORGANOHALIDES

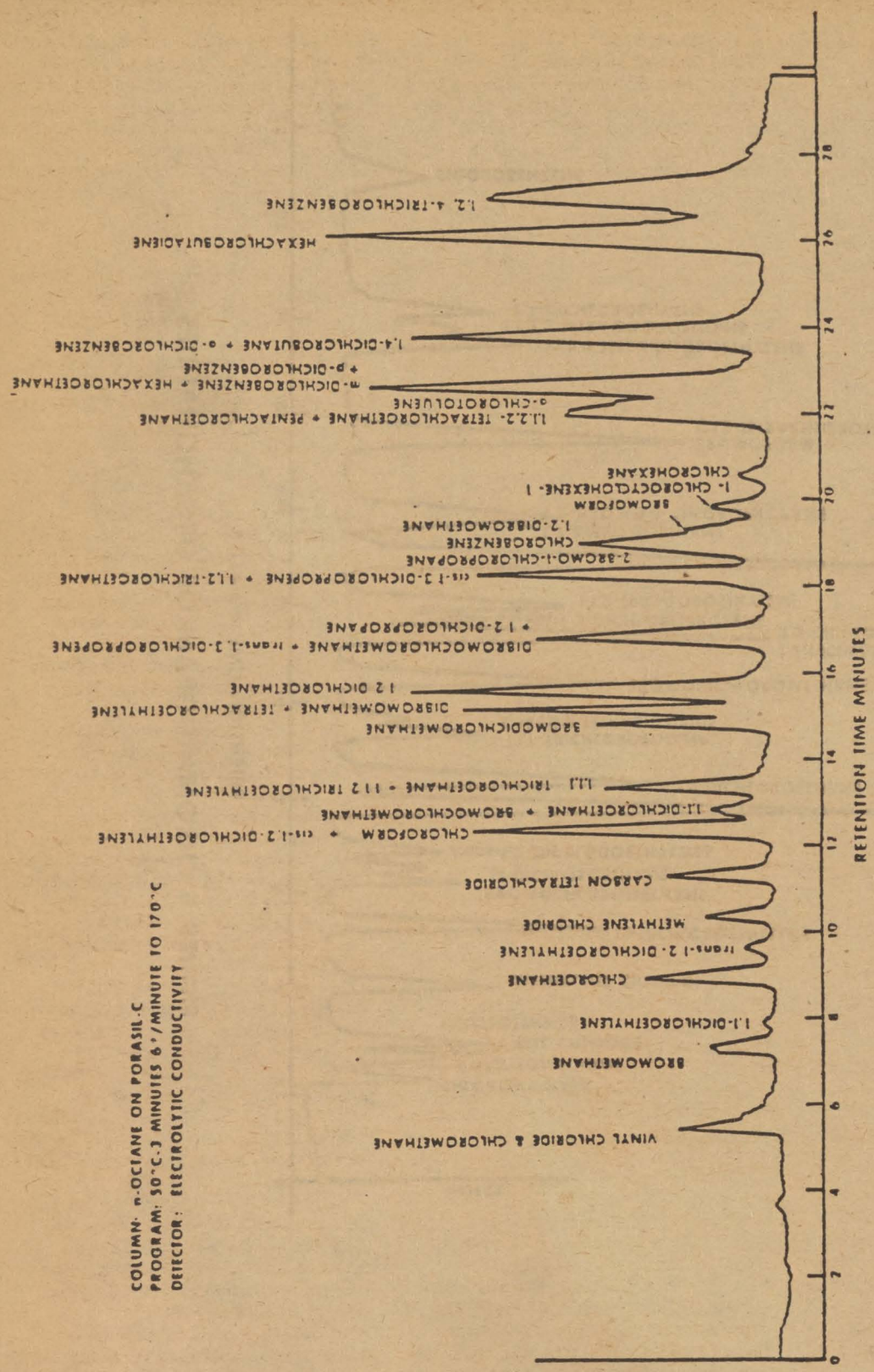

FIGURE 6 CHROMATOGRAM OF ORGANOHALIDES

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Part II: Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction

1. *Scope.*

1.1 This method (1,2) is applicable only to the determination of four trihalomethanes, i.e., chloroform, bromodichloromethane, chlorodibromomethane, and bromoform in finished drinking water, drinking water during intermediate stages of treatment, and the raw source water.

1.2 For compounds other than the above-mentioned trihalomethanes, or for other sample sources, the analyst must demonstrate the usefulness of the method by collecting precision and accuracy data on actual samples as described in (3) and provide qualitative confirmation of results by Gas Chromatography/Mass Spectrometry (GC/MS) (4).

1.3 Qualitative analyses using GC/MS or the purge and trap method (5) must be performed to characterize each raw source water if peaks appear as interferences in the raw source analysis.

1.4 The method has been shown to be useful for the trihalomethanes over a concentration range from approximately 0.5 to 200 μg/l. Actual detection limits are highly dependent upon the characteristics of the gas chromatographic system used.

2. *Summary*

2.1 Ten milliliters of sample are extracted one time with 2 ml of solvent. Three μl of the extract are then injected into a gas chromatograph equipped with a linearized electron capture detector for separation and analysis.

2.2 The extraction and analysis time is 10 to 50 minutes per sample depending upon the analytical conditions chosen. (See Table 1 and Figures 1, 2, and 3.)

2.3 Confirmatory evidence is obtained using dissimilar columns and temperature programming. When component concentrations are sufficiently high (>50 μg/l), halogen specific detectors may be employed for improved specificity.

2.4 Unequivocal confirmatory analyses at high levels (>50 μg/l) can be performed using GC/MS in place of the electron capture detector. At levels below 50 μg/l, unequivocal confirmation can only be performed by the purge and trap technique using GC/MS (4, 5).

2.5 Standards dosed into organic free water and the samples are extracted and analyzed in an identical manner in order to compensate for possible extraction losses.

2.6 The concentration of each trihalomethane is summed and reported as total trihalomethanes in μg/l.

3. *Interferences*

3.1 Impurities contained in the extracting solvent usually account for the majority of the analytical problems. Solvent blanks should be analyzed before a new bottle of solvent is used to extract samples. Indirect daily checks on the extracting solvent are obtained by monitoring the sample blanks (6.4.10). Whenever an interference is noted in the sample blank, the analyst should reanalyze the extracting solvent. The extraction solvent should be discarded whenever a high level (>10 μg/l) of interfering compounds are traced to it. Low level interferences generally can be removed by distillation or column chromatography (6); however, it is generally more economical to obtain a new source of solvent or select one of the approved alternative solvents listed in Section 5.1. Interference free solvent is defined as a solvent containing less than 0.4 μg/l individual trihalomethane interference. Protect interference-free solvents by storing in a non-laboratory area known to be free of organochlorine solvents. *Subtracting blank values is not recommended.*

3.2 Several instances of accidental sample contamination have been attributed to diffusion of volatile organics through the septum seal on the sample bottle during shipment and storage. The sample blank (6.4.10) is used to monitor for this problem.

3.3 This liquid/liquid extraction technique efficiently extracts a wide boiling range of non-polar organic compounds and, in addition, extracts the polar organic components of the sample with varying efficiencies. In order to perform the trihalomethane analysis as rapidly as possible with sensitivities in the low μg/l range, it is necessary to use the semi-specific electron capture detector and chromatographic columns which have relatively poor resolving power. Because of these concessions, the probability of experiencing chromatographic interferences is high. Trihalomethanes are primarily products of the chlorination process and generally do not appear in the raw source water. The absence of peaks in the raw source water analysis with retention times similar to the trihalomethanes is generally adequate evidence of an interference-free finished drinking water analysis. Because of these possible interferences, in addition to each finished drinking water analysis, a representative raw source water (6.4.5) must be analyzed. When potential interferences are noted in the raw source water analysis, the alternate chromatographic columns must be used to reanalyze the sample set. If interferences are still noted, qualitative identifications should be performed according to Sections 2.3 and 2.4. If the peaks are confirmed to be other than trihalomethanes and add significantly to the total trihalomethane value in the finished drinking water analysis, then the sample set must be analyzed by the purge and trap method (5).

4. *Apparatus*

4.1 Extraction vessel—A 15 ml total volume glass vessel with a Teflon lined screw-cap is required to efficiently extract the samples.

4.1.1 For samples that do not form emulsions 10 ml screw-cap flasks with a Teflon faced septum (total volume is ml) are recommended. Flasks and caps—Pierce—#13310 or equivalent. Septa—Teflon silicone—Pierce #12718 or equivalent.

4.1.2 For samples that form emulsions (turbid source water) 15 ml screw cap centrifuge tubes with a Teflon cap liner are recommended. Centrifuge tube—Corning 8062-15 or equivalent.

4.2 Sampling containers—40 ml screw cap sealed with Teflon faced silicone septa. Vials and caps—Pierce #13075 or equivalent. Septa—Pierce #12722 or equivalent.

4.3 Micro syringes—10, 100 μl.

4.4 Micro syringe—25 μl with a 2-inch by 0.006-inch needle—Hamilton 702N or equivalent.

4.5 Syringes—10 ml glass hypodermic with luerlok tip (2 each).

4.6 Syringe valve—2-way with luer ends (2 each)—Hamilton #86570—1FM1 or equivalent.

4.7 Pipette—2.0 ml transfer.

4.8 Glass stoppered volumetric flasks—10 and 100 ml.

4.9 Gas chromatograph with linearized electron capture detector. (Recommended option—temperature programmable. See Section 4.12.)

4.10 Column A—4 mm ID x 2m long glass packed with 3% SP-1000 on Supelcoport (100/120 mesh) operated at 50°C with 60 ml/min flow. (See Figure 1 for a sample chromatogram and Table 1 for retention data.)

4.11 Column B—2 mm ID x 2m long glass packed with 10% squalane on Chromosorb WAW (80/100 mesh) operated at 67°C with 25 ml/min flow. This column is recommended as the primary analytical column. Trichloroethylene, a common raw source water contaminate, coelutes with bromodichloromethane. (See Figure 2 for a sample chromatogram and Table 1 for retention data.)

4.12 Column C—2 mm ID x 3m long glass packed with 6% OV-11/4% SP-2100 on Supelcoport (100/120 mesh) temperature program 45°C for 12

minutes, then program at 1°/minute to 70°C with a 25 ml/min flow. (See Figure 3 for a sample chromatogram and Table I for retention data.)

4.13 Standard storage containers—15 ml amber screw-cap septum bottles with Teflon faced silicone septa. Bottles and caps—Pierce #19830 or equivalent. Septa—Pierce #12716 or equivalent.

5. Reagents

5.1 Extraction solvent—(See 3.1). Recommended—Pentane[a]. Alternative—hexane, methylcyclohexane or 2,2,4-trimethylpentane.

5.2 Methyl alcohol—ACS Reagent Grade.

5.3 Free and combined chlorine reducing agents—Sodium thiosulfate ACS Reagent Grade—sodium sulfite ACS Reagent Grade.

5.4 Activated carbon—Filtrasorb—200, available from Calgon Corporation, Pittsburgh, PA, or equivalent.

5.5 Standards.[b]

5.5.1 Bromoform 96%—available from Aldrich Chemical Company.

5.5.2 Bromodichloromethane 97%—available from Aldrich Chemical Company.

5.5.3 Chlorodibromomethane—available from Columbia Chemical, Incorporated, Columbia, S.C.

5.5.4 Chloroform 99%—available from Aldrich Chemical Company.

5.6 Organic-free water—Organic-free water is defined as water free of interference when employed in the procedure described herein.

5.6.1 Organic-free water is generated by passing tap water through a carbon filter bed containing carbon. Change the activated carbon whenever the concentration of any trihalomethane exceeds 0.4 μg/l.

5.6.2 A Millipore Super-Q Water System or its equivalent may be used to generate organic-free deionized water.

5.6.3 Organic-free water may also be prepared by boiling water for 15 minutes. Subsequently, while maintaining the temperature at 90° C, bubble a contaminant free inert gas through the water at 100 ml/minute for one hour. While still hot, transfer the water to a narrow mouth screw cap bottle with a Teflon seal.

5.6.4 Test organic free water each day it is used by analyzing it according to Section 7.

5.7 Standard stock solutions.

5.7.1 Fill a 10.0 ml ground glass stoppered volumetric flask with approximately 9.8 ml of methyl alcohol.

5.7.2 Allow the flask to stand unstoppered about 10 minutes or until all alcohol wetted surfaces dry.

5.7.3 Weigh the unstoppered flask to the nearest 0.1 mg.

5.7.4 Using a 100 μl syringe, immediately add 2 to 3 drops of the reference standard to the flask, then reweigh. *Be sure that the reference standard falls directly into the alcohol without contacting the neck of the flask.*

5.7.5 Dilute to volume, stopper, then mix by inverting the flask several times.

5.7.6 Transfer the standard solution to a dated and labeled 15 ml screw-cap bottle with a Teflon cap liner.

Note.—Because of the toxicity of trihalomethanes, it is necessary to prepare primary dilutions in a hood. It is further recommended that a NIOSH/MESA-approved toxic gas respirator be used when the analyst handles high concentrations of such materials.

5.7.7 Calculate the concentration in micrograms per microliter from the net gain in weight.

5.7.8 Store the solution at 4° C.

Note.—All standard solutions prepared in methyl alcohol are stable up to 4 weeks when stored under these conditions. They should be discarded after that time has elapsed.

5.8 Aqueous calibration standard precautions.

5.8.1 In order to prepare accurate aqueous standard solutions, the following precautions must be observed:

a. Do not inject more than 20 μl of alcoholic standards into 100 ml of organic-free water.

b. Use a 25 μl Hamilton 702N microsyringe or equivalent. (Variations in needle geometry will adversely affect the ability to deliver reproducible volumes of methanolic standards into water.)

c. Rapidly inject the aloholic standard into the expanded area of the filled volumetric flask. Remove the needle as fast as possible after injection.

d. Mix aqueous standards by inverting the flask three times only.

e. Discard the contents contained in the neck of the flask. Fill the sample syringe from the standard solution contained in the expanded area of the flask as directed in Section 7.

f. Never use pipets to dilute or transfer samples and aqueous standards.

g. Aqueous standards, when stored with a headspace, are not stable and should be discarded after one hour. Aqueous standards can be stored according to Sections 6.4.9 and 7.2.

5.9 Calibration standards.

5.9.1 Prepare, from the standard stock solutions, a multicomponent secondary dilution mixture in methyl alcohol so that a 20 μl injection into 100 ml of organic-free water will generate a calibration standard which produces a response close (± 25%) to that of the unknown. (See 8.1.)

5.9.2 Alternative calibration procedure.

5.9.2.1 Construct a calibration curve for each trihalomethane containing a minimum of 3 different concentrations. Two of the concentrations must bracket each unknown.

5.9.3 Extract and analyze the aqueous calibration standards in the same manner as the unknowns.

5.9.4 Other calibration procedures (7) which require the delivery of less than 20 μl of methanolic standards to 10.0 ml volumes of water contained in the sample syringe are acceptable only if the methanolic standard is delivered by the solvent flush technique (8).

5.10 Quality Check Standard Mixture.

5.10.1 Prepare, from the standard stock solutions, a secondary dilution mixture in methyl alcohol that contains 10.0 ng/μl of each compound. (See 5.7.6 and 5.7.8.)

5.10.2 Daily, prepare and analyze a 2.0 μg/l aqueous dilution from this mixture by dosing 20.0 μl into 100 ml of organic-free water (See Section 8.1).

6. *Sample Collection and Handling.*

6.1 The sample containers should have a total volume of at least 25 ml.

6.1.1 Narrow-mouth screw-cap bottles with the TFE fluorocarbon faced silicone septa cap liners are strongly recommended.

6.2 Glassware Preparation.

6.2.1 Wash all sample bottles, TFE seals, and extraction flasks in detergent. Rinse with tap water and finally with distilled water.

6.2.2 Allow the bottles and seals to air dry, then place in an 105° C oven for 1 hour, then allow to cool in an area known to be free of organics.

Note.—Do not heat the TFE seals for extended periods of time (>1 hour) because the silicone layer slowly degrades at 105° C.

6.2.3 When cool, seal the bottles using the TFE seals that will be used for sealing the samples.

6.3 Sample stabilization—A chemical reducing agent (Section 5.3) is added to all samples in order to arrest the formation of additional

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[a] Pentane has been selected as the best solvent for this analysis because it elutes, on all of the columns, well before any of the trihalomethanes. High altitudes or laboratory temperatures in excess of 75°F may make the use of this solvent impractical. For these reasons, alternative solvents are acceptable; however, the analyst may experience baseline variances in the elution areas of the trihalomethanes due to coelution of these solvents. The degree of difficulty appears to be dependent upon the design and condition of the electron capture detector. Such problems should be insignificant when concentrations of the coeluting trihalomethane are in excess of 5 μg/l.

[b] As a precautionary measure, all standards must be checked for purity by boiling point determinations or GC/MS assays.

trihalomethanes after sample collection (7,9) and to eliminate the possibility of free chlorine reacting with impurities in the extraction solvent to form interfering organohalides. *DO NOT ADD THE REDUCING AGENT TO SAMPLES AT COLLECTION TIME WHEN DATA FOR MAXIMUM TRIHALOMETHANE FORMATION IS DESIRED.* If chemical stabilization is employed, then the reagent is also added to the blanks. The chemical agent (2.5 to 3 mg/40 ml) is added in crystalline form to the empty sample bottle just prior to shipping to the sampling site. If chemical stabilization is not employed at sampling time then the reducing agent is added just before extraction.

6.4 Sample Collection.

6.4.1 Collect all samples in duplicate.

6.4.2 Fill the sample bottles in such a manner that no air bubbles pass through the sample as the bottle is filled.

6.4.3 Seal the bottle so that no air bubbles are entrapped in it.

6.4.4 Maintain the hermetic seal on the sample bottle until analysis.

6.4.5 The raw source water sample history should resemble the finished drinking water. The average retention time of the finished drinking water within the water plant should be taken into account when sampling the raw source water.

6.4.6 Sampling from a water tap.

6.4.6.1 Turn on the water and allow the system to flush until the temperature of the water has stabilized. Adjust the flow to about 500 ml/minute and collect duplicate samples from the flowing stream.

6.4.7 Sampling from an open body of water.

6.4.7.1 Fill a 1-quart wide-mouth bottle with sample from a representative area. Carefully fill duplicate sample bottles from the 1-quart bottle as in 6.4.

6.4.8 If a chemical reducing agent has been added to the sample bottles, fill with sample just to overflowing, seal the bottle, and shake vigorously for 1 minute.

6.4.9 Sealing practice for septum seal screw cap bottles.

6.4.9.1 Open the bottle and fill to overflowing. Place on a level surface. Position the TFE side of the septum seal upon the convex sample meniscus and seal the bottle by screwing the cap on tightly.

6.4.9.2 Invert the sample and lightly tap the cap on a solid surface. The absence of entrapped air indicates a successful seal. If bubbles are present, open the bottle, add a few additional drops of sample, then reseal bottle as above.

6.4.10 Sample blanks.

6.4.10.1 Prepare blanks in duplicate at the laboratory by filling and sealing sample bottles with organic-free water just prior to shipping the sample bottles to the sampling site.

6.4.10.2 If the sample is to be stabilized, add an identical amount of reducing agent to the blanks.

6.4.10.3 Ship the blanks to and from the sampling site along with the sample bottles.

6.4.10.4 Store the blanks and the samples, collected at a given site (sample set), together in a protected area known to be free from contamination. A sample set is defined as all the samples collected at a given site (i.e., at a water treatment plant, duplicate raw source water, duplicate finished water and the duplicate sample blanks comprise the sample set).

6.5 When samples are collected and stored under these conditions, no measurable loss of trihalomethanes has been detected over extended periods of time (7). It is recommended that the samples be analyzed within 14 days of collection.

7. *Extraction and Analysis.*

7.1 Remove the plungers from two 10-ml syringes and attach a closed syringe valve to each.

7.2 Open the sample bottle [c] (or standard) and carefully pour the sample into one of the syringe barrels until it overflows. Replace the plunger and compress the sample. Open the syringe valve and vent any residue air while adjusting the sample volume to 10.0 ml. Close the valve.

7.3 Fill the second syringe in an identical manner from the same sample bottle. This syringe is reserved for a replicate analysis (see 8.3 and 8.4).

7.4 Pipette 2.0 ml of extraction solvent into a clean extraction flask.

7.5 Carefully inject the contents of the syringe into the extraction flask.

7.6 Seal with a Teflon faced septum.

7.7 Shake vigorously for 1 minute.

7.8 Let stand until the phases separate ($\int$60 seconds).

7.8.1 If the phases do not separate on standing then centrifugation can be used to facilitate separation.

7.9 Analyze the sample by injecting 3.0 μl (solvent flush technique, (8)) of the upper (organic) phase into the gas chromatograph.

8. *Analytical Quality Control.*

8.1 A 2 μg/l quality check standard (See 5.10) should be extracted and analyzed each day before any samples are analyzed. Instrument status checks and lower limit of detection estimations based upon response factor calculations at 5 times the noise level are obtained from these data. In addition, the data obtained from the quality check standard can be used to estimate the concentration of the unknowns. From this information the appropriate standards can be determined.

8.2 Analyze the sample blank and the raw source water to monitor for potential interferences as described in Sections 3.1, 3.2, and 3.3.

8.3 Spiked samples.

8.3.1 For those laboratories analyzing more than 10 samples a day, each 10th sample analyzed should be a laboratory-generated spike which closely duplicates the average finished drinking water in trihalomethane composition and concentration. Prepare the spiked sample in organic-free water as described in section 5.9.

8.3.2 In those laboratories analyzing less than 10 samples daily, each time the analysis is performed, analyze at least one laboratory generated spike sample which closely duplicates the average finished drinking water in trihalomethane composition and concentration. Prepare the spiked sample in organic-free water as described in section 5.9.

8.3.3 Maintain an up-to-date log on the accuracy and precision data collected in Sections 8.3 and 8.4. If results are significantly different than those cited in Section 10.1, the analyst should check out the entire analysis scheme to determine why the laboratory's precision and accuracy limits are greater.

8.4 Randomly select and analyze 10% of all samples in duplicate.

8.5 Analyze all samples in duplicate which appear to deviate more than 30% from any established norm.

8.6 Quarterly, spike an EMSL-Cincinnati trihalomethane quality control sample into organic-free water and analyze.

8.6.1 The results of the EMSL trihalomethane quality control sample should agree within 20% of the true value for each trihalomethane. If they do not, the analyst must check each step in the standard generation procedure to solve the problem.

8.7 It is important that the analyst be aware of the linear response characteristics of the electron capture system that is utilized. Calibration curves should be generated and rechecked quarterly for each trihalomethane over the concentration range encountered in the samples in order to confirm the linear response range of the system. Quantitative data cannot be calculated from non-linear

[c] If for any reason the chemical reducing agent has not been added to the sample, then it must be added just prior to analyses at the rate of 2.5 to 3 mg/40 ml or by adding 1 mg directly to the sample in the extraction flask.

responses. Whenever non-linear responses are noted, the analyst must dilute the sample for reanalysis.

8.8 Maintain a record of the retention times for each trihalomethane using data gathered from spiked samples and standards.

8.8.1 Daily calculate the average retention time for each trihalomethane and the variance encountered for the analyses.

8.8.2 If individual trihalomethane retention time varies by more than 10% over an eight hour period or does not fall within 10% of an established norm, the system is "out of control." The source of retention data variation must be corrected before acceptable data can be generated.

9. *Calculations.*

9.1 Locate each trihalomethane in the sample chromatogram by comparing the retention time of the suspect peak to the data gathered in 8.8.1. The retention time of the suspect peak must fall within the limits established in 8.8.1 for a single column identification.

9.2 Calculate the concentration of each trihalomethane by comparing the peak heights or peak areas of the samples to those of the standards. Round off the data to the nearest $\mu g/l$ or two significant Figures.

Concentration, $\mu g/l$ = sample peak height/standard peak height × standard concentration, $\mu g/l$.

9.3 Calculate the total trihalomethane concentration (TTHM) by summing the 4 individual trihalomethane concentrations in $\mu g/l$:

TTHM ($\mu g/l$) = (conc. $CHCl_3$) + (conc. $CHBrCl_2$) + (conc. $CHBr_2Cl$) + (conc. $CHBr_3$)

9.4 Calculate the limit of detection (LOD) for each trihalomethane not detected using the following criteria:

$$\text{LOD } (\mu g/l) = \left(\frac{(AXATT)}{(BXATT)}\right) \times (2\ \mu g/l)$$

Where:

B = peak height (mm) of 2 $\mu g/l$ quality check standard

A = 5 times the noise level in mm at the exact retention time of the trihalomethane or the base line displacement in mm from theoretical zero at the exact retention time for the trihalomethane.

ATT = attenuation factor.

9.5 Report the results obtained from the lower limit of detection estimates along with the data for the samples.

10. *Precision and Accuracy*

10.1 Single lab precision and accuracy. The data in Table II were generated by spiking organic-free water with trihalomethanes as described in 5.9. The mixtures were analyzed by the analyst as true unknowns.

Table I.—*Retention Times for Trihalomethanes*

Trihalomethane	Retention time minutes		
	Column A	Column B	Column C
Chloroform	1.0	1.3	4.9
Bromodichloromethane	1.5	[a]2.5	11.0
Chlorodibromomethane	2.6	5.6	23.1
(Dibromochloromethane) bromoform	5.5	10.9	39.4

[a] On this column, trichloroethylene, a common raw source water contaminate, coelutes with bromodichloromethane.

