

240), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9254.

Issued in Washington, DC, on September 22, 1988.

Shelomo Wugalter,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 88-22364 Filed 9-28-88; 8:45 am]

BILLING CODE 4910-13-M

Federal Highway Administration

Environmental Impact Statement; Southern Tier Expressway—Corning Area—Painted Post to State Route 414, Steuben County, NY

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that a supplement to a final environmental impact statement will be prepared for a proposed highway project on the Southern Tier Expressway—Corning area, Painted Post to State Route 414, Steuben County.

FOR FURTHER INFORMATION CONTACT: Frank H. Platt, District Engineer, Federal Highway Administration, Leo W. O'Brien Federal Building, Ninth Floor, Clinton Avenue and Pearl Street, Albany, New York 12207, Telephone (518) 472-2860.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the New York State Department of Transportation, will prepare a supplement to the Final Environmental Impact Statement (EIS) on a proposal to construct a portion of the Southern Tier Expressway through the Village of Riverside, City of Corning and Town of Corning, Steuben County, New York. The original EIS for the arterial highway (FHWA-NYS-EIS-72-13F) was approved on September 17, 1973.

This segment of the Southern Tier Expressway proposes to close the gap between previously completed sections of the Expressway in the Village of Painted Post to the west and the Post Creek to Chemung-Steuben County line section to the east. The new project is proposed on new location through open space areas in the City of Corning and Town of Corning and through some residential and commercial locations of the City of Corning, Town of Corning

and the Village of Riverside. The project length is 2.8 miles. The completion of the Expressway is considered necessary to close the gap in the Expressway system in Steuben County, to provide relief of current highway capacity and accident problems through the City of Corning, and to provide for economic development in the Chemung River Valley in the Painted Post-Riverside, Corning area.

The location for the Expressway was approved with the stipulation that an alignment in the Winfield Street-Pine Hill area not previously discussed in the original EIS be investigated to removed the alignment from the center of a residential neighborhood in the City of Corning. Substantial changes in the state-of-the-art analysis of environmental issues and discussion of viable design alternatives in the arterial corridor warrant a detailed reanalysis of impacts within the corridor.

Alternatives under consideration are a combination of sixteen design alternatives to determine the best location and degree of access to the expressway to close the gap in the existing highway system.

The project has been the subject of extensive previous coordination between interested agencies. A series of public information meetings were held to review project location and potential impacts in the various neighborhoods. A formal public hearing for the project is anticipated in the fall of 1988. Public notice will be given of the time and place of the hearing. The draft supplemental EIS will be available for public and agency review and comment prior to the public hearing. No formal scoping meeting will be held.

To ensure that a full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued on: September 20, 1988.

Harold J. Brown,

Division Administrator, Albany, New York.

[FR Doc. 88-22271 Filed 9-28-88; 8:45 am]

BILLING CODE 4910-22-M

UNITED STATES INFORMATION AGENCY

Grants Program for Private Not-for-Profit Organizations in Support of International Educational and Cultural Activities

The deadline for submission of a statement of interest in the subject program has been extended to five working days from the date of this announcement. The original announcement was published in the *Federal Register* of August 26, 1988. Following is a repeat of the information published in the original announcement, with a new deadline date specified.

The United States Information Agency's Division for the Study of the U.S. seeks to secure the services of an institution to coordinate and implement five thirty-day study programs in the field of American studies for foreign secondary school educators. The programs will take place in the spring and fall of 1989.

The Division for the Study of the U.S. provides opportunities for foreign education ministry officials, teacher trainers, textbook writers, and curriculum developers to receive information, training, and resource materials which will enable them to more accurately and effectively teach about the U.S. in the secondary schools of their home countries.

Interested programming institutions in metropolitan Washington, DC, with experience in international education, in particular the social sciences, should submit a request for complete application materials to Mr. Richard Taylor at the following address no later than 5 working days from the date of this notice. The Division for the Study of the U.S. will then forward a set of materials which contain the proposal guidelines and project prospectus. This announcement is not a solicitation for proposals. It requests letters of interest from potential grantee institutions. Information on proposal submission deadlines will be forwarded with the application materials.

United States Information Agency,
Office of Academic Programs,
American Studies Branch, E/AAS—
Attn: Richard Taylor, Room 256, 301
4th Street, SW., Washington, DC
20547, Phone: (202) 485-2578

Dated: September 21, 1988.

Barry Ballow,

Chief, Division for the Study of the U.S.

[FR Doc. 88-22409 Filed 9-28-88; 8:45 am]

BILLING CODE 8230-01-M

Sunshine Act Meetings

Federal Register

Vol. 53, No. 189

Thursday, September 29, 1988

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).

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, October 5, 1988.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Federal Reserve Bank and Branch director appointments.
2. Proposals regarding fees for directors of Federal Reserve Banks. (This item was originally announced for a closed meeting on September 16, 1988.)
3. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
4. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE

INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Date: September 27, 1988.

James McAfee,
Associate Secretary of the Board.

[FR Doc. 88-22550 Filed 9-27-88; 3:34 pm]

BILLING CODE 6210-01-M

FEDERAL TRADE COMMISSION

TIME AND DATE: 2:30 p.m., Friday, September 30, 1988.

PLACE: Room 432, Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, NW., Washington, DC 20580.

STATUS: Open.

MATTER TO BE CONSIDERED:

Consideration of whether to begin rulemaking proceedings to revise the Transistor Rule.

CONTACT PERSON FOR MORE

INFORMATION: Susan B. Ticknor, Office of Public Affairs; (202) 326-2179. Recorded Message: (202) 326-2711. Donald S. Clark,

Secretary.

[FR Doc. 88-22398 Filed 9-27-88; 9:36 am]

BILLING CODE 6750-01-M

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of October 3, 1988.

A closed meeting will be held on Tuesday, October 4, 1988, at 2:30 p.m. An open meeting will be held on Friday, October 7, 1988, at 10:00 a.m. in Room 1C30.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17

CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Fleischman, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, October 4, 1988, at 2:30 p.m., will be:

Institution of administrative proceedings of an enforcement nature.

Settlement of injunctive actions.

Institution of injunctive actions.

Settlement of administrative proceedings of an enforcement nature.

The subject matter of the open meeting scheduled for Friday, October 7, 1988, at 10:00 a.m. will be:

Consideration of whether to publish for comment a release proposing alternative versions of new Rule 144A that would provide a safe harbor from the registration requirements of the Securities Act of 1933 for resale of securities to institutional investors. Additionally, the Commission will consider whether to publish for comment a proposal to amend Rules 144 and 145 under the Securities Act, under which the holding period for restricted securities would commence at the time the securities are sold by the issuer or its affiliate. For further information, please contact Sara Hanks or Samuel Wolff at (202) 272-3246, or as to changes to Rules 144 and 145, Catherine Dixon at (202) 272-2573.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Max Berueffly at (202) 272-2400.

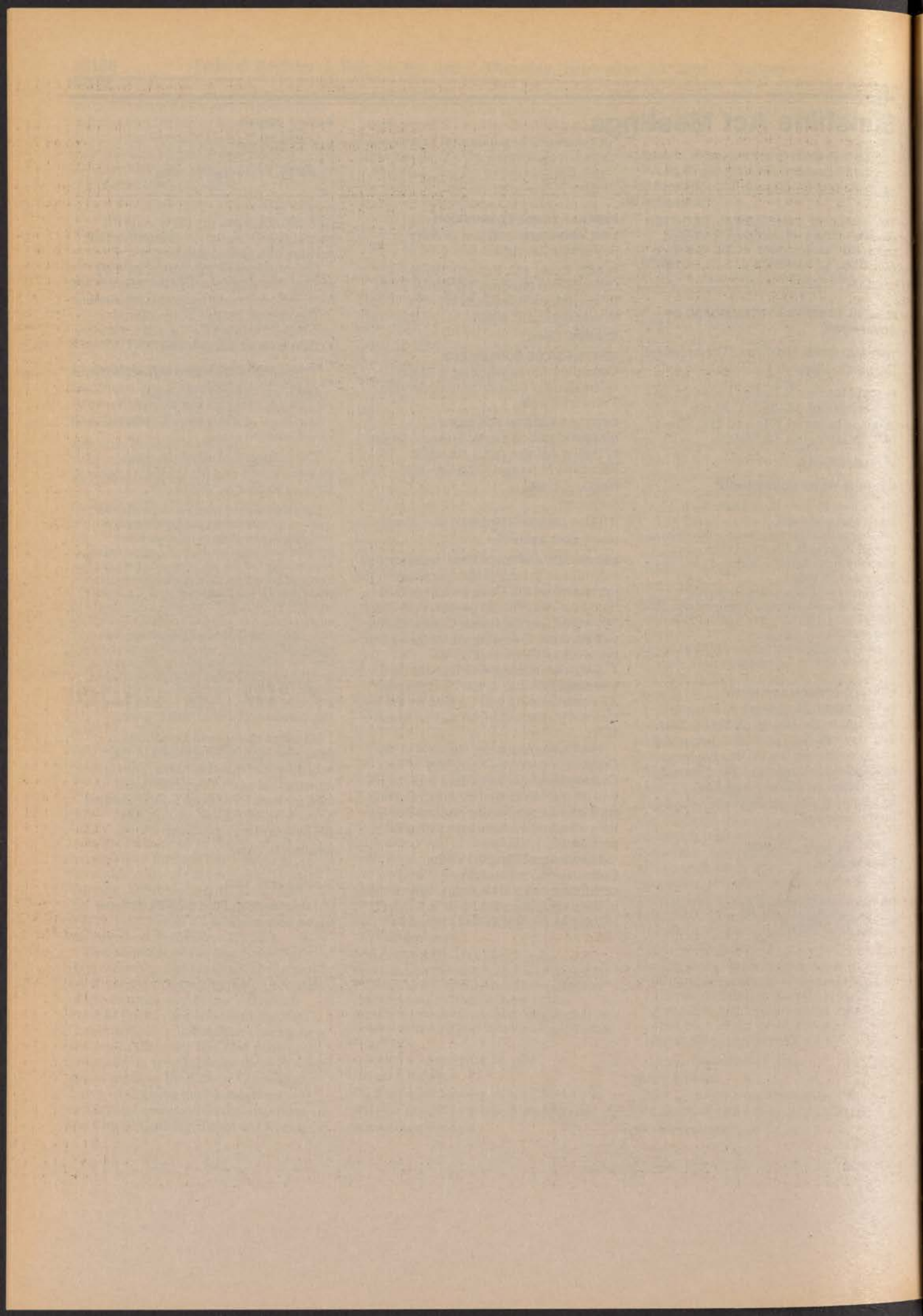
Jonathan G. Katz,

Secretary.

September 26, 1988.

[FR Doc. 88-22551 Filed 9-27-88; 3:34 pm]

BILLING CODE 8010-01-M



Federal Register

Thursday
September 29, 1988

Part II

Department of Labor

Occupational Safety and Health
Administration

29 CFR Part 1910

Access to Employee Exposure and
Medical Records; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-112E]

Access to Employee Exposure and Medical Records

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: This final occupational safety and health regulation, promulgated today as a revised 29 CFR 1910.20, provides for employee, designated representative, and OSHA access to employer-maintained exposure and medical records relevant to employees exposed to toxic substances and harmful physical agents. This rule incorporates essentially the same provisions as those promulgated May 23, 1980 (45 FR 35212), with the major exceptions that: (1) First aid records and medical records of short-term employees are exempted from records retention requirements; (2) the microfilm storage of all employee X-rays except chest X-rays is permitted; (3) employer trade secrets are provided additional protection and are made to conform with OSHA's new Hazard Communication standard; (4) union representatives are required to show an occupational health need for requested records when seeking unconsented access to employee exposure records; and (5) no industries are treated separately with respect to trade secret disclosure.

EFFECTIVE DATE: This final rule shall become effective November 28, 1988, except for the recordkeeping requirements in paragraphs (d), (e), (f)(2), (f)(8), (f)(12), (g) and (h) which shall become effective upon approval by the Office of Management and Budget. A notice of the effective date of these requirements will be published in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Department of Labor, OSHA Office of Public Affairs, Third Street and Constitution Avenue, NW., Room N-3641, Washington, DC 20210 (202-523-8151). Copies of this document may be obtained at any time by request to the OSHA Office of Public Affairs at the address or telephone number listed above, or by contacting any OSHA regional or area office.

SUPPLEMENTARY INFORMATION:

Recordkeeping Requirements

The recordkeeping requirements in the unamended rule were approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. 3501, *et seq.* The OMB approval number is 1218-0065 which expires in November, 1988. OSHA is currently in the process of submitting the recordkeeping requirements in the final rule for OMB approval. The existing standard, which has paperwork clearance, remains in effect until the new standard becomes effective and receives paperwork clearance.

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I. Introduction

A. Background

On May 21, 1980, the Occupational Safety and Health Administration

(OSHA) issued its rule entitled Access to Employee Exposure and Medical Records. 29 CFR 1910.20; 45 FR 35212 *et seq.* (hereinafter "Records Access" rule). The rule imposed three major obligations on employers. First, employers were required to preserve and maintain exposure and medical records pertinent to an employee's occupational exposure to toxic substances or harmful physical agents. 29 CFR 1910.20(d). Generally, employee exposure records and analyses based on exposure or medical records were to be retained for thirty years. 29 CFR 1910.20(d)(1)(ii) and (iii). Employee medical records were to be retained for the duration of employment plus thirty years. 29 CFR 1910.20(d)(1)(i).

Second, throughout these time periods the employer was required to ensure access to pertinent exposure records by the exposed employee, fellow employees exposed or potentially exposed to similar job hazards, designated employee representatives, and OSHA. 29 CFR 1910.20(e). Access to medical records was also to be ensured to the employee who is the subject of the records, and to OSHA. Likewise, access to medical records was required to be ensured to an employee's designated representative, such as the employee's collective bargaining agent, but, because of the privacy interests involved, only if the employee has provided specific written consent for such access. 29 CFR 1910.20(e)(2)(ii)(B); *cf.* § 1910.20(c)(10).

Employee and designated representative access was to be provided at a reasonable time, place, and manner, but in no event later than fifteen (15) days after the request is made. 29 CFR 1910.20(e)(1). OSHA access was required to be provided immediately upon request, 29 CFR 1910.20(e)(3), but because of the personal privacy interests affected by access to medical records, OSHA's access to such records was further conditioned upon the agency's compliance with the procedures and protections which were simultaneously promulgated as 29 CFR 1913.10.

Third, upon entering into employment and annually thereafter, employees were to be informed by their employers of their rights under the regulation and of the requisite procedures for exercising those rights. 29 CFR 1910.20(g).

In issuing the regulation, the Secretary considered its potential impact on trade secrets. 29 CFR 1910.20(f). Although disclosure upon request of identities of toxic substances, levels of exposure, and health status data was required, the

employer was allowed to delete any other trade secret data which disclosed manufacturing processes or the percentage of a chemical substance in a mixture. In addition, the provisions of the final rule permitted employers to condition access to trade secrets upon basic written agreements not to misuse this information.

On November 25, 1983 (48 FR 53280), OSHA promulgated its new final Hazard Communication standard, codified at 29 CFR 1910.1200. The standard requires chemical manufacturers and importers to assess the hazards of chemicals which they produce or import, label containers with the hazards of the chemicals they ship, and supply downstream users with material safety data sheets. All employers in the manufacturing sector, SIC Codes 20 through 39, are to provide information to their employees concerning the hazards of chemicals the employees are exposed to. These employers must not remove hazard labels from containers, must save and provide employee access to material safety data sheets, and train employees in the hazards of the chemicals present. In addition, distributors of hazardous chemicals are required to ensure that containers they distribute are properly labeled, and that material safety data sheets are provided to their customers in the manufacturing sector. An effort has been made to make provisions of the employee exposure and medical records access rule as nearly identical as possible to those found in the hazard communication standard in order to provide uniformity and policy consistency.

