openings used to load personnel, equipment, cargo, and stores, in the collision bulkhead, the side shell, and the boundaries of enclosed superstructures that are continuous with the shell of the vessel.

(c) The master shall enter into the log book the time and door location of every closing of the loading doors.

(d) The master shall enter into the log book any opening of the doors in accordance with paragraph (a)(2) of this section setting forth the time of the opening of the doors and the circumstances warranting this action.

41. Section 196.35–5 is amended by redesignating paragraphs (a)(4) through (a)(11) as paragraphs (a)(6) through (a)(13) and by adding new paragraphs (a)(4) and (a)(5) to read as follows:

§ 196.35–5 Actions required to be logged.

* * * * *

(a) * * *

(4) Verification of vessel compliance with applicable stability requirements. After loading and prior to departure and at all other times necessary to assure the safety of the vessel. See § 196.15–7.

(5) Loading doors. Every closing and any opening when not docked. See § 196.15–18.

* * * * *

42. In § 196.40–10, by revising paragraph (a); by redesignating paragraphs (b) and (c) as paragraphs (c) and (d); and by adding new paragraphs (b), (e), (f), and (g) to read as follows:

§ 196.40–10 Draft marks and draft indicating systems.

(a) All vessels must have the draft of the vessel marked plainly and legibly upon the stem and upon the sternpost or rudderpost or at any place at the stern of the vessel as may be necessary for easy observance. The bottom of each mark must indicate the draft.

(b) The draft must be taken from the bottom of the keel to the surface of the water at the location of the marks.

* * * * *

(e) Draft marks must be separated so that the projections of the marks onto a vertical plane are of uniform height equal to the vertical spacing between consecutive marks.

(f) Draft marks must be painted in contrasting color to the hull.

(g) In cases where draft marks are obscured due to operational constraints or by protrusions, the vessel must be fitted with a reliable draft indicating system from which the bow and stern drafts can be determined.

Dated: November 20, 1989.

J.D. Sipes,

Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 90–3307 Filed 2–12–90; 8:45 am]

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federal register

Tuesday
February 13, 1990

Part III

Department of Education

34 CFR Part 363

The State Supported Employment Services Program; Proposed Rule

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services

34 CFR Part 363

The State Supported Employment Services Program

AGENCY: Department of Education.

ACTION: Notice of Intent to Regulate.

SUMMARY: The Secretary of Education provides notice that the Department intends to amend the regulations implementing the State Supported Employment Services Program authorized under title VI, part C of the Rehabilitation Act of 1973, as amended, in order to clarify certain program requirements and make other changes that are needed to increase program effectiveness and flexibility.

DATES: All comments, suggestions, or recommendations in response to this notice must be received on or before April 16, 1990.

ADDRESSES: All comments concerning this notice should be addressed to Nell C. Carney, Commissioner, Rehabilitation Services Administration, Department of Education, Mary E. Switzer Building, Room 3325, 330 C Street, SW., Washington, DC 20202–2899.

FOR FURTHER INFORMATION CONTACT: Mr. Fred Isbister, Rehabilitation Services Administration, Department of Education, Mary E. Switzer Building, Room 3228, 330 C Street, SW., Washington, DC 20202–2899, telephone (202) 732–1297.

SUPPLEMENTARY INFORMATION: Final regulations for this program were published on August 14, 1987. In the preamble to the regulations, the Secretary stated that, because the State Supported Employment Services Program is a new kind of rehabilitation program with which neither the Department nor States have much experience, the Department would consider within the next two years whether to solicit additional public comment on the need for regulatory revision. The Secretary now believes it is appropriate to solicit this kind of public comment.

The Department is publishing this notice of intent to regulate to give interested parties an opportunity to comment on five issues of program concern that it believes may require regulatory revision, prior to the publication of specific proposed regulations. The Department is also interested in soliciting public comment on any other regulatory provisions that may need revision in order to increase program effectiveness and flexibility.

(1) *Twenty hours per week work requirement.* The statutory definition of "supported employment" includes a requirement that individuals with severe handicaps who receive supported employment services be able to perform competitive work. Current program regulations define "competitive work" to require that each individual work an average of at least 20 hours per week for each pay period, beginning at the time of job placement by the vocational rehabilitation (VR) State agency.

Some providers of supported employment services have expressed concern that this particular work requirement excludes from eligibility certain populations of individuals with severe handicaps, such as the chronically mentally ill or the traumatically brain-injured, who would otherwise be appropriate candidates for supported employment but for their inability to meet a 20-hour work requirement at the time services are initiated.