Table II.—*Single Laboratory Accuracy and Precision*

	Dose level $\mu g/l$	Number of samples	Mean $\mu g/l$	Precision relative standard deviation, percent	Accuracy percent recovery
Compound:					
$CHCl_3$	9.1	5	10	11	110
$CHCl_3$	69	3	73	5.3	106
$CHBrCl_2$	1.2	5	1.3	9.8	108
$CHBrCl_2$	12	2	15	1.4	125
$CHBr_2Cl$	2.7	5	2.0	17	74
$CHBr_2Cl$	17	3	16	9.9	94
$CHBr_3$	2.9	5	2.2	10	76
$CHBr_3$	14	3	16	12	114

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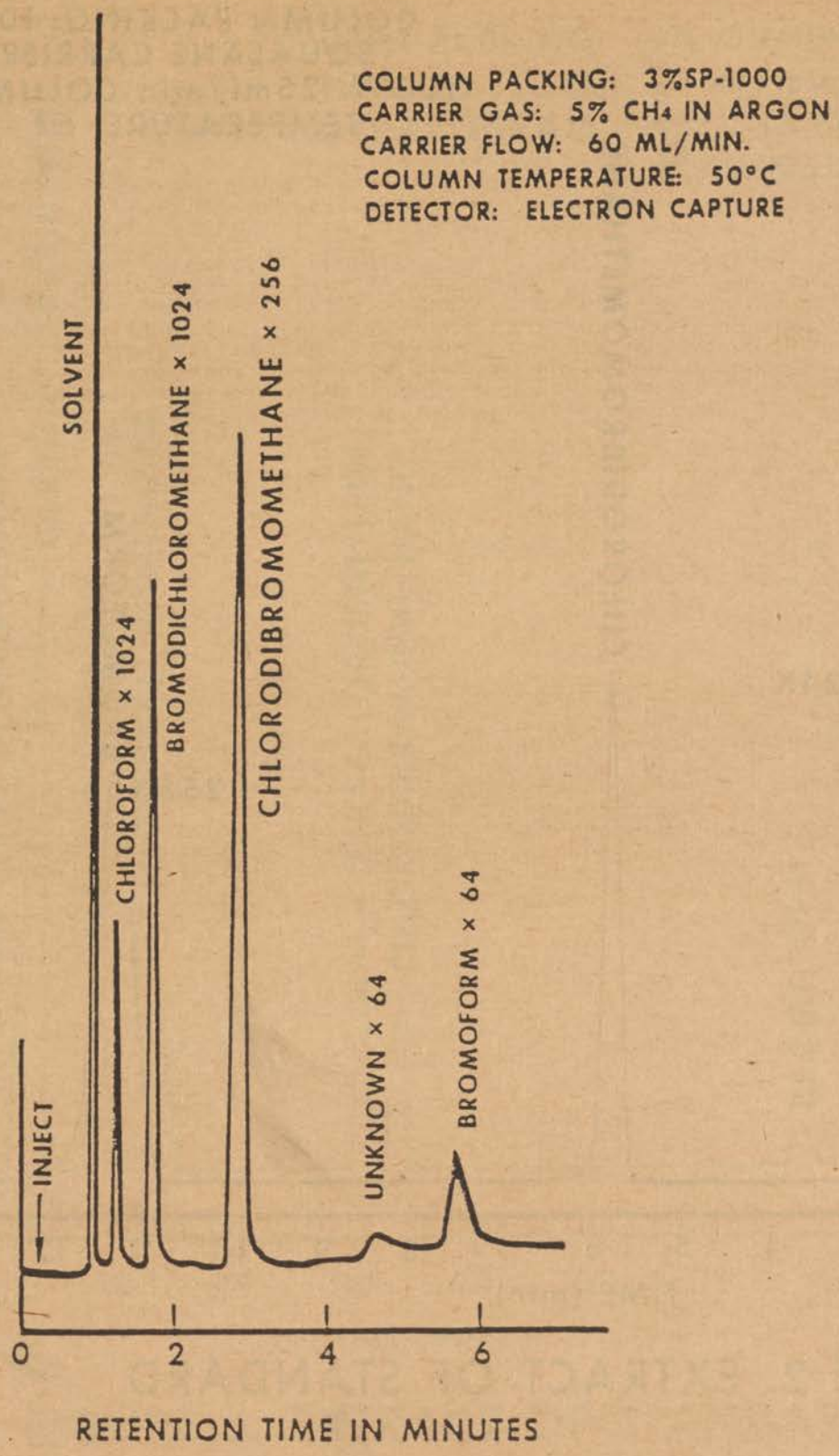

FIGURE 1. FINISHED WATER EXTRACT

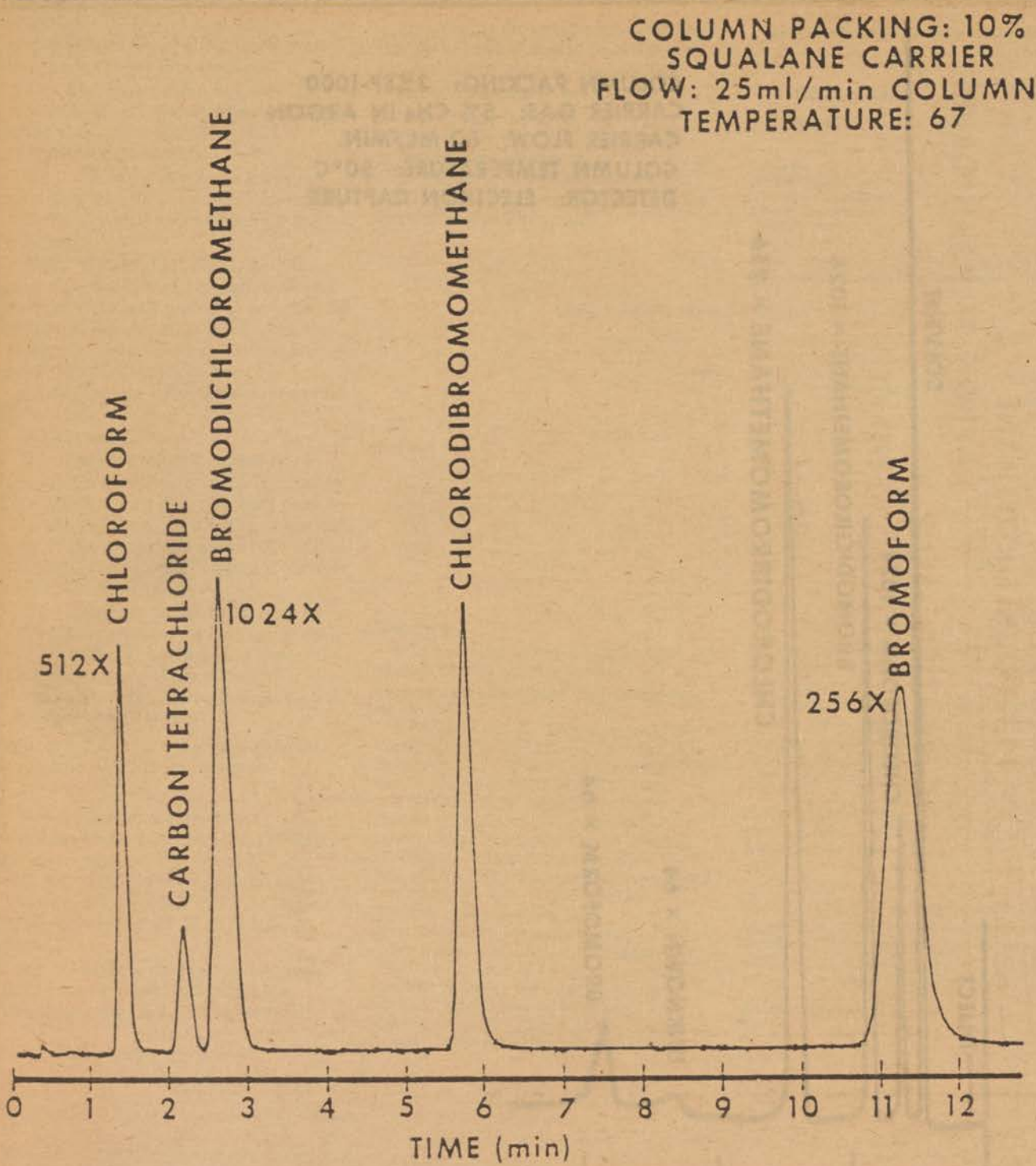

FIGURE 2. EXTRACT OF STANDARD

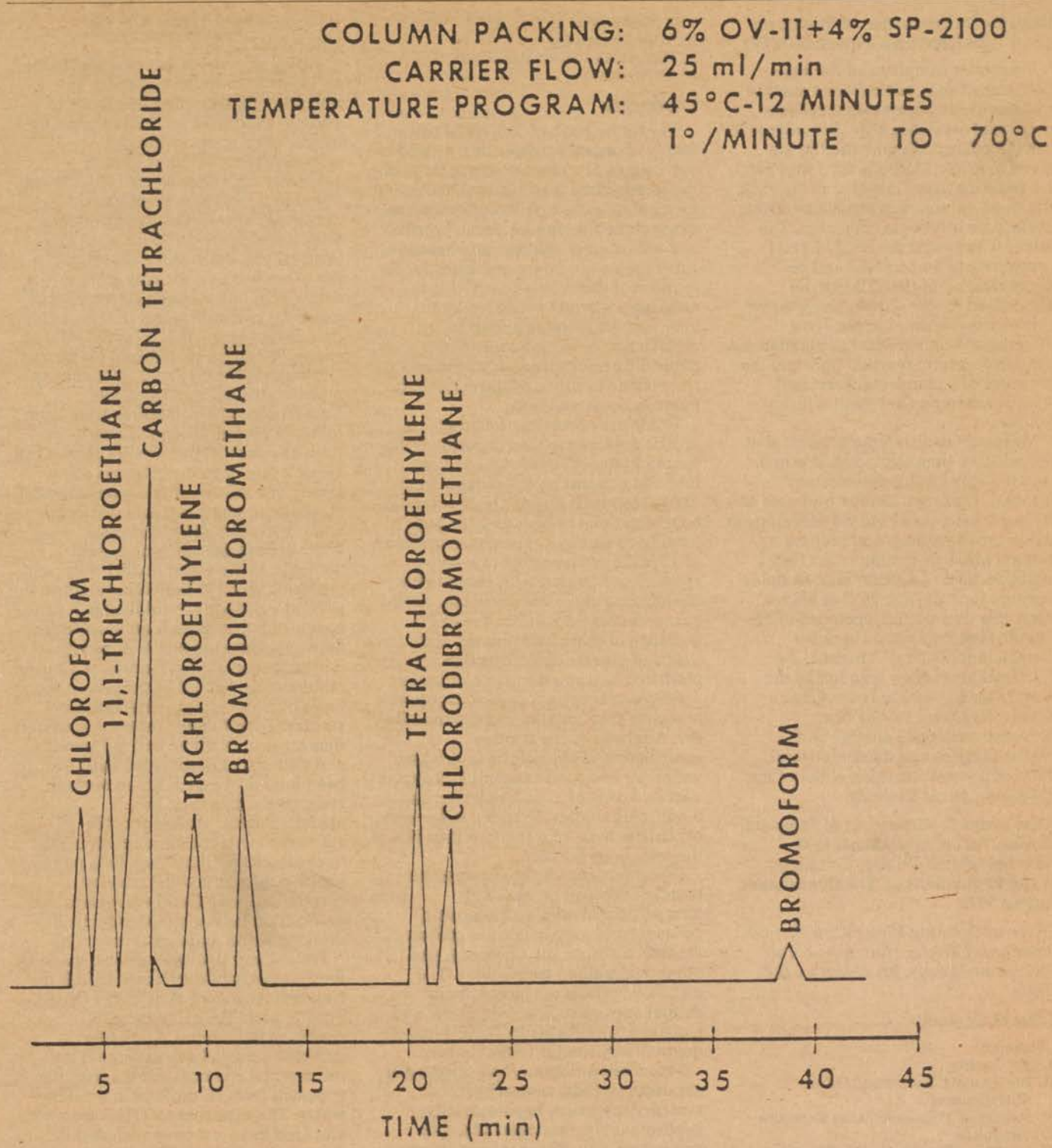

FIGURE 3. EXTRACT OF STANDARD

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Part III—Determination of Maximum Total Trihalomethane Potential (MTP)

The water sample used for this determination is taken from a point in the distribution system that reflects maximum residence time. Procedures for sample collection and handling are given in EMSL Methods 501.1 and 501.2. No reducing agent is added to "quench" the chemical reaction producing THMs at the time of sample collection. The intent is to permit the level of THM precursors to be depleted and the concentration of the THMs to be maximized for the supply being tested.

Four experimental parameters affecting maximum THM production are pH, temperature, reaction time and the presence of a disinfectant residual. These parameters are dealt with as follows:

Measure the disinfectant residual at the selected sampling point. Proceed only if a measurable disinfectant residual is present. Collect triplicate 40 ml water samples at the pH prevailing at the time of sampling, and prepare a method blank according to the EMSL methods. Seal and store these samples together for 7 days at 25°C or above. After this time period, open one of the sample containers and check for disinfectant residual. Absence of a disinfectant residual invalidates the sample for further analyses. Once a disinfectant residual has been demonstrated, open another of the sealed samples and determine total THM concentration using either of the EMSL analytical methods.

Attachment 7.—Statement of Basis and Purpose for an Amendment to the National Interim Primary Drinking Water Regulations on Trihalomethanes, August 1979

Office of Drinking Water Criteria and Standards Division, Environmental Protection Agency, Washington, D.C. 20460.

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I. Summary

The trihalomethanes (THMs) are a family of organic compounds, named as derivatives of methane, where three of the four hydrogen atoms are substituted by a halogen atom. Although halogens can include fluorine, chlorine, bromine and iodine, only chlorine and bromine substituents are now considered for the purpose of this regulation. THMs in drinking water are produced by the action of the chlorine added for disinfection or oxidation, with the naturally occurring organic precursors (e.g., humic or fulvic acids) commonly found in source waters.

THMs are commonly found in drinking water supplies throughout the United States. Chloroform has been found at concentrations ranging from 0.001–0.540 mg/l and (TTHM) potential concentrations as high as 0.784 mg/l have been detected. The concentrations of TTHM increase when raw water supplies are treated with chlorine for disinfection and other purposes. TTHM concentrations are indicative of the presence of other halogenated and oxidized organic chemicals that are produced in water during chlorination.

People are also exposed to chloroform in the air they breathe and the food they eat. Analyses of the relative contribution of chloroform in drinking water, air and food exposures assumed various levels of exposure based on monitoring studies. Drinking water may contribute from zero to more than 90% of the total body burden.

Chloroform has been shown to be rapidly absorbed on oral and intraperitoneal administration and subsequently metabolized to carbon dioxide, chloride ion, phosgene, and other unidentified metabolites. The metabolic profile of chloroform in animal species such as mice, rats, and monkeys is indicated in Table 4 and is qualitatively similar to that in man.

Mammalian responses to chloroform exposure include: central nervous system depression, hepatotoxicity, nephrotoxicity, teratogenicity, and carcinogenicity. These responses are discernible in mammals after oral and inhalation exposures to high levels of chloroform ranging from 30–350 mg/kg; the intensity of response is dependent upon the dose. Although less toxicological information is available for the brominated THMs, mutagenicity and carcinogenicity have been detected in some test systems. Physiological chemical activity should be greater for the brominated THMs than for chloroform.

Although short-term toxic responses to THMs in drinking water are not documented, the potential effects of chronic exposures to THMs should be a matter of concern. Prolonged administration of chloroform at relatively high dose levels (100–138 mg/kg) to rats and mice, manifested oncogenic effects. Oncogenic effects were not observed at the lowest dose level (17 mg/kg) in three experiments. Since methods do not now exist to establish a threshold no effect level of exposure to carcinogens, the preceding data do not imply that a "safe" level of exposure can be established for humans.

Human epidemiological evidence is inconclusive, although positive correlations with some sites have been found in several studies. There have been 18 retrospective studies shown in Table 7 that have investigated some aspect of a relationship between cancer mortality or morbidity and drinking water variables. Due to various limitations in the epidemiological methods, in the water quality data, and problems with the individual studies, the present evidence cannot lead to a firm conclusion that there is an association between contaminants in drinking water and cancer mortality/morbidity. Causal relationships cannot be proven on the basis of results from epidemiological studies. The evidence from these studies thus far is incomplete and the trends and patterns of association have not been fully developed. When viewed collectively, however, the epidemiological studies provide sufficient evidence for maintaining the hypotheses that there may be a potential health risk, and that the positive correlations may be reflecting a causal association between constituents of drinking water and cancer mortality.

Preliminary risk assessments made by the Science Advisory Board (SAB), the National Academy of Sciences (NAS), Tardiff, and EPA's Carcinogen Assessment Group (CAG) using different models have estimated the incremental risks associated with the exposure from chloroform in drinking water. The exposure to THMs from air and food have not been included in these computations. The risk estimates associated with the MCL at the 0.10 mg/l level are essentially the same from the NAS and CAG computations (3.4×10^{-4} and 4×10^{-4}) assuming two liters of water at 0.10 mg/l chloroform consumed daily for 70 years.

On the basis of the available toxicological data summarized in the following report, chloroform has been shown to be a carcinogen in rodents

(mice and rats) at high dose levels. Since its metabolic pattern in animals is qualitatively similar to that in man, it should be suspected of being a human carcinogen. Epidemiological studies also suggest a human risk. Therefore, because a potential human health risk does exist, levels of chloroform in drinking water should be reduced as much as is technologically and economically feasible using methods that will not compromise protection from waterborne infectious disease transmission.

Although documentation of their toxicity is not so well established, other THMs should be suspected of posing similar risks. Because the treatment process that can reduce drinking water levels of chloroform have about the same effectiveness in reducing levels of the other THMs, the proposed regulation is addressed to these substances, as well.

II. Introduction

The extent and significance of organic chemical contamination of drinking water or drinking water sources first came to public attention in 1972, when a report, "Industrial Pollution of the Lower Mississippi River in Louisiana" was published (EPA, 1972). While this report did not include quantification of the pollutants found, and was directed toward locating industrial discharges responsible for the pollution, the report did include analyses of finished (treated) drinking water and provided evidence of the presence of THMs. Subsequently, a more thorough examination of finished drinking water in the New Orleans area was carried out, using the most sophisticated analytical methods available (EPA, 1974). This latter study confirmed the presence of THMs and many other organic chemicals in finished drinking water, and furthermore it demonstrated that one of them, chloroform, was present in high relative concentrations.

The findings in New Orleans promoted other studies, primarily for the purpose of determining how widespread and serious the organic chemical contamination of drinking water was. Impetus was added by the passage of the Safe Drinking Water Act (Pub. L. 93-523), which directed the EPA to conduct a comprehensive study of public water supplies and drinking water sources to determine the nature, extent, sources, and means of control of contamination by substances suspected of being carcinogenic. The National Organics Reconnaissance Survey of Halogenated Organics (NORS) (Symons, et al, 1975), or "80 City Study", was aimed primarily at determining the extent of the presence of four THMs, *chloroform, bromodichloromethane, dibromochloromethane* and *bromoform*, along with carbon tetrachloride and 1,2-dichloroethane, and at determining what effect raw water source and water treatment practices had on the formation of these compounds (Table 1). The presence of THMs in finished drinking water was confirmed, and some trend relating non-volatile total organic carbon (NVTOC) of the raw water and the total trihalomethane (TTHM) was postulated. Chloroform occurred invariably in water which had been chlorinated, while it was absent or present at much lower concentrations in the raw water. Water samples were collected at the treatment plant in winter and iced for shipment but not dechlorinated. Thus, those values might approximate minima for human exposure in the areas selected. Of the various THMs, chloroform was found at the highest concentrations (averaging approximately 75 percent of the TTHM), with progressively less bromodichloromethane, dibromochloromethane and bromoform being detected. In some cases chloroform was found at concentrations greater than 0.300 mg/l; (the highest value found was 0.540 mg/l). Carbon tetrachloride and 1,2-dichloroethane were found at very low concentrations. The concentration of these two components did not increase after chlorination; therefore, it can be assumed that these compounds are not related to the chlorination process.

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TABLE I - Analytical results of chloroform, bromoform, bromodichloromethane, and dibromochloromethane and total trihalomethanes in water supplies from NORS and NOMS

(Concentrations in milligrams per liter)

	NORS	NOMS			
		Phase I	Phase II	Phase III	
				Dechlorinated	Terminal
Chloroform					
Median	0.021	0.027	0.059	0.022	0.044
Mean	-	0.043	0.083	0.035	0.069
Range	NF-0.311	NF-0.271	NF-0.47	NF-0.20	NF-0.540
Bromoform					
Median	0.005	LD	LD	LD	LD
Mean	-	0.003	0.004	0.002	0.004
Range	NF-0.092	NF-0.039	NF-0.280	NF-0.137	NF-0.190
Dibromochloromethane					
Median	0.001	LD	0.004	0.002	0.003
Mean	-	0.008	0.012	0.006	0.011
Range	NF-0.100	NF-0.19	NF-0.290	NF-0.114	NF-0.250
Bromodichloromethane					
Median	0.006	0.010	0.014	0.006	0.011
Mean	-	0.018	0.018	0.009	0.017
Range	NF-0.116	NF-0.183	NF-0.180	NF-0.072	NF-0.125
Total Trihalomethanes					
Median	0.027	0.045	0.087	0.037	0.074
Mean	0.067	0.068	0.117	0.053	0.100
Range	NF-0.482	NF-0.457	NF-0.784	NF-0.295	NF-0.695

NF = not found
LD = less than detection limit

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A Joint Federal/State Survey of Organics and Inorganics in 83 Selected Drinking Water Supplies, carried out by EPA's Region V (Chicago) provided additional evidence of the ubiquitous nature of chloroform and other THMs in chlorinated drinking water (EPA, 1975). Two conclusions reached in that study were that raw water relatively free of organic matter results in finished water that is relatively free of chloroform and related halogenated compounds, and that there is a correlation in some instances between the concentrations of chloroform, bromodichloromethane, dibromochloromethane and bromoform in finished water and the amount of organic matter found in raw water.

The National Organics Monitoring Survey (NOMS), directed by § 141.40 of the National Interim Primary Drinking Water Regulations (40 FR 59574, December 24, 1975), was aimed not only at determining the presence of THMs in additional water supplies, but also at determining the seasonal variations in concentration of these substances.

The NOMS sampling included 113 public water systems designated by the Administrator, and also included analyses for approximately 20 specific synthetic organic chemicals deemed to be candidates of particular concern as well as analyses of several surrogate group chemical parameters which are indicators of the total amount of organic contamination. Three phases of this study were completed and the mean, minimum, and maximum values of chloroform and THMs in drinking water are reported in Table 1. Phase I analyses in the NOMS were conducted similarly to the NORS. Phase II analyses were performed after the THM-producing reactions were allowed to run to completion. Phase III analyses were conducted on both declorinated samples and on samples that were allowed to run to completion (terminal). Again chloroform was found at the highest concentrations in most cases, however, in a few cases bromoform was found to be the highest concentration of the THMs (0.280mg/l). The mean concentrations of chloroform were 0.043 mg/l, 0.083 mg/l, 0.035 mg/l, and 0.069 mg/l for Phase I, II, III (dechlorinated) and III (terminal), respectively; the mean concentrations for TTHMs were 0.068 mg/l, 0.117mg/l, 0.053 mg/l and 0.100 mg/l for Phase I, II, III (dechlorinated) and III (terminal), respectively.

III. The Role of Chlorine and Other Disinfectants

All available evidence indicates that chlorination of drinking water containing naturally occurring organic chemicals is the major factor in the formation of halogenated organic chemicals, particularly the THMs in finished drinking water. Chlorinated organic compounds, however, can also be introduced into drinking water from industrial outfalls, urban and rural runoff, rainfall, through polluted air, or from the chlorination in sewage and industrial wastewater.

Several studies in addition to those mentioned above, have demonstrated increased THM concentrations in drinking water. Work by J. J. Rook (1974) in the Netherlands, and the studies by Bellar, Lichtenberg and Kroner (1974), showed that chloroform and other halogenated methanes are formed during the water chlorination process. It should be noted that these findings came as a result of the development and application of more sensitive and refined analytical techniques. Recent work by Rook (1974, 1977) has provided some insight into the organic precursors which might be responsible for the formation of the THMs. Studies by Sontheimer and Kuhn (1977) indicate that the THMs may represent only a portion of the total halogenated products of chlorination of water. Bunn et al. (1975), have demonstrated that hypochlorite in the presence of bromide and iodide ions but not fluoride will react with natural organic matter to produce all ten possible trihalogenated methanes.

It can be concluded from the above studies and others that the THMs occur in chlorinated drinking waters, and that the concentrations of the various THMs are dependent on the type and quality of organic precursor substances, the amount of chlorine used, and the presence of other halogen ions as well as contact time, temperature and pH.

A number of methods are available for reducing levels of THMs in drinking water. These options include modifications of current treatment practices, such as moving the point of chlorination, the use of alternative disinfectants such as chlorine dioxide, chloramines, or ozone, and various methods that will reduce organic precursor concentrations such as use of adsorbents like granular activated carbon (GAC).

Two chemicals often mentioned as alternative disinfectants, chlorine dioxide and ozone, are both well known as effective disinfectants and chemical oxidents, and some history of their practical use in water treatment has been accumulated particularly in Europe, but also in the United States.

Chlorine dioxide is usually prepared at the water plant by the reaction of chlorine (either as gas or as sodium hypochlorite) with sodium chlorite. Unless an excess of chlorine is used, there will be unreacted sodium chlorite left over from the reaction. When chlorine dioxide reacts with organic matter in the water, one of the reaction products is the chlorite ion. Thus, whenever chlorine dioxide is used to treat water, the presence of chlorite ion in the treated water can be expected.

EPA is studying the health effects of chlorine dioxide in water, utilizing several animal species as well as human volunteers. Studies of the toxicology of chlorine dioxide and chlorite ion in drinking water reveal considerable variations. These compounds have been reported to affect the hematopoietic systems such as oxidative changes in hemoglobins and hemolysis of red blood cells. Other bioeffects observed include gastrointestinal disturbances. The preliminary results indicate species variability in biological manifestations. Cats and African green monkeys appear to lie at the extreme ends of the spectrum from among the species studied; cats are very sensitive to hematopoietic effects whereas monkeys were apparently insensitive even at levels as high as 400 mg/l (Bull, 1979). An upper limit for chlorine dioxide by-product exposure is being considered primarily because of the lack of data concerning the safety of this material, and particularly its decomposition products, at higher concentrations (Musil et al., 1963 and Fridyland and Kagan, 1971. Studies with cats have shown that chlorite, which is oxidant that can cause anemias, has a deleterious effect on red blood cell survival rate at chlorine dioxide concentrations above 10 mg/l. Preliminary studies in a small human population did not demonstrate substantial blood chemistry changes, except possibly in one person known to be deficient in glucose-6-phosphotase dehydrogenase. Lack of sufficient health effects data on human toxicity for ClO_2 and its by-products prevents establishment of an MCL at this time, however, work in progress is expected to provide much additional information within the coming year. In the meantime, EPA recommends that monitoring be conducted when chlorine dioxide is used, and that residual oxidant should not exceed 0.5 mg/l as ClO_2.