B. Litigation

The May 1980 regulation has been the subject of litigation in several courts. On May 21, 1980, the Industrial Union Department, AFL-CIO, petitioned the United States Court of Appeals for the District of Columbia Circuit to review the rule pursuant to section 6(f) of the OSH Act, 29 U.S.C. 655(f). *Industrial Union Dept. AFL-CIO v. Marshall*, No. 80-1550.

The Chemical Manufacturers Association and the Chamber of Commerce of the United States later intervened in that lawsuit. In July 1980, a number of individuals and two trade associations, the Association of Diving Contractors and the Louisiana Chemical Association, subsequently petitioned the Fifth Circuit Court of Appeals under the same section 6(f) review provision. These cases were transferred to the D.C. Circuit under 28 U.S.C. 2112(a) and consolidated with the pending IUD case. These cases are currently in abeyance to permit this reconsideration of the

regulation to be completed. Also in abeyance in the D.C. Circuit is *National Constructors Association v. OSHA*, No. 80-1820, a challenge to the regulation's application to the construction industry.

A separate challenge to the rule was filed in January 1981 by the trade associations representing the flavor and fragrance industries in the United States District Court for the District of Maryland (Civ. Action Nos. Y-81-66, Y-81-67). This case was withdrawn and ultimately dismissed when a partial administrative stay was issued covering these industries.

In addition, the Louisiana Chemical Association and several individuals challenged the rule in July 1980 in the United States District Court for the Western District of Louisiana, claiming the Court had jurisdiction by reason of, *inter alia*; 28 U.S.C. 1331 and 1337. The District Court originally dismissed the case on the basis that review of OSHA regulations was vested in the Circuit Court of Appeals. The case was appealed to the Fifth Circuit Court of Appeals. The Fifth Circuit ultimately held that the rule was a section 8 regulation and therefore the District Court had jurisdiction to consider the case. *Louisiana Chemical Association v. Bingham*, 657 F.2d 777 (5th Cir. 1981). It therefore returned the case to the District Court to consider it on the merits.

On November 5, 1982, the United States District Court for the Western District of Louisiana upheld the validity of OSHA's records access regulation. *Louisiana Chemical Association v. Bingham*, 550 F. Supp. 1136 (W.D. La. 1982). This decision was affirmed by the Fifth Circuit in *Louisiana Chemical Association v. Bingham*, 731 F.2d 280 (5th Cir. 1984).

C. Administrative Stay for Construction

On April 28, 1981, OSHA administratively stayed the records access rule with respect to the construction industry (46 FR 23740). The stay was granted to allow a review of the regulation by the Advisory Committee on Construction Safety and Health (the "Construction Advisory Committee"), which had not been consulted during the original development of the rule. The terms of the stay required that employers in the industry: (1) Continue to preserve exposure and medical records and make them available to OSHA, and (2) make employee medical records available to employees. The April 28 notice also requested other interested parties to submit written comments concerning the impact of the records access standard on the construction industry. Docket H-

112C was established to receive these comments.

The Construction Advisory Committee met on June 10-12, 1981, and, after considering the impact of the records access rule on the construction industry, voted that the stay should be lifted, and further offered 13 suggestions and recommendations concerning the standard (Exs. 3-62, 3-63). OSHA also received 45 written comments concerning the issues raised by the stay.

After a review of the comments submitted into Docket H-112C and of the recommendations made by the Construction Advisory Committee, OSHA lifted the administrative stay on September 15, 1981 (46 FR 45758). In this notice OSHA dealt specifically with the 13 recommendations submitted by the Construction Advisory Committee and stated further that the issue of the appropriateness of the records access rule for construction would be considered as part of its review of the entire records access regulation in general.

D. Proposed Interim Modification

On August 7, 1981 (46 FR 40490), OSHA published interpretations of the records access regulation concerning: (1) The 15-day limit for providing records (§ 1910.20(e)(1)(i)), (2) the coverage of exposure records of "similarly exposed employees" (§ 1910.20(e)(2)(i)(B)), (3) the coverage of records privileged from discovery, and (4) the sanctions permitted for employee breaches of confidentiality agreements (§ 1910.20(f)(3)). In this notice OSHA also announced a partial stay of the records access rule for the flavor and fragrance industry.

OSHA also published on August 7 a proposed interim modification of the regulation to permit employers to include liquidated damages clauses or the like in confidentiality agreements while they may require of employee designated representatives prior to disclosing toxic substance information which is a trade secret (46 FR 40492). This notice requested interested parties to submit written comments concerning this issue. Docket H-112D was established to receive these comments. 46 written comments were subsequently submitted. This proposed interim modification was later merged into OSHA's overall reconsideration of the records access rule (47 FR 20429).

E. The Proposal

Because the record access regulation raised complex policy and legal questions with respect to several of its provisions, the Secretary determined

that it was an appropriate subject for reconsideration in light of current policies and experience. Accordingly, on July 13, 1982, OSHA published its proposal to modify the Access to Employee Exposure and Medical Records rule (47 FR 30420). The proposal was based on all comments and information submitted to OSHA since the regulation was originally promulgated in May 1980 (45 FR 35212 *et seq.*), including the comments contained in Dockets H-112C and H-112D. The proposal gave interested parties until September 14, 1982 to submit comments, views, and arguments on any issues raised by the proposal. Comments were specifically invited on: (1) The definition of "employee"; (2) the definition of "exposure"; (3) the definition of "toxic substance"; (4) the preservation requirements for employee exposure and medical records; (5) the prohibition on the microfilm storage of X-rays; (6) union access to exposure records; (7) trade secret protection provisions; and (8) the provision of regulatory relief for small businesses. Docket H-112E was established to receive all evidence concerning the proposed modifications, and a total of 116 comments were received.

F. The Hearings

The July 13 proposal also announced a schedule of informal public hearings. These hearings were held from October 5, 1982 through October 13, 1982 in Washington, DC, and were presided over by Administrative Law Judge Frank J. Marcellino. All hearing participants were afforded the opportunity to present oral testimony and to question other witnesses. A total of 20 interested individuals and organizations testified at these hearings, and five additional participants submitted written testimony. Hearing participants were given until November 12, 1982, to submit additional evidence and factual material, and until December 13, 1982, to submit post-hearing comments or arguments.

G. The Record

The public record on the proposed regulation was certified by Judge Marcellino on January 10, 1983. The record consists of all material submitted to the OSHA Docket Office, Docket No. H-112E, by either OSHA or the public, including: (1) Comments on the July 13 proposal; (2) background materials collected by OSHA; (3) notices of intent to appear at the public hearings; (4) verbatim transcripts of the public hearings; (5) hearing exhibits; and (6) post-hearing comments. Dockets No. H-112C and H-112D have also been

incorporated by reference into the H-112E record. OSHA also relies on the original H-112 Docket, which was compiled at the time of the rulemaking for the May 1980 regulation, in issuing this modified rule.

Copies of the official list of items in the total record, as well as the items themselves, are available from the OSHA Docket Office, Docket No. H-112E, Room S-6212, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone 202-523-7894.

II. Legal Authority

This modification of OSHA's Access to Employee Exposure and Medical Records Regulation, 29 CFR 1910.20, is being issued under the authority granted to the Secretary in section 8 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 657. Authority for the standard may be found in sections 8(g)(2) and 8(c)(1) of the Act, 29 U.S.C. 657(g)(2), 657(c)(1). Section 8(g)(2) reads as follows:

The Secretary * * * shall * * * prescribe such rules and regulations as he may deem necessary to carry out (his) responsibilities under this chapter, including rules and regulations dealing with the inspection of an employer's establishment.

Section 8(c)(1) states:

Each employer shall make, keep and preserve, and make available to the Secretary * * * such records regarding his activities relating to this chapter as the Secretary * * * may prescribe by regulations as necessary or appropriate for the enforcement of this chapter or for developing information regarding the causes and prevention of occupational accidents and illnesses.

The May 1980 standard was issued under both section 6 and section 8 authority. The issue of whether 29 CFR 1910.20 could legitimately be characterized as an occupational safety and health standard under section 6, which would determine whether it was properly challengeable in a district court or the courts of appeals, was the subject of litigation in the United States Court of Appeals for the Fifth Circuit. The Fifth Circuit decided that as a jurisdictional matter it could not be considered a section 6 standard but could be considered a section 8 regulation. Its reasoning was that Congress apparently intended standards to aim toward correction of specific and already identified hazards, and that the records access standard does not do so. Rather, its function, as the Court stated it, is possible detection, over a long period, of significant risks not yet covered by standards. In addition, it fits neatly within the language and history of

section 8, which authorizes issuance of enforcement and detection regulations. *Louisiana Chemical Association, et al. v. Bingham, et al.*, 657 F.2d 777 (1981).

On remand, the District Court for the Western District of Louisiana held on the merits that the promulgation of 29 CFR 1910.20 was in fact a valid exercise of the Secretary's section 8 general rulemaking authority. *Louisiana Chemical Association, et al. v. Bingham, et al.*, 550 F. Supp. 1136 (1982). The Court held:

Even a cursory examination of the Act's overarching policy and the means by which it may be achieved make plain the fact that the records access rule bears at least a reasonable relation to that purpose. The rule will serve to establish a primary data base regarding long-term exposure to toxic substances and harmful physical agents. Such a pool of information will obviously be of great utility to medical/industrial research in the isolation and identification of latent occupational diseases and health hazards yet unknown. Therefore, the records access rule aids in the research effort noted in 29 U.S.C. § 651(b)(5); provides an additional means of discovering latent diseases and establishing causal connections between diseases and work in environmental conditions within the meaning of (b)(6); establishes an additional reporting procedure as outlined in (b)(12); and serves to encourage labor-management efforts to reduce disease arising out of employment in accordance with (b)(13). Given the insidious nature and long-term effects of many latent occupational diseases, a rule which establishes a data base for medical research, as does the record access rule bears more than a mere reasonable relation to the major policy goal of the Act. The records access rule is quite directly related to the goals of assuring "safe and healthful working conditions" and "preserving our human resources." (Ex. 49, pp. 5-6)

It also held that while section 8(g)(2) would by itself provide sufficient authority for the records access rule and more specific support for the regulations with respect to OSHA access to the records covered by it, is found in section 8(c)(1), 29 U.S.C. 657(c)(1).

Based on these foregoing court decisions, it is the law of the case that the Record Access rule is issued pursuant to section 8 of the Act. Therefore OSHA is promulgating these amendments to the Records Access rule pursuant to section 8. OSHA continues to conclude that the Record Access rule is important to carry out the purposes of the Act. These amendments modify 29 CFR 1910.20 in several respects, but its essential character and purpose have not changed. As before, the records access rule is designed to yield both direct and indirect improvements in the detection, treatment, and prevention of

occupational disease. To this end, employee access to exposure and medical data will enable workers and their representatives to play an important role in their own health management. The data obtained will enable an employee's personal physician to diagnose, treat and possibly prevent permanent disease. It will also serve to decrease the incidence of occupational health problems, for once an employee is informed of the identity of hazardous substances he or she faces on the job and the potential health consequences or exposure to them, the individual can minimize future exposure through prudent work practices.

Second, access to exposure and medical records by employees, their designated representatives, health professionals acting on behalf of employees, and OSHA will facilitate research to uncover patterns of health impairment and disease, and to establish causal connections between disease and exposure to particular hazards. In turn, this will enable the Secretary to effectuate the purposes of the Act, including the establishment of uniform national health and safety standards.

Third, employees can use this information to obtain implementation of new protective control measures. The use of the data may take any of several forms. Most importantly, informed employees will be in a better position to exercise their statutory rights (e.g., complaints to OSHA, participation in OSHA inspections). Employees may also marshal this information to discuss improving conditions in the workplace directly with their employers, through whatever means are available to them.

A fuller discussion of the basis for these findings may be found in the preamble to the May 1980 regulation (45 FR 35212 *et seq.*).

Because the Records Access regulation, as modified herein, is related to those statutorily sanctioned purposes, the Secretary finds that it is necessary to carry out his responsibilities under the Act. It remains therefore a valid exercise of his section 8 general rulemaking authority. Cf., *Mourning v. Family Publications Service, Inc.*, 411 U.S. 356 (1973); *Whirlpool Corp. v. Marshall*, 445 U.S. 1 (1980).

OSHA has made a conscious effort to make the provisions of the Records Access rule, as far as possible, parallel to those found in the Hazard Communication standard (29 CFR 1910.1200). The Records Access rule and the Hazard Communication standard will work together to form a comprehensive regulatory structure for

informing employees of the hazardous substances found in their workplace and the steps to be taken to control such exposures. The Hazard Communication standard requires the development of MSDS's and their communication to workers in the manufacturing sector of industry. The Records Access rule supplements the Hazard Communication standard by extending access to current MSDS's which have been retained to employees in general industry, construction and maritime.

III. Discussion of Significant Issues and Summary of the Final Regulation

This rulemaking, initiated in 1982, has addressed several important issues concerning the 1980 regulation. The decisions reflected in this revised standard reflect the evidence currently in the record. The Office of Management and Budget, in its review of the paperwork requirements of this rule, has recommended that OSHA consider whether additional rulemaking would be appropriate in order to further evaluate the effectiveness of record retention provisions of the current rule and the appropriateness of the definition of "employee" as defined by this final rule. At issue is whether OSHA's experience under the current rule points to possible improvements which could be made. More specifically, are changes necessary and appropriate to reduce the recordkeeping burdens while retaining the effectiveness of the standard?

In order to examine these issues more closely, and in the context of other Federal programs and activities, OSHA will participate in an interagency working group to examine this regulation and make recommendations, as appropriate, for revisions that may be needed to assure that the records most useful to employee health and health research purposes are retained. The recommendations of this working group will be evaluated by OSHA to determine the need for further rulemaking. In order to give OSHA sufficient flexibility to respond to the recommendations of the working group, OSHA is continuing to consider the definitions of "employee", "employee exposure records" and "toxic substance" pending receipt of the working group recommendations. Based on the working group recommendations, OSHA will either publish its final determination to retain the definitions in the existing standard or repropose new definitions as the basis for further rulemaking. In the interim, of course, pending final resolution of these definitions, the existing definitions will continue to apply.

A. Scope and Application

1. General

The 1980 regulation applied "to each general industry, maritime, and construction employer who makes, maintains, contracts for, or has access to employee exposure or medical records, or analyses thereof, pertaining to employees exposed to toxic substances or harmful physical agents" (paragraph (b)(1)). The regulation applied to records whether or not they were related to specific occupational safety and health standards, and also applied to records created prior to the effective date of the standard, August 21, 1980. The broad scope of the 1980 regulation was a major issue in the proposal.

The issue of scope is best considered through evaluation of its three major components: (1) The number of employees covered, (2) the industries covered, and (3) the types of records covered. The latter component, the types of records covered, is directly dependent upon the definitions of "employee exposure record" and "employee medical record," and is therefore discussed in the "definitions" section below.

2. Employees Covered

The 1980 rule applies to the exposure and medical records of all employees exposed to toxic substances and harmful physical agents. Following issuance of the 1980 regulation, several commenters argued that the rule's scope was too broad. They noted that literal construction of the 1980 regulation indicated that records of employees only marginally exposed to toxic substances and arguably not at health risk from such exposures were evidently covered by the rule as long as the nature of their exposure was different from typical non-occupational exposure. For example, the concern was expressed that records of office workers who make only infrequent or sporadic visits to production areas where toxic substances or harmful physical agents are present would be subject to the retention and access provisions of the regulation (SOCMA, Ex. 3-58; Prudential, Ex. 3-31).