The Secretary is considering whether to amend the definition of "competitive work" to reduce the work requirement. Among the options under consideration are whether to make the average 20 hours per week work requirement applicable at the time an individual makes the transition from VR State agency support to extended services from other providers, rather than an initial placement requirement, and whether to require fewer hours of work at the time VR services are initiated, for example 10 hours per week.

(2) *Availability of post-transition on post-closure services from the VR State agency.* VR agency support under the State Supported Employment Services Program is limited to providing training and traditionally time-limited post-employment services. Under the current program regulatory definition of "traditionally time-limited post-employment services," supported employment services can no longer be provided by the VR State agency once an individual has made the transition to extended services made available by another service provider under a cooperative agreement. Transition must occur no later than 18 months after the initiation of services by the VR State agency.

Occasionally, following transition, an individual may require, in order to maintain a supported employment placement, one or more discrete, short-term services that are not available under a cooperative agreement with an extended services provider but that would be available from the VR State agency. The Secretary is considering whether to provide authority in regulations for this kind of limited post-transition re-intervention by the VR State agency.

The purpose of any regulatory revision would be to make available to supported employment clients the same kind of post-closure services (traditional title I post-employment services) that are available under the title I program to individuals who have been successfully rehabilitated in placements other than supported employment.

(3) *Definitions of "on-going support services" and "extended services."* The Secretary is considering clarifying the current regulatory definition of "on-going support services" and adding to the regulations a definition of "extended services" to clarify the use of the two terms. "On-going support services" is a required component of supported employment. It refers to the job skill training and other support services that are needed on a regular basis by supported employment clients if they are to perform competitive work. The one exception is that supported employment clients who are chronically mentally ill are not required to receive "on-going support services" that include job skill training, but they must receive other kinds of support services.

On-going support services are provided by both the VR State agency during the maximum 18-month period of its support as well as by an extended service provider following transition.

"Extended services" refers to the on-going support services that are furnished by providers other than the VR agency (from other State, Federal or private programs) after the 18-month period of VR agency support has elapsed.

(4) *Clarification of the exemption of the chronically mentally ill from the job skill training services requirement.* The intent of current regulations is to exclude all individuals who are chronically mentally ill and who are receiving services under the State Supported Employment Services Program from the requirement that program beneficiaries receive job skill training services at least twice monthly at the job site throughout the term of employment. This intent is reflected in the preamble to the final regulations which states: "The Secretary believes that individuals with severe handicaps, with the exception of the chronically mentally ill, would be inappropriate candidates for supported employment if they did not receive job skill training at least twice monthly."

However, the regulations do not recognize that individuals with chronic

metal illness served under this program may receive either transitional employment services if the employment outcome may not be permanent or regular supported employment services leading to a permanent employment outcome, or both. Thus, current regulations only clearly exempt from the job skill training requirement individuals with chronic mental illness who are receiving transitional employment services.

The Secretary is considering amending the definition of "on-going support services" to make it clear that individuals with chronic mental illness who are receiving regular supported employment services are also exempt from the job skill training requirement.

(5) *Clarification of job skill training services.* Current regulations require that all individuals with severe handicaps served under this program, with the exception of the chronically mentally ill, receive job skill training services. The regulations, however, do not define this term. The Secretary is considering adding to the regulations a definition of "job skill training services" to clarify that it includes, in addition to training in the specific functions of the job, related training services to address behavioral and other problems that affect job performance.

Note: Supported employment services are also provided under the State Vocational Rehabilitation Services Program (34 CFR part 361) and under the Program of Special Projects and Demonstrations for Providing Supported Employment Services to Individuals with Severe Handicaps and Technical Assistance Projects (34 CFR part 380).

Therefore, any regulatory revisions in part 363 of requirements that are common to these two other programs would also result in changes to parts 361 and 380.

(Authority: 29 U.S.C. 795 j–q)

Dated: December 14, 1989.

Lauro F. Cavazos,

Secretary of Education.