A preliminary study concerning ozonation of 29 organic compounds potentially present in water supply sources indicated the formation of a number of products (Cotruvo, Simmon, Spanggord, 1976, 1977). These reaction mixtures were assayed for mutagenic activity employing 1) five strains of *Salmonella typhimurium* (Ames

Salmonella/microsome assay); and 2) mitotic recombination in the yeast *Saccharomyces cerevisiae D3*. After very extensive ozonation in water some of the organic compounds exhibited mutagenic activity in these systems. Similar more recent studies under extreme conditions with chlorine dioxide by-products did not exhibit mutagenic activity (SRI Report).

Combining ammonia with chlorine to form chloramines has been called the chloramine process, chloramination, and combined residual chlorination. The products of this process are monochloramine, dichloramine or trichloramines (nitrogen trichloride) depending on the pH and the chlorine to ammonia ratio. The production of the latter species may contribute to taste and odor problems in the finished water; however, chloramination does not reduce the formation of THMs.

Based on the results of numerous investigations, the comparative disinfectant efficiency of chloramines ranks last when compared to ozone, chlorine dioxide, hypochlorous acid ($HOCl$), and hypochlorite ion (OCl^-) (NAS, 1977, 1979). Early studies by Butterfield and Waties (1944, 1946, 1948) demonstrated that chloramines required approximately a 100-fold increase in contact time to inactivate coliform bacteria and enteric pathogens as compared to free available chlorine at pH 9.5. This work was later confirmed by Kabler (1953) and by Clarke et al., (1962).

Results with cysts of *Entamoeba histolytica* and viruses also confirm the decreased effectiveness of chloramines as disinfectants. Studies by Fair, et al., (1947) showed that additional dichloramine is about 60 percent and monochloroamine about 22 percent as effective as hypochlorous acid at pH 4.5 against cysts of *E. histolytica*. Kelly and Sanderson (1960) found that chloramines in the concentration of 1 mg/l at 25° C required 3 hours at pH 6, or 6 to 8 hours at pH 10 to achieve 99.7 percent inactivation of polio virus. With 0.5 mg/l free chlorine at pH 7.8, by comparison, inactivation of 99.99 percent of polio virus can be achieved in approximately 15 minutes (Liu and McGrowan, 1973). Chloramine treatment finds its widest application in maintenance of chlorine residuals in the distributing systems. The human health effects of consuming water treated with chloramine have not been studied in detail.

Although all of these disinfectants can reduce THM formation, questions have been raised on both their toxicity and the toxicity of their by-products. Studies are underway to clarify these matters, and could result in the designation of maximum permissible levels for certain disinfectants applied to drinking water.

The use of adsorbents for THM removal has also introduced some unknown factors. Assuming that the adsorption process is effective for its intended purpose, there is the possibility that a breakthrough of some of the adsorbed chemicals may occur, that these substances will be adsorbed and subsequently slough off to produce intermittent contamination, or that bacteria and/or toxins will be added to the water from growth on the adsorbent. All of these potential effects are controllable in practice, and EPA encourages the use of GAC to purify contaminated waters and to control THM precursors.

Thus, THM concentrations should be reduced, but without compromising public health from either increased risk of infectious disease transmission or from the chemicals that are used. Outbreaks of infectious waterborne disease have been noted when chlorination systems have been improperly operated. The alternative control methods outlined previously are effective, and are also being studied for their possible side effects. As soon as data become available, EPA will make specific recommendations regarding their use. At the present time, the best approach to reduce THMs in finished water is to reduce precursors prior to chlorination, such as with GAC. This approach has the benefit of reducing the concentration of many other organic chemicals in the water as well as to the precursors to THM and other chlorinated organics. Thus, once the organic chemical concentrations in the water have been reduced, the chemical demand for applied disinfectant will be reduced. Thus, human exposure to all disinfectant chemicals and their degradation products and by-products will be minimized. This is the intent of the regulation controlling THMs.

IV. Sources of Trihalomethane Exposure

McConnell et al. (1975), have reported that chloroform occurs in many common foods and that while some halogenated compounds in food may result from manufacturing, canning and pest control practices, chloroform may be introduced as the result of geochemical processes. Chlorinated compounds are the halogenated species most prevalent in food, but at least one food, Limu Kohu, a seaweed or algae eaten in Hawaii, contains an essential oil which is composed largely of bromoform (Burreson, et al 1975).

Chloroform was widely used as an anesthetic in the past, and, until recently, was a common ingredient in dentifrices and cough preparations. The Food and Drug Administration has taken action to halt the use of chloroform in drug products, cosmetic products, and food-contact articles (41 FR 145026, April 9, 1976). EPA has issued a notice of "rebuttable presumption against registration" of chloroform-containing pesticides (41 FR 14588, April 6, 1976). Thus, in addition to drinking water, exposure to some or all of the THMs is complicated by other environmental sources, however, exposure from some of these sources is being reduced.

The relative human chloroform exposures can be estimated for three major sources of human exposure: atmosphere, drinking water, and the food supply. The uptake calculations are based on the fluid intake, respiratory volume, and food consumption data for "reference man" as compiled by the International Commission on Radiological Protection. The combined uptake for adults from all three sources was derived by multiplying estimated exposure levels by the estimated annual intakes and combining the results [ODW protocol].

Human uptake of chloroform from air, food and drinking water is given in Table 2. Chloroform and TTHM uptake from drinking water was estimated by multiplying the chloroform and THM concentrations from NOMS data (Table 1) by the average consumption of 2 liters of water per day for the 70 kg adult male, by 365. One hundred per cent absorption of the amount of chloroform in drinking water is assumed for these calculations. The total chloroform uptake from water was estimated as a mean value of 64 mg per year. The maximum uptake value may be 394 mg per year.

To determine uptake of chloroform from foods, the concentration of chloroform in each food item in North American diets was multiplied by the average annual consumption of that food item by adults in the United States (NAS, 1977), and the results were combined again; one hundred per cent absorption of ingested chloroform was assumed. A calculated maximum value of about 16 mg of chloroform uptake per year from total food an a mean value of 9 mg based on ODW assumptions was obtained.

Table 2—*Human Uptake of Chloroform and Trihalomethanes from Drinking Water, Food, and Air*

Chemical	Exposure levels mg/year Mean (range)		
	Drinking water	Food	Air[1]
Chloroform	64 (0.73–343)	9 (2–15.97)	20 (0.41–204)
Trihalomethanes	85 (0.73–572)		

[1] Calculated from data supplied by Strategies and Air Standards Division, Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park. The air samples were collected both from the rural and industrial areas during the years 1974–76. The mean value was derived from the concentrations obtained from urban industrialized areas, the minimum value from the rural area and the maximum value from an urban industrialized area.

The calculation for the uptake of chloroform by humans from ambient air was based upon the assumptions that 63 percent of inhaled choloroform is absorbed, (NAS, 1977); the volume of air inhaled by an average adult is 8.1×10^6 liters per year; and 0.02 and 10 ppb (by volume) are the respective minimum and maximum chloroform concentrations in urban air. The minimum and maximum values for the annual uptake of chloroform by an adult were estimated at 0.41 and 204 mg, respectively. Assuming minimum exposures from all sources, the atmosphere contributes 12 percent of the total chloroform, the drinking water contributes 23 percent, and food is most significant (65%). Assuming maximum exposures from all sources, drinking water is the major contributor at 61 percent, with air at 36 percent. Thus, the relative contribution of drinking water to the total body burden of chloroform may range from a moderate to a maximum contributor as the annual exposure from water ranges from nil to 394 mg/year, and from 204 to 0.73 mg/year in ambient air (Table 3).

Table 3.—*Uptake of Chloroform for the Adult Human from Air, Water, and Food*

Source	Adult mg/yr	Percent uptake
Maximum Conditions		
Atmosphere	204	36
Water	343	61
Food supply	16	3
Total	563	100
Minimum Conditions		
Atmosphere	0.41	13
Water	0.73	23
Food supply	2.00	64
Total	3.14	100
Max-Water Min-Air		
Atmosphere	0.41	1
Water	343.00	97
Food supply	9.00	2
Total	352.41	100

B. Metabolism

Several reports (Brown, et al., 1974; Labigne & Marchand, 1974; Fry et al., 1972; Paul and Rubenstein, 1963; Taylor et al., 1974) have indicated that chloroform is rapidly absorbed on oral and intraperitoneal administration and subsequently metabolized to carbon dioxide and unidentified metabolites in urine. Species variation in the metabolism of chloroform has been summarized in Table 4. It is noteworthy that the mouse, a species which shows greater sensitivity to the oncogenic effect of chloroform (Eschenbrenner & Miller, 1945; Brown et al. 1974) metabolized chloroform extensively to carbon dioxide (80%) and unidentified metabolites (3%) from an oral dose of 60 mg/kg. Rats also metabolize chloroform to carbon dioxide but to a lesser extent (66%). In another report, Paul and Rubinstein (1963) recovered 4 percent carbon dioxide after administering 1484 mg/kg chloroform intradoudenally to rats. The discrepancy in these two results may be dose related.

Dose related differences in the metabolism of compounds are known and have recently been reported for the carcinogen vinyl chloride. Squirrel monkeys, when given 60 mg/kg of chloroform orally, excreted 97 percent of the dose, with 17 percent as carbon dioxide and 78 percent as chloroform. Fry, et al. (1972), recovered unmetabolized chloroform ranging from 17.8–66.6 percent of a 500 mg dose of chloroform given to human volunteers during an 8 hour time period (equivalent to about 7 mg/kg). Since the metabolism of chemicals is also dependent on age and sex, the widespread variation in the quantitative disposition of chloroform in human subjects may be due to the experimental protocols wherein subjects ranging from 18–50 years of age were used. Individual variability in the non-homogenous human population is a major factor.

Metabolic similarities between carbon tetrachloride and chloroform include the appearance of halide ions in urine and carbon dioxide in breath. A related chemical, carbon tetrachloride, is a common contaminant of the chlorine used in water disinfection. Carbon tetrachloride also is metabolized to chloroform in trace amounts, which may in turn, be biotransformed to carbon dioxide. Both chloroform and carbon tetrachloride are proven animal carcinogens (see below). However, this is mentioned because of possible metabolic production of proximal carcinogens. Toxicity of carbon tetrachloride, however, has been attributed to a free radical (CCl_3) which is postulated as a metabolic intermediate. Chloroform appears to be metabolized to form phosgene (Krishna, 1979).

Table 4.—*Disposition of Chloroform—Species Variation*

Animal species	Sex	Strain	Dose mg/kg	Metabolism (percent)				References
				$CHCL_3$	CO_2	Urine feces	Total excretion	
Mouse	M	CBA CF/LP C57.	60 po	6	80	3	[1] 93	Brown *et al* (1974).
Rat	M	Sprague Dawley.	60 po	20	66	7	93	Brown *et al* (1974).
Rat			1,484 id	70				Paul & Rubstein (1963).
Rat	M	Sprague Dawley.	4,710 ip		0.39			
Monkey	M	Squirrel	60 po	78	17	2	97	Brown *et al* (1974).

[1] Includes radioactivity in carcas.
Po = Orally.
id = intradeudenally.
ip = intraperitoneal.

Many carcinogens have been reported to form complexes with proteins, DNA and RNA (Miller & Miller, 1966). In the case of chloroform, Ilett et al., (1973) reported covalent bonding of chloroform metabolite(s) to tissue macromolecules in mice. The covalent bonding increased or decreased when the animals were pretreated with phenobarbital or piperonyl butoxide, agents which stimulate or inhibit the metabolism of foreign compounds by mixed function

oxidase enzymes. This is suggestive of the involvement of chloroform metabolism in these processes. These results may be interpreted to mean that the potency of an ingested chemical will be dependent upon its rate of metabolism to the active form.

Information regarding the metabolism of bromoform and other haloforms is not available. However, the structural similarities of these haloforms with chloroform indicate that they should also be absorbed by the oral and inhalation routes of exposure and then metabolized into carbon dioxide and halide ions. Related halogenated hydrocarbons of the dihalomethane series (e.g., dichloromethane, dibromomethane and bromochloromethane) have been reported (Kubic et al. 1974) to be metabolized to carbon monoxide; the rate of metabolism of dibromomethane was higher than that of the dichloromethane.

VI. Acute and Chronic Health Effects in Animals

Mammalian responses to chloroform include effects on: the central nervous system, hepatotoxicity, nephrotoxicity, teratogenicity, and carcinogenicity. Reported oral LD_{50} values are as follows: for rats, 300 mg/kg (DHEW, 1978); and for mice, 705 mg/kg (Plaa, et al., 1958).

Jones, et al. (1958), reported the effect of various oral doses of chloroform on mice 72 hours after exposure:

35 mg/kg—threshold hepatotoxic effect—minimal midzonal fatty changes
70 mg/kg—minimal hepatic central fatty infiltration
140 mg/kg—massive hepatic fatty infiltration
350 mg/kg—hepatic centrilobular necrosis
1,100 mg/kg—minimum lethal dose

Acute effects of exposure to chloroform and bromoform vary among species. Reported lethal doses for chloroform and bromoform are:

Species	Subcutaneous lethal dose	Values in mg/kg
Mouse	LD_{50}	704 (Chloroform). 1820 (Bromoform).
Rabbit	LD_{50}	800 (Chloroform). 410 (Bromoform.

Data on the acute toxicity of dibromochloromethane and dichlorobromomethane are not available.

A. Hepatotoxicity

Plaa, et al. (1968) established a dose-response relationship in mice, measuring parameters indicative of hepatotoxicity. Median effective dose (ED_{50}) values of 1.4 mM/kg (166 mg/kg) were found in mice exposed to chloroform by subcutaneous injection. The inhalation exposure of chloroform by mice for 4 hours at concentrations ranging from 100–800 ppm resulted in fatty infiltration of the liver at all dose levels. These changes were observed at necropsy 1–3 days after exposure.

Like chloroform, bromoform exposure leads to fatty degeneration and centrilobular necrosis of the liver (von Oettingen, 1950). Dibromochloromethane and dichlorobromomethane may bring about similar responses, although no experiments have been reported.

B. Nephrotoxicity

Nephrotoxic effects of chloroform were studied by Plaa and Larson (1965). The ED_{50} for orally administered chloroform in mice was 178 mg/kg as measured by phenolsulfo-phthalein excretion. Increases in urinary protein and glucose excretion, indices of kidney damage, indicated an ED_{50} of 104 mg/kg chloroform. Data concerning the nephrotoxic effect of other THMs are not available.

C. Central Nervous System Effects

Chloroform was used extensively as an anesthetic because of its effect on the central nervous system. Lehmann and Hasegawa (1910) reported dizziness and light intoxication during 20-minute exposures to chloroform concentrations of 4300–5100 ppm. Repeated exposures up to six days to concentrations as low as 920 ppm for 7 minutes resulted in symptoms of central nervous system depression (Lehman & Schmidt-Kehn, 1936). Additional important information has been submitted to EPA and is discussed below.

Effects of acute and subchronic chloroform exposure on cholinergic parameters in mouse brain were studied by Vocci, et al., (1977). Male Swiss Webster ICR mice were gavaged with single doses of chloroform (30 and 300 mg/kg) and sacrificed 15 minutes after administration of chloroform. In another experiment, the mice were gavaged with 14 or 90 daily doses of chloroform (3 or 30 mg/kg) and sacrificed 18 hours after the last administration. Neither of the above dosage regimens had any effect on *in vitro* [^{3}H] choline uptake in synaptosomes. In another study (ibid) of biosynthesis of acetylcholine in mouse brain, chloroform (30 mg/kg) significantly decreased the [^{3}H] acetylcholine synthesis (57% of control). Administration of chloroform (3 mg/kg) for 14 days produced a reduction in [^{3}H] acetylcholine (57% of control) (Vocci, Personal Communication, April 1979).

Chloroform, dichlorobromomethane, chlorodibromomethane and bromoform, at concentrations of 8×10^{-4} M did not alter the update of norepinephrine or dopamine into brain synaptosomes *in vitro* (Vocci, Personal Communication, April 1979).

D. Teratogenicity

Teratogenic responses to oral dosing of animals with chloroform were investigated. Rats and rabbits were administered chloroform at 126 and 50 mg/kg respectively. No significant fetal deformities were observed (Thompson et al. 1973). Inhalation of chloroform by Sprague Dawley rats at 30, 100 and 300 ppm for 7 hours a day, on days 6 through 15 of gestation revealed significant fetal abnormalities including: acaudia, imperforate anus, subcutaneous edema, missing ribs and delayed skull ossification (Schwetz et al. 1974).

In an attempt to explain reproductive failure in laboratory animals, i.e., mice and rabbits, McKinney et al. (1976) conducted a study using CD–1 mice wherein groups of mice were given tap water and purified tap water (passed through a Corning 3508 ORC and a Corning 3508 B demineralizer), respectively. Analysis indicated reduced amounts of chlorinated compounds in the purified water. The study could not relate chloroform and other chlorinated organics in tap water to reproductive failures in laboratory animals, since the concentrations of chlorinated organics in water were lowest in those months that reproductive failure was highest, although there did appear to be small, non-significant differences in this parameter between the highly purified and tap water. In a reevaluation involving the effect of Durham tap water and purified tap water as in the above study, Chernoff (1977) did not find striking differences in the reproductive success of CD–1 mice. No teratogenic studies on haloforms other than chloroform were available.

E. Mutagenicity

The THMs (chloroform, bromodichloromethane, dibromochloromethane, dibromochloromethane and bromoform) were assayed *in vitro* for mutagenic activity using strains of *Salmonella typhimurium* (TA 100 & TA 1535). The assays were conducted in desiccators to allow each compound to volatilize so that only the vapor phase came in contact with bacteria on the petri dishes. The activation system was tested and found not to be required for the bromohalomethanes since they were positive in the absence of activation. The results obtained were as follows: (a)

Chloroform was not mutagenic in TA 100 with or without activation, nor in TA 1535 without activation; (b) bromodichloromethane was mutagenic in TA 100 without activation, with a doubling dose of approximately 25 microliters; (c) dibromochloromethane was mutagenic in TA 100 without metabolic activation, with a doubling dose of approximately 3.5 microliters; (d) bromoform was mutagenic in TA 100 without metabolic activation, with a doubling dose of approximately 25 microliters, and was also mutagenic in TA 1535 with metabolic activation, with a doubling dose of approximately 100 microliters (Tardiff, 1976). All three compounds demonstrating mutagenic activity did so in a dose-response mode. For certain classes of compounds, except for many chlorinated hydrocarbons (Ames, 1973) the Ames test which utilizes *Salmonella typhimurium* bacteria correlates highly (90 percent) with the *in vivo* carcinogenicity bioassay.

F. Carcinogenicity

Prolonged administration of chloroform at relatively high dose levels to animals, specifically mice and rats, manifested oncogenic effects. The investigation conducted by Eschenbrenner and Miller (1945) produced hepatomas in female mice (strain A) given repeated dosages ranging from 0.145 to 2.32 mg of chloroform for a period of only four months. Minimum doses of 593 mg/kg chloroform per day (total of 30 doses) produced tumors in all of the surviving animals.

In a recent bioassay (NCI, 1976) linking chloroform with oncogenicity, rats and mice of both sexes were fed doses of chloroform ranging from 90 to 200 (rats), and 138–477 (mice) mg/kg. In this study, the lowest dose for observed carcinogenic effect (kidney epithelial tumors) in male rats was 100 mg/kg and for mice 138 mg/kg administered to the animals for a total period of 78 weeks. A related halogenated hydrocarbon, carbon tetrachloride, was carcinogenic in Osborne Mendel rats and in B6C3F1 mice at dosages ranging from 57 to 160 mg/kg and 1250 to 2500 mg/kg, respectively. The incidence of hepatocellular tumors formed in these animals at both dose levels almost approached one hundred percent (Table 5). The percent survival in mice treated with chloroform and carbon tetrachloride is depicted in Table 6. Almost all the animals on treatment with carbon tetrachloride died between 91–92 weeks whereas with chloroform treatment at both dose levels, 73 and 46 percent of the animals survived. Miklashevskii et al. (1966) fed chloroform to rats at 0.4 mg/kg apparently for 5 months and detected no histopathological abnormalities after this treatment. A recent study on the carcinogenic effect of chloroform at dose levels of 17 mg/kg/day and 60 mg/kg/day was conducted by Roe (1976), utilizing the rat (Sprague-Dawley), the beagle dog and four strains of mice (ICC Swiss, C57B1, CVA and CF/1). Comparison with the NCI study (1976) indicates that the number of animals and the duration of the experiment were essentially similar; the major differences were the dosages, which were lower than in the NCI study, and the vehicle, which was toothpaste. The only finding of neoplasia was an excess of tumors of the renal cortex in the male ICI-Swiss mice at a dose level of 60 mg/kg/day. However, animals fed 17 mg/kg/day of chloroform showed no incidence of renal carcinoma.

Table 5.—*Comparison of Hepatocellular Carcinoma Incidence in Chloroform and Carbon Tetrachloride-Treated Mice*

Animal group	Chloroform	Carbon tetrachloride
Males:		
Controls	5/77	5/77
Low Dose	18/50	49/49
High Dose	44/45	47/48
Females:		
Controls	1/80	1/80
Low Dose	36/45	40/40
High Dose	39/41	43/45

Table 6.—*Comparison of Survival of Chloroform and Carbon Tetrachloride-Treated Mice*

Animal group	Chloroform			Carbon tetrachloride		
	Initial No.	78 weeks	90 weeks	Initial No.	78 weeks	91-92weeks
Males:						
Controls	77	53	38	77	53	38
Low Dose	50	43	37	50	11	0
High Dose	50	41	35	50	2	0
Females:						
Controls	80	71	65	80	71	65
Low Dose	50	43	36	50	10	0
High Dose	50	36	11	50	4	1

Some renal tumors were also seen in control animals in a later study. The negative results observed in the dog experiment may be explained on the basis that either the animals were not exposed for a suitable length of time (i.e. duration of life span) or that an insufficient number of animals were tested, or that this species may not have been responsive to the oncogenic effect of chloroform. The negative results of the rat study may be explained on the basis of lack of strain sensitivity. Based on the extrapolation from the NCI study, the dose was too low to produce an effect in so few animals (Cueto, NCI, 1979).

Much less information is available on the carcinogenicity of bromohalomethanes. Preliminary results from the strain A mouse pulmonary tumor induction technique (Theiss et al., 1977) indicated that bromoform produced a positive pulmonary adenoma response while chloroform did not. Other studies (Poirier, et al., 1975) indicated that in several instances brominated compounds exhibited more carcinogenic activity than their chlorinated analogs in the pulmonary adenoma bioassay.

VII. Human Health Effects

A. NAS Principles of Toxicological Evaluation

The recent NAS (1977) report entitled "Drinking Water and Health" identified several principles for assessing the irreversible human effects of long and continued low dose exposure to carcinogenic substances.

Principle 1: Effects in animals, properly qualified, are applicable to man.

Principle 2: Methods do not now exist to establish a threshold for long-term effects of toxic agents.

Principle 3: The exposure of experimental animals to toxic agents in high doses is a necessary and valid method of discovering possible carcinogenic hazards in man.

Principle 4: Materials should be assessed in terms of human risk, rather than as "safe" or "unsafe".

On the basis of studies in animals and human toxicological data the NAS (1977) has recommended that strict criteria should be applied for establishing exposure limits to chloroform.

The National Institute for Occupational Safety and Health has recommended that the occupational exposure to chloroform should not

exceed 2 ppm determined as time-weighted average exposure for up to a 10 hour work day.

The human health effects as observed in accidental, habitual, and occupational exposures appear to indicate that the effects produced by exposure to chloroform are similar to those found in experimental animals. These include effects on the central nervous system, liver, and kidney.

The symptoms observed (Storms, 1973) in a 14 year old patient following an accidental exposure to an unknown amount of chloroform included cyanosis, difficulty in breathing and unconsciousness. Liver function tests measured by serum enzyme levels four days after ingestion indicated high levels of SGOT, SGPT, and LDH. The authors also noted damage to the cerebellum characterized by an instability of gait and a slight tremor on finger-to-nose testing. The symptoms disappeared in two weeks.

Several cases of habitual chloroform use have also been recorded by Heilbrunn et al. (1945). A case study of interest was a 33 year old male who had habitually inhaled chloroform for 12 years. The subject showed psychiatric and neurological symptoms including restlessness, hallucinations, convulsions, dysarthria, ataxia, and tremors of the tongue and fingers.

Lunt (1953) reported that delayed chloroform poisoning in obstetric patients, anaesthetized with chloroform is characterized by renal dysfunction as indicated by: Albumin, red blood cells, and pus in the urine. Chloroform exposure of humans by inhalation was studied by Lehman and Schmidt-Kehl (1936). Ten different concentrations of chloroform were used and the chloroform concentrations were determined by the alkaline hydrolysis method. Exposure at concentrations of 7 ppm for 7 minutes and at all higher levels up to 3000 ppm caused symptoms of central nervous system depression.

Desalva et al. (1975) studied the effects of chloroform in humans; the subjects were given dentifrice containing 3.4% chloroform and mouthwash with 0.43% chloroform for 1 to 5 years. No hepatotoxic effects were observed at estimated daily ingestion of 0.3 to 0.96 mg/kg chloroform. Reversible hepatotoxic effects were manifested at 23 to 27 mg/kg/day chloroform ingested for 10 years in a study conducted by Wallace (1959).