Responding to these concerns, OSHA proposed to limit the rule's coverage to only those employees "whose work directly involve(s) the manufacturing, processing, installation, handling, packaging, transport, disposal, or use of toxic substances, or who (are) subject to harmful physical agents (e.g., noise, ionizing and non-ionizing radiation, hypo- or hyperbaric pressure) in any

manner different from non-occupational situations; including, but not limited to, coverage of production, maintenance, transport and construction workers" (paragraph (b)(1); 47 FR 30434). This modification would have targeted the regulation at those groups of employees whose job duties typically involve substantial exposure to toxic substances or harmful physical agents. Production, maintenance, construction, and transport workers would have been covered if toxic substances or harmful physical agents were present in their workplaces, with no further inquiry necessary on whether each individual is working directly with a toxic substance or harmful physical agent. For instance, an electrician working near a welding operation on a construction site would have been covered. At the suggestion of the Advisory Committee for Construction Safety and Health, "installation" was added to paragraph (b)(1) to clarify the broad coverage of construction workers (Exs. 3-62, 3-63).

In addition, those workers whose job duties do not usually involve substantial exposures (e.g., most office workers) would not ordinarily have been covered. However, the proposed revision would have continued to provide for access to exposure and medical records of any general industry, construction or maritime employee not otherwise covered by the standard who was accidentally exposed to a toxic substance or harmful physical agent to a degree sufficient to require medical treatment.

Many employers supported the proposed changes in their written and oral submissions (Exs. 4-1, 4-7, 4-17, 4-27, 4-28, 4-30, 4-41, 4-62, 4-66, 4-68, 4-69, 4-76, 4-80, 4-92, 4-109, 4-113; Tr. 828, 1047). In general, they maintained that "the new definition of 'employee' reasonably limits the application of this regulation to those workers who are more than casually exposed to toxic substances" (AFMA, Tr. 828).

Although no estimates were submitted from industry concerning the possible cost savings of the proposed provision, testimony was submitted that "as initially promulgated, the records access rule covered too many employees to be a truly useful means of additional protection, and imposed a considerable burden on employers to maintain accurate and comprehensive records which provided reasonably rapid access" (Pennzoil, Ex. 4-30).

Employee groups and other participants responded that the proposed provision excluded many groups of employees clearly at risk from exposure to toxic substances and harmful physical agents, and who are

therefore likely to benefit from access to exposure and medical records (Exs. 4-77, 4-98; Tr. 100, 123, 144, 187, 347, 415, 471, 503, 527, 919, 1020, 1079).

To illustrate that workers not directly involved with the handling of toxic substances are potentially at risk from exposure, the ICWU gave as an example "a situation where asbestos dust due to the poor ventilation in the plant was mixed with other dust and spread throughout the plant. So there was no worker in the plant itself that was not at risk to asbestos" (ICWU, Tr. 347).

Cal/OSHA also noted that "office workers connected with manufacturing areas may become exposed to high levels of manufacturing contaminants if there are sloppy work practices" (Ex. 17, p. 10). Specifically, Cal/OSHA cited an investigation of a battery plant which found dangerous levels of lead in the front office, and a study of the Virginia kepone incident which stated that "employees had been exposed to kepone wherever they worked, rested, ate or drank within the confines of the plant." Cal/OSHA also cited a case where workers in an office building were made ill by workplace exposures:

In March of 1982, 250 state employees who work in the Bateson Building in Sacramento complained of recurring health problems involving headaches, burning eyes, and general poor health. These health complaints have been associated with noxious fumes and poor air circulation in the building. (Ex. 17, p. 10)

After considering the rulemaking record, OSHA has determined that it is appropriate to retain coverage of employees as stated in the 1980 regulation. OSHA finds insufficient evidence for categorically excluding "casually exposed" workers from the scope of the rule for purposes of providing access to the records of such workers. Because the rulemaking record is less clear with respect to the practical utility of retaining the records of "casually exposed" workers, OSHA will continue to consider this issue through participation in the working group described earlier. In the interim, the existing definition of "employee" will continue to apply. The record shows that both production line workers and executives have become ill from brief exposures to toxic substances.

3. Records Created Under Contract

The status under the 1980 regulation of records created under contract was a source of confusion to several affected parties who were concerned that employers would be held strictly liable in collateral litigation for actions by physicians not fully under their control (Ex. 62, pp. 37-46; Ex. 60, p. 3). The

proposal would have modified paragraph (b)(3) to clarify the obligations of employers who contract for exposure measurement or medical services. The proposed modification required that "each employer shall ensure that the requirements of this section are made known to physicians and others providing medical or industrial hygiene services under contract to the employer and shall make a good faith effort to ensure, by modification of the contract if necessary, that such persons comply with the preservation and access requirements of the section" (47 FR 30434).

The proposed provision was challenged by some participants. Mr. Peter Weiner (Cal/OSHA) noted that:

If an employer does not create the violation and does everything reasonably possible to modify the contract in an attempt to comply, existing case law which we have cited clearly states that the employer will not be subject to citation. (Tr. 420)

Therefore it would not be necessary to modify the regulation in response to these concerns. Mr. Robert Frase (UPIU) also testified:

We have no objection to contracting medical services out to qualified occupational health providers—in fact, care is often more objective and comprehensive when provided by independent occupational health specialists.

These specialists certainly recognize the value of maintaining records for epidemiological research. But we strongly oppose creating the option for employers to abrogate their legal and ethical responsibility to make records compiled on their employees available to these individuals and to retain those records for a period of time that makes health research feasible. (Tr. 763-764)

OSHA has determined that, under the language of the 1980 rule, employers can not be penalized if they make reasonable efforts to comply with the access rule when using contract services if such efforts fail for reasons beyond their control. This is not only a matter of OSHA interpretation but of applicable legal principles. Altering the language of the regulation, however, to conform to the proposal could result in reduced efforts to assure compliance when contract services are being used. OSHA, therefore, will retain the 1980 provision for the final rule, and to provide this clarification of its intent with respect to enforcement.

4. Industries Covered

Several trade groups have argued that certain industries ought to be exempted from coverage. In particular, employer groups in the flavor and fragrance

industries (Exs. 3-44, 3-45, 3-47, 3-48, 3-50, 3-52), the construction industry (Exs. 3-40, 3-43), and the commercial diving industry (Ex. 3-86), have argued for limited or full exemption from the provisions of the regulation. The flavor and fragrance industries were the subject of a partial administrative stay designed to protect their trade secrets (46 FR 40490-91). This stay was extended to August 15, 1983 (48 FR 6332), and was later extended to February 1, 1984 (48 FR 36576). The stay was further extended to February 1986 pending final revisions to the Access Rule (49 FR 5112, 50 FR 5752).

a. *Flavor and fragrance industries.* The flavor and fragrance industries based their justifications for exemption primarily on the following assertions: (1) The broad definition of "toxic substance" includes many food and fragrance substances which, on the basis of objective data, are demonstrated to be safe; (2) the possibility under the regulation for disclosure of valuable trade secret formulas greatly outweighs the benefits of disclosure; and (3) the Records Access rule overlaps regulation of these industries by the Food and Drug Administration (FDA) and the Department of Agriculture (USDA).

For example, the Flavor and Extract Manufacturers Association (FEMA) stated that "(T)he standard's definition of toxic substances is so broad that many traditional innocuous food ingredients (i.e., sugar, vanilla, and lemon oil) would be considered 'toxic' within the meaning of the standard. The sheer number of substances considered 'toxic' under the standard will make compliance with requests for disclosure both extremely costly and very difficult" (Ex. 3-44, p. 1). FEMA also notes that "(T)rade secrets are the lifeblood of the flavor industry and are most carefully guarded by flavor manufacturers * * *. The disclosure required by the standard would threaten the very existence of the flavor industry without any showing that flavors and flavor materials present significant risks to any worker or that those risks would be lessened or eliminated because of the standard" (Ex. 3-44, p. 2).

In the proposal, OSHA decided that rather than exempt these industries entirely, their legitimate concerns would be addressed through modification of specific provisions of the regulation. In particular, OSHA proposed both narrowing the definition of "toxic substance" and modifying the trade secret provisions to substantially reduce the likelihood that the release of trade secrets would be required. The proposed

trade secret modifications paralleled in significant respects the current stay for the flavor and fragrance industries, which had evidently satisfied those industries' concerns in this interim period (Tr. 214). OSHA permitted the stay to remain in effect while considering comments in response to this issue as raised in the proposal. No convincing arguments were found in the record refute the Agency's discussion that the proposed modifications would alleviate the concerns expressed over trade secret access.

Therefore, this final regulation adopts the more specific provisions described above and which are discussed in detail later in this preamble. OSHA believes that the new definition of "toxic substance" and more protective requirements with respect to trade secret access will provide the necessary protection for employers in the flavor and fragrance industries, as well as other concerned employers.

Finally, the fact that these industries are subject to extensive Food and Drug Administration regulation does not detract from the need for this standard because the FDA has no comparable records access regulation.

b. *Commercial diving industry.* The Association of Diving Contractors (ADC), representing the commercial diving industry, sought a stay of the Records Access rule it applied to employees engaged in commercial diving on the grounds that: (1) The rule was improperly promulgated as it applied to them; (2) divers are not exposed to "toxic substances or harmful physical agents"; and (3) the regulation jeopardized valuable trade secrets such as proprietary decompression tables (Ex. 3-86). The Agency, while denying this stay request as lacking merit, issued an official interpretation of recordkeeping obligations in the diving industry which explained the interaction between the records access regulation, 29 CFR 1910.20, and the commercial diving standard, 29 CFR 1910.401-441, and clarified how these obligations could be met without jeopardizing the trade secrecy of the tables (Ex. 3-87). Since employees in the commercial diving industry are subject to occupational illness associated with their workplace exposure (e.g., mixed gases, hyperbaric pressure), OSHA saw no basis for excluding the industry from the records access regulation.

At the hearings, the ADC argued that OSHA has no jurisdiction over offshore diving because it has been totally preempted by the Coast Guard. It further argued that even with respect to inshore diving, the records access rule could not

apply to them because: (1) Diving employees are not subject to "toxic substances or harmful physical agents" other than "latent but basically uncontrollable safety hazards," and (2) the decision in ADC's challenge to the commercial diving standard, *Taylor Diving and Salvage Co., Inc. v. U.S. Department of Labor*, 599 F.2d 622 (5th Cir. 1979), bars application of records access regulation to the diving industry (Tr. 628-34).

The ADC subsequently sued OSHA in another case with the same name, *Taylor Diving v. U.S. Dept. of Labor* (No. 68-3400, District Ct. for the Dist. of Col.), to move that the records access regulation be held invalid for offshore diving. The Court rejected the challenge and upheld the standard for diving. It held that the Coast Guard's regulation of offshore diving did not preempt the OSHA regulation because of the legislative history, Supreme Court, and other court interpretations of the relevant language and because the OSHA regulation served a different purpose. It also upheld the purpose of the OSHA regulation as necessary for research into diver's diseases. An appeal was filed but a motion to withdraw the appeal was filed September 28, 1987.

Consequently, the legal contentions of the ADC have been rejected by the Court. OSHA policy of the need for this regulation for research into diver's diseases has been upheld. In addition, as discussed below, offshore divers need information about their medical conditions and exposure to protect their health.

Therefore, OSHA concludes that it is appropriate to continue to have the Records Access regulation apply to offshore diving operations.

With respect to OSHA's coverage of inshore diving, the following points apply. First, the Coast Guard does not regulate inshore diving so section 4(b)(1) does not generally apply. Second, the existence of hazards in the diving industry is well-documented (see 42 FR 37651-52). The fact that some of these hazards are in a sense "naturally occurring" due to the nature of diving and the environment in which it takes place is irrelevant to OSHA's authority to require the maintenance and availability of records documenting their effects. To the extent that divers are subject to substances that may be toxic under their conditions of use (e.g., breathing gases under pressure, carbon monoxide) or harmful physical agents (e.g., hyperbaric pressure, noise), their need for the regulation is no less than other employees who are covered by it.

The commercial diving standard, 29 CFR 1910.401 *et seq.*, whose purpose is to control the hazards inherent in commercial diving practices, itself requires the keeping of certain exposure records, and the keeping of medical records, while no longer required by the standard, is common to the industry. While there is much that is already known about the adverse physiological effects that can be caused by diving, there is also much that remains to be known, especially concerning its long-term effects. By requiring the keeping and availability of these records, the Records Access rule, as elsewhere, promotes occupational safety and health in this industry by ensuring the preservation of this invaluable data base.

c. *Construction Industry.* The 1980 Access rule did not provide exemption or special treatment to any industry segment, including construction. The Agency determined at that time that there was no rational basis for categorically excluding any broad class of employers from coverage. OSHA argued that the rule did not impose burdensome or unreasonable administrative or economic costs on any class of employers. In addition, OSHA pointed out that the NIOSH National Occupational Hazards Survey documented the fact that exposures to toxic substances occur throughout industry among all types and sizes of employers. Finally, the Agency argued that there was no justification for excluding employees exposed to toxic substances for a matter of weeks or months as opposed to years since even short-term exposures to toxic substances have been associated with the occurrence of chronic and acute disease.

After issuance of the 1980 rule, however, the construction industry objected to having it cover that segment due primarily to the transient nature of construction workers. They argued that long-term retention of numerous records of short-term employees would be of little use. In addition, it was pointed out that the Construction Advisory Committee had not been solicited by OSHA to review and comment on the 1980 rule prior to its promulgation.

In response to these concerns OSHA partially stayed the Records Access regulation with respect to the construction industry (46 FR 23740; April 28, 1981). In that notice, OSHA solicited comments from interested parties concerning the experience of the construction industry under the rule, and specifically what aspects of the construction industry render the

standard inappropriate. A total of 47 comments were received. Also, the Advisory Committee for Construction Safety and Health (CAC) met June 10-12, 1981, in Washington, DC and considered the issue of records access (Exs. 3-62, 3-63). OSHA published a summary and analysis of the comments and the Advisory Committee recommendations in the *Federal Register* on September 15, 1981 (46 FR 45758).

Employers in the construction industry argued during the rulemaking that the Records Access regulation posed certain practical compliance difficulties. The industry maintained that: (1) Construction employees are exposed to toxic substances, if at all, for only brief periods of time since their work requires movement from place to place on the construction site; (2) due to the large number of temporary employees (the typical construction employee annual turnover rate is between 300 and 600 percent), the regulation requires long-term retention of huge numbers of individual records having a negligible degree of occupational health significance; (3) the principal types of employee records generated on a construction site are much different from those generated in general industry—most monitoring is done on an area basis, and records do not reveal the identities of employees who may have been working in those areas; and (4) medical records generated are primarily those concerned with first aid and emergency treatment (Docket H-112C; Ex. 2-42A, pp. 4-6).

On the other hand, worker organizations (Ex. 2-31) maintained that the transience and mobility of construction workers make the access standard particularly appropriate for the construction industry, since construction workers do not have the benefit of many of the industrial hygiene controls found at permanent fixed work site and there is currently no other mechanism for providing a continuous medical history for construction workers. Those supporting construction coverage also argued that modern computerized recordkeeping methods make the storage and access of medical and exposure records feasible and inexpensive.

Finally, the CAC recommended, among other things, that OSHA lift the stay in recognition of the fact that construction employees are exposed to a wide variety of toxic substances and that access to and retention of records is necessary due to latency periods of many occupational diseases.

Based on its analysis of the comments and CAC recommendations, OSHA lifted the stay for the construction industry. At the same time, the agency issued interpretations which incorporated most of the CAC recommendations that alleviated many of construction's concerns and stated that the construction records access issues would continue to be reviewed as part of the general modification process.