[FR Doc. 90–3309 Filed 2–12–90; 8:45 am]

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federal register

Tuesday
February 13, 1990

Part IV

Department of Health and Human Services

Public Health Service

42 CFR Part 90

Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 90

RIN 0905-AC84

Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Public Health Service, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: On August 24, 1988 ATSDR published in the **Federal Register** (53 FR 32259) a notice of proposed rulemaking of a new regulation dealing with the conduct of ATSDR health assessments and health effects studies. The notice proposed a new regulation at 42 CFR part 90 to set forth procedures for ATSDR to conduct health assessments under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (42 U.S.C. 9604(i)) and the Resource Conservation and Recovery Act (RCRA) (42 U.S.C. 6939a(c)), as well as health effects studies under CERCLA. The regulation also includes, among other things, procedures for persons to request ATSDR to conduct health assessments, provisions for the notification of parties of the results of health assessments and health effects studies, and provisions for cost recovery accounting.

ATSDR received several comments in response to the notice of proposed rulemaking and as a result has made a number of revisions in the regulation and preamble.

EFFECTIVE DATE: February 13, 1990.

FOR FURTHER INFORMATION CONTACT: Robert C. Williams, P.E., Director, Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, Atlanta, Georgia 30333, 404-639-0610, FTS 236-0610.

SUPPLEMENTARY INFORMATION: The primary purpose of this regulation is to set forth general procedures which ATSDR will follow in determining when and how to conduct health assessments and related health effects studies. The Superfund Amendments and Reauthorization Act of 1986 (SARA) (Pub. L. 99-499), which amended CERCLA, greatly expanded the responsibilities and mandates of ATSDR. ATSDR is now authorized to conduct a wide range of health-related activities at sites where hazardous substances are or have been released.

These activities include conducting (1) health assessments at all sites on, or proposed for inclusion on, the Environmental Protection Agency's (EPA) National Priorities List (NPL), (2) health assessments in response to requests from interested persons, and (3) a wide variety of health effects studies to determine whether there exists at a particular site or sites a risk to human health as a result of exposure to hazardous substances. This regulation also applies to ATSDR's health assessment activities conducted pursuant to RCRA.

In response to the notice of proposed rulemaking (53 FR 32259), ATSDR received comments on the proposed regulation from the following: American Industrial Health Council, American Petroleum Institute, Chemical Manufacturers Association, Edison Electric Institute, Motor Vehicle Manufacturers Association, Syntex (U.S.A.), Inc., and Texaco. ATSDR has made a number of revisions in the regulation based upon these comments.

Several commenters stated that the proposed regulation should be revised to provide additional mechanisms for ATSDR to notify potentially responsible parties and others of its intention to conduct a health assessment at a particular site. The regulation specifies notification requirements according to how the health assessment is initiated. If the health assessment is required for a site because the site is proposed for inclusion on the NPL, ATSDR assumes that potentially responsible parties (PRPs) and the community will know that a site of interest to them has been proposed to be included on the list. In this case, ATSDR believes no formal notification of intent to conduct a health assessment for a site proposed to be added to the NPL is necessary.

If, however, ATSDR decides to conduct a health assessment in response to a petition from the public, the Agency will notify specific parties in writing as stated in the proposed regulation. These parties include EPA, appropriate State and local environmental and health agencies, the requestor of the health assessment, and the owner or operator of the facility of concern, if that information is readily available to ATSDR.

In addition, the regulation specifies that ATSDR, at its discretion, may notify other parties—those with a direct interest in the site or who might have information necessary to complete a health assessment. A large percentage of petitioned health assessments involve sites which have not been proposed to be added to the NPL. Normally, much information about such sites, such as the identity of PRPs, is unavailable. For petitioned sites where PRPs have been identified, ATSDR will notify by mail these and other parties of its intent to conduct a health assessment when the Agency believes such parties have information essential to the conduct of a health assessment for the site.

Generally, ATSDR's position is that it would be an inefficient and unnecessary use of limited resources to routinely notify, either specifically or through individual announcements in the **Federal Register**, other parties of ATSDR's intention to conduct health assessments at the hundreds of sites for which it has such responsibility. However, ATSDR will publish on a quarterly basis in the **Federal Register** a notice of non-NPL sites for which it has decided to conduct health assessments.

In addition, at least one commenter requested that PRPs be routinely notified at the time ATSDR receives a request to conduct a health assessment. The commenter felt the PRPs might be able to provide ATSDR with information which would be helpful in making its decision to conduct a health assessment in response to the request. Generally, ATSDR believes that information provided by the requestor or government agencies will be sufficient to allow ATSDR to make a decision whether to conduct a health assessment in response to a request from the public. However, ATSDR is changing § 90.5(b) of the proposed regulation to allow the Agency to request, where appropriate, information from other parties concerning sites which are the subject of a request.