B. Epidemiologic Studies

By August 1979, 18 epidemiological studies, and additional unpublished reports discussed possible relationships between cancer mortality and morbidity and drinking water supplies. The results of the studies are shown in Table 7 in the approximate chronological order of completion. The table shows the statistically significant results of analysis by anatomical site. The statistically significant positive results are denoted by "M" for males and "F" to females and the statistically significant negative results are denoted by "−" before the "M" or "F".

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Table 7. Statistically Significant Results of Epidemiological Cancer Studies on Drinking Water and Cancer Sites

No.	Author	Yr.	Oral	Esophagus	Stomach	Intestine (not rectum)	Rectum	Combined G.I.	Liver and Gallbladder	Pancreas	Respiratory (not lung)	Lung, trachae, bronchi	Breast	Cervix	Uterus, ovary	Prostate	Bladder	Kidney	Combined Urinary	Lymphatic	Leukemia	Non-Hodgkins Lymphoma	Hodgkins	Thyroid	Brain	Larnyx	All Cancer	Study Type
1	Page, H.E.	74 76						M F											M								M	E
2	Tarone	75										M															M	E
3	Vasilenko	75		—	F	(studied females only)						F															F	E
4	DeRouen	75			F	M F	M		-M						F		M			-M							F	E
5	Harris/ Reiches	76		M	M F			M		M							M		M								M F	E
6	Buncher	75			M F				F	F			F				M F											E
7	Kuzma	77			M F					F			F				M										M F	E
8	McCabe	75	(total cancer and total mortality only)																								M F	E
9	Cantor	78			-F					-M		F				M	M F								M			E
10	Hogan	79	-M	-M	-M -F	M F	F		-M								M F							-M -F				E
11	Salg	77		M	-F	M	M F	M				M	F				M			F			M F			M F	M	E
12	Kruse	77	(studied liver and kidney sites only)																									C-C
13	Mah	77	(Eight sites studied -- no statistically positive associations/geographic and data analysis problems																									E
14	Alavanja	77 78		M	M F	M	M	M F				M					M		M F								M F	C-C
15	Wilkins	78							F								M		(liver, kidney and bladder only)									C-C
16	Rafferty, M.	79	(Completed but results not useable) (Females Only)																									E
17	Brenniman	78				F		F	F										F									C=C
18	Tuthill[1] Tuthill[2]	78 79		M	M,F							-F																E E

E = Ecological C = Case-Control R = Retrospective

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Five of the studies were published through August 1979. All of the studies were retrospective in design; sixteen were correlation studies, and four used a case-control approach. Four studies utilized cancer morbidity or incidence rather than mortality as a measure of disease frequency. The studies vary in sample size, cancer sites considered, factors selected as possible explanatory variables, parameters selected as indicators of water quality, and in the statistical techniques used for analysis, so caution must be used in comparing the results of one study with the results of another study.

There are several problems which make the results difficult to interpret: (1) There is limited water quality data on organics and other contaminants in the finished drinking water, and the data which exist cover less than five years; and (2) the water quality data are often from geographic areas other than those (usually counties) reporting cancer mortality data.

The water quality data are recent, and it is not known to what extent they reflect past exposure to THMs. This is important, since the latent period for most types of cancer is measured in decades. Comparison of the various study results is difficult also because of the different approaches used.

In general, retrospective epidemiological studies are a useful methodological tool in hypothesis generation. The results from these studies, when viewed collectively, can provide some insight into the postulation of causal relationships which then need to be tested further, using epidemiological designs such as case-control or cohort studies, for documentation.

When the evidence from all studies is weighed, an emphasis can be placed not only on the statistical significance of single correlation coefficients but on their consistency and patterns. When more than one independent study shows positive associations for *site-specific* cancers, then the association may not be due to chance alone. When the association is verified by consistent results across all four sex-race groups (white male, non-white male, white female, non-white female), the association is more likely to be used due to the variable considered and the evidence should be viewed more seriously. The studies done so far suggest the appropriateness of concern.

There is much evidence (both epidemiological and experimental) that most human cancers result from a combination of causes (Weisburger, 1977). Etiologic factors (e.g. smoking as a cause of lung cancer, soot as a cause of scrotal cancer in chimney sweeps) that result in increased relative risk greater than 5, were among the first to be discovered. The etiologic factors associated with cancers of gastrointestinal and urinary tract are more difficult to isolate from epidemiological studies because of the lower incidence and mortality rates, the interaction of environmental causes, and site-specific differences. The increased relative risk of populations exposed to most factors suspected of being associated with gastrointestinal and urinary cancers are less than three. Effects as small as, or smaller than these, are difficult to detect or quantify.

A number of the epidemiologic studies relating "water quality" to cancer did not define the water quality parameter by chemical constituents but instead compared cancers in persons who used water from different sources. Among the first of these was an investigation by Page, Talbot, and Harris (1974). The study considered Louisiana parish (county) cancer mortality rates for 1950–69, for total cancers and various selected cancer sites, and related these to the percentage of the parish populations drinking water from the Mississippi River, which is known to be contaminated by many organic chemicals (Laseter, 1972). The variables controlled were the rural-urban character of the parish, median income, population density, and proportion of population employed in the petroleum, chemical, and mining industries. An unweighted regression analysis showed a positive correlation between drinking water and total cancer (excluding cancer of the lung, urinary tract, GI tract, and liver), and then separately for cancer of the gastrointestinal organs and lung cancer. These investigations suggested an association between cancer mortality rates and use of drinking water from the Mississippi.

Meinhardt, et al. (1975), commenting on the Page-Harris report, looked at the cancer mortality gradient by apparent "dose" of river water and concluded that there was a random distribution of high and low cancer mortality rates among the river water consumers along the lengths of the Missouri and Mississippi River systems.

Subsequent reports by Page and Harris (1975, 1976) on the "Relation Between Cancer Mortality and Drinking Water in Louisiana" utilized explanatory variables and cancer sites similar to those in the first study; relationships for all four sex-race groups were considered. Positive regression coefficients for the water variable that were found statistically significant were:

Total cancer sites: WM, NWM, NWF.
All other than lung: WM.
Urinary Tract: WM, NWF.
Gastrointestinal: WM, NWM, WF, NWF.

Tarone and Gart (1975) reviewed the Page-Harris work and included an additional variable, elevation above sea level. By using a weighted regression analysis for four race-sex groups, statistically significant, positive correlations were found between the water variable and total cancer and lung cancer mortality for white males (WM), non-white males (NWM), and non-white females (NWF). The correlations were not statistically significant for white females (WF) for the same sites. Thus, there was a lack of consistency across the four sex-race groups for the aforementioned cancer sites.

Vasilenko and Magno (1975) conducted an ecological study in New Jersey and determined the relation between water source and age-adjusted cancer mortality from lung, stomach and urinary tract cancer of white females. Water quality was estimated from the ratio of the number of households served by public systems and private water companies to the number served by individual wells. Positive associations were found for lung and stomach cancer.

DeRouen and Diem (1975) also reviewed the relationship of cancer mortality in Louisiana and the Mississippi River as the drinking water source looking at ethnic variables as a possible confounding factor. By dividing Louisiana into a northern and southern section, they were able to mimic an ethnic division of the population. Many of the variables (urban-rural characteristics, median income, employment characteristics, and elevation above sea level) included in the previous studies were omitted. The water variable was handled differently by the investigators. Population groups were dichotomized into those who obtained none of the water from the Mississippi River, and those who obtained some or all from the river. The results show a positive relationship between cancer mortality and drinking water, for gastrointestinal cancer. The cancer mortality rates for southern parishes of Louisiana whose source of drinking water is the Mississippi River are higher than in the southern parishes whose source of drinking water is not the Mississippi River for the following:

Stomach: NWF.
Rectum: WM.
Large Intestine: WF, NWF.
Cervix: NWF.
Lung: NWF.
Total Cancer: NWF.

The cancer mortality rates tend to be higher for the southern parishes with river water use than northern for river water parishes for cancer of the urinary tract, gastrointestinal tract, and the lung.

In another set of analyses and comments, DeRouen and Diem (1975) discuss the problems associated with interpretation of regression coefficients as they relate to the Page and Harris Report, particularly the problem of making interferences from correlational studies. They concluded that inconsistencies such as the failure to see the same relationships for all sex-race groups reduces the credibility of the hypothesis of a causal relationship between water source and cancer risk.

An analysis was done by McCabe (1975) of EPA using the 50 (of a total of 80) NORS cities with a 1950 population greater than 25,000 and 70 percent or more of the city's population receiving water comparable to that sampled by EPA. McCabe showed a statistically significant correlation between the chloroform concentrations in the drinking water and the cancer mortality rate by city for all cancers combined.

In a second analysis by McCabe using water quality data from Region V, correlations between chloroform and TTHMs and total cancer mortality were not positive. When the same correlations were done using Region V plus NORS data for chloroform and total trihalogenated methane concentration levels, a positive statistically significant result was obtained.

Several epidemiological studies have been conducted in the Ohio River area. Buncher (1975) conducted a study of 88 counties (in Ohio, bordering the Ohio River) of which 14 used the Ohio River as a drinking water source. Buncher reports no significant relationship with drinking water from the Ohio River and the higher cancer mortality rates. There was a weak positive correlation between the chloroform concentration in 23 cities and the cancer mortality rate for all cancer sites in white males. Similar results were found in 77 cities (59 with surface water supplies) between chloroform concentrations and pancreatic cancer mortality in white females. For cities that accounted for more than 70 percent of the county population, there was a significant correlation between chloroform concentration and bladder cancer mortality rates for both white males and white females.

As a follow up on the Buncher study, a study by Kuzma, et al. (1977), considered the 88 Ohio counties, classified as either ground water or surface water counties based on the source of the drinking water used by a majority of the county residents. A two-stage analysis was performed and no statistically significant results were shown between the drinking water from the Ohio River and cancer mortality rates. However, rates for stomach, bladder, and total cancers were higher for white males in counties served by surface water supplies (probably chlorinated) than in counties served by ground water supplies (probably not chlorinated).

Reiches, et al. (1976), re-examined the Ohio data using a different methodology. Correlations between the surface drinking water variable and cancer mortality rates for stomach cancer and total cancers for both white males and females were statistically significant. The correlations between the drinking water variable and cancer mortality rates of the pancreas, bladder, esophagus, gastrointestinal tract, and urinary organs were significant for white males only.

Although several studies defined the water quality parameter by chlorination or levels of chloroform, only one study has considered the relationships of cancer with all THMs, both collectively and separately. Cantor et al. (1978) studied the correlation of cancer mortality at sixteen anatomical sites with the presence of concentration levels for each THM and TTHM in drinking water for whites. Counties were grouped according to the percentage of the county population served by the sampled water supply. In both sexes, there was a positive dose-response gradient of increasing correlation between trihalomethane concentration and bladder cancer. The correlation was stronger for bromoform than with chloroform. There was a negative correlation in white females of stomach cancer with total THM levels. Kidney cancer in white males showed a positive correlation with chloroform levels. Lung cancer in white females showed a positive correlation with THM levels. Among white males non-Hodgkins' lymphoma showed a positive correlation with bromoform. A positive dose-response was observed between brain cancer mortality (in both sexes) with increasing use of water containing chloroform, but the associations were not strong.

Alavanja, et al. (1976) conducted a retrospective, case-control study of female cancer mortality and its relationship to drinking water chlorination in seven selected New York counties. A statistically significant association was found between a region being served from a chlorinated drinking water supply and combined gastrointestinal and urinary tract cancer mortality rates in that region. There was also a higher mortality for the summed gastrointestinal and urinary cancer in urban areas served by chlorinated surface or ground drinking water supplies than in urban areas served by nonchlorinated supplies, however, the results should be viewed cautiously due to the small numbers in the sample.

Alavanja (1977) expanded this study and included gastrointestinal and urinary cancer deaths. Results showed that males living in the chlorinated water areas of three counties and females living in the chlorinated water areas of two counties were at greater risk of gastrointestinal and urinary tract cancer mortality than individuals living in the non-chlorinated areas. Alavanja (1978) did a second study (shown on Table 7), which expanded the first to nineteen counties in New York and several specific cancer sites. Statistically significant positive associations were found for males and lung cancer and for females and pancreatic cancer. Statistically significant positive associations were found for both males and females and cancer of the large intestine, combined gastrointestinal, and all cancers.

Kruse (1977) conducted a retrospective, case control study of white males and females in Washington County, Maryland. The relationship between mortality and morbidity from liver (including biliary passages) and kidney cancer in areas supplied by chlorinated public water supplies was analyzed. While there was a higher incidence of liver cancer among the exposed group; i.e., the group which consumed chlorinated drinking water, the correlations were not statistically significant. It should be noted that the sample size was small and that fewer than 50 cases each of liver cancer and kidney cancer were counted.

Salg (1977) also conducted a retrospective study of various cancer mortality rates and drinking water from a variety of sources and receiving different types of treatment in 346 counties in seven states in the Ohio River Valley Basin. She compared mortality rates for white and non-white males and females using weighted regression analyses, surface water usage showed weak but statistically significant associations between chlorinated water supplies (regardless of source) and the following cancers: For white males—esophagus, respiratory organs, large intestine, rectum, bladder, other urinary organs and lymphosarcoma and reticulosarcoma; for white females—breast and rectum,

and for non-white females—esophagus and larynx. Rectal cancer showed positive correlations across all race-sex groups. It should be noted that the test of significance utilized for this study was $p < 0.10$, which is less stringent than that used in other studies.

Mah, et al. (1977), conducted a retrospective study of the white population in the Los Angeles County area of the relationship between cancer mortality and morbidity and the chlorinated drinking water supply. They did not reveal any trends and showed no significant relationships for either cancer mortality or morbidity. The authors pointed out several methodological problems, including the diluting effect of migration into the area covered by this study.

Hogan, et al. (1979) also utilized the NORS and Region V data sets and applied various statistical procedures to the data in order to determine the effects of using different statistical models. Their results were similar to previous studies showing a positive correlation between rectal-intestinal and bladder cancer mortality rates and chloroform levels in drinking water when weighted regression analysis were applied. However, as the authors pointed out, "the marked extent to which these results were dependent on (1) the weighting scheme adopted in the analysis, (2) the presumed appropriateness of the data, and (3) the characteristics of the statistical model, was also clearly illustrated."

Wilkins (1978) conducted a case-control study in Washington County, Maryland and investigated the association between liver, kidney and bladder cancer and chlorinated water source. A positive correlation was found for female liver cancer and male bladder cancer and the chlorinated drinking water source. Due to small numbers of cases the outcome of this study should be viewed with suspicion.

Rafferty (1979) studied associations between drinking water quality in North Carolina communities and cancer mortality rates. The drinking water supplies were characterized by domestic and/or industrial contribution. No significant positive association were found.

Tuthill and Moore (1978) investigated the association between cancer mortality rates and parameters of water quality for Massachusetts community public water supplies. The average annual chlorine dose was one of the independent water characteristics. Simple correlations showed that the average chlorine dose level in the water was negatively associated with female buccal cancer, and positively associated with female esophageal and male respiratory cancers. Occupation, population mobility, and other demographic variables were controlled.

In summary, many but not all of the studies have found positive correlations between some characteristics of drinking water and various cancer mortality/morbidity rates. However, these correlations are dependent upon the selection and appropriateness of the data, the weighting scheme and extrapolation in the analysis, and the characteristics of the statistical model. Because of these dependencies the quantitative, causal interpretation of results generated from an indirect or ecological study should be viewed as tenuous for the primary purpose of generating hypotheses and even questionable in most cases.

It is important in the evaluation process to consider the results from other epidemiological studies as they develop hypothesis of potential causal associations between cancer mortality and other agents. For example, the confounding factors of diet, occupation, and smoking all have been suggested as potential causative agents of bladder cancer, Cole (1972). Therefore, any epidemiological study that investigates the possible association between bladder cancer and drinking water should be designed to avoid the problems that result in confounding of the data. None of the studies completed thus far have obtained data on or controlled for diet; several studies have attempted to control for occupational exposure (Page and Harris, 1974 and 1975; Cantor, et al., 1978; Tuthill and Moore, 1978); only the studies by Kruse (1977) and Wilkins (1978) obtained smoking data. Only a few studies considered four sex-race groups (the number of non-whites is too small in some of the geographic areas) and of those studies only a few showed consistent patterns of association of *specific cancer sites*, e.g., Salg (1977)-rectum. Several studies which considered only white populations found positive correlation coefficients for both sexes: Kuzma (1977)—stomach; De Rouen (1975)— intestine, stomach and bladder; Buncher (1975)—bladder; Reiches (1976)—stomach; Cantor (1978)—bladder; Hogan (1979)—intestine and bladder; and Alavanja (1978)—intestine. Only a few studies defined the water quality variable by the chloroform concentrations (McCabe, 1975; Buncher, 1975; Cantor et al., 1977; Hogan et al., 1977; Alvanja, 1978), and by the THM concentrations (Cantor et al. 1977).

Of particular interest are possible correlations of liver and kidney cancer rates with drinking water, since the animal exposure data indicate that hepatocellular carcinomas and hepatic modular hyperplasias have been observed in B6C3F1 strains of mice after life time exposure to chloroform. Several of the preliminary studies grouped the cancer sites for the anatomical systems, e.g., gastrointestinal and urinary organs, in order to increase the sample size. One of the studies (Cantor, 1978) which considered site-specific cancer mortality showed a positive association between drinking water and cancer of the kidneys in white males. The absence of any positive association between drinking water and liver cancer mortality may be due in part to small sample sizes, very low incidence of the disease, or because the exposure levels of contaminants in trace amounts over a lifetime may be below a no-effect level (Weisburger, 1977). The incremental increase may be too small to measure for statistical significance. On the other hand, many scientists believe that the specific site in which cancer appears in animal tests need not necessarily be the same site in which the cancer is likely to appear in humans.

Thus, the evidence is incomplete and the trends and patterns of association have not been fully developed. As stated previously, a causal relationship cannot be established by correlation studies. When viewed collectively, the epidemiological studies completed thus far provide evidence for maintaining a hypothesis that there may be a health risk and that the positive correlations may be due to an association between some constituents of drinking water and cancer mortality. The animal test data alone provide a firm basis for policy decisionmaking. Additional epidemiological studies may provide evidence regarding the strength of the associations and the possibility of a causal relationship between drinking water and cancer mortality, and thus provide a stronger basis for further regulatory action.

The NAS Epidemiology Subcommittee of the Safe Drinking Water Committee reviewed the first thirteen of the aforementioned eighteen studies. In the report, "Epidemiological Studies of Cancer Frequency and Certain Organic Constituents of Drinking Water—A Review of Recent Literature Published and Unpublished," September 1978, the Committee reached the following conclusions, which are consistent with EPA. Among the group of studies that characterized water quality by actual measurements, the results suggest:

That higher concentrations of THMs in drinking water may be associated with an

increased frequency of cancer of the bladder. The results do not establish causality, and the quantitative estimates of increased or decreased risk are extremely crude. The positive association found for bladder cancer was small and had a large margin of error; not only statistical, but much more importantly, because of the very nature of the studies.

Further research is being conducted with more definitive analytical studies. A large case-control bladder cancer study with 3,000 cases and 6,000 controls is being conducted by the National Cancer Institute (NCI). Three other case-control colon cancer studies are being conducted in Louisiana, Pennsylvania, and Utah. The results of these studies may provide more solid evidence to answer the question of possible associations between water quality and increased incidence of bladder and colon cancer.

VIII. Mechanism of Toxicity

Biologic responses upon exposure of mammals to chloroform include effects on the central nervous system resulting in narcosis, hepatotoxicity, nephrotoxicity, teratogenicity and carcinogenicity. Elucidation of the mechanism of toxicity of chloroform and related compounds has been attempted by several researchers.

Scholler (1968) and McLean (1970) observed that phenobarbital pretreatment of rats caused an increase in liver necrosis after administration of chloroform. Later, Brown, et al. (1974) reported that exposure of rats to an atmosphere containing chloroform (0.5%) for 2 hour markedly decreases glutathione (GSH) concentration in the liver when the animals have been pretreated with phenobarbital. In an attempt to further elucidate the role of GSH in chloroform-induced hepatotoxicity, Docks and Krishna (1976) injected chloroform into rats pretreated with microsomal enzyme inducers–phenobarbital, 3-methlcholanthrene, acetone and isopropanal. A dose of chloroform as little as 0.2 mg/kg decreased liver GSH levels and caused centrilobular necrosis within 24 hours in phenobarbital pre-treated rats. At a dose of 0.05 ml/kg, chloroform did not decrease liver GSH or cause liver necrosis. When the rats were not pretreated with phenobarbital, a chloroform dose of 0.2 ml/kg caused neither GSH depletion nor necrosis. In this connection, it is interesting to note that cysteine, which is a precursor of GSH and a common amino acid in one's diet, protected the liver from the hepatotoxicity produced by chloroform. The animals were also protected from the hepatotoxic effect by pretreatment with cystamine, not a precursor of GSH, thus suggestive of a mechanism other than of GSH depletion in the hepatotoxicity of $CHCl_3$.

Earlier reports by Ilett, et al. (1973) suggested the possibility of another mechanism involving the formation of an active metabolite of chloroform responsible for the chloroform-induced hepatotoxicity. This study correlated the renal and hepatic necrosis with covalent binding of chloroform metabolites to tissue macromolecule. Bioactivation of xenobiotics including chloroform, involves mixed function enzymes; the NADPH cytochrome reductase-cytochrome P–450 coupled systems. Sipes, et al. (1972) studied the bioactivation of carbon tetrachloride, chloroform and bromotrichloromethane utilizing 14_C-labled compounds and rat liver microsomes. The covalent binding of radiolabel to microsomal protein was used as a measure of conversion of the compounds to reactive intermediates. The authors concluded that cytochrome P–450 is the site of bioactivation of these three compounds rather than NADPH cytochrome C reductase. CCl_4 bioactivation proceeds by cytochrome P–450 dependent reductive pathways, while $CHCl_3$ activation, proceeds by cytochrome P–450 dependent oxidative pathways.

The isolation and identification of an active metabolite of chloroform supposedly responsible for toxicity was attempted by Pohl and his co-workers (1977). 2-oxithiazolidine-4-carboxylic-acid, an *in vitro* metabolite of chloroform, and presumably formed by the reaction of cysteine and phosgene ($COCl_2$), was isolated and characterized. When the incubation was conducted in an atmosphere of [^{18}O] O_2, the trapped $COCl_2$ contained [^{18}O]. These findings suggest that C–H bond of $CHCl_3$ is oxidized by a cytochrome P–450 mono-oxygenase to produce trichloromethanol which spontaneously dehydrochlorinates to phosgene. The electrophilic phosgene could react with water to form carbon dioxide, a known metabolite of $CHCl_3$ *in vitro* and *in vivo* or with microsomes to yield a covalently bound product. The *in vitro* oxidation of chloroform and its relationship to chloroform toxicity has been further substantiated by the studies wherein deuterated chloroform was used. Pohl and Krishna (1978) reported that $CDCl_3$ was metabolized slower than chloroform suggesting that the cleavage of C–H bond of chloroform is the rate determining step in the enzymatic process. The observation that $CDCl_3$ is less hepatotoxic than $CHCl_3$ indicates that the cleavage of the C–H bond is also the critical step in the process leading to $CHCl_3$ induced hepatotoxicity. The finding that $CDCl_3$ depletes less glutathione in the liver of rats than $CHCl_3$ suggests the active metabolite phosgene is responsible for the depletion of glutathione.

In the experiments involving the isolation and characterization of metabolites of chloroform, the evidence for the metabolism of chloroform to phosgene *in vitro*, by the oxidative pathway was present. Recent research has indicated the possibility of formation of phosgene *in vivo*. Pohl, et al. (1979), isolated and characterized 2-oxo-thiazolidine-4-carboxylic acid from the liver of rats pretreated with cysteine carboxylic acid after a dose of chloroform and/or deuterated chloroform. In these experiments, deuterated chloroform yielded less amount of metabolite, confirming once again the specificity of the cytochrome P–450 dependent enzymes in the mediation of oxidative dehalogenation of chloroform and its toxicity.

IX. Risk Assessment

The establishment of chloroform as an animal carcinogen, plus the epidemiological data and mutagenesis data on THMs, show that a potential human risk exists from the consumption of THMs, but these data do not quantify the risk. Methods have been developed to estimate the level of risk, based on an assumption that there is no threshold level for the action of a carcinogen. The state-of-the-art at the present time is such that no experimental tools can accurately define the absolute numbers of excess cancer deaths attributable to chloroform in drinking water. Due to the biological variability and a number of assumptions required, each of the risk-estimating procedures leads to a different value. There is wide variation among these estimates and their interpretation.

The EPA Science Advisory Board (SAB) (1975), using the highest levels of chloroform then reported in drinking water by the NORS data (0.300 mg/l) and assuming a maximum daily intake of 4 liters of water for a 70 kg man, attempted to estimate the risk. The estimates were based on the Eschenbrenner and Miller (1945) animal data, which themselves are subject to great variability since the experiments used only 5 animals per sex per dose. Using a linear extrapolation of the animal data over more than 2 orders of magnitude dose from mice to humans at the 0.300 mg/l concentration level, the lifetime incidence for liver tumors in man were estimated to range from 0 to .001 (95% confidence limits) or 0 to 100 ×

10^{-5} in a lifetime. This rate may be compared with the lifetime incidence of 260×10^{-5} for malignancy of liver derived from the data of the Third National Cancer Survey (1976). This estimate would range from zero to approximately 40% of the observed incidence of liver cancer in the United States that may be attributable to exposure to chloroform in drinking water at the 0.300 mg/l level. It should be noted that this value is at the upper limit of the confidence interval and the linear non-threshold dose-effect model allows an estimate of maximal risk where a risk has actually been observed. Most other models would yield lower estimates. The SAB, however, also stated that a more reasonable assumption would yield lower estimates of the risk.