In developing the proposed revisions, OSHA determined that the needs of construction workers for access to records that are kept on toxic exposures or health status are at least as great as the needs of industrial workers (Docket H-112C; Exs. 3-24, 3-31, 3-33, 3-41, and 3-45). Most complaints from affected employers did not challenge, and in fact largely supported, the basic premises of the regulation, but instead targeted certain specific provisions, such as the broad scope of the rule, as being too burdensome.

To tailor the regulation to the needs of the construction industry, OSHA proposed: (1) Incorporation of various interpretations which were made in response to the June 11, 1981, CAC recommendations; (2) exemption of construction industry from medical records retention requirements beyond the duration of employment; (3) modification of the definition of "toxic substance;" (4) removal of records of most first aid and emergency treatment from the definition of "employee medical record;" and (5) elimination of purchase order type records of chemical identity from the definition of "exposure record." The latter three proposed changes were not specific to the construction industry, but were expected to be of particular relevance to it.

A draft of the proposal was submitted to the Advisory Committee which met on March 3-5, 1982, for its further consideration. The CAC submitted seven additional recommendations, which were considered and, for the most part, accepted in developing the proposal (Exs. 3-77, 3-78, 3-82). It is important to note that none of the CAC recommendations goes to the basic issue of construction industry coverage. On that question, the CAC position has been that the regulation is necessary and appropriate for the construction industry. Several commenters, however, disagreed with the CAC position and asserted that construction employment should not be covered by the regulation. In general, however, these commenters did not provide evidence that access to exposure and medical records was not of occupational health importance to

construction workers, nor did they present evidence indicating that the current rule has placed an intolerable burden on employers. For example, several commentors submitted the identical following statement, but did not demonstrate the "practical" difficulties attributed to the rule with respect to construction or their company: "It is our view that the proposed Medical Records Access Standards is not practical for use in the construction industry, and especially for our company" (Exs. 4-32, 4-32, 4-34, 4-114, 4-115). Another commentor's submission consisted of the following: "The proposed Medical Records Access Standards 1910.20 is not practical for the construction industry. It is definitely not practical for our company and WE DO STRONGLY OPPOSE IT". (Ex. 4-25)

While expressing a strong preference, the foregoing comments do not contain any substantive information that demonstrates the validity of that preference.

Therefore, OSHA finds that the record supports the determination to accept the CAC position and continue to include construction employment within the scope of the regulation. The changes in this rule to exclude retention of first aid records and records of short term employees for 30 years eliminates any possible practical difficulties.

Several of the proposed changes were opposed by labor representatives in the construction industry (Exs. 4-22, 4-43; Tr. 1076-1109). With regard to the proposed changes to the records retention requirements, the Building and Construction Trades Department, AFL-CIO, noted:

The BCTD does not agree that the record retention requirement in the construction industry should be different from that in other industries. While we recognize that there exists in the construction industry a greater turnover of employees, the need for long-term medical recordkeeping as a tool for epidemiological studies is just as important in the construction industry as in other industries. (Ex. 4-43, p. 4)

Mr. Ronald Wollford (IBPAT) added:

Excluding construction employers from the data storage requirements of this standard is, therefore, one of the worst things that could be done for the future of the construction industry. These records could be provided and stored through services that already exist at very low costs * * * (Tr. 1082)

Based on this evidence that retention of personal medical records in the construction industry is of occupational health importance, OSHA has determined that it is appropriate to accept the CAC position and not promulgate separate medical records

retention periods for the construction industry.

However, in response to concerns from both general industry and construction employers, OSHA has incorporated the final rule an exemption for medical records of short-term (less than one year) employees and most first aid records from the records retention requirements of the regulation. Employee access to these records would continue to be required to the extent available, but employers would be relieved of the burden of having to retain these records for extended periods of time. Since in the construction industry employee turnover is high (Ex. 4-57, Att. I, p. 5) and most records of a medical nature are first aid records (Ex. 4-57, Att. J, p. 6), these exemptions should provide construction employers considerable relief from the burdens of the regulation. Yet, at the same time, the exposure records for all employees and the medical records of long-term employees will remain available for epidemiologic evaluation concerning occupational diseases associated with the construction industry.

Full discussions of the regulation's retention requirements and the specific treatment of first aid records and medical records of short-term employees are discussed elsewhere in this preamble.

After reviewing all the evidence and comments in the record of this proceeding, OSHA has concluded that construction should be covered by the Access rule. OSHA finds that the health needs of construction workers are similar to employees in other sectors and that various changes that have been made in the rule overcome specific problems which might exist in construction.

B. Definitions

1. Analysis Using Exposure or Medical Records.

Among the records covered by this rule are "analyses using exposure or medical records." The definition of this phrase was modified in the proposal to exclude "research" and "other" studies, thereby including only data compilations or statistical studies based on information contained at least in part in employee exposure or medical records. This modification was meant to conform the language of the regulation closer to the original intent, which was to cover such records as "charts, graphs, tables, industrial hygiene surveys, evaluation of disease experience, and other summaries and evaluations" of exposure and/or medical data, but not

such records as engineering reports or the records of experimental toxicological research, which typically bear only a tenuous relationship to the actual workplace exposures or health of employees. In making this distinction, OSHA was particularly concerned that the rule not act as a disincentive to employers who are inclined to conduct research in the occupational health area beyond routine measuring or monitoring of toxic exposures. Many commentors favored this modification (Exs. 4-11, 4-30, 4-60, 4-62, 4-68).

Some parties, however, objected to this provision, maintaining that records of experimental toxicological research are important in diagnosing occupational health problems (Exs. 4-9, 4-77; Tr. 481, 507, 528). Dr. Grace Ziem, M.D. (Johns Hopkins University) wrote that:

I do feel, however, that in addition to trade secret information, physicians should also have access to experimental toxicological research. OSHA's proposal currently explicitly denies such access to workers and it is important for the medical consultant to have the most up-to-date information on each chemical. (Ex. 4-9, p. 1)

Also, Mr. Barry Scott, C.T.H., stated that the proposed revisions "apparently" ignores the fact that these engineering and toxicological research and reports have historically been the basis for setting and modifying guidelines for exposure to chemical substances and physical agents. In the absence of more conventional occupational exposure information this information can be used by a competent health professional, in conjunction with the employee to draw the appropriate conclusions" (Ex. 4-98, p. 2).

While OSHA does not dispute that health professional access to engineering studies and experimental toxicological research can assist in the detection and diagnosis of occupational health diseases, OSHA continues to maintain that these records do not properly fall within the scope of this regulation in that they are not based on employee exposure or medical information. This conclusion is consistent with OSHA's original intent in promulgating the 1980 regulation. The preamble to that rule states that "the phrase 'any compilation of data, or any research, statistical or other study' more clearly expresses the intention to cover all situations where an employer evaluates or compiles exposure and/or medical data, charts, graphs, tables, industrial hygiene surveys, evaluations of disease experience, and other summaries and evaluations are covered by the definition" (45 FR 35260). Clearly,

records or studies not based on employee exposure and/or medical information, such as animal toxicological research or engineering studies, were not intended to be covered by this regulation.

Since the proposed provision better expresses OSHA's original intent, it has been adopted for the final rule.

2. Employee

Modification of the definition of "employee" (paragraph (c)(4) was proposed to be consistent with the "scope and application" section. The proposal defined "employee" as any employee "whose work directly involves the manufacturing, processing, handling, installation, packaging, transport, disposal, or use of toxic substances, or who is subject to harmful physical agents in any manner different from typical non-occupational situations, and includes, but is not limited to, coverage of production, maintenance, construction and transport workers" (47 FR 30434). The need for "direct involvement" was a limitation not found in the original rule.

As noted previously in the discussion of the scope of the regulation, OSHA has decided not to alter the scope of the rule at this time. Therefore, "employee" continues to be defined in the final rule as "a current employee, a former employee, or an employee being assigned or transferred to work where there will be exposure to toxic substances or harmful physical agents. In the case of a deceased or legally incapacitated employee, the employee's legal representative may directly exercise all the employee's rights under this section." This is the same definition that appeared in the 1989 regulations.

3. Employee Exposure Record

OSHA proposed narrowing the definition of "exposure record" to conform more closely to the common meaning of that term. The proposal required retention and access for only the following types of exposure records: (1) Environmental (workplace) monitoring results; (2) biological monitoring results defined as exposure records by OSHA standards (other biological monitoring would now be treated as medical records, which are entitled to greater confidentiality protection); and (3) material safety data sheets. Other records which reveal the identity of a toxic substance or harmful physical agent would no longer have to be treated as exposure records.

In the absence of more formal exposure records (air contaminant measurements, biological monitoring data, material safety data sheets),

paragraph (c)(5) of the 1980 rule also treated any other record which reveals the identity of a toxic substance (e.g., purchase records) as an "exposure record." The requirement to keep and make available this information, when coupled with the broad definitions for "toxic substance" and "exposure," was the source for much of the concern regarding trade secret disclosure and the practical burdens of complying with the regulation. The proposal dropped this aspect of the definition.

Mr. David Bossman (American Feed Manufacturers Association) commented with respect to the 1980 regulation that "(T)he rule, as adopted * * * requires employers to retain for at least 30 years massive quantities of routine documents, including production records, shipping records, invoices, etc., which are not at all directly related to the purpose of the rule" (Ex. 3-26, p. 7).

Similarly, the feed manufacturing industry submitted a petition in September, 1981, which sought a stay of the regulation as it applies to employee exposure records (Ex. 3-26). The industry maintained that "Exposure records" have been so broadly defined so as to include nearly every piece of paper generated in many workplaces * * * (we) did not fully realize that the regulation likewise requires retention of literally thousands of routine documents." (Ex. 3-26, p. 2).

The proposed provision therefore responded favorably to the major concerns of many employers, including the construction, flavor and fragrance, food processing and feed manufacturing industries, who maintained that access to records such as purchase orders was burdensome and could have jeopardized many valuable trade secrets (Ex. 3-44).

Industry groups testified that the proposed provisions are justified due to the compliance burden of maintaining large numbers of records, and that only records made for health, safety and environmental purposes should be included under the "exposure record" definition (Exs. 4-11, 4-20, 4-37, 4-60, 4-62, 4-66, 4-68, 4-78, 4-79, 4-109; Tr. 829). Dupont noted that:

Commonly, employees are required to perform tasks at various locations throughout the plant site. In the case of an employee required to travel through various areas, a site must conduct an extensive and burdensome search to locate all of the records which are covered by the access rule. When records are collected, they rarely, if ever, are correlated to particular employees and do not quantify a particular employee's exposures. If it is possible to extrapolate employee exposures from these data, it is extremely tedious. The end result is that sites spend an extraordinary number of man hours collecting data which really do not provide

useful exposure information for employees. (Dupont, Ex. 4-68).

By contrast, many interested parties commented that the proposed definition went too far in limiting the definition of "exposure record," particularly in eliminating qualitative records of chemical identity from the definition (Ex. 4-98; Tr. 147, 165, 177, 760, 901, 1021). These parties maintain that qualitative information can be extremely helpful in detecting the causes of occupational disease, since quantitative data often does not exist concerning toxic workplace exposures. Mr. Wright (USW) noted in his testimony that "sometimes the worst problem in a workplace is the one for which the least sampling exists" (Tr. 901), indicating that at times companies may not be aware that hazards exist in certain work areas, and therefore have not conducted exposure monitoring (Tr. 902).

Dr. Michael Silverstein of the United Auto Workers noted a specific case where qualitative information was used in detecting an occupational illness:

In this regard, I'd like to draw attention to an outbreak of neurologic damage to the bladders of workers exposed to a foam catalyst, trade name NIAX ESN, in 1978 at a plant manufacturing automobile seat cushions.

In this case, no traditional industrial hygiene exposure data was available. However, the plant maintained production records indicating the amount of all the catalyst used on different assembly lines from week to week and these records made it possible to reconstruct exposure histories for the sick workers and to identify NIAX ESN as the culprit.

NIAX ESN was removed from the plant and the epidemic abruptly stopped. (Tr. 147)

Moreover, employee groups make the argument that the current "exposure record" definition does not place an unrealistic compliance burden on employers. They note that the current definition specifies coverage of qualitative records of chemical identity only in the absence of other types of exposure records. Therefore, if a chemical inventory, for instance, is available, there would be no requirement to retain records such as sales receipts, purchase orders, batch cards, or other records which may contain chemical identities. The regulation requires that some record of identity and exposure be kept, if available, not that all such records with duplicative information be kept. Even though the regulation itself does not require the creation of records, these parties indicated that by voluntarily generating an inventory list, as many do

for their own purposes, an employer could in fact reduce the total compliance burdens of the rule. The AFL-CIO stated in its post-hearing comments that:

Industry has claimed that requirements covering "other" exposure records are burdensome and require the maintenance of voluminous unnecessary records. We do not agree. First, "other" records of exposure must be maintained only in the absence of quantitative measurements, or material safety data sheets for those toxic substances to which workers are exposed. The AFL-CIO believes the current standard is sufficiently flexible to allow the preservation of lists of toxic substances, as opposed to copies of all purchase orders, if all toxic chemicals and other identifying information (such as year of use, department location, etc.) are included (Ex. 16; Tr. 404). While the standard does not mandate the generation of such a list, it does in our view permit the development of a list on a voluntary basis as an alternative means of compliance. (Ex. 59, p. 9)

In assessing the burdens of the "exposure record" provision, the cost-saving features of the current regulation should also be noted. Of primary importance is the provision which allows employers to charge reasonable administrative costs for repeat requests of records. This cost-saving provision will remain unchanged in the final rule. Thus, any broad request for historical records should represent only a one-time employer expense, with the requesting party bearing the expenses for any subsequent requests.

In light of the evidence presented above, OSHA is modifying the "employee exposure record" definition contained in the 1980 regulation. The first modification expressly indicates that a chemical inventory may be substituted for any other record which reveals the identity (e.g., chemical, common, or trade name) of a toxic substance or harmful physical agent. This change does not alter in any way the requirements of the regulation, but instead indicates that a chemical inventory is an acceptable compliance alternative to the keeping of production records, shipping records, invoices, batch cards or other records containing chemical identities. It should also be noted that the Hazard Communication standard requires employers in the manufacturing section of general industry to develop work area lists of hazardous chemicals, as well as material safety data sheets (MSDS). As before, if an employer has an MSDS on a substance or a monitoring record, it is not necessary for an employer to keep an inventory or other such record.

A second modification defines an exposure record as, in the absence of environmental or biological monitoring records or MSDS's, a chemical inventory

or any other record which reveals where and when used and the identity of the toxic substance or harmful physical agent. This modification limits the number of "other records" that need be kept to those that most directly relate to employee exposures. Narrowing the definition of "other records" eliminates the need to retain a massive quantity of routine documents such as shipping records, purchase orders, invoices, etc. which only contain the chemical identity but do not describe where and when the chemical was used. In the absence of more formal exposure records, these other records may be the only record of employee exposures. As was the case with exposure to NIAH ESN, the preservation of production records which indicate where and when a chemical was used can be crucial in identifying a problem chemical in the workplace. This modified definition of exposure records preserves access to necessary records while eliminating the burden of maintaining records of limited occupational importance. With these modifications, the regulation's coverage of exposure records should not pose an excessive compliance burden to any of the complaining industries or employers, yet should fulfill the underlying purposes of the regulation.

The 1980 rule also included in its definition of "exposure record", "biological monitoring results which directly assess the absorption of a substance or agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc.) but not including results which assess the biological effect of a substance or agent." In response to comments that there are some privacy concerns connected with biological monitoring results, OSHA in its 1982 proposal narrowed this provision to include only "biological monitoring results which are designated as exposure records by specific occupational safety and health standards."