The preamble to the proposed regulation stated that the regulation was not intended to provide a detailed scientific statement of the factors ATSDR will consider when conducting a health assessment. The preamble also stated that ATSDR intended to issue a general scientific policy document which would discuss the scientific process and factors ATSDR will consider in performing health assessments. Several of the commenters urged ATSDR to immediately release this scientific policy document. In addition, several commenters said that ATSDR should develop and publish criteria to guide the Agency in making decisions about issuing health advisories and how and when to conduct health effects studies.

ATSDR has developed a draft guidance document for the conduct of health assessments. ATSDR plans to submit this document to its Board of

Scientific Counselors at its next meeting for review. After the Board has reviewed and commented on this document, ATSDR will publish it in the Federal Register for public review and comment.

ATSDR intends in the future to develop guidance documents regarding public health advisories and health effects studies. Once developed, these documents will also be submitted for review by the Board and then the public.

ATSDR has also added a new § 90.7 to clarify the criteria it will utilize when determining whether to conduct a health effects study at a particular site.

Several commenters recommended that PRPs be notified of the availability of completed ATSDR health assessments. Section 90.11 of the regulations specifies the ATSDR will provide a report of the results of a health assessment to EPA, appropriate State and local government agencies, those requesting ATSDR to conduct the health assessment, and PRPs, where their identity is readily available to ATSDR. In addition, the reports of health assessments will be available to the general public upon request. In response to the comments in this area, ATSDR will publish in the Federal Register on a quarterly basis a report of the health assessments completed during the previous three months and which are available to the public. ATSDR believes that these measures will address the need of parties to be informed in a concise manner of the availability of health assessment reports without overburdening ATSDR and the public with detailed and cumbersome notification procedures.

Two commenters suggested that ATSDR adhere strictly to the sequence of health assessments and health effects studies set forth in section 104(i) of CERCLA. Among other things, section 104(i)(6) directs ATSDR to conduct health assessments at all sites on, or proposed for inclusion on, the NPL, as well as authorizes the Agency to conduct health assessments in response to requests from the public. This section specifies that one purpose of a health assessment is to determine the need for health effects studies, such as an epidemiological study, registry, or health surveillance program. Section 104(i)(7) furthermore states that on the basis of a health assessment, ATSDR may decide to conduct a pilot study to determine the desirability of conducting a full-scale epidemiological or other health effects study.

ATSDR will generally follow the sequential approach outlined in sections 104(i) (6), (7), (8), and (9) of CERCLA (health assessment, and where appropriate, followed by a pilot study, epidemiological study, registry, and health surveillance program). However, ATSDR recognizes that instances arise where the public health is not served by a strict adherence to this sequential approach. For instance, circumstances at a particular site may necessitate the immediate commencement of a pilot study or other activity prior to the completion of a health assessment for the site. This approach is consistent with the language and intention of CERCLA. ATSDR does not interpret the sequential approach set forth in section 104(i) of CERCLA to constitute the exclusive manner in which ATSDR is to fulfill its public health responsibility. ATSDR generally will follow this sequential approach; however, it is necessary to retain flexibility in responding to emergency or other unique circumstances in an appropriate manner.

Two commenters recommended that ATSDR redefine the term "health effects studies" so as to exclude from this definition registries and health surveillance programs. These commenters argued that section 104(i) of CERCLA establishes a difference between "health effects studies" like epidemiological studies on one hand and registries and health surveillance programs on the other hand. In addition, these commenters also argue that by including registries and health surveillance programs within the definition of "health effects studies," ATSDR improperly concludes that the costs of such programs are recoverable from responsible parties under section 107 of CERCLA.

The primary purpose of this regulation is not to define what ATSDR activities at Superfund sites are subject to cost recovery actions. The parameters for cost recovery actions are set by CERCLA and EPA in its National Contingency Plan. Rather, ATSDR seeks to establish procedures, through this regulation, for how it will conduct health assessments and health effects studies.

Moreover, ATSDR has found it feasible to follow the same procedures, outlined in this regulation, when conducting the activities included in the definition of "health effects studies," such as epidemiologic studies, registries, and health surveillance programs. ATSDR does not interpret section 104(i) of CERCLA to preclude the inclusion of these activities and others from being considered "health effects studies." The term "health effects studies" is not defined in CERCLA and appears only in section 107(a)(4)(D). Although section 104(i) does make separate reference to epidemiologic studies, registries, and health surveillance programs, there is no indication in CERCLA or its statutory history that each of these various activities of ATSDR cannot be considered "health effects studies."