Tardiff (1976) using four different models, calculated the maximum risks from chloroform ingestion via tap water. Using a margin of safety of 5000 applied to the minimum effect animal dose, i.e., the Weil conjecture, the "safe" level was calculated to be 0.2 mg/kg/day. Using the logprobit model and the slope recommended by Mantel and Bryan, the conclusion reached was that at a maximum daily dose of 0.01 mg/kg the risk would be between 0.016 and 0.683 cancers per million exposed population per year. Using the identical data, but with the experimental slope of the dose response curve as found in the mice as opposed to the slope of the one in the previous calculation, the conclusion reached was that a maximum daily dose of 0.01 mg/kg would produce less than one tumor per billion population per lifetime. Using the linear, or one hit model, usually considered to be the most conservative, a risk estimate of between 0.42 and 0.84 cancers per million population per year was calculated to result from a dosage level of 0.01 mg/kg/day. The two step model produced an estimated maximum risk of between 0.267 and 0.283 cancers per million population per year at a dose level of 0.01 mg/kg/day.

In the National Academy of Sciences (1977) report on "Drinking Water and Health," lifetime risks were estimated from the more recent, and much more extensive NCI animal data using a multi-stage model.

For a concentration of chloroform at 1 ug/liter the estimated incremental lifetime cancer risk would fall at approximately 1.7×10^{-6} per microgram per liter at the upper 95% confidence limit, assuming 70 year daily consumption of water at that level. Assuming lifetime exposure at the standard of 0.10 mg/l level in drinking water the incremental risk would be 3.4×10^{-4} assuming two liters of water at 0.10 mg/l consumed daily for 70 years.

In evaluating the risk estimates, it is important to compare the calculated maximum risk with the current cancer mortality data. Both liver and kidney cancer are rare diseases in the U.S. (< 5 per 100,000 population per year). The standardized mortality rates in the U.S. for white males and females combined are 52.5 per million per year for liver cancer and 29.2 per million per year for kidney carcinoma.

Based on the various risk estimates, Tardiff (1976) calculated that the percent of the annual cancer mortality attributable to chloroform in drinking water could be 1.60% and 1.44% for liver and kidney cancer respectively assuming the maximum exposure levels. Applying these percentages to the actual cancer mortality rates, the number of cancer deaths per year would be 168 from liver carcinoma or 84 from kidney carcinoma; an estimated maximum of 252 cancer deaths per year attributable to chloroform in drinking water.

Reitz, Gehring, and Park (1978) discussed EPA's procedures in estimating risk. They stated that EPA "seriously overestimates the actual potential of chloroform * * * (for) two major reasons." These are: (1) The mechanism through which chloroform exerts its toxicity, and (2) reliance on the NCI bioassay protocols which call for high doses of chloroform, and by not conducting studies at lower doses which usually induce relatively less carcinogenicity, there is a likelihood of ignoring a possible detoxification mechanism which protects test animals until they are overwhelmed by very large doses. They also suggest that an experiment to evaluate the carcinogenicity of chloroform at lower doses must be performed before high/low dose extrapolations can be performed. Definitive data do not exist to prove or to disprove the above claims.

The authors indicated that EPA's proposed standard for THMs of 0.10 mg/l in drinking water supplies was based on the carcinogenic risk estimates. It should be pointed out the EPA's proposed standard for THM was based upon that feasibility of achieving the TTHM concentration in drinking water, as well as the potential adverse health effects.

EPA's Office of Water Planning and Standards and Office of Research and Development with EPA's Carcinogen Assessment Group, developed a risk estimate in the draft document, "Chloroform—The Consent Decree Ambient Water Quality Criteria Document" (1979). The method used assumed consumption of 2 liters/per day of drinking water and 18.7 gm/per day of fish and shellfish. The lifetime risk estimates for excess cancers range from 10^{-5}, 10^{-6}, and 10^{-7} with corresponding consumption of 2.1 ug/l, 0.21 ug/l and 0.021 ug/l, respectively. The difference in these risk estimations may be explained by the assumption of daily fish consumption as well as other exposure sources. Without the fish consumption, the equivalent concentrations are 4.8 ug/l and 0.48 ug/l for estimated cancer risk of 1×10^{-5} and 1×10^{-6}, respectively. When this estimate is computed for the concentration of 0.10 mg/l for levels in drinking water, the incremental risk would be 4.0×10^{-4} assuming two liters of water at 0.10 mg/l was consumed daily for 70 years.

At an assumed lifetime exposure of 2 liters of water per day at 0.10 mg/l chloroform the risk reduction to the impacted population was estimated as a range of approximately 200–500 total cases. It should be noted however, that these average exposure levels in the impacted population may result in overestimates of the risk in light of the facts that: (1) The computations are based upon lifetime exposures. In actuality the proposed interim standard will likely be reduced in the future as technologically feasible, and, therefore, the lifetime exposure values will be less. (2) The interim standard encourages maximum reduction obtainable using current technology. A much lower average exposure is likely in the future because technology will most likely improve and result in greater exposure reductions. On the other hand, these may be underestimated because they are based upon toxicity exposure data from chloroform, which is only a portion of the TTHMs, which are only a portion of the by-products of the chlorination process; therefore, the magnitude of the contribution to the risk of the other THMs, which in some cases contribute significantly to TTHMs, is unknown. The exposure to THMs from air and food have not been included in these computations.

X. Selected Maximum Contaminant Levels (MCLs)

Since a risk to the public exists from exposure to TTHMs and other chlorination by-products in drinking water, the potential for that risk should be reduced as much as is technologically and economically feasible without increasing the risk of microbiological contamination. This can be accomplished by several means, and the Safe Drinking Water Act (Pub. L. 93-523) provides two major regulatory

avenues—(1) the establishment of an MCL, or (2) the institution of a treatment requirement.

EPA has determined that the establishment of an MCL in the Interim Primary Drinking Water Regulations, along with monitoring requirements, is the most effective and immediate approach to reducing the levels of THMs in drinking water. The Administrator has determined that monitoring is both technically and economically feasible (refer to "Economic Impact Analysis of a Trihalomethane Regulation for Drinking Water," EPA, 1977). Measures taken to reduce the THM concentrations will concurrently provide the additional benefit of reducing human exposure to the other undefined by-products of chlorination and possibly other synthetic organic contaminants.

Since it is known that chlorination of water is primarily responsible for the relatively high levels of THMs in drinking water, modifications in the chlorination process, the substitution of other disinfectants, and the use of adsorbents and other technologies to remove precursor chemicals are possible approaches to control. The optimal approach would be to reduce organic precursor concentrations prior to addition of a disinfectant in order to reduce disinfectant demand and minimize all by-products.

Use of a chlorine residual in a less active form such as combined chlorine or chloramine will significantly reduce THM formation; however, chloramines are much less potent disinfectants than free chlorine, and therefore, this approach must only be used after careful consideration, and assurance of maintenance of excellent biological quality. The two chemicals most often mentioned as substitute disinfectants, ozone and chlorine dioxide, are both well known as effective disinfectants and chemical oxidants. The issues of the biological effects and toxicity of these disinfectants and their by-products are being clarified by studies underway. In the meantime, EPA recommended that the residual total oxidant levels after application of chlorine dioxide should be limited to 0.5 milligram per liter.

The National Organics Monitoring Survey found that the mean total trihalomethane (TTHM) concentrations in the drinking water systems evaluated were approximately 0.068, 0.117, 0.053 and 0.100 mg/l for Phase I, II, III (dechlorinated) and III (terminal) respectively, with the highest levels of 0.784 mg/l in Phase II (refer to Table 1).

It is reasonable to assume that the various calculated risk estimates for chloroform indicate a potential risk to public health. It is possible that a percentage of the total number of liver and/or kidney cancers are attributable to exposure of chloroform in drinking water, although it is most likely that drinking water exposure would interact with a number of other variables such as smoking and diet as effect modifiers in a multifactorial manner. It is also likely that the other by-products of chlorination also present a potential risk.

Thus, based upon a number of risk extrapolations assuming various levels of exposure to chloroform in drinking water, it has been estimated that such exposures may cause an annual excess of cancers in the U.S. population (ranging from 0 to several hundred). At higher levels of exposure of chloroform (>0.300 mg/l) the cancer risk estimates are even higher.

The reduction of TTHMs to an MCL level of 0.10 mg/l would reduce the unnecessary and excessive exposure to these potential human carcinogens, mutagens, and chronic toxicants, and other effects. At the same time, measures taken to reduce THM levels (such as the use of adsorbents) will concurrently result in reduction of human exposure to other contaminants in drinking water.

Since it is economically and technologically feasible to reduce the THM levels in drinking water, and since benefits are achieved by reducing the health risks of exposure, EPA has decided to establish the MCL at 0.10 mg/l as the initial feasible step in a phased, regulatory approach. As more data become available from implementation experience, and toxicology and epidemiology, standards are expected to become more restrictive. In the meantime, EPA and the States should continue to take steps as necessary on a case-by-case basis to provide adequate protection for the delivery of safe drinking water to the public, by minimizing the amounts of toxic chemicals in the water.

XI. References

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Part IV

Environmental Protection Agency

Gum and Wood Chemicals Manufacturing Point Source Category Effluent Limitations Guidelines; Pretreatment Standards, and New Source Performance Standards

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 454

[FRL 1311-8]

Gum and Wood Chemicals Manufacturing Point Source Category Effluent Limitations Guidelines; Pretreatment Standards, and New Source Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Regulation.

SUMMARY: EPA proposes regulations to limit effluent discharges to navigable waters and publicly owned treatment works from facilities engaged in processing sulfate turpentine; tall oil rosin, fatty acids, and pitch; wood rosin, turpentine, and pine oil; and from rosin-based derivatives plants associated with manufacturing facilities in SIC Code 2861. The purpose of this proposal is to provide effluent limitations guidelines for "best available technology" for the Rosin-based Derivatives and Sulfate Turpentine subcategories and to establish "best practicable technology", "best conventional pollutant control technology", and "new source performance standards" for the four subcategories and "pretreatment standards" for the Rosin-based Derivatives and Sulfate Turpentine subcategories, under sections 301, 304, 306, 307, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, as amended by the Clean Water Act of 1977). These regulations are also proposed in compliance with the Settlement Agreement in *Natural Resources Defense Council, Inc.* v. *Train*, 8 ERC 2120 (D.O.C. 1976).

The effect of these regulations on the Gum and Wood Chemicals Industry would be to require pretreatment of process wastewaters discharged to publicly owned treatment works (POTWs), and treatment of process wastewaters discharged to waters of the United States. After considering comments received in response to this proposal, EPA will promulgate a final rule.

This notice also contains information on three additional subcategories: Char and Charcoal Briquets; Gum Rosin and Turpentine; and Essential Oils. By virtue of either the effect of existing regulations or current industry practices, the majority of plants in these subcategories are achieving no discharge of process wastewater. Therefore, the Agency concludes that no further guidelines or standards are necessary for these subcategories.

The Supplementary Information section of this preamble describes the legal authority and background, the technical and economic bases, and other aspects of the proposed regulations. That section also summarizes comments on a draft technical document circulated on January 19, 1979, and solicits comments on specific areas of interest. The abbreviations, acronyms, and other terms used in the Supplementary Information section are defined in Appendix A to this notice.

These proposed regulations are supported by three major documents available from EPA. Analytical methods are discussed in *Sampling and Analysis Procedures for Screening of Industrial Effluents for Priority Pollutants.* EPA's technical conclusions are detailed in the *Development Document for Proposed Effluent Limitations Guidelines, New Source Performance Standards, and Pretreatment Standards for the Gum and Wood Chemicals Industry Point Source Category.*

The Agency's economic analysis is found in *Economic Impact Analysis of Proposed Effluent Limitations Guidelines, New Source Performance Standards, and Pretreatment Standards for the Gum and Wood Chemicals Point Source Category.*

DATES: Comments on this proposal must be submitted by January 28, 1980.

ADDRESS: Send comments to: Mr. William Thomson II, P.E., Effluent Guidelines Division, Environmental Protection Agency, 401 M Street, Southwest, Washington, D.C. 20460. Attention: EGD Docket Clerk, Gum and Wood (WH-552). The supporting information and all comments on this proposal will be available for inspection and copying at the EPA Public Information Reference Unit, Room 2404 (Rear) PM-213 (EPA Library). The EPA information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Technical information and copies of technical documents may be obtained from Mr. William Tomson II, P.E., at the address listed above or call (202) 426-2554. The economic analysis may be obtained from Ms. L. Jean Noroian, Economic Analysis Staff (WH-586), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, (202) 426-2617.

SUPPLEMENTARY INFORMATION:

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I. Legal Authority

The regulations described in this notice are proposed under authority of sections 301, 304, 306, 307, 308, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. 1251 *et seq.*, as amended by the Clean Water Act of 1977, Pub. L. 92-517). These regulations are also proposed in compliance with the Settlement Agreement in *Natural Resources Defense Council, Inc.* v *Train*, 8 ERC 2120 (D.D.C. 1976), modified March 9, 1979.

II. Background

A. The Clean Water Act

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to "restore and maintain the chemical, physical, and

biological integrity of the Nation's waters" section 101(a). By July 1, 1977, existing industrial dischargers were required to achieve "effluent limitations requiring the application of the best practicable control technology currently available" ("BPT"), section 301(b)(1)(A); and achieve "effluent limitations requiring the application of the best available technology economically achievable * * * which will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants" ("BAT"), section 301(b)(2)(A). New industrial direct dischargers were required to comply with section 306 new source performance standards ("NSPS"), based on best available demonstrated technology; and new ("PSNS") and existing ("PSES") dischargers to publicly owned treatment works ("POTWs") were subject to pretreatment standards under sections 307(b) and (c) of the Act. While the requirements for direct dischargers were to be incorporated into National Pollutant Discharge Elimination System (NPDES) permits issued under section 402 of the Act, pretreatment standards were made enforceable directly against dischargers to POTWs (indirect dischargers).

Although section 402(a)(1) of the 1972 Act authorized the setting of requirements for direct dischargers on a case-by-case basis, Congress intended that, for the most part, control requirements would be based on regulations promulgated by the Administrator of EPA. Section 304(b) of the Act required the Administrator to promulgate regulations providing guidelines for effluent limitations setting forth the degree of effluent reduction attainable through the application of BPT and BAT. Moreover, sections 304(c) and 306 of the Act required promulgation of regulations for NSPS, and sections 304(f), 307(b), and 307(c) required promulgation of regulations for pretreatment standards. In addition to these regulations for designated industry categories, section 307(a) of the Act required the Administrator to promulgate effluent standards applicable to all dischargers of toxic pollutants. Finally, section 501(a) of the Act authorized the Administrator to prescribe any additional regulations "necessary to carry out his functions" under the Act.

The EPA was unable to promulgate many of the these regulations by the dates contained in the Act. In 1976, EPA was sued by several environmental groups, and in settlement of this lawsuit EPA and the plaintiffs executed a "Settlement Agreement" which was approved by the Court. This Agreement required EPA to develop a program and adhere to a schedule for promulgating for 21 major industries BAT effluent limitations guidelines, pretreatment standards, and new source performance standards for 65 "priority" pollutants and classes of pollutants. See *Natural Resources Defence Council, Inc.* v. *Train*, 8 ERC 2120 (D.D.C. 1976), modified March 9, 1979.

On December 27, 1977, the President signed into law the Clean Water Act of 1977. Although this law makes several important changes in the Federal water pollution control program, its most significant feature is its incorporation into the Act of several of the basic elements of the Settlement Agreement program for toxic pollution control. Sections 301(b)(2)(A) and 301(b)(2)(C) of the Act now require the achievement by July 1, 1984, of effluent limitations requiring application of BAT for "toxic" pollutants, including the 65 "priority" pollutants and classes of pollutants which Congress declared "toxic" under section 307(a) of the Act. Likewise, EPA's programs for new source performance standards and pretreatment standards are now aimed principally at toxic pollutant controls. Moreover, to strengthen the toxics control program, Congress added section 304(e) to the Act, authorizing the Administrator to prescribe "best management practices" ("BMPs") to prevent the release of toxic and hazardous pollutants from plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage associated with, or ancillary to, the manufacturing or treatment process.

In keeping with its emphasis on toxic pollutants, the Clean Water Act of 1977 also revised the control program for non-toxic pollutants. Instead of BAT for "conventional" pollutants identified under section 304(a)(4) (including biochemical oxygen demand, suspended solids, fecal coliform, and pH), the new section 301(b)(2)(E) requires achievement by July 1, 1984, of "effluent limitations requiring the application of the best conventional pollutant control technology" ("BCT"). The factors considered in assessing BCT for an industry include the costs and benefits of attaining a reduction in effluents, compared to the costs and effluent reduction benefits from the discharge of publicly owned treatment works (section 304(b)(4)(B)). For non-toxic, nonconventional pollutants, sections 301 (b)(2)(A) and (b)(2)(F) require achievement of BAT effluent limitations within three years after their establishment or July 1, 1984, whichever is later, but not later than July 1, 1987.

The purpose of these proposed regulations is to provide effluent limitations guidelines for BAT and pretreatment standards in the existing sources (PSES) for Sulfate Turpentine and Rosin-based Derivatives subcategories, and to establish BPT, BCT, and NSPS in the Wood Rosin, Turpentine, and Pine Oil; Tall Oil Rosin, Fatty Acids, and Pitch; Sulfate Turpentine; and Rosin-based Derivatives subcategories under sections 301, 304, 306, 307, and 501 of the Clean Water Act.

B. Prior EPA Regulations

EPA promulgated Interim Final BPT and proposed BAT, NSPS, and PSNS for the Char and Charcoal Briquets; Gum Rosin and Turpentine; Wood Rosin, Turpentine and Pine Oil; Tall Oil Rosin, Fatty Acids, and Pitch; Essential Oils; and Rosin-Based Derivatives subcategories of the Gum and Wood Chemicals Manufacturing Point Source Category on May 18, 1976 (Part 41 FR 20506).

The regulations proposed in this notice include new BAT, BCT, NSPS, PSES, and PSNS regulations for the Rosin-based Derivatives subcategory. BCT and NSPS regulations are proposed for the Wood Rosin and Tall Oil subcategories. BPT, BAT, BCT, NSPS, PSES, and PSNS regulations are proposed for a new subcategory, Sulfate Turpentine.

C. Overview of the Industry

The Char and Charcoal Briquets (Segment A); Gum Rosin and Turpentine (Segment B); Wood Rosin, Turpentine, and Pine Oil (Segment C); Tall Oil Rosin, Fatty Acids, and Pitch (Segment D); and Essential Oils (Segment E) subcategories are included within the U.S. Department of Commerce, Bureau of the Census Standard Industrial Classification (SIC) 2861. Facilities for manufacturing rosin-based derivatives (Segment F) are included in SIC 2821; this study covers only those rosin-based derivatives manufacturing plants located within and operated in conjunction with Gum and Wood Chemicals plants (SIC 2861). Sulfate turpentine manufacturing (Segment G) has not been included in the Standard Industrial Classification system. However, since sulfate turpentine, like tall oil, is a by-product of the Kraft pulping process in the pulp and paper industry and is refined and further processed primarily by facilities with other SIC 2861 manufacturing processes, EPA has included it as a part of this study.

The Gum and Wood Chemicals Industry originated in the Naval Stores industry. North American colonists harvested pine oleoresin for use in construction of naval vessels and the industry has grown and expanded since then as new uses for pine products have arisen. One of the more significant innovations has been development of the use of by-products from the Kraft paper process—tall oil and sulfate turpentine—as raw materials for the Gum and Wood Chemicals Industry.

Char results from the destructive distillation of softwood and hardwood and may be further processed into charcoal or activated carbon.

Gum rosin and turpentine are produced from the sap of live pines, which is distilled to separate the turpentine and gum rosin.

Wood rosin, turpentine, and pine oil are produced by solvent extraction from pine chips. After recovery of the solvent, distillation separates turpenes, rosin, pine oil, and residual pitch.

Crude tall oil, derived from the Kraft pulping process, is acidulated (treated with dilute sulfuric acid) and then distilled to separate pitch, rosin acids, and fatty acids.

Essential oils are produced by steaming the oil containing raw material under pressure. The resulting oil/water mixture is allowed to separate and the finished oil product is sold.

Rosin derivatives processing is usually a batch modification of rosins. Process operating conditions in the reaction kettle depend on product specifications, raw materials, and other variables.

Sulfate turpentine is condensed from relief gas from the digester of the Kraft pulping process. Distillation separates the turpentine into its components: alpha-pinene, beta-pinene, dipentene, sulfated pine oil, limonene, camphene, and anethol.

EPA has identified 114 plants in the Gum and Wood Chemicals Industry in the United States, primarily located in the South, Mid-Atlantic, and Midwest states. Plant age, number of employees, and wastewater volume vary from subcategory to subcategory. Char and Charcoal Briquets, Gum Rosin, and Essential Oils (91 plants) all have processing techniques that have not changed for years. These plants also have the lowest flows ranging from zero in Char and Charcoal Briquets to one plant in Essential Oils with an average flow of 5,000 gallons per day. Sulfate Turpentine and Tall Oil are two of the newest processing technologies in the industry with most units being less than 30 years old. Rosin-Based Derivatives processing is a continually changing segment of the industry.

While the industry historically is characterized by small independent companies processing wood stumps or gum exudate from pine trees, considerable consolidation has taken place over the past 15 years such that all but two of the plants in the four subcategories covered by these proposed regulations are operated by multi-industry corporations (14 plants) or pulp and paper companies (7 plants). Of the eight major corporations operating plants in the four subcategories the largest accounts for 42% of sales, the two largest account for 65% of sales and the four largest account for 83% of sales.

During the past 10 years, the industry has maintained a modest but cyclical rate of sales growth that has averaged about 3–4% annually. However, most of the growth has been due to price increases and a general trend of upgrading the value of products produced. Real growth in production volume has declined slightly. Tall oil production alone has increased measurably over this period. In addition to supporting the low growth in sales, the industry ranks fairly low with regard to profitability. The industry's annual return on sales is around 4–5% which is 1–2% below the average for all chemicals and allied products. The major reason for the low levels of profitability has been the intense competition from higher performance material based on petroleum products which have kept prices well below desirable levels. The trend to production of upgraded, higher value products has helped alleviate some of this competition and has resulted in some profitability improvement. Currently, however, the Agency is aware of plants for only one new plant (in the tall oil subcategory) in the four subcategories covered by these proposed regulations.

Capital expenditures have typically been small and over the period 1972 through 1976 have averaged less than 3% of sales. It is expected, however, that future trends toward product upgrading will require significantly increased capital expenditures. Since depreciation is a very small percent of sales (estimated as less than 5%), funds for these investments will likely not be generated entirely from operations.

Water is essential to the Gum and Wood Chemicals Industry and is used invirturally all processes except those for char and charcoal briquets. Water cleans out the tank cars which transport the raw material. It is used in gum rosin, wood rosin, tall oil, and sulfate turpentine in barometric condensers which generate the vacuum in the distillation columns. Water steams the oil out of the raw material for essential oils. Chemical reactions in rosin derivatives generate water and water cleans the reaction kettles. The wastewater from all these operations contains high levels of oils, biodegradable organic matter, and toxic pollutants.

The most important pollutants or pollutant paramenters are: (1) Toxic pollutants (benzene, toluene, ethylbenzene, phenol, methylene chloide, copper, chromium, nickel, and zinc); (2) conventional pollutants (BOD5, TSS, Oil and Grease, and pH); and (3) non-conventional pollutants (COD).

III. Scope of this rulemaking and summary of methodology

These proposed regulations open a new chapter in water pollution control requirements for the Gum and Wood Chemicals Industry. EPA's 1973–1976 round of rulemakings emphasized the achievement of best practicable technology (BPT) by July 1, 1977. In general, this technology level represents the average of the best performances a of well known technologies for control of familiar (i.e., "classical") pollutants.

This round of rulemaking, in contrast, aims for the achievement by July 1, 1984, of the best available technology economically achievable (BAT), which will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants. At a minimum, this technology level represents the very best economically achievable performance in any industrial category or subcategory. Moreover, as a result of the Clean Water Act of 1977, the emphasis of EPA's program has shifted from control of "classical" pollutants to control of toxic substances.

In its 1977 legislation, Congress recognized that it was dealing with areas of scientific uncertainty when it declared the 65 "priority" pollutants and classes of pollutants "toxic" under section 307(a) of the Act. The "priority" pollutants have been relatively unknown outside of the scientific community, and those engaged in wastewater sampling and contol have had little experience dealing with them. Additionally, these pollutants often appear and have toxic effects at concentrations which severely tax current analytical techniques. Though Congress was aware of the state-of-the-art difficulties and expense of "toxics" control and detection, it nevertheless directed EPA to act quickly and decisively to detect, measure, and regulate these substances.

EPA's implementation of the Act required a complex development program. Initially, because in many cases no public or private agency had done so, EPA and its laboratories and consultants had to develop analytical methods for toxic pollutant detection and measurement, which are discussed under Sampling and Analytical Program. EPA then gathered technical and financial data about the industry, which are summarized under Data Gathering Efforts. The Agency developed these proposed regulations on the basis of its information.

EPA first studied the Gum and Wood Chemicals Industry to determine whether differences in raw materials, final products, manfacturing processes, equipment, age and size of plants, water usage, wastewater constituents, or other factors required the development of separate effluent limitations and standards for different segments of the industry. This study included the identification of the raw waste and treated effluent characteristics, including the sources and volume of water used, the processes employed, and the sources of pollutants and wastewaters in the plant.

Next, EPA identified several distinct control and treatment technologies, both in-plant and end-of-process, which are either in use or capable of use in the Gum and Wood Chemicals Industry.

The Agency compiled and analyzed both historical and newly generated data on the effluent quality resulting from the application of these technologies. The long-term performance, operational limitations, and reliability of each of the treatment and control technologies were also indentified. In addition, EPA considered the non-water quality environmental impacts of these technologies, including impacts on air quality, solid waste generation, water scarcity, and energy requirements.

EPA derived unit process costs from model plant characteristics (production and flow) applied to each treatment process unit cost curve (i.e., pH adjustment, activated sludge, metals precipitation by pH adjustment, activated carbon columns, etc). These unit process costs were estimated at each treatment level for ease of analysis. Total costs at each treatment level were then calculated by adding the unit costs at that level to the cost of previous levels. After confirming the reasonableness of this methodology, the Agency evaluated the economic impacts of these costs. (Cost and economic impacts are discussed in detail under the various technology options, and in the section of this notice entitled Costs, Effluent Reduction Benefits, and Economic Impacts).