The AFL-CIO challenged the biological monitoring modification asserting it would unduly remove union access to an important body of exposure information. They stated that "it is important that unions have direct access to this information to assess the extent of workplace exposures" (Ex. 59, p. 10). Ms. Margaret Seminario (AFL-CIO) also stated at the hearings that union access to this information is necessary in support of the union role in OSHA standard-setting processes (Tr. 77).

In view of the AFL-CIO position and the absence of any industrial objection, and since no specific evidence was presented indicating that the 1980 biological monitoring provision had

actually caused the release of information for which there were justifiable privacy concerns, OSHA has determined that it is appropriate to retain the 1980 provision with minor modifications discussed as follows.

However, both OSHA and the AFL-CIO agree that certain biological monitoring results, such as those which measure levels of alcohol or drugs in the blood, do deserve confidential treatment (Tr. 78). OSHA, therefore, is modifying the biological monitoring provision to exclude from the definition of "exposure record" biological monitoring tests which assess an employee's use of alcohol or drugs.

Many commenters argued that MSDS's should not be considered "employee exposure records" (Exs. 4-11, 4-36, 4-37, 4-55, 4-56, 4-79, 4-95). They noted that OSHA's Hazard Communication standard deals with MSDS's (Ex. 4-79), that MSDS's are neither a quantitative or qualitative indication of exposure (Ex. 4-37), and that MSDS's are developed for many safe substances (Ex. 4-76).

OSHA does not agree with the first two arguments. First, the Hazard Communication standard (29 1910.1200) presently applies only to manufacturing industries (see 48 FR 53280, November 25, 1983), whereas the Records Access regulation applies to all general industry, construction and maritime employments where there is employee exposure to toxic substances or harmful physical agents. Therefore, yielding to the Hazard Communication standard could preclude important employee access to MSDS's in non-manufacturing employments.

Second, OSHA does not accept the argument that the information contained in MSDS's does not supply useful exposure and health data. MSDS's normally contain information on the identity of a chemical, its known toxic properties, signs and symptoms of over-exposure, personal protection precautions, and appropriate first aid and procedures. Access to this information is necessary to ensure that employees are properly protected against the hazardous properties of the chemical present.

However, OSHA does agree that employers do generate MSDS's for products which are not toxic in the common usage of that term. Customers often demand MSDS's for all products purchased, regardless of toxicity, and that the mandatory retention of these MSDS's would serve little occupational health purpose. Therefore OSHA has modified the MSDS provision under the definition of "exposure record"

(paragraph (c)(5)(iii)) to read "Material safety data sheets indicating that the material may pose a hazard to human health." This modification is consistent with the MSDS provision under the rule's definition of "toxic substance or harmful physical agent" (paragraph (c)(13)(iii)). As previously noted, OSHA will continue to examine this issue.

4. Employee Medical Record.

The proposal included three limited exclusions from the definition of employee medical record. First, the 1980 definition included all employee X-rays, regardless of the purpose for which they were taken. The proposal would have modified this requirement by considering only those X-rays taken for the purposes of establishing a baseline or determining specific occupational illness as part of the medical record. This revision would primarily remove from coverage X-rays taken to detect or treat broken bones due to falls or other traumatic occurrences. This modification was favored by several commenter (Exs. 4-27, 4-30, 4-60, 4-68, 4-79).

The AFL-CIO objected to this revision, noting that X-rays of broken bones could be related to chemical exposures (Tr. 404-406). However, OSHA continues to believe that even in such cases where chemical exposures do cause falls resulting in broken bones, written records of the diagnosis and necessary medical treatment would be adequate for epidemiologic purposes.

Second, the proposal added paragraph (c)(6)(ii)(B) to clarify that OSHA did not consider certain first aid records to be a part of the employee's medical record. OSHA based this clarification on the assertion that, like X-rays of traumatic injuries, first aid records are not typically used to detect occupational disease (Exs. 4-62, 4-76, 4-82, 4-109; Tr. 831). However, the proposal provided that if a first aid record was made by a physician or otherwise became part of an individual worker's medical record, it would then be considered part of the medical record and subject to the regulation's retention and access provisions.

Several commenters objected to this modification arguing that first aid records are indeed important in the detection of occupational diseases, and that any exemption for first aid records would tempt employers to classify treatment of significant injuries and illnesses as "first aid" (Exs. 4-24, 4-38; Tr. 188, 765, 850, 949, 1034, 1042). The International Association of Machinists and Aerospace workers noted that:

We also feel that your proposal for the exemption of first aid records from access unless specifically made by a physician is in error. In many cases, gas inhalations are recorded as first aid cases by industry. These gas inhalation cases result from exposure to many varied chemicals in the workplace. In many cases, physicians do not fill out these first aid reports especially if they occur on the off-shifts. The responsibility for filling out the first aid forms may lie with a nurse, medical technician or supervisor * * * First aid reports such as gas inhalations can prove to be useful if an employee is continually exposed to a particular chemical. Trends can be followed and they could give insight to any problems an employee may have due to his/her workplace exposure. (Ex. 4-38, pp. 3-4)

Mr. Daniel Edwards (OCAW) further testified.

OCAW has some concern about removing first aid and emergency treatment cases from the definition of records. There seems already to be a problem in some industries where employers are recording many relatively severe injuries as first aid to avoid reporting them in the OSHA 200 Form. (Tr. 188)

Since this testimony indicates that access to first aid data can in some instances be of occupational health value, OSHA has decided not to remove first aid records from the definition of "employee medical record." However, OSHA has also decided that requiring the long-term retention of vast amounts of data concerning the treatment of relatively minor traumatic injuries such as cuts, scrapes and bruises would be of little overall benefit to the occupational safety and health purposes of the standard. OSHA also noted the statutory exclusion of first aid records in the keeping of injury and illness logs under section 8(c)(2) of the Act. This Section specifically states that records of injuries or illnesses involving loss of consciousness, restriction of work or motion, or transfer to another job are not considered first aid records.

Therefore, although access to these records will continue to be mandated, the regulation will not require the records to be kept beyond what is normal practice absent the rule. Since these records are created by employers for some administrative or medical purpose other than compliance with this rule, it is reasonable to assume that employers maintain this information for some extended period of time during which it would be available for analysis. Further, to preclude undue restriction of employee access to important medical information through the recording of the treatment of relatively severe injuries as "first aid," OSHA has modified the first aid provision to indicate that first aid records are records of one-time

treatment and subsequent observation of minor scratches, cuts, burns, splinters and the like, which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job. Therefore, a record of an injury or illness involving serious incapacitation, such as loss of consciousness, restriction of work or motion, or transfer to another job, would not be considered a "first aid" record regardless of whether or not the record was created by a physician.

The final regulation therefore includes first aid records within the paragraph (c)(6) definition of "employee medical record," but exempts in paragraph (d)(1)(i), "First aid records (not including medical histories) of one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters and the like which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job, if made on-site by a non-physician and if maintained separately from the employer's medical program and its records" from the long-term retention periods mandated for employee medical records.

The third proposed exclusion from the definition of "employee medical record" involved "records created solely in preparation for litigation which are privileged from discovery under the applicable rules of procedure or evidence." This modification incorporated an interpretation that had already been made with respect to the 1980 standard. The purpose of this exclusion was to make clear that the regulation is not meant to provide a route around local rules of discovery or evidence when the claim to which the record in question relates is being litigated and the record itself is a product of the litigation. As OSHA explained when the interpretation was first published:

The question has been raised whether an employer must provide access to records which are created solely in anticipation of litigation and which are otherwise privileged from discovery under the prevailing rules of procedure or evidence. An example could be a medical opinion prepared for the employer for purposes of aiding the employer's case by a company physician after a workmen's compensation claim has been filed. It has been OSHA's interpretation that the standard does not contemplate coverage of such a record if the record would not otherwise be available to the employee or his attorney in the litigation. On the other hand, the mere fact that a medical record (see definition at 29 CFR 1910.20(c)(6)) not originally created in anticipation of specific litigation will ultimately be used as evidence in a private

legal proceeding does not put it outside the scope of the standard. (46 FR 40490).

This continues to be OSHA's view of how the regulation should operate and is incorporated into the final rule.

5. Exposure

The proposal would have deleted the definition of the term "exposure" contained in paragraph (c)(8) of the 1980 regulation. The action was taken to make this section consistent with the proposed changes in the scope of the rule. Since the scope of the 1980 rule will be retained, the definition of exposure contained in the 1980 regulation will also be retained for the final regulation.

Therefore "exposure" or "exposed" as defined in the final rule, means "that an employee is subjected to a toxic substance or harmful physical agent in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes past exposure and potential (e.g., accidental or possible) exposure, but does not include situations where the employer can demonstrate that the toxic substance or harmful physical agent is not used, handled, stored, generated, or present in the workplace in any manner different from typical non-occupational situations."

The preamble to the 1980 regulation explained:

This final standard thus does not apply to every situation where any chemical or hazard is present in the workplace. While the final rule presumptively applies to all occupational exposures to toxic substances and harmful physical agents, the agency does not intend to cover situations where the employer can demonstrate that an employee is solely exposed to general environmental pollution, or to casual use of consumer products. For example, basic chemical manufacturing processes and abnormal exposures to heat, noise, and vibration are covered by the rule, but typical office working conditions are not. The applicability of the standard does not, however, depend on any showing that the level of actual exposure to a toxic substance or harmful physical agent is particularly excessive, but rather on the unique fact of occupational exposure. (45 FR 35265)

This continues to be OSHA's interpretation of the degree of exposure necessary to trigger the requirements of the rule.

6. Specific Chemical Identity

A definition of "specific chemical identity" (paragraph (c)(11)) was not included in either the 1980 regulation or the proposed revisions. The definition is included in the final rule to indicate the kind of information covered by the access and preservation provisions permitted to be withheld if judged by the employer to be trade secret. Access to

trade secret "specific chemical identity" information is governed by the procedures specified in paragraph (F).

7. Specific Written Consent

The definition of "specific written consent" remained unchanged in the proposal except for a clarifying modification of the language indicating that "specific written consent" would not authorize the release of medical information not in existence on the date of the written authorization unless the release of future information is expressly authorized. This modification was recommended by the CAC. This modification was uncontested in the record and is therefore adopted for the final regulation (paragraph (c)(12)).

8. Toxic Substance

The 1980 rule required the retention and disclosure of exposure information regarding any "Toxic substance or harmful physical agent." "toxic substance" was defined broadly, most notably by including any substance listed in the NIOSH RTECS list—a compendium of over 39,000 chemicals. Many affected parties have criticized RTECS as overinclusive. The definition of "toxic substance" was narrowed in the proposal to include only those chemicals on the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS) list which met certain toxicological criteria.

The 1980 regulation also defined as toxic any substance which "is regulated by any Federal law or rule due to a hazard to health." This provision was broadly interpreted by some to mean that all food ingredients are "toxic" since they are substances regulated by the Food and Drug Administration. Mr. Sherwin Gardner (GMA) noted that "this regulation does not discriminate between the few genuine hazards (eg: flour dust inhalation) and the vast majority of safe food substances to which workers are exposed" (Ex. 3-55, p. 1). This was not OSHA's original intent, which was to cover such regulated substances as air and water pollutants and other health hazards, most, if not all, of which were already included within RTECS. The proposal therefore deleted this provision because it is essentially duplicative and potentially confusing, and the final regulation also does not contain this provision.

The "toxic substance" definition in the 1980 rule also included any substance which "has yielded positive evidence of an acute or chronic health hazard in human, animal, or other biological testing conducted by, or

known to, the employer," ((c)(11)(iii)) and any substance which "has a material safety data sheet available to the employer indicating that the material may pose a hazard to human health" ((c)(11)(iv)). These provisions were unchanged in the proposal, except to reference them to the toxicological criteria contained in paragraph (c)(10)(iii). For the reasons stated below, these provisions have reverted to their original form.

As stated, the core of the 1980 "toxic substance" definition was its inclusion of any substance on the NIOSH RTECS list. The proposed modification of (c)(11)(ii) (renumbered as (c)(10)(iii)) retained the use of RTECS as a basic source of information, but greatly limited its application by adding specific toxicity criteria designed to indicate whether or not a substance would likely pose an occupational health risk. To come under the definition of "toxic substance" a substance would not only have to be listed in RTECS but would have to fulfill one of the following conditions: (1) Be reported to cause human toxicity at any dose level; (2) be reported to cause cancer or reproductive effects in animals at any dose level; (3) have a reported oral rat LD50 (that dose required to kill 50% of the treated animals) of less than 500 milligrams per kilogram of body weight; (4) have a reported rabbit skin contact LD50 of less than 1000 milligrams per kilogram of body weight; or (5) have a reported rat inhalation LC50 (that atmospheric concentration required to kill 50% of the exposed animals) of less than 2000 parts per million of gas or vapor, or less than 20 milligrams per liter of mist, fume or dust. Conditions (3), (4) and (5) were adopted from the "toxic chemical" definition in the American National Standards Institute's document, "American National Standard for the Precautionary Labeling of Hazardous Industrial Chemicals" (ANSI Z39.1-1976).

At OSHA's request, NIOSH generated from RTECS a list designed to meet these criteria (Ex. 3-88). This list of 3,492 substances represented a greater than 90 percent decrease in the number of chemicals specified under the "toxic substance" definition.

The proposed definition of "toxic substance" was a major issue in the rulemaking, and much testimony was received ranging from further restriction of the definition to include only OSHA regulated substances (e.g., CMA, Tr. 651) to retaining the 1980 definition, including the entire RTECS listing (e.g., Cal/ OSHA, Tr. 429-435). Industry representatives generally supported the

proposal or favored a more restrictive approach (Exs. 4-1, 4-3, 4-10, 4-11, 4-17, 4-28, 4-30, 4-40, 4-41, 4-54, 4-59, 4-60, 4-62, 4-66, 4-68, 4-69, 4-79, 4-91, 4-92, 4-95, 4-102, 4-106, 4-107, 4-109, 4-110, 4-113; Tr. 651, 731, 830), while labor representatives advocated a broadly inclusive definition (Exs. 4-38, 4-43, 4-77, 4-98; Tr. 104, 151, 189, 334, 374, 429, 758, 1022, 1077).

The following comments are characteristic of the industry position:

We strongly endorse OSHA's decision to narrow the definition of "toxic substance." The approach of the May 1980 rule—that any substance listed in the Registry of Toxic Effects of Chemical Substances ("RTECS") is a toxic substance—was vastly overbroad and covered many substances that could not reasonably be considered toxic as used in the workplace. (CMA, Ex. 4-62, p. 10)

OSHA, we believe, demonstrated sound scientific judgment in its definitions of "employee" and "toxic substance." We are particularly impressed with OSHA's intention of providing employers with a specific list of substances covered by its rule. This extraction from the NIOSH Registry of Toxic Substances will be of great assistance to smaller employers and help preserve the scarce resources of large employers by eliminating the need for each employer to perform its own extraction. (American Cyanamid, Ex. 4-63, p. 1)

The proposed revision of the term "toxic substance" in paragraph (c)(10) is an important improvement in the regulation, but is still too broad. For example, under the proposed definition a single report that a substance appearing in RTECS may cause cancer in animals at very high doses would be sufficient to cause the substance to be considered "toxic", thereby triggering the rule. (SOCMA, Ex. 4-69, p. 2)

In their opposition to the proposed definition, labor leaders and public health officials stated that it would both exclude many dangerous chemicals from coverage and frustrate one of the principal purposes of the access regulation—the detection of previously unknown occupational diseases. The AFL-CIO testified to this point as follows:

The record clearly shows that these (OSHA) criteria, and their application to the RTECS list fail to encompass a broad range of toxic effects, and exclude vast numbers of known and potential hazards * * *

The (ANSI) criteria fail to consider the results of toxicity tests conducted in species other than rats and albino rabbits, (such as mice, guinea pigs, etc.), and ignore organ specific effects such as neurotoxicity, liver toxicity or kidney toxicity, if acute mortality is not the outcome (Exs. 6, 16, 17; Tr. 29, 32). Thus many toxic substances are missing using these restrictive animal toxicity criteria. (Exs. 6, 16, 17; Tr. 128). While the proposed language theoretically includes substances with human health effects, in practice such substances are excluded, since

RTECS generally does a poor job of reporting human health effects. (Exs. 6, 15, 16, 17; Tr. 115). Therefore, application of "human health effects" criteria to the RTECS list fails to catch many toxic substances (Tr. 115). (AFL-CIO, Ex. 59, 6-7)

Further, Dr. James Melius of NIOSH testified:

A major problem with the access and retention being based on current knowledge of toxicity (is the) likelihood that what we now consider to be a non-toxic substance will later be found to be a substantially toxic (one). We all have many examples of that from our experience in occupational health, asbestos, vinyl chloride, DBCP, etc.