Furthermore, we believe that the costs of ATSDR registries and health surveillance programs are fully recoverable from responsible parties. Accordingly, ATSDR will pursue, on a case-by-case basis in appropriate circumstances, recovery of the costs of these and other health effects studies and health assessment.

Several commenters suggested that ATSDR make draft health assessments available for public comment. ATSDR is currently conducting a pilot study of the impact and effectiveness of providing a public comment period for health assessments. As part of this study, ATSDR has released several draft final health assessments for public comment. ATSDR is not legally required to provide a public comment period for health assessments. However, if the provision of a public comment period allows for meaningful input without unduly delaying the completion of health assessments in accordance with statutory deadlines, ATSDR may allow for public comment as a policy matter. Therefore, a routine public comment period for health assessments is not included in the current regulation.

One commenter suggested that ATSDR rely only upon previously gathered data when conducting a health assessment. For most sites, ATSDR does rely primarily on data provided by EPA, supplemented occasionally by additional information provided by State and local governments, PRPs, and members of the local community. In rare instances, little or no information is available on a site for which ATSDR is required to conduct a health assessment. For this reason ATSDR has reserved the right in this regulation to arrange for the gathering of additional information, where necessary, about a site.

One commenter recommended that ATSDR allow responsible parties to comment on a decision by the Agency to bring additional individuals onto a site to facilitate the conduct of a health assessment or health effects study. A decision to bring additional individuals, such as contractors or representatives of other governmental agencies, onto a site is strictly an internal management decision for which outside comment would not be appropriate.

ATSDR has also made several changes in § 90.13 of the regulation, which dealt with administrative record requirements. So as not to confuse these requirements with the administrative

record requirements of EPA as established by section 113(k) of CERCLA (42 U.S.C. 9613(k)), references in the regulation have been changed from "administrative record" to "recordkeeping requirements." In addition, a new § 90.13(f) has been added to state clearly that ATSDR does not intend to establish or imply a standard of judicial review of health assessments or health effects studies. Since the reports of health assessments and health effects studies contain only agency opinion and recommendations which are not binding on any parties, there is no judicial review of these reports. See *Industrial Safety Equipment Association, Inc.* v. *Environmental Protection Agency*, 837 F.2d 1115 (D.C. Cir. 1988). Also, a decision to conduct a health assessment or a health effects study is retained for agency discretion.

One commenter suggested that the regulation contain definitions for "pilot study of health effects," "registry," and "health surveillance program." The definition for registry and health surveillance program may be found in ATSDR's Policies and Procedures for Establishing a National Registry of Persons Exposed to Hazardous Substances. The definition for pilot study is given in a **Federal Register** notice announcing the availability of funds to States to conduct pilot and epidemiologic studies (54 FR 22488 (1989)). Given the fact that definitions of these terms are included in public documents, ATSDR does not feel there is a need to include them in the regulations.

Paperwork Reduction Act

This final rule contains information collections which have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980 and assigned control number 0920–0204. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: ATSDR Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities.

Description: Information submitted by respondents is used by ATSDR staff to evaluate the need for a health assessment, and to plan the health assessment, if one is needed.

Description of Respondents: Individuals or households, State and local governments, business or other for-profit organizations, non-profit institutions, and small businesses.

Estimated Annual Reporting and Recordkeeping Burden:

Regular citation	Annual number of respondents	Annual frequency	Average burden per response	Annual burden hours
90.4	100	Once	.5 hours	50

We received no public comments on the estimated public reporting burden, and it remains the same as that contained in the proposed rule.

Cost Regulatory Analysis

One commenter also suggested that ATSDR should consider the regulation to be a "major" rule, thereby requiring the Agency to conduct a regulatory impact analysis. The Secretary has determined, in accordance with Executive Order 12291, that this regulation will not constitute a "major" rule and is therefore not subject to the regulatory impact analysis of the Order. A "major" rule is any regulation that is likely to result in:

—An annual effect on the economy of $100 million or more;
—A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
—Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The regulation is strictly procedural in nature and does not institute any new substantive requirements. The costs of health assessments or health effects studies are not expected to reach the $100 million annual threshold requiring the conduct of an impact analysis. Finally, the cost of litigation arising out of Superfund sites, costs cited by the commenter as a rationale for developing a regulatory impact statement, are not considered to be costs attributable to the procedures outlined in the regulation. Rather, such costs arise out of the actions of responsible parties at a site. Accordingly, this regulation does not constitute a "major" rule necessitating the preparation of a regulatory impact analysis.