Upon consideration of these factors, as more fully described below, EPA identified various control and treatment technologies as BPT, BCT, BAT, PSES, PSNS, and NSPS. The proposed regulations, however, do not require the installation of any particular technology. Rather, they require achievement of effluent limitations representative of the proper operation of these technologies or equivalent technologies.

IV. Data Gathering Efforts

Section III of the Development Document describes in detail the data gathering program.

EPA derived the mailing list for the data gathering effort from previous plant listings in the BPT administrative record: the 1977 Dun and Bradstreet listings; Standard and Poor listings; the Stanford Research Institute Directory of Chemical Producers; and the available State Chamber of Commerce's Directory of Manufacturing. Detailed questionnaires were then mailed to 338 addressees in the seven subcategories. Of this total, 224, plants indicated no gum and wood chemicals processing at the location. For the 114 potential plants, 72 returned questionnaires. Followup telephone contact confirmed an additional 10 processors in the seven subcategories of interest. Thirty-two charcoal plants remain unconfirmed.

Distribution of the eighty-two plants by subcategory is as follows: Forty-five process char and charcoal briquets; nine process essential oils; seven process gum rosin and turpentine; four process wood rosin, turpentine, and pine oil; twelve process tall oil rosin, fatty acids, and pitch; thirteen process rosin-based derivatives; and seven process sulfate turpentine. Thirteen plants have processes in more than one subcategory.

In addition to the above data sources, EPA also consulted the Pulp Chemicals Association (PCA), obtained NPDES permit files in EPA regional offices, obtained engineering studies on treatment systems for several gum and wood chemicals plants, made contacts with state pollution control offices, and obtained a report from a demonstration project sponsored by the EPA Office of Research and Development.

Data for the economic analysis of the industry were obtained from the Development Document and from technical 308 surveys, government publications, industry association sources, publicly available financial reports and industry reports, and personal interviews with representatives of three companies whose plants manufacture gum and wood chemicals.

V. Sampling and Analytical Program

As Congress recognized in enacting the Clean Water Act of 1977, the state-of-the-art ability to monitor and detect toxic pollutants is limited. Most of the toxic pollutants were relatively unknown until only a few years ago, and only on rare occasions has EPA regulated or has industry monitored or even developed methods to monitor for these pollutants. As a result, analytical methods for many toxic pollutants under section 304(h) of the Act have not yet been promulgated.

As the state-of-the-art has matured, EPA has refined the sampling and analytical protocols, and intends to continue this refinement to keep pace with technology advancements. Resource constraints, however, prevent EPA from reworking completed sampling and analyses to keep up with the evolution of analytical methods. As a result, the analytical techniques used in some rulemakings may differ slightly from those used in other rulemaking efforts. In each case, however, the analytical methods used represent the best state-of-the-art available for a given industry study. One of the goals of EPA's analytical program is the promulgation of additional section 304(h) analytical methods for toxic pollutants, scheduled to be completed within calendar year 1979.

EPA ascertained the presence or absence and magnitude of the 129 specific toxic pollutants in gum and wood chemicals wastewaters in a two-phase (screening and verification) sampling and analysis program involving ten facilities. The plants were selected primarily to be representative of the manufacturing processes, the prevalent mix of production among plants, and the current treatment technology in the industry.

The sampling and analysis program was conducted during April and May of 1978. Five plants were sampled that represented six of the seven major Gum and Wood Chemicals processes (the seventh process, Char and Charcoal Briquets, is dry). A single 24-hour composite sample was obtained from the raw and treated wastewater streams at each plant for screening analysis and analyzed for the 129 toxic pollutants. Sampling and analyses were conducted according to *Sampling and Analysis Procedures for Screening of Industrial Effluents for Priority Pollutants*, U.S. EPA, Cincinnati, March 1977 (revised April 1977), and *Analytical Methods for the Verification Phase of the BAT*

Review, U.S. EPA Effluent Guidelines Division, Washington, D.C., June 1977.

The screening sampling and analysis program determined which toxic pollutants were present in wastewaters from each industrial segment sampled, and the order of magnitude of the contamination.

EPA evaluated the results of the screening analyses along with the process engineering review for each subcategory. The toxic pollutants found to be present or suspected present due to their use as raw materials, by-products, final products, etc., were selected for verification. As a result of screening analysis, the following pollutants were not analyzed for during verification because they were not detected during screening analysis: PCB's, pesticides, cyanide, antimony, beryllium, selenium, silver, and thallium. During the screening sampling visits to four of the five selected plants, two additional 24-hour samples were collected and analyzed for the second phase of the program.

The verification sampling and analysis program, conducted over a three-month period, was intended to obtain as much quantitative data as possible for each subcategory on the 98 toxic pollutants that were identified during the screening phase. The plants selected for sampling represented the full range of inplace process and wastewater treatment technology for each subcategory. Nine plants were sampled for verification analysis.

The primary objective of the field sampling program was to collect samples of wastewater from which the concentrations of toxic pollutants could be ascertained if present. Verification sampling visits to the plants were made during three consecutive days of plant operation. Verification sampling at four of these plants was done in conjunction with screening sampling. Raw wastewater samples were taken either before treatment or after oil skimming depending upon accessibility to the wastewater stream. Treated effluent samples were taken either following pretreatment (usually indirect dischargers) or biological treatment (direct dischargers) where these technologies were in place. EPA also collected one sample of intake water to determine the presence of toxic pollutants prior to contamination by Gum and Wood Chemicals processes.

At raw waste, final discharge, and some intermediate sample points, automatic samplers took samples at timed intervals. Samples for conventional, non-toxic nonconventional and some toxic pollutants were obtained from the 24-hour composite. Grab samples were taken in specially prepared vials for volatile (purgeable) toxic organics and cyanide.

Toxic pollutants were analyzed according to groups of chemicals and associated analytical schemes. Organic toxic pollutants included volatile (purgeable), base-neutral, and acid (extractable) pollutants, and pesticides. Inorganic toxic pollutants included heavy metals and cyanide.

The primary screening and verification method for the volatiles, base-neutral, and acid organics was gas chromatography with confirmation and quantification on all samples by mass spectrometry (GC/MS). Total phenols were analyzed by the 4–AAP method. Analysis of pesticides employed GC with electron capture detection. The Agency analyzed the toxic heavy metals by atomic absorption spectrometry (AAS), with flame or graphite furnace atomization following appropriate digestion of the sample. Cyanides were determined through the colorimetric method of distillation and analysis. Analyses for conventional pollutants (BOD5, TSS, Oil and Grease, and pH) and non-conventionals (COD) were accomplished using "Methods for Chemical Analysis of Water and Wastes," (EPA 625/6–74–003) and amendments.

Although EPA believes that the available data support these regulations, the Agency would have preferred a larger data base for some of the toxic pollutants and will continue to seek additional data. EPA will periodically review these regulations, as required by the Act, and make any revisions supported by new data. In developing these regulations, moreover, EPA has taken a number of steps to deal with the limits of science and available data. (See Regulated Pollutants).

VI. Industry Subcategorization

Subcategorization of the Gum and Wood Chemicals industry was first accomplished during the development of the original BPT guidelines. These subcategories were published in the **Federal Register**, May 18, 1976 (41 FR 20506). For the present study, the previous subcategorization was re-evaluated. This evaluation included a determination of whether differences in raw material used, product produced, manufacturing process employed, equipment, age, size, wastewater constituents, and other factors require development of different subcategorization of the industry. A review of the subcategories from the BPT study indicated that no further subcategorization of these segments of the industry was warranted. However, the processing of sulfate turpentine involves a completely different raw material and results in different products with some differences in manufacturing processes. In addition, the wastewater constituents appear to be significantly different from wastewaters produced in the other subcategories. As a result, it was determined that a new industry segment, sulfate turpentine, should be added. With the addition of the sulfate turpentine subcategory, the BPT subcategorization is satisfactory. Section IV of the Development Document contains a detailed description of the factors considered and the rationale for subcategorization.

The subcategories of the Gum and Wood Chemicals industry are defined as follows:

Subcategory, Product, and Raw Material Source

A—Char and Charcoal Briquets, Hardwood and softwood scraps

B—Gum Rosin and Turpentine, Crude "gum" oleresin from the sapwood of living trees

C—Wood Rosin, Turpentine, and Pine Oil, Wood stumps and other resinous woods from cut over forest

D—Tall Oil Rosin, Pitch, and Fatty Acids, By-product crude tall oil from the Kraft process

E—Essential Oils, Scrap wood fines, twigs, barks, or roots of select woods or plants

F—Rosin Derivatives, Rosin products from gum, wood, and tall oil chemicals

G—Sulfate Turpentine, Low boiling vapors condensed from the Kraft pulping of pine wood

VII. Available Wastewater Control and Treatment Technology

A. Status of In-Place Technology

Current treatment practices in the Gum and Wood Chemicals Industry range from oil/water separation by all plants to biological treatment by most direct dischargers. Most indirect dischargers and dischargers to combined industrial treatment systems have only oil/water separation and equalization, although one indirect discharger has extensive pretreatment in place. There are 12 direct dischargers (four comingle with industrial treatment systems which discharge directly). The four dischargers to combined treatment have oil/water separation and settling. Six direct dischargers have aerated lagoon biological treatment. One direct discharger utilizes an activated sludge biological treatment system. One direct discharger uses activated carbon in lieu of biological treatment. There are six dischargers to POTWs and two dischargers who comingle their wastes

with other industrial wastewaters prior to discharge to a POTW.

B. Control Technologies Considered

The control and treatment technologies used in arriving at the previously promulgated BPT effluent limitations for tall oil rosin, fatty acids, and pitch; wood rosin, turpentine, and pine oil; and rosin-based derivatives were: (1) In-plant control—wastewater reduction through decreasing and recycling process water, segregating waste streams, and oil/water separation; (2) equalization; (3) dissolved air flotation for the wood rosin and tall oil subcategories only; (4) biological treatment by activated sludge; and (5) flocculation and clarification. These same treatment technologies, except for dissolved air flotation, were used as the candidate BPT treatment levels for the sulfate turpentine subcategory presented in this proposal. Additional control and treatment technologies available for this industry include: (1) Metals precipitation and (2) granular activated carbon columns. In considering these additional control and treatment technologies, the four existing plants who comingle their wastes with other industrial wastewaters prior to treatment and discharge to waters of the United States are considered as indirect dischargers.

In-plant control, preliminary treatment, and biological treatment technologies have been demonstrated within the Gum and Wood Chemicals Industry. Metals precipitation is currently in use at one sulfate turpentine facility where the plant has isolated a wastewater source and is treating only that stream. A granular activated carbon column unit is in use at one plant in lieu of biological treatment. Performance data of activated carbon columns following biological treatment of gum and wood chemicals wastewater are not available.

VIII. BPT Effluent Limitations—Sulfate Turpentine

The factors considered in defining best practicable control technology currently available (BPT) include the total cost of application of technology in relation to the effluent reduction benefits achieved from such application; the age of equipment and facilities involved; the process employed; non-water quality environmental impacts (including energy requirements); and other factors considered appropriate by the Administrator. In general, the BPT technology level represents the average of the best performances of plants of various ages, sizes, processes, or other common characteristics. Where existing performance is uniformly inadequate, the Agency may transfer BPT from a different subcategory or category. Limitations based on transfer technology must be supported by a conclusion that the technology is indeed transferable, and by a reasonable prediction that it can achieve the prescribed effluent limits. BPT focuses on end-of-pipe treatment rather than process changes or internal controls, except where such are common industry practice.

The cost/benefit inquiry for BPT is a limited balancing, committed to EPA's discretion, which does not require the Agency to quantify benefits in monetary terms. See e.g., *American Iron and Steel Institute* v. *EPA*, 526 F.2d 1027 (3rd Cir. 1975). In balancing costs in relation to effluent reduction benefits, EPA considers the volume and nature of existing discharges, the volume and nature of discharges expected after application of BPT, the general environmental effects of the pollutants, and the cost and economic impacts of the required pollution control level. The Act does not permit consideration of water quality problems attributable to particular sources or water quality improvements in particular water bodies. See *Weyerhaeuser Company* v. *Costle*, 11 ERC 2149 (D.C. Cir. 1978).

The Agency has concluded that BPT effluent limitations guidelines should be developed for sulfate turpentine producing plants because the two direct dischargers in this subcategory are located at facilities which also produce other gum and wood chemicals products. Development of numerical guidelines for BPT for this subcategory would provide the NPDES authorities the information necessary for application of BPT at these two plants. The BPT technology selected includes oil/water separation, equalization, neutralization, nutrient addition, biological treatment, and final settling. Application of this technology will result in the removal of 70 and 80.3 additional pounds per day of BOD5 and TSS respectively from the direct discharging sulfate turpentine plants.

Economic analysis indicates that compliance with this option would require one of the two direct discharge plants producing sulfate turpentine to invest a total of $104.5 thousand and incur annualized costs (including operation and maintenance, interest, and depreciation) of $183 thousand. These costs are projected to effect minimal price increases. The Agency projects that selection of this option will not result in any plant closures or unemployment.

IX. BCT Effluent Limitations

The 1977 amendments added section 301(b)(4)(E) to the Act, establishing "best conventional pollutant control technology" (BCT) for discharges of conventional pollutants from existing industrial point sources. Conventional pollutants are those defined in section 304(b)(4)—BOD, TSS, fecal coliform, and pH—and any additional pollutants defined by the Administrator as "conventional." On July 30, 1979, EPA added oil and grease to the conventional pollutant list (44 FR 44501).

BCT is not an additional limitation, but replaces BAT for the control of conventional pollutants. BCT requires that limitations for conventional pollutants be assessed in light of a new "cost-reasonableness" test, which involves a comparison of the cost and level of reduction of conventional pollutants from the discharge of publicly owned treatment works to the cost and level of such pollutants from a class or category of industrial sources. As part of its review of BAT for certain "secondary" industries, the Agency has promulgated a methodology for this cost test. See 44 FR 50732 (August 26, 1979).

EPA identified no treatment technologies beyond BPT for control of the conventional pollutants. Therefore, the proposed BCT regulations are equal to BPT.

X. BAT Effluent Limitations

The factors considered in assessing best available technology economically achievable (BAT) include the age of equipment and facilities involved, the process employed, process changes, non-water quality environmental impacts (including energy requirements), and the costs of application of such technology (section 304(b)(2)B)). At a minimum, the BAT technology level represents the best existing economically achievable performance of plants of various ages, sizes, processes or other shared characteristics. As with BPT, where existing performance is uniformly inadequate, the Agency may transfer BAT from a different subcategory or category. BAT may include process changes or internal controls, even when not common industry practice.

The statutory assessment of BAT "considers" costs, but does not require a balancing of costs against effluent reduction benefits (see *Weyerhaeuser* v. *Costle, supra*). In developing the proposed BAT, however, EPA has given substantial weight to the reasonableness of costs. The Agency has considered the volume and nature of discharges, the volume and nature of discharges

expected after application of BAT, the general environmental effects of the pollutants, and the costs and economic impacts of the required pollution control levels.

Despite this expanded consideration of costs, the primary determinant of BAT is effluent reduction capability. As a result of the Clean Water Act of 1977, the achievement of BAT has become the principal national means of controlling toxic water pollution.

Seventeen toxic pollutants were found at levels above the detection limits in the analyses of discharges from the Gum and Wood Chemicals Industry. EPA has selected from four available options a BAT technology which will reduce this toxic pollution by a significant amount.

These options (which are described in greater detail in Section VII of the Development Document) are:

(A) Option One—Determine that effluent limitations based upon BPT technology (oil/water separation, equalization, air flotation, and biological treatment) reflect the technology which should be imposed under BAT.

No costs or economic impacts beyond that of BPT will result from selection of this option.

(B) Option Two—Require effluent limitations based upon BAT Option One plus metals removal at-the-source (at a reaction kettle or other designated site where intermediates are modified by use of a metallic catalyst) for those plants using metals in their processes. This option incorporates at-the-source metals removal by pH adjustment as described in Section VII of the Development Document.

Application of metals removal at-the-source ensures a high degree of metallic pollutants removal. One sample collected at a sulfate turpentine plant using this technology showed 155 mg/l copper in the raw waste to the metals removal unit and 1 mg/l after treatment. EPA estimates that application at-the-source (in-plant) will result in the removal of 44 pounds per day of zinc (96 percent) from three direct discharging plants which modify rosins by use of zinc as a catalyst. Since the data indicate that application of biological treatment as exemplified by activated sludge or aerated lagoons results in significant reductions of the organic toxic pollutants of concern, this option will result in effective control of all toxic pollutants shown to be present in substantial quantities in the raw wastewater generated by this industry.

Economic analysis indicates that compliance with this option would require 3 of the 8 direct dischargers to invest a total of $225.6 thousand and incur annualized costs of $512 thousand. Costs of up to 5 percent of sales may be passed on through price increases. The Agency projects that selection of this option will not result in any plant closures or unemployment.

(C) Option Three—Require effluent limitations based upon BAT Option One plus metals removal at the end-of-pipe for those plants using metals in their processes or deriving them from process steps. This option incorporates end-of-pipe metals removal by pH adjustment as described in Section VII of the Development Document. However, because the metal source waste stream is diluted by other wastewater sources, this option would not result in the highest possible removal efficiency and would require significantly higher capital and operating expenses because of the high volumes of wastewater that would require treatment.

EPA estimates that application of metals removal at the end-of-pipe would result in the removal of 31.5 pounds per day of zinc (76.5 percent removal) from the three direct discharge plants using zinc as a catalyst.

Economic analysis indicates that compliance with this option would require 3 of the 8 direct discharges to invest a total of $561 thousand and incur annualized cost of $1.93 million. Costs of up to 5 percent of sales may be passed on through price increases. The Agency projects that selection of this option may result in one plant closure and loss of less than one percent of industry employment.

(D) Option Four—Require effluent limitations based upon BAT Option Two plus the end-of-pipe addition of granular activated carbon (GAC) columns to control residual toxic organic pollutants remaining after biological treatment.

This option would ensure an advanced degree of toxic pollutant removal, including residues of dissolved high molecular weight organic compounds to estimated concentrations of less than 50 parts per billion (ppb). However, the most prevalent toxic organic pollutants found in this industry (phenol, toluene, benzene, and ethylbenzene) usually are much lower in the effluent from BPT treatment facilities than in the raw waste load to these treatment facilities. The highest value from a biological treatment system for organic toxics was 200 ppb benzene. The Agency projects that application of GAC after biological treatment would result in the removal of 2.1 pounds per day of toxic organic pollutants from the eight direct discharging plants.

Economic analysis indicates that compliance with this option would require 7 of the 8 direct dischargers to invest a total of $15.7 million and incur annualized cost of $7.1 million. The costs may range 2.3 to 40.2 percent of sales. Costs up to 5 percent of sales may be passed on through price increases. The Agency projects that selection of this option may result in eight plant closures and a loss of 29 percent of industry employment.

(E) BAT Selection and Decision Criteria—EPA has selected Option Two as the basis for proposed BAT effluent limitations. This option was selected because it assures, through the continued application of biological treatment, adequate removals of the organic toxic pollutants of concern and, in addition, provides significant removal of the toxic pollutants which continue to be of concern in this industry (copper, nickel, and zinc) after application of BPT.

At-the-source limitations based on concentration rather than mass limitations was chosen because modification of the rosins and turpenes is a batch process with production dependent upon demand; dilution of the metal bearing waste stream prior to final discharge causing the final concentration to approach the detection limit; most plants would treat in-plant because of less expensive treatment; and varying dilutions between plants would require varying levels of treatment if the concentration limitations were applied at the end-of-pipe.

Although not required by the Act, a balancing of costs of the technology options weighed heavily in this decision (see Section IX of the Development Document for detailed discussion).

The Agency rejected Option Three because of the higher cost in comparison to the lower expected removals of toxic metallic pollutants. The Agency also rejected Option Four because of the high cost of activated carbon columns in comparison to the expected additional removals of toxic organic pollutants.

Because of the limited data base for metals removal in this industry, the Agency compared the results obtained by metals removal technology used in other industrial categories currently under study. While the technology is being used in some of the other categories to treat for the metals of interest here (i.e., Ferric Chloride Production Subcategory in the Inorganic Chemicals Point Source Category), most were rejected because the wastewaters were not characteristic of the type of wastewaters generated in the Gum and Wood industry. The Agency chose to use the numerical limitations from the Electroplating Category because many of the problems associated with treatment in this category (i.e., chelating

agents and the presence of oils) more closely resembled the wastewater characteristics from gum and wood chemicals processing.

XI. New Source Performance Standards

The basis for new source performance standards (NSPS) under section 306 of the Act is the best available demonstrated technology. New plants have the opportunity to design the best and most efficient gum and wood chemicals manufacturing processes and wastewater treatment technologies, and, therefore, Congress directed EPA to consider the best demonstrated process changes, in-plant controls, and end-of-pipe treatment technologies which reduce pollution to the maximum extent feasible. EPA considered the four options previously described in the Section X BAT Effluent Limitations for selection of NSPS technology.

NSPS Selection and Decision Criteria—EPA has selected Option Two as described in Section X as the basis for proposed new source performance standards because it provides acceptable control of conventional pollutants and the maximum feasible removal of toxic pollutants of concern. The Agency rejected Option One because that treatment scheme does not address the removal of toxic metal pollutants. Option Three was rejected because of the lower removal rate and higher cost in comparison to Option Two. Option Four would change the rate of entry into this industry and would slow the rate of industry growth.

XII. Pretreatment Standards for Existing Sources (PSES)

Section 307(b) of the Act requires EPA to promulgate pretreatment standards for existing sources (PSES), which must be achieved within three years of promulgation. PSES are designed to prevent the discharge of pollutants which pass through, interfere with, or are otherwise incompatible with the operation of POTWs. The legislative history of the 1977 Act indicates that pretreatment standards are to be technology-based, analagous to the best available technology for removal of toxic pollutants.

(A) Option One—Do not regulate. The data base indicates that levels of organic toxic pollutants expected to be discharged range from below the detection limit to 19 mg/l. These levels of organic toxic pollutants can be readily removed in a POTW without incompatibility or pass-through. However, two subcategories, Sulfate Turpentine and Rosin-based Derivatives, use processes which involve metals as catalysts. These metals are present in the wastewater from some plants which discharge to POTW's. Conventional POTW treatment would fail to remove the metals.

No costs or economic impacts will result from selection of this option.

(B) Option Two—

(a) Do not require specific pretreatment standards for the two subcategories (Wood Rosin and Tall Oil) that discharge only conventional pollutants and organic toxic pollutants. As noted above, the data available indicate that the conventional pollutants and organic toxic pollutants discharged by these subcategories can be removed in a POTW without incompatibility or passthrough.

(b) Require specific pretreatment standards for those subcategories (Sulfate Turpentine and Rosin-based Derivatives) that generate metallic bearing wastewater. Application of metals removal at-the-source of the pollutants can remove substantial quantities of the metals generated by these subcategories. EPA estimates that application of metals removal at-the-source would result in the removal of 11.1 pounds per day of copper (73.5 percent) and 2.0 pounds per day of nickel (39 percent) from two sulfate turpentine plants (one plant has technology in-place) and 136.2 pounds per day of zinc (96 percent) from three rosin-based derivatives plants.

Economic analysis indicates that compliance with this option would require 4 of the 12 indirect dischargers to invest a total of $258 thousand and incur annualized costs of $521 thousand. These costs may effect minimal price increases. The Agency projects that selection of this option will not result in any plant closure or unemployment.

(C) Option Three—

(a) Do not require specific pretreatment standards for the two subcategories (Wood Rosin and Tall Oil) that discharge only conventional pollutants and organic toxic pollutants.

(b) Require specific pretreatment standards for those subcategories (Sulfate Turpentine and Rosin-based derivatives) that generate metallic bearing wastewater. Application of metals removal at the end-of-pipe can remove some of the metals generated by these subcategories. EPA estimates that application of metals removal at the end-of-pipe would result in the removal of 7.6 pounds per day of copper (72.5 percent) and no nickel from two sulfate turpentine plants and 38.7 pounds per day of copper (72.5 percent) and no nickel from two sulfate turpentine plants and 38.7 pounds per day of zinc (94.5 percent) from three rosin-based derivatives plants.

Economic analysis indicates that compliance with this option would require four of the twelve indirect dischargers to invest a total of $368 thousand and incur annualized costs of $958.6 thousand. These costs may effect minimal price increases. The Agency projects that selection of this option will not result in any plant closures or unemployment.

(D) Selection of Pretreatment Technology and Decision Criteria—EPA has selected Option Two as the technology basis for proposing pretreatment standards for existing sources. This option will ensure removal of the bulk of the zinc, nickel, and copper at the industrial site. The Agency has selected Option Two because at-the-source metals removal provides for more removal of the metals of concern at less cost. In selecting this option, EPA does not preclude the imposition of more stringent standards by a POTW as needed to ensure compliance by the POTW with its NPDES permit.

XIII. Pretreatment Standards for New Sources

Section 307(c) of the Act requires EPA to promulgate pretreatment standards for new sources (PSNS) at the same time that it promulgates NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate the best available demonstrated technologies including process changes, in-plant controls, and end-of-pipe treatment technologies, and to use plant site selection to ensure adequate treatment system installation.

The Agency evaluated the same options for new discharges to POTW's as were evaluated for existing discharges to POTW's.

Selection of New Source Pretreatment Technology and Decision Criteria—EPA has selected OPTION TWO as the technology basis for proposed pretreatment standards for new sources. This option will provide the removal of the heavy metals at-the-source for greater efficiency of removal at less cost. In selecting this option, EPA does not preclude the imposition of more stringent standards by a POTW as needed to ensure compliance by the POTW with its NPDES Permit.

XIV. Regulated Pollutants

The basis upon which the controlled pollutants were selected, as well as the general nature and environmental effects of these pollutants, is set out in Section VI of the Development Document. Some of these pollutants are designated as toxic under section 307(a) of the Act, and no evidence has been

found to warrant removal of any pollutant from the toxics list.