However, under the proposed regulation, the changes in the regulation, the records necessary for an epidemiological or medical study of the human toxicity of a formerly non-toxic compound might not be available * * *

Similarly, workers with access to the records might have discovered clues to the toxicity of the substance much before it came to our attention in other ways * * *

In summary, NIOSH believes that OSHA's plan to use the set of toxicological criteria applied to RTECS would not adequately identify substances which could cause significant occupational health hazards. (NIOSH, Tr. 103-104).

Similarly, Mr. Peter Weiner (Cal/OSHA) observed:

OSHA doesn't know nor does any other scientist, really, whether the RTECS list is over-inclusive, under-inclusive or just right. The entire purpose of the rule is to overcome the dangers of under-regulation of use and exposure by at least requiring the maintenance of existing, not new, exposure and medical records on the vast sea of chemicals upon which the ship of science has yet to chart a safe course.

The criticism of RTECS on the basis of including common substances such as sugar and salt is certainly misplaced. Non-occupational exposures are not covered and it is clear from the record that there can be instances where common substances can be harmful in bulk quantities. (Tr. 431-432)

The use of RTECS as a basis for the definition of "toxic substance" was also a major issue in the Louisiana Chemical Association court case which was decided while this rulemaking was underway. In upholding OSHA's original "toxic substance" definition, the Court found:

The Registry is a compilation of substances which have produced positive results in toxicity tests. Its editors make no attempt however to interpret contradictory data or test results, and even include toxic effects produced in laboratory animals by means unlikely to occur in the workplace. Also, the Registry includes certain substances found in household use on a daily basis such as table salt, sugar, lemon oil, Vitamins B and C, and baking soda. For each of the above

enumerated substances not considered by the laymen to be dangerous, however, are thousands of other chemicals and industrial compounds, the toxic effects of which are immediate and severe. There are additionally, tens of thousands of chemicals listed in the Registry, the long term toxic effects of which are simply unknown. In short, the Registry is a listing of those chemicals research scientists will be keeping an especially close eye on in attempting to identify the sources of occupational diseases. These are the chemicals presently considered to pose the greatest potential threat as causal factors of occupational disease and illness * * * (Ex. 49)

The court further stated that:

In "defining a class subject to regulation, '[t]he inclusion of a reasonable margin to insure effective enforcement, will not put upon a [rule] otherwise valid, the stamp of invalidity.'" *Mourning v. Family Publications Service, Inc.*, 441 U.S. at 374, 93 S. Ct., at 1663. (Ex. 49)

Further, the Court has recognized the point made by OSHA that only records voluntarily created by the employer are subject to retention under the Access rule and, therefore, the rule cannot be considered as overly broad or unduly burdensome. In the Court's opinion:

* * * the records access rule, while including a "reasonable margin to insure effective enforcement" in its definition of "toxic substance," can hardly be said to "grind with a rough edge." Strikingly absent from the plaintiff's brief has been any recognition of the critical ingredient of the records access rule—that it applies only to records created voluntarily by employers * * * Considering the disclosure-type regulation found in the records access rule, it poses no burden on the plaintiffs except to maintain records they choose to compile. (Ex. 49)

Other alternatives to the use of either the OSHA RTECS subset of 3500 substances or the entire RTECS list were also explored as part of this rulemaking. Primarily, the alternative of expanding the OSHA RTECS subset through the use of other less inclusive lists of toxic substances was investigated. OSHA's Dr. Leonard Vance specifically noted these alternatives in the opening statement of the rulemaking hearing:

There were comments both that irritants be added as a separate toxicological criterion and that the OSHA and ACGIH lists be specifically referred. We are presently looking at the appropriateness of including all OSHA/ACGIH listed substances in the definition of toxic substance * * *

It was also suggested that other lists, for example, the IARC and NTP cancer lists could be incorporated into the definition to assure that no substances of obvious occupational health concern fall through the cracks of the definition. (Tr. 19)

NIOSH also addressed this alternative, stating:

The current use of the full RTECS file could be retained, or less stringent toxicological criteria could be applied to RTECS to generate a list providing better coverage. A list generated from RTECS could also be combined with other lists, including at least the OSHA-regulated substances and the National Toxicology Program Annual Report with consideration given to including also the ACGIH TLV list and the International Agency for Research on Cancer (IARC) evaluation chemical list. (Ex. 4-70, p. 5)

This alternative did not receive support from hearing participants. Mr. William Danchuck, testifying on behalf of the Chemical Manufacturers' Association noted:

If you try to list it, either with 3900 or if you try to list it with California's 700 or West Virginia's 600, you're going to find yourself with things falling through the cracks and we don't want that as much as you don't want that. (Tr. 672)

The AFL-CIO also commented:

Inclusion of OSHA regulated substances, the ACGIH TLV's IARC carcinogens, etc. will only cover substances for which adverse health effects have been firmly established. However, substances for which the health effects are only suspect would remain excluded. Such an approach would completely undermine one of the standard's main purposes—the development of an adequate data base for the future evaluation of workplace hazards. (Ex. 59, p. 7)

On the basis of these and other comments OSHA has decided that supplementing the toxicological criteria with other lists would not be adequate in defining "toxic substance" for the purposes of this regulation.

CMA supported as an alternative the use of professional judgment in determining which substances should be considered "toxic" for the purpose of this rule:

While the approach of the July 13 proposal is an improvement, it still fails to recognize the high degree of professional judgment required to make a sound decision as to whether a substance could pose a chronic health hazard in a particular workplace environment. No simple citation of published lists or uncritical reliance on reported test results can avoid the need for judgment.

OSHA should take a performance-oriented approach consistent with the hazard communication standard. As we have argued in that proceeding, coverage of chemicals presenting chronic health hazards should be limited to chemicals which are generally recognized, on the basis of well-established scientific evidence, to lead to serious adverse health effects in employees. (Ex 4-62, pp. 10-11)

Evidence from a 1972 survey presented in the rulemaking for the 1980 regulation indicated that only 3.1% of all

industrial plants used industrial hygiene services. In the manufacturing and chemical industries, where toxic substance exposures are most likely to occur, the percentages were 12.4% and 29.0% respectively (45 FR 35255). While these percentages have undoubtedly increased in the last decade, a reliance on professional judgment would still clearly fail to provide adequate benefits to workers in a substantial majority of industrial plants where services of health professionals are not normally available. For most employers, therefore, the approach of using the RTECS list is preferable.

In light of the above testimony and decisional authority, OSHA has decided to retain the use of RTECS in defining the term "toxic substance" (paragraph (c)(13)(i)). A broad definition of "toxic substance" is desirable due to the regulation's hazards detection orientation. RTECS is a readily available source which was designed for just such a purpose. The criteria for selecting a substance for inclusion on RTECS and the limitations on its use are fully set forth in its introductory section (see 45 FR 35267). To the extent that an employer has records relating to exposure to any of these substances, or there are medical records of employees exposed to any of these substances, prudent public health policy dictates that these records be kept and made available in accordance with this regulation pending receipt of and action on the recommendations of the working group. Otherwise, valuable information concerning substances with a documented potential for causing harm if misused may be irretrievably lost.

A definition of "Health professional" has been added to this final regulation. This definition was not included in the 1980 Access rule but is added for the purpose of clarity. A "Health professional" means a physician, occupational nurse, industrial hygienist, toxicologist, or epidemiologist providing medical or other occupational health services to exposed employees. Health professionals are afforded the opportunity to gain access to trade secret information in non-emergency situations when the need is demonstrated to be legitimate. For non-emergencies, OSHA believes that access to trade secret information lie in the treatment of an employee as a patient, in the evaluation of workplace hazards, and in their potential use as data for epidemiological studies. Physician and nurse access is appropriate for use in evaluation of the record in terms of continuing health care or who suspects that a patient's health problems may be the result of chemical exposure. In

addition, both physicians and nurses have access to trade secret information in emergency situations for the same reasons.

Industrial hygienists, where utilized, may require chemical identity information in order to access the conditions under which the hazardous situation arose and to confirm the existence of an exposure history.

Epidemiologists and toxicologists may require trade secret data in order to link patterns of disease with exposure to a particular chemical.

C. Retention Periods.

The 1980 regulation required exposure and analysis records to be kept for thirty years and medical records to be kept for the duration of employment plus thirty years. These periods were chosen to reflect the latency periods associated with some occupational diseases, most notably cancer.

Affected parties, construction industry employers in particular, expressed concern over the value and expense of retaining records of short-term employees for the full thirty year periods (See Exs. 3-36, 4-30; Docket H-112C, Ex. 2-42A). They argued that exposure and medical records of short-term employees would likely not be of occupational health benefit, since in twenty or thirty years it would be nearly impossible for a researcher to trace the cause of an occupational disease to short-term employment at a particular job site when the employee had worked at dozens of essentially similar job sites. It would also be nearly impossible to locate the former employees should follow-up be necessary.

In response, OSHA proposed exempting from the retention requirements any individually identified medical records of short-term (i.e., less than one year) employees provided these employees were instead given a copy of their records upon termination of employment. The agency explained that although records of short-term employees may often be of future occupational health significance, the total burdens of maintaining these records did not appear to be justified.

Also based on comments from construction industry employers that due to the nature of construction employment extensive recordkeeping would unduly burden employers (Docket H-112C, Exs. 2-3, 2-6A, 2-14), OSHA proposed to modify the current regulation's retention requirements for medical records generated and maintained by construction industry employers to the duration of an employee's employment (regardless of

duration) provided that the record is turned over to the employee upon termination of employment. This modification would not apply, however, to any medical records retention requirements contained in substance-specific OSHA standards.

In addition, OSHA proposed changing the retention period for medical records to length of employment plus 5 years, but in no event less than thirty years after the beginning of employment. This modification was designed to reduce the burden of the current rule by shortening the outer limit of how long medical records of permanent employees will have to be kept while retaining the benefit of long-term records retention.

Several interested parties opposed any reduction in the required records retention periods (Ex. 4-9, 4-22, 4-24, 4-38, 4-43, 4-68, 4-70, 4-77, 4-78, 4-98, 4-111; Tr. 105, 136, 148, 191, 380, 435, 485, 509, 766, 921, 1026, 1033, 1082). In its written comments, NIOSH noted that:

NIOSH is very concerned about OSHA's proposal to limit the retention of medical records * * *. This change could seriously undermine the improvement of the epidemiological data base used to identify occupational illnesses and injuries. There has been much criticism of the reliance on animal studies as a basis for regulation of substances. It is imperative that the best possible data base of human experience be available. Short-changing the source materials for epidemiological studies would serve only to undermine the scientific basis for health and safety regulations. This, in turn, would affect the ability of NIOSH and other occupational health research groups to conduct epidemiological studies * * *.

In summary, NIOSH recommends that no changes be made in the general medical record retention time provisions of the current regulation and that no limitation of this provision be made based on plant size. It has been our experience that most employers retain medical records for long periods of time after employment for other reasons. Therefore, we do not believe that the current regulation imposes inordinate extra burden beyond the common practice of most industries. (Ex. 4-70, pp. 6, 8)

The American Public Health Association (APHA) also commented on this issue as follows:

Medical records and their retention are a particular concern for the APHA because of our interest in research and epidemiology.

The proposal requires only five years retention for workers who had put in 25 years before retirement. This would result in more rapid destruction of records of long-term employees—presumed to have more cumulative exposure. At the other end of the spectrum, the proposal uses a minimum of one year of employment to trigger the retention of records * * *. For epidemiologic studies the trigger time should be much shorter. For example, in dibromochloropropane (DBCP) morbidity

studies, work exposure for less than one year was shown to cause significant disease.

In summary, there is no evidence that these rules represent an improvement over existing provisions. (Ex. 14, pp. 5-7)

Other commenters, however, supported the proposed reductions (Exs. 4-10, 4-17, 4-20, 4-35, 4-39, 4-41, 4-52, 4-54, 4-58, 4-62, 4-66, 4-67, 4-76, 4-80, 4-97, 4-100, 4-109). The Marathon Oil Company commented:

While we are in favor of the OSHA's attempt in this proposed rule to make the retention period shorter in some cases, it still has saddled employers with a great and costly burden. More specifically, the retention period for medical records is unduly burdensome. As part of retention, such things as allergy shot records, hay fever prescriptions, and most health insurance payments, etc., will have to be retained for the duration of employment plus five years, with a minimum retention of thirty years. Employers literally will have to rent buildings to store everything OSHA requires us to save. (Ex. 4-39, pp. 4-5)

However, several employers testified that they would maintain employee medical records for extended periods of time absent the standard (Ex. 4-1, 4-11, 4-111; Tr. 108, 748). For instance, Dow Chemical requires that their industrial hygiene records, medical records, and personnel records be maintained for a period of 75 years after the date of employment (Ex. 4-111, p. 2). Dr. John Dougherty, M.D. (Celanese Corporation) and Mr. William A. Danchuck (United States Steel Corporation), both testifying for CMA, noted that their companies do not contemplate destroying employee medical and exposure records (Tr. 748-749).

Based on the evidence submitted, OSHA has determined that the proposed reduction in the retention period for medical records is not justified. The long-term retention of records is necessary to provide a data base for the detection of occupational diseases that may not manifest themselves for many years after onset of exposure.

Additionally, OSHA is persuaded by evidence that modern computerized recordkeeping systems can significantly reduce long-term recordkeeping costs (Tr. 1082). Therefore, the revised Access rule retains the duration of employment plus thirty years retention requirement of the 1980 regulation. However, as discussed earlier under "employee medical record," first aid records need not be retained beyond normal practice.

OSHA's proposal to exclude the records of short-term employees was opposed by several parties (Exs. 17, 59; Tr. 118, 191, 381, 437, 767). Mr. Peter Weiner (Cal/OSHA) noted:

There are many examples of short-term exposures which have proved harmful to

human health. Former Assistant Secretary Dr. Morton Corn has noted that Kepone workers were exposed to Kepone for a maximum of 16 months and usually less, yet sustained irreversible and tragic disease as a consequence * * *.