Because of the strictly procedural nature of the regulation, it will not have a significant economic impact on a substantial number of small entities. The rule does not impose any reporting requirements on small entities and will not result in any added financial burdens for such entities. Accordingly, the preparation of a regulatory flexibility analysis is not required.

List of Subjects in 42 CFR Part 90

Administrative practice and procedure, Hazardous substances, Public health.

For the reasons stated in the preamble, subchapter H, consisting of part 90, is added, as set forth below, to title 42 of the Code of Federal Regulations.

James O. Mason,
Assistant Secretary for Health.

Approved: November 16, 1989.

Louis W. Sullivan,
Secretary.

SUBCHAPTER H—HEALTH ASSESSMENTS AND HEALTH EFFECTS STUDIES OF HAZARDOUS SUBSTANCES RELEASES AND FACILITIES

PART 90—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Sec.

Sec.
90.14 Documentation and cost recovery.

Authority: 42 U.S.C. 9615; 42 U.S.C. 6939a(c).

§ 90.1 Purpose and applicability.

The provisions of this part set forth the policies and procedures of the Agency for Toxic Substances and Disease Registry (ATSDR) with respect to its conduct of health assessments and health effects studies under section 104(i) of Comprehensive Environmental Response, Compensation, and Liability Act, as amended by the Superfund Amendments and Reauthorization Act of 1986, and section 3019 of the Resource Conservation and Recovery Act. These provisions apply to ATSDR, as well as its contractors, agents, and those carrying out health assessments and health effects studies pursuant to agreements with ATSDR, such as other Federal agencies and States.

§ 90.2 Definitions.

"Administrator" means the Administrator of the Agency for Toxic Substances and Disease Registry or designee.

"ATSDR" means the Agency for Toxic Substances and Disease Registry, Public Health Service, U.S. Department of Health and Human Services.

"CERCLA" means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601 *et seq.*, Pub. L. 96–520), as amended by the Superfund Amendments and Reauthorization Act of 1986 (Pub. L. 99–499).

"EPA" means the U.S. Environmental Protection Agency.

"Facility" is defined in 42 U.S.C. 9601(9).

"Hazardous substance" is defined in 42 U.S.C. 9601(14). In addition, the term includes any pollutant or contaminant which the Administrator determines is appropriate for the purposes of carrying out his or her responsibilities under CERCLA.

"Health assessment" means the evaluation of data and information on the release of hazardous substances into the environment in order to assess any current or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects.

"Health effects study" means research, investigation, or study performed by ATSDR or other parties pursuant to an agreement with ATSDR to evaluate the health effects of exposure to hazardous substances at specific sites This term includes, but is not limited to, epidemiological studies, exposure and disease registries, and health surveillance programs. This term does not include health assessments.

"Owner or operator" is defined in 42 U.S.C. 9601(20).

"Peer review" means review for scientific quality by a panel consisting of no less than three nor more than seven members, who shall be disinterested scientific experts selected by the Administrator of ATSDR on the basis of their reputation for scientific objectivity and the lack of institutional ties with any person involved in the conduct of the study or research under review.

"Person" means an individual, firm, corporation, association, partnership, consortium, joint venture, commercial entity, United States Government, State, municipality, commission, political subdivision of a State, Indian tribe, or any interstate body.

"Pollutant or contaminant" is defined in 42 U.S.C. 9601(33).

"Public health advisory" is a statement by ATSDR containing a finding that a release poses a significant risk to human health and recommending measures to be taken to reduce exposure and eliminate or substantially mitigate the significant risk to human health.

"Release" is defined in 42 U.S.C. 9601(22).

§ 90.3 Procedures for requesting health assessments.

(a) ATSDR will accept requests to perform health assessments for a particular facility or release from any person or group of persons.

(b) All requests to ATSDR to perform health assessments should be addressed to: Assistant Administrator, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road NE., Atlanta, GA. 30333.

§ 90.4 Contents of requests for health assessments.