A. BPT

The pollutants in the sulfate turpentine subcategory controlled by this regulation include the same pollutants as those controlled by the previously promulgated regulations for the other subcategories, specifically BOD5, TSS, and pH. The discharge of these pollutants is controlled by maximum monthly average and maximum daily mass effluent limitations (pounds per 1,000 pounds of processed material), which are calculated by multiplying raw waste loads concentrations from one of the two stand-alone sulfate turpentine plants, average flow from the sampling period, treatability performance data from the 1976 reguations, and variability factors from the petroleum refining category.

B. BCT

As noted in the section of the preamble entitled BCT Effluent Limitations, EPA identified no additional reasonably available technologies either in the Gum and Wood Chemicals Industry or transferrable from other industrial categories for control of the conventional pollutants. Therefore, BCT is proposed at the same level as BPT.

C. BAT and NSPS

Appendix D is a list of toxic pollutants which were found in treated effluents at more than two plants and in concentrations greater than available analytical detection limits. EPA concludes that the organic toxic pollutants will be effectively controlled by biological treatment as exemplified by activated sludge or aerated lagoons even though the organic toxics are not expressly regulated by numerical limitations.

(1) Toxic Pollutants—the toxic pollutants expressly controlled by BAT and NSPS are copper, nickel, and zinc which are subject to numerical limitations expressed as maximum concentrations at the source of the metal bearing wastewater. These pollutants are controlled because of their use in the processing of turpenes and rosins.

D. PSES and PSNS

The pollutants controlled by proposed PSES and PSNS include copper, nickel, and zinc. EPA is limiting these pollutants becasue they may pass through POTW's and because these pollutants may interfere with bilogical treatment. Recent studies have shown that these metals may concentrate in the sludge at activated sludge plants and interfere with proper operation of anaerobic digestion. The PSES and PSNS effluent limitations are expressed as maximum monthly average and maximum day concentrations (mg/1).

At this time, the Agency has not identified any additional unit processes in use in this industry other than biological treatment for control of the organic toxic pollutants. Based upon the data available from biological treatment units in the industry, the organic toxic pollutants are removed by biological treatment to low levels and they do not interfere with biological treatment as used by POTWs.

XV. Pollutants and Subcategories Not Regulated

The Settlement Agreement contained provisions authorizing the exclusion from regulation, in certain instances, of toxic pollutants and industry subcategories. These provisions have been re-written in a Revised Settlement Agreement which was approved by the District Court for the District of Columbia on March 9, 1979.

Paragraph 8(a)(iii) of the Revised Settlement Agreement allows the Administrator to exclude from regulation toxic pollutants not detectable by section 304(h) analytical methods or other state-of-the-art methods. The toxic pollutants not detected and therefore excluded from regulation are listed in Appendix B to this notice.

While the Settlement Agreement required EPA to regulate the entire Gum and Wood Chemicals Industry listed under the U.S. Department of Commerce, Bureau of the Census, Standard Industrial Classification (SIC) code 2861, Paragraph 8(a)(iv) of the Revised Settlement Agreement authorizes EPA to exclude portions of the industry from regulation. The Agency first developed a profile of the total gum and wood chemicals industry. After this initial profile information was assembled and reviewed and screening samples from all subcategories except Char and Charcoal Briquets were collected and analyzed, the Agency concluded that three subcategories should be excluded from regulation because they either do not discharge process wastewater or they do not discharge significant quantities of process wastewater.

The Char and Charcoal Briquets subcategory produces its products by the thermal decomposition of raw wood. Seventy-seven potential plants were identified in the industry profile. Of the forty-five plants responding, none discharged process wastewater. BPT regulations promulgated May 18, 1976 require zero discharge of process wastewater. The Agency concludes, therefore, that additional effluent guidelines or standards for this subcategory are unnecessary.

The Essential Oils subcategory currently consists of nine plants which extract cedarwood oil by steaming cedarwood sawdust in pressure retorts to remove the oil from the wood particles. The process wastewater from eight of the plants is self-contained by a lagoon or by spray irrigation. The ninth plant at full operation discharges approximately 15,000 gallons per day to a POTW. The Agency does not believe that national PSES for only one plant are either appropriate or necessary. No new sources are expected to enter the market because of low market demand and shortages of raw materials.

The Gum Rosin and Turpentine subcategory produces its products by the distillation of pine oleoresin which is obtained by exposing the sapwood of the pine tree. This subcategory consists of seven plants, of which six have achieved zero discharge through the use of evaporation/percolation lagoons. The seventh plant discharges approximately 2,300 gallons of gum rosin wastewater to a POTW. The Agency does not believe that national PSES for only one plant are either appropriate or necessary. No new sources are expected to enter the market and existing plants are expected to close within the next ten years for economic reasons.

XVI. Monitoring Requirements

The Agency intends to establish a regulation requiring permittees to conduct additional monitoring when they violate permit limitations on indicator pollutants. The provisions of such monitoring requirements will be specified for each permittee and may include analysis for some or all of the toxic pollutants or the use of biomonitoring techniques. The additional monitoring is designed to determine the cause of the violation, necessary corrective measures, and the identity and quantity of toxic pollutants discharged. Each violation will be evaluated on a case-by-case basis by the permitting authority to determine whether or not the additional monitoring contained in the permit is necessary.

The Agency's sampling data shows benzene, toluene, ethylbenzene, and phenol in the untreated gum and wood chemicals wastewater in the range of below the detection limit to 30 ppm. The data also reveal that BPT technology (i.e. efficient biological treatment) reduces each of these pollutants to concentrations of 200 ppb or less. At these levels, there is no known cost effective technology applicable on a nationally uniform basis. However, individual plants are likely to be able to

take corrective action (e.g. in-plant controls) if organic toxic residuals become excessive and contribute to problems in meeting BPT limitations. Accordingly, if the BOD5 limitation is violated, then the permitting authority may require that the permittee monitor the organic toxic pollutants otherwise controlled by the BPT technology.

XVII. Costs, Effluent Reduction Benefits, and Economic Impacts

Exective Order 12044 requires EPA and other agencies to perform regulatory analyses of certain regulations. (See 43 FR 12661 (March 23, 1978)). EPA's proposed regulations for implementing Executive Order 12044 require a regulatory analysis for major significant regulations involving annualized compliance costs of more than $100 million or meeting other specified criteria. (See 43 FR 29891 (July 11, 1978)). Where these criteria are met, the proposed regulations require EPA to prepare a formal regulatory analysis, including an economic impact analysis and an evaluation of alternatives such as: (1) Alternative types of regulations, (2) alternative stringency levels, (3) alternative timing, and (4) alternative methods of ensuring compliance.

The proposed regulations for the gum and wood chemicals industry do not meet the proposed criteria for a formal regulatory analysis. Nonetheless, this proposed rulemaking satisfies the formal regulatory analysis requirements. While the Clean Water Act does not permit consideration of alternative timing or alternative methods of ensuring compliance, EPA has considered alternative stringency levels and alternative types or regulations, as discussed above. Moreover, the Agency has performed a detailed analysis of the economic impact of these proposed regulations.

EPA's economic impact assessment is set forth in *Economic Impact analysis of Proposed Effluent Limitations Guidelines, New source Performance Standards and Pretreatment Standards for the Gum and Wood Chemicals Point source Category*. November 1979. This report details the investment and annualized costs for the industry as a whole and for model plants covered by the proposed gum and wood chemicals regulations. The data underlying the analysis were obtained from the Development Document, publicly available financial studies and surveys, and the results of EPA's economic survey program described under Data Gathering Efforts. The report assesses the impact of compliance costs in terms of plant closures, production changes, price changes, employment changes, local community impacts, and balance of trade effects.

The methodology used in the economic analysis employs estimation of the profit reduction expected for plants currently operating in this industry assuming no cost pass-through. Compliance costs as a percent of sales revenue were estimated as a point of reference to qualitatively judge the possibility of recovering all or part of the compliance costs. The analysis was carried out for each of the 20 major plants operating in this industry affected by these regulations.

The decision criteria for plant closures are based on both compliance costs as a percent of estimated profits before taxes and compliance costs as a percent of sales revenue. Plants are projected to close if compliance costs are more than 50 percent of profits and more than 5 percent of sales. Even though the basis of competition for many of the products produced in this industry is price, and the industry is operating at relatively low capacity utilization rates, the trend to upgrading the value of products produced, the relative scarcity of raw materials, and the expected higher prices for competitive products based on petroleum derivatives make small price pass-through possible. It is expected that costs less than 5 percent of sales would be relatively easily recovered. The Agency projects that 7 of the 20 plants may be required to make pollution control expenditures to comply with the proposed effluent limitations. This estimate is based on a telephone survey of the industry which determined metallic catalyst usage at each plant. The Agency further estimates that the remaining plants will be able to meet the proposed limitations without additional expenditure.

The Agency estimates that the total investment costs for all the proposed regulations will approximate $588.4 thousand, and that associated annualized costs (including interest, depreciation, operation and maintenance) will approximate $1.22 million. Further, the Agency projects that the proposed regulations will not result in any plant closures, unemployment, or effects on production. It is not believed that the balance of trade will be affected at all. EPA believes that the rate of entry into this industry will not be affected by the proposed regulations. Diversion of capital from projects intended to upgrade products to higher value materials could reduce the long term potential for profit improvement in this industry. The costs, effluent reduction benefits, and economic impacts for each proposed regulation are summarized below.

(A) BPT—There are two sulfate turpentine producing plants that discharge wastewater to the Nation's waters and are thus subject to proposed BPT limitations. EPA estimates that the proposed limitations will result in the removal of 70 and 80.3 pounds per day of BOD5 and TSS, respectively.

EPA estimates that compliance with proposed BPT limitations may require a total investment of $104.5 thousand. Annualized costs may equal a total of $183 thousand. EPA does not expect the proposed BPT requirements to result in any closures, job losses, production losses, community effects or balance of trade effects.

(A) BAT—There are 8 Gum and Wood Chemicals plants that discharge wastewater directly to the Nation's waters. Three of these plants currently modify rosins by use of zinc as a catalyst and thus subject to proposed BAT limitations. These limitations will result in the removal of approximately 44 pounds per day of zinc.

EPA estimates that compliance with proposed BAT limitations may require a total investment of $225.6 thousand by these three plants, assuming BPT and proposed BPT for the Sulfate Turpentine subcategory are already in place. Annualized costs may equal a total of $512 thousand. Costs of up to five percent of sales may be passed on through price increases. EPA does not expect the proposed BAT requirements to result in any closures, job losses, production losses, community effects or balance of trade effects.

(B) NSPS—There have been virtually no new plants constructed in this industry over the past 10 years. At the current projected rates of growth for this industry the Agency expects that little or no new plant construction will be experienced over the next five years. One tall oil fractionation plant has been announced to come on stream in 1980. Since this plant is relatively small (35,000 tons/year) and will discharge its wastewater to a pulp and paper mills treatment system, the Agency estimates that no additional capital investment or operating costs will be incurred.

In general the new source performance standards will have little short term impact on industry growth and plant construction or expansion plans but will raise the overall price levels required to encourage new capacity. However, as indicated above, little new plant capacity is needed to meet the industry growth projections.

(C) PSES—There are 12 plants that discharge process related wastewater to POTWs or other industrial wastewater

treatment systems. EPA estimates that the total investment costs for 4 of these plants to comply with the proposed PSES regulations will be approximately $258.3 thousand. PSES annualized costs may equal $521 thousand. Costs of up to five percent of sales may be passed on through price increases. EPA does not expect the proposed PSES requirements to result in any closures, job losses, production losses, community effects, or balance of trade effects.

(D) PSNS—As pointed out in connection with NSPS, there have been virtually no new plants constructed in this industry over the past 10 years and the Agency expects little or no new plant construction over the next five years.

In general the new source performance standards will have little short term impacts on industry growth and plant construction or expansion plans but will raise the overall price levels required to encourage new capacity. However, as indicated above, little new plant capacity is needed to meet the industry growth projections.

XVIII. Small Business Administration Financial Assistance

There are two Small Business Administration programs that may be important sources of funding for the Gum and Wood Chemicals Manufacturing Point Source Category. They are the SBA's Economic Injury Loan Program and Pollution Control Financing Guarantees.

Section 8 of the FWPCA authorizes the SBA, through its Economic Injury Loan Program, to make loans to assist any small business concern in effecting additions to or alterations in equipment, facilities, or methods of operation in order to meet water pollution control requirements under the Federal Water Pollution Control Act, if the concern is likely to suffer a substantial economic injury without such assistance. This program is open to small business firms as defined by the Small Business Administration. Loans can be made either directly by SBA or through a bank using an SBA guarantee. The interest on direct loans depends on the cost of money to the Federal government and is currently set at 7⅜ percent. Loan repayment periods may extend up to thirty years depending on the ability of the firm to repay the loan and the useful life of the equipment. SBA loans made through banks are at somewhat higher interest rates. Firms in the Gum and Wood Chemicals Manufacturing Point Source Category may be eligible for direct or indirect SBA loans. For further details on this Federal loan program please contact: Coordinator— Mr. Sheldon Sacks, Environmental Protection Agency, Financial Assistance Coordinator, Office of Analysis & Evaluation (WH-586), 401 M Street SW., Washington, D.C. 20460, Telephone: (202) 755-3624.

In addition, the Small Business Investment Act, as amended by Public Law 94-305, authorizes SBA to guarantee the payments on qualified contracts entered into by eligible small businesses to acquire needed pollution facilities when the financing is provided through taxable and tax-exempt revenue or pollution control bonds. This program is open to all eligible small businesses. Bond financing with SBA's guarantee of the payments make available long term (20-25 years), low interest (usually 5% to 7%) financing to small businesses on the same basis as that available to larger national or international companies. For further details on this program write to SBA, Pollution Control Financing Division, Office of Special Guarantees, 1815 North Lynn Street, Magazine Building, Rosslyn, Virginia 22209 (703) 235-2900.

XIX. Nonwater Quality Aspects of Pollution Control

The elimination or reduction of one form of pollution may aggravate other environmental problems. Therefore, Sections 304(b) and 306 of the Act require EPA to consider the non-water quality environmental impacts (including energy requirements) of certain regulations. In compliance with these provisions, EPA has considered the effect of these regulations on air pollution, solid waste generation, water scarcity, and energy consumption. While it is difficult to balance pollution problems against each other and against energy utilization, EPA is proposing regulations which it believes best serve often competing national goals.

The following are the non-water quality environmental impacts (including energy requirements) associated with the proposed regulations:

A. Air Pollution—Imposition of BPT, BCT, BAT, NSPS, PSES and PSNS will not create any substantial increase in air pollution problems, although some increase in hydrocarbon content may occur if increased aeration in the biological treatment systems causes additional stripping of volatile organic compounds. Metals removal technology is accomplished in the aqueous phase and no releases of metals or hydrocarbons should result.

B. Solid Waste—The major non-water quality aspect of the proposed regulation will be the generation of metal sludges from the metals removal processes required for the rosin derivatives and sulfate turpentine operation. These sludges will contain high concentrations of the inorganic toxic pollutants copper and nickel or zinc. While the Agency has proposed certain solid wastes as hazardous (43 FR 58946, 58959 December 18, 1978) none of the wastes from the gum and wood chemicals industry are included. Disposal of these sludges may, however, become subject to RCRA regulation as finally promulgated.

Additional sludges may be generated as the result of the proposed BPT regulations for sulfate turpentine. These biological sludges usually accumulate in the aerated lagoons and settling ponds and must be dredged and disposed of periodically.

The Agency estimates that up to 500 pounds/day (668 gallons/day) of metal bearing and biological sludges may be generated as a result of these regulations. Hauling costs of $0.12 per gallon in 1977 dollars was used in estimating the disposal costs included in the annual operating costs.

C. Consumptive Water Loss—Some minor water loss may occur as a result of these regulations. Water becomes entrained in the hydroxide flocs generated in the metals precipitation units and would be lost to landfill. Some evaporative losses may occur as a result of increased aeration for biological treatment. However, the quantities of water involved are not significant and the industry is located in areas with sufficient water supplies.

D. Energy Requirements—Achievement of the proposed regulations will require additional energy use for pumps at the metals precipitation units for BAT and some additional aerators for BPT sulfate turpentine. Energy cost estimates are reflected in the operation and maintenance costs in the Development Document. EPA estimates electrical energy consumption will increase less than 420,000 kilowatt hours per year.

XX. Best Management Practices

Section 304(e) of the Clean Water Act authorizes the Administrator to prescribe "best management practices" ("BMPs"), described under Authority and Background. EPA intends to develop BMPs which: (1) Apply to all industrial sites; (2) Apply to a designated industrial category; and (3) offer guidance to permit authorities in establishing BMPs required by unique circumstances at a given plant.

EPA is considering promulgating BMP's specific to the Gum and Wood Chemicals Industry. A separate study of

the seven subcategories will be initiated at a later date.

XXI. Upset and Bypass Provisions

An issue of recurrent concern has been whether industry guidelines should include provisions authorizing noncompliance with effluent limitations during periods of "upset" or "bypass." An upset, sometimes called an "excursion," is unintentional noncompliance occurring for reasons beyond the reasonable control of the permittee. It has been argued that an upset provision in EPA's effluent limitations guidelines is necessary because such upsets will inevitably occur due to limitations in even properly operated control equipment. Because technology-based limitations are to require only what technology can achieve, it is claimed that liability for such situations is improper. When confronted with this issue, courts have divided on the question of whether an explicit upset or excursion exemption is necessary or whether upset or excursion incidents may be handled through EPA's exercise of enforcement discretion. Compare *Marathon Oil Co.* v. *EPA*, 564 F. 2d 1253 (9th Cir. 1977) with *Weyerhaeuser* v. *Costle, supra.* See also *American Petroleum Institute* v. *EPA*, 540 F. 2d 1023 (10th Cir. 1976); *CPC International, Inc.* v. *Train*, 540 F. 2d 1320 (8th Cir. 1976); *FMC Corp.* v. *Train*, 539 F. 2d 973 (4th Cir. 1976).

While an upset is an unintentional episode during which effluent limits are exceeded, a bypass is an act of intentional noncompliance during which waste treatment facilities are circumvented in emergency situations. Bypass provisions have, in the past, been included in NPDES permits.

EPA has determined that both upset and bypass provisions should be included in NPDES permits, and has recently promulgated NPDES regulations which include upset and bypass permit provisions. See 44 FR 32905 (June 7, 1979). The upset provision establishes an upset as an affirmative defense to prosecution for violation of technology-based effluent limitations. The bypass provision authorizes bypassing to prevent loss of life, personal injury or severe property damage. Consequently, although permittees in the Gum and Wood Chemicals Industry will be entitled to upset and bypass provisions in NPDES permits, these proposed regulations do not address these issues.

XXII. Variances and Modifications

Upon the promulgation of final regulations, the numerical effluent limitations for the appropriate subcategory must be applied in all Federal and state NPDES permits thereafter issued to Gum and Wood Chemicals direct dischargers. In addition, on promulgation, the pretreatment limitations are directly applicable to indirect dischargers.

For the BPT effluent limitations, the only exception to the binding limitations is EPA's "fundamentally different factors" variance. See *E. I. duPont de Nemours and Co.* v. *Train*, 430 U.S. 112 (1977); *Weyerhaeuser Co.* v. *Costle, supra.* This variance recognizes factors concerning a particular discharger which are fundamentally different from the factors considered in the industry-wide rulemaking. Although this variance clause was set forth in EPA's 1973–1976 industry regulations, it now will be included only in the NPDES regulations. (See 44 FR 32854, 32950 (June 7, 1979) for the text and explanation of the "fundamentally different factors" variance).

The BAT limitations in these regulations are subject to EPA's "fundamentally different factors" variance provision. The Act also provides that BAT limitations for conventional and non-conventional pollutants are subject to modifications under sections 301(c) and 301(g) of the Act. According to section 301(j)(1)(B), applications for those modifications must be filed within 270 days after promulgation of final effluent limitations guidelines. See 43 FR 40859 (Sept. 13, 1978). Under section 301(1) of the Act these statutory modifications are not applicable to toxic pollutants. Likewise, limitations on conventional and non-conventional pollutants used as "indicators" for toxic pollutants are not subject to section 301(c) or section 301(g) modifications, unless the discharger demonstrates that a waste stream does not contain any of the toxic pollutants for which the "indicator" was designed to demonstrate removal.

Pretreatment standards for existing sources are subject to the "fundamentally different factors" variance and credits for pollutants removed by POTWs. See 40 CFR 403.7, 403.13; 43 FR 27736 (June 26, 1978). Pretreatment standards for new sources are subject only to the credits provision in 40 CFR 403.7. New source performance standards are not subject to EPA's "fundamentally different factors" variance or any statutory or regulatory modifications. See *duPont* v. *Train, supra.*

XXIII. Relationship to NPDES Permits

The BAT limitations for the Rosin-based Derivatives and Sulfate Turpentine subcategories and BPT, BCT, and NSPS limitations for four subcategories in these regulations will be applied to individual Gum and Wood Chemicals Industry plants through NPDES permits issued by EPA or approved state agencies, under section 402 of the Act. The preceding section of this preamble discussed the binding effect of these regulations on NPDES permits, except to the extent that variances are expressly authorized. This section describes several other aspects of the interaction of these regulations and NPDES permits.

One matter which has been the subject of differing judicial views is the scope of NPDES permit proceedings in the absence of effluent limitations guidelines and standards. Under the NPDES regulations, states and EPA regions issuing NPDES permits prior to promulgation of these regulations must include a "reopener clause," providing for permits to be modified to incorporate "toxics" regulations when they are promulgated. See 44 FR 32906 (June 7, 1979). To avoid cumbersome modification procedures, EPA has adopted a policy of issuing short-term permits, with a view toward issuing long-term permits only after promulgation of these and other BAT regulations. The Agency has published rules designed to encourage states to do the same. See 43 FR 58066 (December 11, 1978). However, in the event that EPA finds it necessary to issue long-term permits prior to promulgation of BAT regulations, EPA and states will follow essentially the same procedures utilized in many cases of initial permit issuance. The permit issuer will assess the appropriate technology levels and limitations on a case-by-case basis, on consideration of the statutory factors. See *U.S. Steel Corp.* v. *Train*, 556 F. 2d 822, 844, 854 (7th Cir. 1977). In these situations, EPA documents and draft documents (including these proposed regulations and supporting documents) are relevant evidence, but not binding, in NPDES permit proceedings. See 44 FR 32854 (June 7, 1979).

Another question is the effect of these regulations on the powers of NPDES permit issuing authorities. The promulgation of these regulations does not restrict the power of any permit-issuing authority to act in any manner consistent with law or these or any other EPA regulations, guidelines, or policy. For example, the fact that these regulations do not control a particular pollutant does not preclude the permit issuer from limiting such pollutant on a case-by-case basis, when it is necessary to carry out the purposes of the Act. In addition, to the extent that state water quality standards or other provisions of

state of Federal law require limitation of pollutants not covered by these regulations (or require more stringent limitations on covered pollutants, such limitations *must* be applied by the permit-issuing authority.

One additional topic that warrants discussion is the operation of EPA's NPDES enforcement program, of which many aspects have been considered in developing these regulations. The Agency wishes to emphasize that although the Clean Water Act is a strict liability statute, the initiation of enforcement proceedings by EPA is discretionary. EPA has exercised and intends to exercise that discretion in a manner which recognizes and promotes good faith compliance efforts and conserves enforcement resources for those who fail to make good faith efforts to comply with the Act.

XXIV. Summary of Public Participation

On January 19, 1979, the Agency circulated for public comment a draft technical report to a number of interested parties. The report was made available to members of the Pulp Chemicals Association, the Natural Resources Defense Council, the U.S. Department of Commerce, EPA Regional Offices, and some states that have authority to issue National Pollution Discharge Elimination System (NPDES) permits. This document included the technical information that served as the basis for the regulations proposed at this time, but did not make recommendations or present conclusions. Reviewers of the technical report were asked to forward to the Agency their written comments by March 9, 1979; they also were invited to a meeting March 23, 1979 where they could discuss their comments with the technical and legal staffs of the Agency. However, since there were no requests for time for oral presentations, the meeting was cancelled. A brief summary of the written comments is presented here.

Comment: Activated carbon was identified as a candidate treatment technology because of its ability to remove toxic pollutants which may remain after biological treatment. Since BPT treatment apparently reduces the organic toxic pollutants to fairly low levels, should activated carbon be required?

Response: The data show that biological treatment results in substantial reductions of organic toxic pollutants. Also, the high cost of activated carbon treatment for organic toxic pollutants makes this type of treatment expensive for this industry. Activated carbon will not be the basis for BAT or NSPS.

Comment: Regulations should be limited to periodic testing of only those substances which have been demonstrated to be present in significant concentrations at any given location rather than monitoring for the full 129 toxic pollutants.

Response: The proposed regulations identify certain pollutants and identify effluent limitations for those pollutants. The regulations do not require monitoring for the full 129 toxic pollutants. However, this does not preclude more stringent effluent limits or more stringent monitoring requirements at the option of the NPDES authority, as required to carry out the Act.

Comment: The narrative description and the results of the sample analyses suggest that the sulfate turpentine subcategory could be further subdivided as follows:

a. Sulfate turpentine

b. Sulfate turpentine/flavors and fragrances

c. Sulfate turpentine/other

Response: The proposed regulations do not subdivide the sulfate turpentine subcategory because of the small number of plants (seven) and because the Agency believes it has addressed the proposed subcategorization by basing the proposed sulfate turpentine guidelines on raw waste load data from a plant producing sulfate turpentine/flavor and fragrances. This segment utilizes most of the processes of the other two proposed subcategories plus the use of metal catalyst.

Comment: The narrative description of the sampling program in Section III of the contractor's technical report indicates that the screening and verification samplings were two distinct efforts when in fact this was not the case at some plants.

Response: The description of the sampling program in Section III of the Development Document to accompany these proposed regulations more fully explains the methodology used in screening and verification sampling.