The records of short-term employees can be extremely useful in research. For example, Dr. Roger Glass and his colleagues were able to use company-maintained records of short-term exposures of field applicators to dibromochloropropane is studying sperm count depression in these applicators. Indeed, it was found that short-term exposure created specifically significant depressions in sperm count among such workers. (Ex. 17, pp. 49-51)

Other commenters, however, supported the proposed revision (Exs. 4-5, 4-27, 4-30, 4-60, 4-66, 4-70, 4-79, 4-80, 4-82, 4-106, 4-109). The Pennzoil Company stated:

Pennzoil supports revisions to the records retention rules, especially the changes affecting transient or short-term employees (i.e., those with less than one year of service) * * *. Therefore, complex records systems need not be maintained for short-term employees, provided that they are given their records when they leave the employ. * * * we believe that the basic purpose of the rule will be served by permitting employers to hand over medical records to short-term employees. This improvement will reduce the burdens incumbent in a mandatory, extended preservation of such records, and at the same time would provide the transient employees with useful medical information for future use. (Ex. 4-30, pp. 4-5)

After considering both arguments, OSHA believes that although medical records of short-term employees may be valuable in some instances in the detection of occupational disease, this would not generally be the case. Therefore, OSHA is providing the option to employers of short-term employees to either maintain the medical records of short-term employees for the duration of employment plus 30 years, or provide these employees a copy of their medical record upon termination of employment, with no further retention required.

Providing short-term employees with copies of their medical records upon termination of employment does not eliminate all employer records of occupational injuries and illnesses for short-term employees. Under 29 CFR Part 1904, employers are required to record all occupational injuries and illnesses on the OSHA 200 Log and the OSHA 101 Supplementary Record. For short-term employees who suffered an occupational injury or illness during their employment, the OSHA 200 and OSHA 101 Forms are a record the employer maintains after the medical records are given to the employee, and can be examined if the need arises.

The short-term employee retention exemption should not reduce the overall benefits of the regulation. Having the medical record travel with the employee will better inform that employee of his or her health status and greatly assist the development of a work-life exposure history for that employee. Additionally, it is important to note that the records of long-term employees will be available for epidemiologic study, thus providing a data base for the study of substances to which short-term employees are likewise exposed.

D. Access to Records

The 1980 regulation required that requested records be made available within 15 days of the request. However, several commenters argued that situations may arise where it is not possible to comply with the fifteen day limit (Exs. 3-27, 3-28). Records may be stored at locations remote from where the request is made, or extraordinarily large numbers of records may be requested.

The proposed modification of paragraph (e)(1)(i) clarified OSHA's intent in requiring records to be made available within 15 working days. The modification, which incorporated a previous OSHA interpretation (46 FR 40490), allowed employers to exceed the 15 day limit providing that: (1) It is not reasonably possible to fulfill the request within 15 days; and (2) within the 15 day period the employer apprises the requesting party of the reasons for the delay and provides an approximation of when the requested records will be available. The CAC recommended that OSHA explicitly require the 15 day limit with regard to the employer's obligation to notify the requesting party of any reasons for delay.

Several commenters favored this revision (Exs. 4-11, 4-20, 4-29, 4-62, 4-79, 4-80, 4-82, 4-95). Air Products and Chemicals, Inc. noted:

We support the changes in paragraph (e) which recognize the impossibility of immediate access to all data. This is particularly true in multisite organizations. For example, some of the analyses and compilations of the raw data of the kind which may be most useful to an inquirer likely will not be at the plant site, but at a corporate office or another location. Thus the proposal to acknowledge the request promptly and to supply the data in a reasonable time frame is appropriate. This limitation is particularly necessary in view of the broad requirements of (the regulation). (Ex. 4-11, p. 6)

The Chemical Manufacturers Association also noted:

OSHA has appropriately taken notice of the fact that it is sometimes impossible for an

employer to make exposure and medical records available within 15 days of the request and that the assistance of the requester may be needed to locate records. Since large numbers of documents may be generated during the lengthy retention periods, and large numbers of employees may be requesting records at a given time (especially if designated representatives are entitled to access), these provisions for extension of the 15-day response period are necessary to make this rule workable. (Ex. 4-62, p. 20)

Union representatives and Cal/OSHA objected to the proposed modification of the 15-day requirement. (Exs. 4-38; Tr. 192, 383-384, 440-441, 887-888; Ex. 59, pp. 13-14). The AFL-CIO noted that "the extension, however, is open-ended, and there is no guidance provided on what constitutes just cause for an extension", and that "employers often delay transmittal of requested information as long as possible, even in the presence of a regulatory time limit" (Ex. 59, p. 13).

However, OSHA is not convinced that a return to the firm 15-day limit is warranted. The agency has provided guidance on what constitutes just cause for an extension by requiring that the cause be "reasonable." In issuing the interpretation, OSHA stated:

* * * what is a "reasonable" time will vary from situation to situation. Factors such as the location of requested records, the number of pending competing requests for records, the scope of a request and the availability of technical personnel necessary to process the request, are all relevant in determining what is a reasonable time. It is our expectation, however, that the vast majority of requests for records can be satisfied within 15 days, and the standard established this as a mandatory requirement * * *

Thus, as long as an employer is making a diligent, good faith effort to provide requested records as soon as possible, and is keeping the employee or employee representative informed of any reasons for delay, OSHA will not cite for violations of the standard. (46 FR 40490)

OSHA therefore has adopted the proposed provision in the final rule.

OSHA has also adopted the proposed paragraph (e)(1)(ii), which was added in the proposal to indicate that an employer may require of the requesting party reasonable information to assist the employer in the location or identification of requested records. This information would assist employers in locating requested records and will avoid extensive searches of records by employers to determine which specific records are covered by a request. This information is to be used only for locating records, not for the purposes of restricting or preventing access to records to which the employee is otherwise entitled. OSHA has also adopted a CAC recommendation that, in

this case, only information related to locating the record may be requested by the employer.

The final regulation also includes proposed paragraph (e)(1)(iv). This paragraph states that "in the case of an original X-ray, the employer may restrict access to on-site examination or make other suitable arrangements for the temporary loan of the X-ray." This modification, which incorporates a prior official interpretation provided to the DuPont Company (Ex. 3-65), is intended to clarify an employer's responsibility in providing access to X-rays. Under paragraph (e)(1)(iii) of the regulation the employer is required to provide an employee a copy of the record, or make copying facilities available to the requestor. However, in the case of X-rays a copy is not interchangeable with the original. Also, specialized equipment is required for copying X-rays, and this equipment is not normally available to employers (see Exs. 3-32, 3-65). This modification indicates that the copying provisions of the rule are intended to apply to the parts of the employee medical record which can be easily photocopied or reproduced, and not to X-rays. In requiring "other suitable arrangements" if on-site examination cannot be arranged, it is expected that accepted medical practices for making X-rays available to other physicians or to employees will be followed. This modification also responds to concerns that limiting access solely to on-site examination would discourage review of X-rays by employee physicians (Tr. 501; Ex. 55).

A clarifying modification was also proposed for paragraph (e)(2) concerning employee and designated representative access to records. The 1980 regulation required employers to provide an employee or designated representative access to exposure records of all employees having exposures similar to those of the subject employee. This provision was capable of overly broad interpretation, suggesting employee and designated representative rights of access to potentially large numbers of duplicative records, or records of exposures at similar workplaces at distant plants and locations. However, allowing access to exposure records of similarly exposed employees was intended only as an alternative when personally identified or workplace exposure records are inadequate to determine the amount and nature of toxic substances or harmful physical agents to which the employee is or has been exposed. The proposal therefore permitted access to exposure records of other employees only in the

absence of personal exposure or workplace records adequate to determine the nature of an employee's exposure, and only to the extent necessary to determine the subject employee's exposure adequately.

This provision incorporates a previous interpretation of the 1980 regulation published by OSHA on August 7, 1981 (46 FR 40490). The interpretation stated that:

The standard requires that employees and designated representatives be provided access to "exposure records of other employees with past or present job duties or working conditions related to or similar to those of the employee." 29 CFR 1910.20(e)(2)(i)(B). The basic purpose of this requirement is to assure that an employee may obtain access to relevant exposure information of other employees in similar working conditions. Access to this information is necessary when monitoring has been conducted on a representative or sample basis where not all employees are personally monitored. See 45 FR 35272. The obligation on the employer is to conduct a good faith, diligent search for such records, but there is no intent that the search be "heroic" or unusually disruptive to the employer's operation. For example, if access to exposure records of other employees at the requesting employee's workplace adequately indicates the nature of the employee's exposure, access to records of other workplaces need not be provided. However, if adequate exposure records do not exist at the requesting employee's workplace, but are known to exist at some other workplace of the employer where similar work is performed, access to this information must be provided.

There was no opposition to this interpretation and proposed modification presented during the rulemaking. Because it is a reasonable and cost-effective approach to achieving the purpose of the records access rule, OSHA has adopted the proposed provision for the final regulation.

E. OSHA Access

The 1980 regulation required that each employer, upon request, provide "immediate" access to records for authorized OSHA employees. The proposal substituted the word "prompt," which reflects OSHA's intent that the employer must not unduly delay providing the requested records to the requesting OSHA official, but, consistent with whatever legal protections are available to the employer, makes them available to OSHA as soon as possible. The phrase "without derogation of any constitutional and statutory rights that the employer chooses to exercise" was proposed to be added to make explicit OSHA's recognition that its access to records takes place against a

background of Fourth Amendment law, particularly as explicated in *Marshall v. Barlow's, Inc.*, 436 U.S. 307 (1978). Although issuance of the 1980 regulation was designed to promote voluntary compliance with OSHA access requests, the Agency will seek a search warrant or subpoena, as appropriate, if an employer exercises his right to require that OSHA resort to legal process before obtaining such access. As the District Court in the *Louisiana Chemical* case found, OSHA fully intended to respect these Fourth Amendment rights all along.

Mr. Peter Weiner (Cal/OSHA) commented that this modification could be misinterpreted to mean that the employer could assert rights granted by state law as taking precedence over this OSHA standard (Tr. 443). To preclude this potential misinterpretation, the proposed modification has been changed slightly to "without derogation of any rights under the Constitution or the Occupational Safety and Health Act of 1970, 29 U.S.C. 65 *et seq.*, that the employer chooses to exercise" to better convey OSHA's intent in this matter.

F. Union Access to Records

The 1980 regulation granted recognized or certified collective bargaining agents automatic status as designated representatives, without requiring individual employee authorization, for purposes of access to exposure and analysis records. The purpose of this special status was to assure that unions would have ready access to exposure information so that they could better represent the interests of their members in the occupational safety and health area. Comparable special status was not granted with respect to medical records, however, because of the significantly greater privacy interests involved. Several commenters questioned whether, under the OSH Act, unions should be treated preferentially to other designated representatives who have to obtain written authorization to establish the agency relationship. Further, commenters have also complained that providing unions unconsented access to employee exposure records enables union officials to burden employers with large-scale records access requests and is best handled through traditional collective bargaining (DuPont, Ex. 3-33).

In three 1982 decisions concerning union access to exposure and analyses records, the National Labor Relations Board (NLRB) held that unions do have a right of access to these records since the information contained in the records is presumptively relevant to the union's role as collective bargaining agent for

unit employees. *Minnesota Mining and Mfg. Co.*, 261 NLRB No. 2 (April 9, 1982); *Colgate-Palmolive, Inc.*, 261 NLRB No. 7 (April 9, 1982); *Borden Chemical, a Division of Borden, Inc.*, 261 NLRB No. 6 (April 9, 1982). These decisions were affirmed by the United States Court of Appeals for the District of Columbia Circuit on June 30, 1983.

Although no change to the union access provision was proposed, OSHA encouraged interested parties to comment on whether a modification of the existing standard either limiting or deleting the automatic status of unions as designated representatives would be appropriate in light of experience under the 1980 standard, the NLRB decisions, and considerations of safety and health.

Union officials and other participants testified against OSHA's deferring to NLRB on the issue of union access to records (Exs. 4-12, 4-24, 4-38, 4-43; Tr. 163, 186, 194, 338, 387, 422, 771, 855, 879, 889, 892, 1019, 1034, 1083). They argued that NLRB procedures take long periods of time (Tr. 194, 425); the union access rights under the 1980 regulation are greater than access rights granted by the NLRB (Tr. 339-340); the NLRB decisions are not final, but are currently under appeal (Tr. 389, 856); proper functioning of the OSH Act depends upon union access to information (Tr. 389-390, 422-423); and that the NLRB does not establish standards, but instead makes decisions on individual cases (Tr. 425).

Many commenters favored some restrictions on union access to records (Exs. 4-17, 4-19, 4-20, 4-41, 4-49, 4-59, 4-60, 4-62, 4-66, 4-68, 4-69, 4-78, 4-94, 4-95; Tr. 655, 1048) including deferral to NLRB. Evidence in the record indicates that unions have used the 1980 standard to gain access to large amounts of exposure information (Exs. 39B, 15 (App. 1); Tr. 204, 328). Comments from industry witnesses indicated general concern about the broad-based right of union representatives to demand access to all exposure records. Mr. William Danchuk, testifying on behalf of the Chemical Manufacturers Association, stated:

The provision for automatic designated representative status permits the misuse and misdirection of time and finances merely for the purposes of expediency. It permits unspecified and over-general inquiries which obligate the expenditure of enormous resources by the employer without benefitting the employee. (Tr. 658)

The issue here is whether we can accommodate in these economic times the wholesale request for information of this magnitude. (Tr. 661)

Dr. John Dougherty, M.D., also speaking for CMA, further testified:

I think before I ought to ask for any information on a plant, I'd want to know * * * something about the working conditions in the plant. I'd be looking for specifics.

I think it's an attractive idea to think that if you ask for everything and get everything and try to piece bits and pieces of everything together, you can make scientific progress, but science doesn't work that way.

Unfortunately, in improving both activity of a plant or improving the health and safety of a plant, you have to start with an idea. You have to start with a concept. (Tr. 665-666)

Mr. Ronald Lang, Executive Director of the Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA), commented similarly:

In addition, the OSHA provision is subject to potential abuse by unions as a method of harassing employers in connection with collective bargaining. A SOCMA member recently obtained a blanket request for records from a local of the International Chemical Workers Union which upon investigation proved to be made at the request of the international union * * * SOCMA has previously submitted for the record evidence that the Oil, Chemical and Atomic Workers International Union has urged its locals to submit blanket requests for records under OSHA's rule. It is noteworthy that in one of the NLRB decisions, the Board noted that OCAW's call for blanket requests for records had caused 110 locals to send identical letters to the employers of their members * * * Such blanket requests pose unnecessary burdens for employers and cannot be justified on the basis of protecting employee safety and health. OSHA should ensure that its rule is not used for the purposes of harassment by deleting its duplicative union access provision. (Ex. 4-69, pp. 5-6)

The evidence indicates that there are occupational health benefits to be gained by permitting union access to records (Tr. 157, 201, 328, 341, 347, 358, 388, 448, 494, 498, 772, 847, 858, 868, 870, 1037). The ICWU noted in their testimony 25 specific examples where union access to records benefited worker health (Ex. 15, pp. 5-15). This testimony indicates that the ICWU has used their records access rights for several valuable occupational health purposes, including formaldehyde hazard recognition and abatement, evaluation of nuisance dust exposure, evaluation of the effects of polychlorinated biphenyl (PCB) exposure, evaluation of respiratory protection programs, and evaluation of the effectiveness of eyewash facilities.

Union representatives also testified to the impracticality of obtaining individual employee consent for access to exposure records. Mr. Michael Wright of the United Steelworkers indicated three major problems in obtaining consent from individual workers:

The first is time and red tape. In some cases, for example a primary lead smelter, there may be as many as a thousand workers exposed to a serious toxic substance—lead, arsenic, something like that * * *

The second problem is the inevitable conflicts in interpretation that would arise * * * where the workers currently exposed in that area are not the ones on whom the sampling pumps were physically placed * * *

The third problem * * * is the potential for harassment * * * the OSHA Act itself recognizes the potential for harassment in its own procedures. Workers are allowed to file complaints anonymously * * * Here we have a case where a worker who complains about the potential for a problem in the area, and where we think we need air sampling results to obtain information about that problem, where that potential for harassment exists and is created by * * * this proposed change in the regulation. (Tr. 861-863)

OSHA also notes that the DC Circuit Court found in the lead case (*United Steelworkers v. Marshall* 647 F. 2d. 1189, DC Circuit 1980. Cert. denied 433 U.S. 913, 1981) that requiring specific authorization to give access to records which do not raise significant personal privacy concerns could pose insuperable and unnecessary obstacles to unions, whose access to this information is essential to their role as safety and health advocates for employees.