(a) Each request for a health assessment shall contain:

(1) The name, address (including zip code), and telephone number of the requestor;

(2) The organization or group the requestor represents, if any;

(3) The name, location, and description of the facility or release of concern;

(4) A statement providing information that individuals have been exposed to a hazardous substance and that the probable source is a release, or sufficient information to allow the Administrator to make such a finding;

(5) A statement requesting ATSDR to perform a health assessment.

(b) At his or her discretion, consistent with the requirements of CERCLA, the Administrator may decide not to require the preceding information be submitted with a request for a health assessment.

(c) Each request for a health assessment should include, where possible:

(1) Any other information pertaining to the facility or release, such as the nature and amount of the hazardous substances of concern or the identities of parties believed to be potentially responsible for the release;

(2) Potential pathways for human exposure, including a description of the media contaminated (e.g. soil, groundwater, air, etc.);

(3) The demographic nature and proximity of the potentially affected human population; and

(4) Other Federal, State, or local governmental agencies which were notified or that investigated the facility or release.

(d) This data collection has been reviewed and approved by OMB in accordance with the Paperwork Reduction Act and assigned the control number 0920–0204.

§ 90.5 Acting on requests.

(a) Upon receipt of a request for a health assessment submitted under this part, ATSDR will determine, in its discretion, whether or not there is a reasonable basis to justify conducting a health assessment. ATSDR will base this determination on, among other factors:

(1) Whether individuals have been exposed to a hazardous substance, for which the probable source of such exposure is a release;

(2) The location, concentration, and toxicity of the hazardous substances;

(3) The potential for further human exposure;

(4) The recommendations of other governmental agencies; and

(5) The ATSDR resources available and other ATSDR priorities, such as its responsibilities to conduct other health assessments and health effects studies.

(b) Where appropriate, ATSDR will request information from other Federal, State, and local governmental agencies, as well as other persons, pertaining to a facility or release which is the subject of a request from the public to ATSDR to conduct a health assessment.

(c) The requestor will be notified in writing of ATSDR's determination that either a health assessment will be performed, a health assessment will not be performed, or that further information

concerning the facility or release is required before a decision can be made whether a health assessment will be performed.

(d) If a health assessment is not initiated in response to a request from the public, ATSDR shall provide a written explanation to the requestor of why a health assessment is not appropriate.

§ 90.6 Notification of determination to conduct a health assessment in response to a request from the public.

(a) Following a determination by ATSDR to conduct a health assessment in response to a request from the public, ATSDR shall notify in writing, at a minimum, the following parties of its intent to perform a health assessment:

(1) The U.S. Environmental Protection Agency;

(2) The appropriate State government environmental agency;

(3) The appropriate State and local health departments;

(4) The requestor;

(5) The owner or operator of the facility of concern, if their identity is readily available to ATSDR.

In addition, ATSDR will notify, in writing or by telephone, other potentially responsible parties, if their identity is readily available to ATSDR.

(b) At its discretion, ATSDR may notify any other persons which it feels may be affected by the release or have information pertaining to the release.

§ 90.7 Decision to conduct health effects study.

(a) ATSDR may decide, in its discretion, based upon the results of a health assessment or other available information, to conduct a health effects study for a particular site or sites. Such a decision may, in appropriate circumstances, be made prior to the completion of a health assessment for a site or sites. When deciding whether to conduct a health effects study, ATSDR will consider such factors as the results and recommendations of a health assessment for the site or sites and the need for additional information to determine whether individuals have been exposed to hazardous substances, the degree to which such exposure has occurred, and any possible health effects resulting from such exposure.

(b) Should ATSDR decide, in its discretion, to conduct a health effect study, it will notify the parties as specified in § 90.6.

§ 90.8 Conduct of health assessments and health effects studies.

(a) Any interested person or persons may submit data or information to ATSDR for it to consider in its conduct of a health assessment or a health effects study. In performing a health assessment or a health effects study, ATSDR will consider data and information it has independently generated or received from other parties, such as EPA, other Federal agencies, State and local governmental agencies, businesses, citizen organizations, and community groups.

(b) ATSDR may determine it is necessary to conduct a site visit in connection with a health assessment or health effects study. The ATSDR representative may allow the participation of any person in the site visit which he or she, at his or her discretion, determines will aid in the conduct of the health assessment or health effects study.

(c) In the event that the information necessary to perform a health assessment or health effects study is not readily available from other sources, ATSDR may arrange for sampling or additional data gathering at a facility or release for the limited purpose of determining the existence of current or potential health problems.

§ 90.9 Public health advisory.