Comment: If samples were collected on three consecutive days, the presence of a pollutant in one sample but not in the other two raises the question of whether the pollutant actually occurred, especially if any type of equalization is employed.

Response: In only three cases was a toxic pollutant found on one day during the three-day sampling where it was not also present in the other two samples. In each case, discussions with plant personnel have not revealed any source for the pollutant or any reason for its presence.

Comment: The presence of methylene chloride in the water samples was questioned, since it is neither used in the plant nor present in the raw material, but is a common solvent found in chemical laboratories.

Response: The Agency has confirmed that several research and development laboratories located on plant sites maintain stocks of methylene chloride. Methylene chloride also is required by the EPA sampling methods as a solvent rinse for some of the sample fraction containers. Because of the potential for contamination inherent in the sampling methodology, methylene chloride is not being considered for regulation. However, two plants which were not sampled do use methylene chloride as a process solvent. Methylene chloride is a volatile organic toxic pollutant which should be reduced to the same low levels by bioligical treatment as benzene, toluene, and ethylbenzene.

Comment: Some participants questioned the results of the BOD5 and BOD10 analyses since some BOD10 results were lower than the BOD5 results for the same samples, and significant variances were noted between the sampling results and individual plant results.

Response: The standard method for analysis of BOD requires that the sample must be diluted such that biochemical oxidation of the organics present causes depletion of the available oxygen within the range of 2 to 6 mg/1. In some cases where the dilution required was one part waste to 25 parts dilution water or higher, errors resulted which gave erroneous results. The BOD data, while used to give an indication of the magnitude of the BOD in the waste stream, was not used in determining any of the numerical limitations proposed here.

Comment: One participant questioned the results of the analyses for phenol in light of the fact that phenol by the GC/MS method was greater than total phenol by "Standard Methods." Total phenol by "Standard Methods" should be greater than phenol by GC/MS.

Response: While total phenols by "Standard Methods" should yield higher results than phenols by GC/MS, there are a number of compounds or agents which may interfere with the "Standard Methods" total phenols test. While "Standard Methods" describes several methods for eliminating these interferences, it also notes that "some of the treatment procedures used for removal of interferences before analysis may result in an unavoidable loss of certain types of phenols." While attempting to eliminate interferences suspected present in gum and wood

chemicals waste streams, such a loss may have occurred.

Comment: The contractor's report identified several means of oxidizing phenols. The data presented by the contractor indicate that phenols may be reduced by biological treatment. Is biological treatment an acceptable alternative?

Response: Yes. Biological treatment appears to remove the organic toxics of concern here. However, this treatment technology does not preclude the selection of other wastewater treatment alternatives which provide equivalent or better levels of treatment.

Comment: The industry has limited experience with metals removal by pH adjustment. Two problems are apparent. First, metal hydroxides are difficult flocs to settle or filter, and second, the waste cake or slurry may be classified as hazardous, thus affecting the cost of disposal. Expansion of the discussion of technologies available and the costs basis would be helpful.

Response: The discussion of metals removal in the Development Document has been expanded. Removal of metals by pH adjustment still appears to be the most cost-effective form of treatment. The hydroxide flocs developed by this form of treatment may be difficult to settle or filter by themselves, but flocculant aids or filtering aids are available and should enhance removals. The waste cake or slurry may be classified as hazardous. Determination of whether the waste cake or slurry is hazardous cannot be made, since the regulations for hazardous substances have not been promulgated. The costs for transportation of the waste cake or slurry are based upon 1977 costs of hauling. An estimate of the cost which might be incurred if the waste is hazardous is contained in Section XIX.

XXV. Solicitation of Comments

EPA invites and encourages public participation in this rulemaking. The Agency asks that any deficiencies in the record of this proposal be specifically addressed and that suggested revisions or corrections be supported by data.

EPA is particularly interested in receiving additional comments and information on the following issues:

1. The Agency is proposing treatment for metals at the source for the Sulfate Turpentine and Rosin-Based Derivatives subcategories. Because the processes which utilize metals are operated intermittently and the resulting waste streams are generally small in comparison to total plant flow, the Agency is proposing application of numerical effluent guidelines limitations at the metals source waste stream. The Agency solicits comments on this regulatory approach to control of toxic pollutants.

2. The Agency requests that reviewers of this proposal point out errors in data, tabulation, possible misinterpretation of industry submitted data, or any possible error in the logic of these proposed rules. Comments of this nature should be documented with copies of the originally submitted information, together with either a discussion explaining the participants interpretation of the data or a discussion of the participants logical approach to the rulemaking.

3. The Agency's sampling data shows benzene, toluene, ethlybenzene, and phenol in wastewater from Gum and Wood Chemicals plants. BPT technology reduces the concentration of these pollutants to 200 ppb or less. Accordingly, the Agency is proposing that if the BPT BOD5 limitation is violated, the permitting authority may require that the permittee monitor the organic toxic pollutants otherwise controlled by the BPT technology. EPA requests the submission of data which either support or refute its belief that when BOD5 is removed to low concentrations, the concentrations of organic toxic pollutants are substantially less than when the concentration of BOD5 is high.

4. Characterization of the nature and amount of sludges generated by gum and wood chemicals plants and the costs of sludge handling and disposal are important to these regulations and requlations being developed by EPA's Office of Solid Waste under authority of the Resource Conservation and Recovery Act (RCRA). The Agency solicits additional data concerning the quantities, pollutant content, and handling and disposal costs for all solid wastes.

5. The cost of control technology is a significant issue. In order to perform a meaningful comparison of EPA cost data and industry cost data, EPA requests detailed information on salient design and operating characteristics; actual installed cost (not estimates of replacement costs) for each unit treatment operation or piece of equipment (e.g., screens, clarifiers, aeration equipment, etc.); the date of installation and the amount of installation labor provided by plant personnel; and the actual cost for operation and maintenance, broken down into units of usage and cost for energy (kilowatt hours or equivalent), chemicals, and labor (work-years or equivalent).

6. EPA has obtained from the industry a substantial data base for the control and treatment technologies which serve as the basis for the proposed regulations. Plants which have not submitted data or engineering studies other than those already submitted are requested to forward these data to EPA. These data should be individual data points, not averages or other summary data, including flow, production, and all pollutant parameters for which analyses were run. Please submit any qualifications to the data, such as descriptions of facility design, operating procedures, and upset problems during specified periods.

7. EPA requests that POTWs which receive wastewaters from gum and wood chemicals plants submit data which would document the occurrence of interference with collection system and treatment plant operations, permit violations, sludge disposal difficulties, or other incidents attributable to the pollutants contained in gum and wood chemicals plant's discharges to POTWs.

Dated: November 20, 1979.

Douglas M. Costle,

Administrator.

XXVI. Appendices

Appendix A—Abbreviations, Acronyms and Other Terms Used in This Notice

Act

The Clean Water Act.

Agency

The U.S. Environmental Protection Agency.

At-the-source

At a reaction kettle or other designated site where intermediates are modified by use of a metallic catalyst.

BAT

The best available technology economically achievable, under section 301(b)(2)(A) of the Act.

BCT

The best conventional pollutant control technology, under section 301(b)(2)(E) of the Act.

BMP

Best management practices, under section 304(e) of the Act.

BPT

The best practicable control technology currently available, under section 301(b)(1) of the Act.

Clean Water Act

The Federal Water Pollution Control Act Amendments of 1972 (33 U.S.C. 1251 et eg.), as amended by the Clean Water Act of 1977 (Pub. L. 95–217).

Direct discharger

A facility which discharges or may discharge pollutants into waters of the United States.

Indirect Discharger

A facility which discharges or may discharge pollutants into a publicly owned treatment works.

NPDES

National Pollutant Discharge Elimination System, under section 402 of the Act.

NSPS

New source performance standards, under section 306 of the Act.

POTW

Publicly owned treatment works.

PSES

Pretreatment standards for existing sources of indirect discharges, under section 307(b) of the Act.

PSNS

Pretreatment standards for new sources of direct discharges, under section 307(b) and (c) of the Act.

RCRA

Resource Conservation and Recovery Act of 1976, Amendments to Solid Waste Disposal Act (Public Law 94–580).

Appendix B—Toxic Pollutants not Detected in Treated Effluents

Compound name

1. acenaphthene*
2. acrolein*
3. acrylonitrile*
4. benzidine*
5. carbon tetrachloride (tetrachloromethane)*
6. chlorobenzene
7. 1,2,4-trichlorobenzene
8. hexachlorobenzene
9. 1,2-dichloroethane
10. hexachloroethane
11. 1,1-dichloroethane
12. 1,1,2-trichloroethane
13. 1,1,2,2-tetrachloroethane
14. bis(chloromethyl) ether
15. bis(2-chloroethyl) ether
16. 2-chloroethyl vinyl ether (mixed)
17. 2-chloronaphthalene
18. 2,4,6-trichlorophenol
19. parachlorometa cresol
20. 2-chlorophenol*
21. 1,2-dichlorobenzene
22. 1,3-dichlorobenzene
23. 1,4-dichlorobenzene
24. 3,3'-dichlorobenzidine
25. 1,1-dichloroethylene
26. 1,2-trans-dichloroethylene
27. 2,4-dichlorophenol*
28. 1,2-dichloropropane
29. 1,2-dichloropropylene (1,2-dichloropropene)
30. 2,4-dimethylphenol*
31. 2,4-dinitrotoluene
32. 2,6-dinitrotoluene
33. 1,2-diphenylhydrazine*
34. fluoranthene*
35. 4,chlorophenyl phenyl ether
36. 4-bromophenyl phenyl ether
37. bis(2-chloroisopropyl) ether
38. bis(2-chloroethoxy) methane
39. methyl chloride (chloromethane)
40. methyl bromide (bromomethane)
41. bromoform (tribromomethane)
42. dichlorobromomethane
43. trichlorofluoromethane
44. dichlorodifluoromethane
45. chlorodibromomethane
46. hexachlorobutadiene*
47. hexachlorocyclopentadiene*
48. isophorone*
49. nitrobenzene*
50. 2-nitrophenol
51. 4-nitrophenol
52. 2,4-dinitrophenol*
53. 4,6-dinitro-o-cresol
54. N/nitrosodimethylamine
55. N-nitrosodiphenylamine
56. N-nitrosodi-n-propylamine
57. pentachlorophenol*
58. bis(2-ethylhexyl) phthalate
59. butyl benzyl phthalate
60. di-n-butyl phthalate
61. di-n-octyl phthalate
62. diethyl phthalate
63. dimethyl phthalate
64. benzo(a)anthracene (1,2-benzanthracene)
65. benzo(a)pyrene (3,4-benzopyrene)
66. 3,4-benzofluoranthene
67. benzo(k)fluoranthane (11,12-benzofluoranthene)
68. chrysene
69. acenaphthylene
70. anthracene
71. benzo(ghi)perylene (1,12-benzoperylene)
72. fluorene
73. phenanthrene
74. dibenzo(a,h)anthracene (1,2,5,6-dibenzanthracene)
75. indeno (1,2,3-cd)pyrene (2,3-o-phenylenepyrene)
76. pyrene
77. tetrachloroethylene*
78. trichloroethylene*
79. vinyl chloride (chloroethylene)*
80. aldrin*
81. dieldrin*
82. chlordane (technical mixture and metabolites)*
83. 4,4'-DDT
84. 4,4'-DDE (p,p'-DDX)
85. 4,4'-DDD (p,p'-TDE)
86. a-endosulfan-Alpha
87. b-endosulfan-Beta
88. endosulfan sulfate
89. endrin
90. endrin aldehyde
91. heptachlor
92. heptachlor epoxide
93. a-BHC-Alpha
94. b-BHC-Beta
95. r-BHC(lindane)-Gamma
96. g-BHC-Delta
97. PCB-1242(Arochlor 1242)
98. PCB-1254(Arochlor 1254)
99. PCB-1221(Arochlor 1221)
100. PCB-1232(Arochlor 1232)
101. PCB-1248(Arochlor 1248)
102. PCB-1260(Arochlor 1260)
103. PCB-1016(Arochlor 1016)
104. toxaphene*
105. antimony (total)*
106. asbestos (fibrous)*
107. beryllium (total)*
108. cyanide (total)*
109. mercury (total)*
110. silver (total)*
111. thallium (total)*
112. 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) [1]

*Specific compounds and chemical classes as listed in the Consent Decree.

Appendix C—Toxic Pollutants Detected In Final Effluent Samples

1. benzene*
2. 1,1,1-trichloroethane
3. chloroethane
4. chloroform (trichloromethane)*
5. ethylbenzene*
6. naphthalene*
7. phenol*
8. toluene*
9. methylene chloride (dichloromethane)
10. arsenic (total)*
11. cadmium (total)*
12. chromium (total)*
13. copper (total)*
14. lead (total)*
15. nickel (total)*
16. selenium (total)*
17. zinc (total)*

40 CFR Part 454 is revised to read as follows:

PART 454—GUM AND WOOD CHEMICALS INDUSTRY POINT SOURCE CATEGORY

General Provisions

Sec.
454.01 Applicability.
454.02 Definitions.
454.03 Monitoring requirements.

Subpart A—Char and Charcoal Briquets Subcategory

454.10 Applicability: description of the char and charcoal briquets subcategory.
454.12 Effluent limitations representing the degree or effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
454.13 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
454.14 Effluent limitations representing the degree of effluent reduction attainable by the application of best conventional pollutant control technology (BCT).
454.15 New source performance standards (NSPS).
454.16 Pretreatment standards for new sources (PSNS).

[1] This compound was specifically listed in the Consent Decree. Because of the extreme toxicity (TCDD), EPA recommends that laboratories not acquire analytical standard for this compound.

*Specific compounds and chemical classes as listed in the Consent Decree.

Sec.

454.17 Pretreatment standards for existing sources (PSES).

Subpart B—Gum Rosin and Turpentine Subcategory

454.20 Applicability: description of the gum rosin and turpentine subcategory.
454.22 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
454.23 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
454.24 Effluent limitations representing the degree of effluent reduction attainable by the application of best conventional pollutant control technology (BCT).
454.25 New source performance standards (NSPS).
454.26 Pretreatment standards for new sources (PSNS).
454.27 Pretreatment standards for existing sources (PSES).

Subpart C—Wood Rosin, Turpentine, and Pine Oil Subcategory

454.30 Applicability; decription of the wood rosin, turpentine, and pine oil subcategory.
454.32 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
454.33 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
454.34 Effluent limitations representing the degree of effluent reduction attainable by the application of best conventional pollutant control technology (BCT).
454.35 New source performance standards (NSPS).
454.36 Pretreatment standards for new sources (PSNS).
454.37 Pretreatment standards for existing sources (PSES).

Subpart D—Tall Oil Rosin, Pitch, and Fatty Acids Subcategory

454.40 Applicability; description of the tall oil rosin, pitch, and fatty acids subcategory.
454.42 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
454.43 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
454.44 Effluent limitations representing the degree of effluent reduction attainable by the application of best conventional pollutant control technology (BCT).
454.45 New source performance standards (NSPS).
454.46 Pretreatment standards for new sources (PSNS).

Sec.

454.47 Pretreatment standards for existing sources (PSES).

Subpart E—Essential Oils Subcategory

454.50 Applicability; description of the essential oils acids subcategory.
454.52 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
454.53 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
454.54 Effluent limitations representing the degree of effluent reduction attainable by the application of best conventional pollutant control technology (BCT).
454.55 New source performance standards (NSPS).
454.56 Pretreatment standards for new sources (PSNS).
454.57 Pretreatment standards for existing sources (PSES).

Subpart F—Rosin-Based Derivatives Subcategory

454.60 Applicability; description of the rosin-based derivatives subcategory.
454.62 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
454.63 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
454.64 Effluent limitations representing the degree of effluent reduction attainable by the application of best conventional pollutant control technology (BCT).
454.65 New source performance standards (NSPS).
454.66 Pretreatment standards for new sources (PSNS).
454.67 Pretreatment standards for existing sources (PSNS).

Subpart G—Sulfate Turpentine Subcategory

454–70 Applicability; description of the sulfate turpentine subcategory.
454.72 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
453.73 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
454.74 Effluent limitations representing the degree of effluent reduction attainable by the application of best conventional pollutant control technology (BCT).
454.75 New source performance standards (NSPS).
454.76 Pretreatment standards for new sources (PSNS).
454.77 Pretreatment standards for existing sources (PSES).

Authority: Sections 301, 304(b), (c), (e), and (g), 306 (b) and (c), 307 (b) and (c), and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, as amended by the Clean Water Act of 1977) (the "Act"); 33 U.S.C. 1311, 1314 (b), (c), (e), and (g), 1316 (b) and (c), 1317 (b) and (c), and 1361; 86 Stat. 816, Pub. L. 92–500; 91 Stat. 1567, Pub. L. 95–217.

General Provisions

454.01 Applicability

This part applies to char and charcoal briquet producers; gum rosin and turpentine producers; wood rosin, turpentine, and pine oil producers; tall oil rosin, pitch, and fatty acids producers; essential oils producers; rosin-based derivatives producers associated with other gum and wood chemicals subcategories; and sulfate turpentine producers which discharge or may discharge pollutants to waters of the United States or which introduce or may introduce pollutants into a publicly-owned treatment works.

454.02 General definitions.

In addition to the definitions set forth in 40 CFR Part 401, the following definitions apply to this part:

(a) Char and charcoal briquet production means the destructive distillation of softwood and hardwood to produce char which may be further processed into charcoal.

(b) Gum rosin and turpentine production means the distillation of the sap of live pines to separate turpentine and gum rosin. Production shall be the sum of the final products.

(c) Wood rosin, turpentine, and pine oil production means extraction from wood chips of rosin, turpentine, and pine oil and separation of the components by distillation. Production shall be the sum of the final products plus intermediates.

(d) Tall oil rosin, pitch, and fatty acids production means fractionation of crude tall oil to its constituent components. Production shall be the sum of the final products plus intermediates.

(e) Essential oils production means the steaming of oil containing raw material under pressure to produce a finished oil product. Production shall be the sum of the final product.

(f) Rosin-based derivatives production means chemical modification of the rosins. Production shall be the sum of the final products.

(g) Sulfate turpentine production means the fractionation of Kraft sulfate turpentine into its constituent components and any modifications by chemical reactions. Production shall be the sum of the final products plus intermediates.

(h) At-the-source means at a reaction kettle or other designated site where intermediates are modified by use of a metallic catalyst.

§ 454.03 Monitoring and Reporting. (Reserved]

Subpart A—Char and Charcoal Briquets Subcategory

§ 454.10 Applicability; description of the manufacture of char and charcoal briquets subcategory.

This subpart applies to discharges resulting from the production of char or charcoal briquets.

§ 454.12 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, there shall be no discharge of process wastewater pollutants to waters of the United States from any existing point source subject to this subpart.

§ 454.13 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT). [Reserved]

§ 454.14 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]

§ 454.15 New source performance standards (NSPS). [Reserved]

§ 454.16 Pretreatment standards for new sources (PSNS). [Reserved]

§ 454.17 Pretreatment standards for existing sources (PSES). [Reserved]

Subpart B—Gum Rosin and Turpentine Subcategory

§ 454.20 Applicability; description of the manufacture of gum rosin and turpentine subcategory.

This subpart applies to discharges resulting from the production of gum rosin or turpentine.

§ 454.22 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

Subpart B

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	1.42	0.755
TSS	0.077	0.026
ph	Within the range of 6.0 to 9.0 at all times	

§ 454.23 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT). [Reserved]

§ 454.24 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]

§ 454.25 New source performance standards (NSPS). [Reserved]

§ 454.26 Pretreatment standards for new sources (PSNS). [Reserved]

§ 454.27 Pretreatment standards for existing sources (PSES). [Reserved]

Subpart C—Wood Rosin, Turpentine, and Pine Oil Subcategory

§ 454.30 Applicability; description of the wood rosin, turpentine, and pine oil subcategory.

This subpart applies to discharges to waters of the United States, and introductions of pollutants into publicly-owned treatment works from any gum and wood chemicals plant which, either exclusively or in addition to other gun and wood chemicals operations, processes wood stumps or wood chips into rosin, turpentine, and pine oil products by solvent extraction and distillation.

§ 454.32 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

Subpart C

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	2.08	1.10
TSS	1.38	0.475
pH	Within the range of 6.0 to 9.0 at all times	

§ 454.33 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT). [Reserved]

§ 454.34 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control techology (BCT):

Subpart C

Pollutant or pollutant property	BCT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	2.08	1.10
TSS	1.38	0.475
pH	Within the range of 6.0 to 9.0 at all times.	

454.35 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

Subpart C

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	2.08	1.10
TSS	1.38	0.475
pH	Within the range of 6.0 to 9.0 at all times	

§ 454.36 Pretreatment standards for new sources (PSNS). [Reserved]

§ 454.37 Pretreatment standards for existing sources (PSES). [Reserved]

Subpart D—Tall Soil Rosin, Pitch, and Fatty Acids Subcategory

§ 454.40 Applicability; description of the tall oil, rosin, pitch, and fatty acids subcategory.

This subpart applies to discharges to waters of the United States, and introductions of pollutants into publicly-owned treatment works from any gum and wood chemicals plant which, either exclusively or in addition to other gum and wood chemicals operations, processes crude tall oil into rosin, pitch, and fatty acids by fractionation.

§ 454.42 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

Subpart D

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	0.995	0.529
TSS	0.705	0.243
pH	Within the range of 6.0 to 9.0 at all times.	

§ 454.43 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT). [Reserved]

§ 454.44 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30–32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT):

Subpart D

Pollutant or pollutant property	BCT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	0.995	0.529
TSS	0.705	0.243
pH	Within the range of 6.0 to 9.0 at all times.	

§ 454.45 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

Subpart D

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	0.995	0.529
TSS	0.705	0.243
pH	Within the range of 6.0 to 9.0 at all times.	

§ 454.46 Pretreatment standards for new sources (PSNS). [Reserved]

§ 454.47 Pretreatment standards for existing sources (PSES). [Reserved]

Subpart E—Essential Oils Subcategory

§ 454.50 Applicability; description of the essential oils subcategory.

This subpart applies to discharges resulting from the manufacture of essential oils.

§ 454.52 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

Subpart E

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	22.7	12.0
TSS	9.01	3.11
pH	Within the range of 6.0 to 9.0 at all times	

§ 454.53 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT). [Reserved]

§ 454.54 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]

§ 454.55 New source performance standards (NSPS). [Reserved]

§ 454.56 Pretreatment standards for new sources (PSNS). [Reserved]

§ 454.57 Pretreatment standards for existing sources (PSES). [Reserved]

Subpart F—Rosin-Based Derivatives Subcategory

§ 454.60 Applicability: description of the rosin-based derivatives subcategory.

This subpart applies to discharges to waters of the United States, and introductions of pollutants into publicly-owned treatment works from any gum and wood chemicals plant which, in addition to other gum and wood chemicals operations, chemically modifies rosins.

§ 454.62 Effluent limitations representing the degree of effluent limitations reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

Subpart F

Pollutant or pollutant property	BPT Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	1.41	0.748
TSS	0.045	0.015
pH	Within the range of 6.0 to 9.0 at all times	

§ 454.63 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

Subpart F

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	milligrams per liter (mg/l)	
Zinc [1]	4.2	1.8

[1] At the source.

§ 454.64 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT):

Subpart F

Pollutant or pollutant property	BCT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kkg (or lb/1,000 lb) of product	
BOD5	1.41	0.748
TSS	0.045	0.015
pH	Within the range of 6.0 to 9.0 at all times	

§ 454.65 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

Subpart F

Pollutant or pollutant property	NSPS effluent limitation	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	1.41	0.748
TSS	0.045	0.015
	milligrams per liter (mg/l)	
Zinc [1]	4.2	1.8
pH	Within the range of 6.0 to 9.0 at all times	

1 At the source.

§ 454.66 Pretreatment standards for new sources (PSNS).

Any new source subject to this subpart which introduces pollutants into a publicly-owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS):

Subpart F

Pollutant or pollutant property	PSNS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	milligrams per liter (mg/l)	
Zinc [1]	4.2	1.8

[1] At the source.

§ 454.67 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.13, any existing source subject to this subpart which introduces pollutants into a publicly-owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

Subpart F

Pollutant or pollutant property	PSES effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	milligrams per liter (mg/l)	
Zinc [1]	4.2	1.8

[1] At the source.

Subpart G—Sulfate Turpentine Subcategory

§ 454.70 Applicability: description of the sulfate turpentine subcategory.

This subpart applies to discharges to waters of the United States, and introductions of pollutants into publicly-owned treatment works from any sulfate turpentine plant which, either exclusively or in addition to other gum and wood chemicals operations, processes sulfate turpentine into pinenes, dipentine, and sulfate turpentine.

§ 454.72 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available. (BPT).

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

Subpart G

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	5.504	2.924
TSS	0.686	0.236
pH	Within the range of 6.0 to 9.0 at all times	

§ 454.73 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

Subpart G

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	milligrams per liter (mg/l)	
Copper [1]	4.5	1.8
Nickel [1]	4.1	1.8

[1] At the source.

§ 454.74 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best

conventional pollutant control tchnology (BCT):

Subpart G

Pollutant or pollutant property	BCT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	5.504	2.924
TSS	0.686	0.236
PH	Within the range of 6.0 to 9.0 at all times	

§ 454.75 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

Subpart G

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	kg/kkg (or lb/1,000 lb) of product	
BOD5	5.504	2.924
TSS	0.686	0.236
	milligrams per liter (mg/l)	
Cooper [1]	4.5	1.8
Nickel [1]	4.1	1.8
pH	Within the range of 6.0 to 9.0 at all times	

[1] At the source.

§ 454.76 Pretreatment standards for new sources (PSNS).

Any new source subject to this subpart which introduces pollutants into a publicly-owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS):

Subpart G

Pollutant or Pollutant property	PSMS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Copper [1]	4.5	1.8
Nickel [1]	4.1	1.8

[1] At the source.

§ 454.77 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.13, any existing source subject to this subpart which introduces pollutants into a publicly-owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

Subpart G

Pollutant or Pollutant property	PSMS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Copper [1]	4.5	1.8
Nickel [1]	4.1	1.8

[1] At the source.

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