ATSDR may issue a public health advisory based on the findings of a health assessment, health effects, study, or other ATSDR involvement.

§ 90.10 Notice and comment period.

Following internal review by ATSDR and external peer review of a draft final report of the results of a health effects study, ATSDR will publish a notice that the draft final report is available for public review and comment. At a minimum, the notice shall be published in at least one newspaper of general distribution in the local where the site is located. The notice shall describe how copies of the draft final report of the health effects study can be obtained and set a reasonable time period for interested persons to submit comments concerning the study. ATSDR may, at its discretion, respond in writing to comments it receives.

§ 90.11 Reporting of results of health assessments and health effects studies.

(a) ATSDR shall provide a report of the results of a health assessment or health effects study to EPA, the appropriate State and local governmental agencies, any person requesting ATSDR to conduct the health assessment, and parties potentially responsible for the release, if their identity is readily available to ATSDR. In addition, such reports shall be available to the general public upon request.

(b) In the event that ATSDR or its representatives conduct medical examinations of individuals in the course of a health effects study and the examination reveals a positive significant medical finding, the individual, and a physician if designated by the individual, will be promptly notified of that significant medical finding by ATSDR.

(c) A summary of the findings of all medical examinations for each individual will be sent by ATSDR to that individual.

(d) All studies and results of research conducted under this part (other than health assessments) shall be reported or adopted only after appropriate peer review.

§ 90.12 Confidentiality of information.

(a) ATSDR shall consider any medical information in individually identifiable form to be confidential information and shall release such information only in accordance with the Privacy Act (5 U.S.C. 552a) or other applicable Federal law.

(b) As provided under section 104(e)(7) of CERCLA, any records, reports, or information obtained from any person under this section shall be available to the public, except that upon a showing satisfactory to ATSDR by any person that records, reports, or information, or particular part thereof (other than health or safety effects data), to which any officer, employee, or representative of ATSDR has access under this part if made public would divulge information entitled to protection under the Trade Secrets Act (18 U.S.C. 1905), such information or particular portion thereof shall be considered confidential in accordance with the purposes of that section, except that such record, report, document, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out statutorily mandated duties.

(c) In submitting data to ATSDR, a person may designate the data which such person believes is entitled to protection under paragraph (b) of this section and submit such designated data separately from other data submitted under this part. A designation under this paragraph shall be made in writing to the Administrator. However, should ATSDR at any time question such designation, not less than 15 days notice to the person sumitting the information shall be given of the intention to remove such trade secret designation from such

information. The person may submit a request to the Administrator to reconsider this intention and may provide additional information in support of the trade secret designation. The Administrator shall notify the person in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

§ 90.13 Recordkeeping requirements.

(a) ATSDR shall maintain a record of all health assessments and health effects studies. The Administrator shall, at his or her discretion, determine the contents of the record. At a minimum, the record shall include:

(1) The final ATSDR report of the health assessment or health effects study;

(2) Nonconfidential data and other information upon which that report is based or which was considered by ATSDR;

(3) Nonconfidential data or other information submitted by interested persons pertaining to the health assessment or health effects study;

(4) The protocol for the health effects study;

(5) A list of the individuals responsible for external peer review of the report of a health effects study, their comments, and ATSDR's response to the comments; and

(6) For health effects study, the notice announcing the availability of a draft final report for public review and comment, all comments received in response to the notice, and any responses to the comments by ATSDR.

(b) The record may contain a confidential portion which shall include all information determined to be confidential by the Administrator under this part.

(c) The Administrator may determine other documents are appropriate for inclusion in the record for health assessments or health effects studies.

(d) Predecisional documents, including draft documents, are not documents upon which ATSDR bases its conclusions in health assessments or health effects studies, and are not usually included in the record for health assessments or health effects studies.

(e) The record for ATSDR health assessments and health effects studies will be available for review, upon prior request, at ATSDR headquarters in Atlanta, Georgia.

(f) Nothing in this section is intended to imply that ATSDR's decisions to conduct health assessments or health effects studies, or the reports of health assessments or health effects studies, are subject to judicial review.

§ 90.14 Documentation and cost recovery.

(a) During all phases of ATSDR health assessments and health effects studies, documentation shall be completed and maintained to form the basis for cost recovery, as specified in section 107 of CERCLA.

(b) Where appropriate, the information and reports compiled by ATSDR pertaining to costs shall be forwarded to the appropriate EPA regional office for cost recovery purposes.

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