The issue of union access and NLRB jurisdiction was also addressed by the Court in the Louisiana Chemical Association decision. The Court found that the standard's authorization of records access by unions is not an impermissible invasion of NLRB jurisdiction because it fulfills the statutory goal of promoting healthful working conditions and only incidentally enhances the bargaining status of unions. The Court stated:

LCA argues that OSHA has overstepped its jurisdiction, asserting that the agency's principal motivation for enacting the rule was to gain a benefit for employees and unions which they have been unsuccessful in securing through the NLRB. Specifically, the benefit of records access. The court must make little of such an allegation for two reasons. First, the records access rule is a duly authorized regulation, reasonably related to its underlying statute. While the rule undoubtedly enhances the bargaining status of unions, it is plain on the record that this result was simply incidental to fulfilling the statutory goal of promoting healthful working conditions. Second, due to the requirement of the NLRA that employers provide the information to unions contemplated in this proceeding, and that fact that the Occupational Safety and Health Act was meant to supplement national labor policy, there is no indication that any impropriety has been committed by OSHA. (Ex. 49, p. 17)

However, it is also clear that unions have used the access rights granted by the 1980 regulation to request large amounts of information (Ex. 15, 39; Tr. 204, 328). Employers have expressed a great deal of concern over the potential for harassment through the broad-scale right of access, and remain skeptical with regard to the occupational health benefits derived from providing anyone with access to enormous amounts of data.

OSHA has decided that there are merits to both the labor and industry positions. The final rule continues to permit union access to the broad range of exposure information covered by the regulation without obtaining the individual authorization of employees. However, union officials are now required to state with particularity the records requested to be disclosed, and their specific occupational health need for requesting the information. In this manner, OSHA believes that the occupational health benefits of union access to records will be achieved while keeping the necessary employer burdens of providing the records to a reasonable minimum.

This approach will permit employers to better establish which records are needed to fulfill the union's stated purpose, and should reduce the burdens on employers of providing access to large amounts of information not germane to the reason for access.

G. Trade Secret Provisions

The 1980 regulation required the disclosure of a toxic substance identity even if the employer considered the identity to be a trade secret. At the same time, the rule permitted an employer to delete from requested records any trade secret information which discloses manufacturing processes, or discloses the percentage of a substance in a mixture. If the employer chose to delete such information, he was required to notify the person requesting the records that such information was deleted on trade secret grounds. If the deletion of information adversely affected the ability to determine the nature of an employee's exposure, the employer was required to provide alternative information sufficient to allow adequate exposure evaluation.

The provision requiring toxic substance identity disclosure was troublesome to the flavor and fragrance industries and chemical industries, which maintained that the preservation of trade secrets is vital to corporate profitability, and that the regulation's exclusive reliance on confidentiality agreements to protect trade secrets is

inadequate (Ex. 3-44 (FEMA); Ex. 3-35 (CSMA)).

The purpose of the regulation is to provide employees with information on the chemical hazards to which they are potentially exposed. With this information they can better ensure that they are adequately protected against these hazards. Any barrier to disclosure between an employer and his employees can only serve to limit the effectiveness of the rule. However, OSHA thought it necessary to modify the regulation so as to strike a better balance between providing employees with information necessary to maintain the benefits established by the regulation and at the same time protect legitimate trade secrets.

As stated in the preamble to the proposal, unqualified trade secret protection can act as a significant barrier to the disclosure of exposure information. A trade secret can be anything which a business in fact keeps secret from its competitors and the public, provided it is minimally novel and commercially valuable.

Restatement of Torts, § 757 comment (b) (1939); Cavitch, *Business Organizations* § 232.01 (1975). Absolute secrecy is not essential; information can be considered a trade secret even though it is divulged to employees or licensees with a "need to know," provided the holder of the secret had taken steps to restrict unnecessary access to, and the use of, this privileged knowledge. Cavitch, *supra*, § 232.01(1). Trade secret protection entitles the holder of a trade secret to its commercial exploitation and to certain judicial remedies for a breach of confidence or dispossession of the trade secret through improper or unethical means (industrial theft, bribery, spying, etc.). The Supreme Court had identified the maintenance of standards of commercial ethics and the encouragement of invention as the broadly stated policies behind trade secret law. *Kewanee Oil Co. v. Bicron*, 416 U.S. 470 (1974). Unlike patents or copyrights, however, there is no comprehensive Federal law of trade secrets, as it is basically a right created by the States.

The conflict between access to exposure and medical records and trade secret interests arises whenever an employer is asked to reveal information such as the identity of a chemical which the employer considers to be a trade secret. While most trade secrets relate to process information or formula or percentage mixture information, none of which is required to be disclosed by the standard, the identity of a chemical or mixture ingredient may itself be

considered a trade secret if its existence is unknown to a competitor (e.g. certain intermediates, catalysts) or cannot practically be "reverse engineered" by analytical techniques.

The same identity information, however, may be essential to the detection of occupational disease. Since exact chemical identity is the passkey to the scientific literature, this information must be available to an industrial hygienist or other health professional who is evaluating the hazards associated with a chemical. Likewise, it must be available to an epidemiologist who is attempting to link patterns of disease with exposure to a particular chemical and to a treating or consulting physician or health nurse who suspects that a patient's health problems may be the result of chemical exposure. While not every employee needs the chemical identity, as distinct from hazardous effects and precautionary information, at all times, a primary goal of the regulation is to encourage employees to seek out advice and information about the chemicals in their workplaces. For this to happen effectively, they need to know the identities of the toxic substances they are exposed to.

In attempting to accommodate the competing interests between chemical identity disclosure and trade secret protection, OSHA also took into account the existence of several factors which contribute to the regulatory dilemma. First, a chemical is a trade secret in some contexts but not others, and it may be equally hazardous in either event. Second, whether or not a chemical's identity is a trade secret is basically a matter of an employer's self-definition; therefore, permitting non-disclosure of trade secret identity without any offsetting obligation could result in over classification of chemicals as trade secrets.

Third, the value of a trade secret, once lost, cannot be fully recaptured, although private remedies for unauthorized disclosures can result in the assessment of monetary damages and injunctive relief. And fourth, OSHA possesses neither the capacity nor expertise to act as a screen of all information which an employer is to disclose to employees and claims to be trade secret.

To accommodate these competing interests, OSHA initially proposed (August 7, 1981; 46 FR 40492) to strengthen the current trade secret protection provisions by permitting liquidated damages clauses in confidentiality agreements entered into by designated representatives. That

proposal was later merged into the current rulemaking.

OSHA further proposed other modifications of the trade secret provisions to make them more protective of trade secrets. In general, these proposed provisions would have limited the requirements of disclosure to only certain categories of highly toxic chemicals (e.g., carcinogens) and make the confidentiality agreement authorization a more meaningful protection. More particularly, the proposal included a provision which would permit the employer to withhold precise chemical identity information of hazardous chemicals which constitute a trade secret, unless the chemical is a carcinogen, mutagen, teratogen, or a cause of significant irreversible damage to human organs or body systems and there is a need to know the precise chemical name. Where trade secret identities were withheld, the proposal required the employer to:

(1) Be capable of substantiating that it is a trade secret;

(2) Identify the chemical by a generic chemical classification;

(3) Provide all other information on the properties and effects of the chemical; and

(4) In any event, release on a confidential basis the chemical identity to a treating or consulting physician who has stated in writing (except in an emergency) that a patient's health problems may be the result of occupational exposure. Since the employee's personal or treating physician may not be familiar with the toxic effects of workplace chemicals, the CAC recommended that trade secrets also be mandatorily disclosed to consulting physicians assisting in the treatment of disorders of suspect occupational causation. OSHA adopted this recommendation.

The 1980 rule permitted the employer to condition access to trade secret information by employees or their designated representatives upon the signing of a confidentiality agreement. The proposal strengthened the agreement provision by allowing that the agreement restrict use of the information to health purposes, prohibit redisclosure of the information to consulting physician, and provide for compensation or other legally appropriate relief for competitive harm which may result from a breach of the agreement. The terms of such an agreement would be worked out between the employer and the requesting party and be governed by the applicable state law. OSHA intended to

be neutral on the kinds of damages provisions that may be included.

At the hearings, Dr. Leonard Vance stated that the trade secret issue would be decided on evidence in the combined records of the hazard communication and records access rulemakings (Tr. 25). A thorough analysis of evidence concerning the trade secret issue in these combined records is found in the preamble to the Hazard Communication standard (48 FR 53280).

OSHA concluded from this analysis that in certain instances trade secret disclosure is warranted to protect the safety and health of employees. However, OSHA also recognizes that specific chemical identity information can constitute a *bona fide* trade secret, and thus has included in the final regulation provisions to protect such an identity while providing for the proper protection of exposed employees. This is accomplished by providing for limited trade secret disclosure to health professionals, employees and designated representatives under prescribed conditions of need and confidentiality.

The term "specific chemical identity" is used to describe the trade secret information being discussed. The term refers to the chemical name, the Chemical Abstracts Service (CAS) Registry Number, or any other specific information which reveals the precise chemical designation. It does not include common names.

The proposed rule did not include a definition for the term "trade secret", although OSHA has stated that it considers the definition derived from the Restatement of Torts to be the appropriate one. In response to comments suggesting that the definition be explicitly stated in the final rule, OSHA has added a definition to clarify what the Agency considers to be a trade secret for purposes of this regulation. This definition is the same as that included in the Hazard Communication standard.

Given that it is recognized that the chemical identification of a chemical may be a trade secret, the rule establishes an information disclosure scheme which requires the release of essential hazard information, and defines the terms under which the chemical identity must also be released.

In general, the regulation requires the disclosure of specific chemical identities, but permits the employer to withhold this information from disclosable records if certain conditions can be met: (1) The employer can support the claim that it is a trade secret; (2) all other information concerning the toxic substance is

disclosed as required; (3) the employer indicates that the specific chemical identity is being withheld as a trade secret; and (4) the chemical name is made available to health professionals, employees and designated representatives under certain specified situations.

In the case of a medical emergency, the employer must immediately disclose the identity of a toxic substance to a treating physician or nurse when it is needed for proper emergency or first aid treatment. As soon as circumstances permit, however, the employer may obtain a written statement of need and a confidentiality agreement as provided for above.

In non-emergency situations, employers are required to disclose the withheld specific chemical identity to employees and designated representatives, and to health professionals providing medical or other occupational health services to exposed employees if certain conditions are met.

A request for trade secret information must be in writing, and must describe with reasonable detail the medical or occupational health need for the information. To be considered a medical or occupational health need for purposes of this regulation, the health professional must be planning to use the specific chemical identity information for one or more of the following activities.

1. To assess the hazards of the chemicals to which the employees will be exposed.
2. To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels.
3. To assess or conduct pre-assignment or periodic medical surveillance of exposed employees.
4. To provide medical treatment to exposed employees.
5. To select appropriate personal protective equipment for exposed employees.
6. To assess engineering controls or other protective measures for exposed employees.
7. To conduct studies to determine the health effects of exposure.

It should be noted that for purposes of this regulation, exposure includes potential, as well as current, exposure situations. Thus the health professional, employee or designated representative will be able to obtain the necessary information prior to actual exposure, and preventive measures, if appropriate, can be implemented to avoid the occurrence of adverse health effects.

In addition, the written request must also explain in detail why the disclosure of the specific chemical identity is

essential to providing the occupational health services, and why disclosure of the following types of information would not satisfy the requesting parties need:

1. Properties and effects of the chemical.
2. Measures for controlling workers' exposure to the chemical.
3. Methods of monitoring and analyzing worker exposure to the chemical.
4. Methods of diagnosing and treating harmful exposures to the chemical.

OSHA anticipates that in many situations the alternative information will be sufficient to satisfy the health professional's needs.

The request for the information must further provide a description of the procedures to be used to protect the confidentiality of the information. An agreement not to use the information for any purpose other than the health need asserted or to release it under any circumstances other than to OSHA must also be included, and signed by the requesting party as well as the employer or contractor of the health professional or designated representative. The requirement that the employer or contractor of the health professional or designated representative be a co-signatory to the agreement applies equally regardless of whether the health professional or designated representative is providing occupational health or medical services to a labor organization, or individual employees, and regardless of whether the health professional or designated representative is being paid for his services. This makes explicit that both the principal and the agent are legally responsible for compliance with the agreement, although only the health professional or designated representative may actually have access to the specific chemical identity information.

The provisions of the confidentiality agreement may not include requiring the posting of a penalty bond. It may restrict use of the information to the purposes indicated in the statement of need, prohibit disclosure to anyone other than OSHA who have not signed an agreement, and provide for appropriate legal remedies, including stipulation of a reasonable pre-estimate of likely damages. Nothing in the regulation is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

If the health professional, employee or designated representative decides there is a need to disclose the information to OSHA, the employer who provided the information must be informed by the

requesting party prior to or at the same time as such disclosure.

If the employer denies the written request for information, the denial must also be in writing, and be provided within thirty days of the request. The denial must provide evidence to support the claim that the chemical identity is a trade secret, state the specific reasons why the request is being denied, and explain in detail how alternative information may satisfy the occupational health need without revealing the chemical identity.

The requesting health professional, employee or designated representative who still needs the information may then refer the matter to OSHA for consideration. The original request, as well as the written denial, must be provided to OSHA at the time of this referral. OSHA will review these documents to determine whether the employer has supported the claim that the chemical identity is a trade secret, and that the health professional has demonstrated a medical or occupational health need for the information, as well as adequate means to protect the confidentiality of the information.

If OSHA determines that the chemical identity is not a trade secret, it is not protected by the regulation and the employer will be subject to citation. Similarly, the employer will be subject to citation if the specific chemical identity is a trade secret, but the requesting party has demonstrated a medical or occupational health need, executed a confidentiality agreement, and has shown adequate means for complying with the terms of the confidentiality agreement. Abatement of the citation will most likely be to divulge the specific chemical identity subject to the confidentiality agreement. However, consistent with the power given to the Secretary in section 15 of the Act, if the employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon disclosure as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the employer. It is contemplated that the Assistant Secretary would personally review and approve such orders, limitations or conditions. The employer is required to divulge to the Assistant Secretary or designee any information required under this regulation. However, the employer may

claim trade secret status at the time the information is provided, and the Assistant Secretary will make the necessary arrangements to ensure protection of such trade secrets, in accordance with the provisions of section 15 of the Act.

The amended trade secrets provisions of this regulation are identical to those for the Hazard Communication standard. OSHA believes that this is an important benefit of the amended provisions since the purposes and policies of both regulations, disclosure of chemical identities, knowledge of hazards and means for health protection, and trade secret provisions are similar. In addition, it is administratively convenient both to the public and OSHA for the provisions to be similar. There are two differences between OSHA's Hazard Communication standard and this rule with regard to trade secret disclosure. First, the Hazard Communication standard presently applies only to chemical manufacturers, distributors and importers, and to all employers in SIC Codes 20 through 39 (Division D, Standard Industrial Classification Manual). The records access rule, on the other hand, applies broadly to all employers in general industry, construction and maritime.

Second, the Hazard Communication standard contemplates disclosure to health professionals who may represent employers and employees other than those of the trade secret holder (i.e., "downstream" disclosure). The Records Access rule does not provide "downstream" employees or designated representatives access rights to trade secret information.

The decision to retain for employee and designated representative as well as health professional access to trade secret chemical identities in the final Records Access rule in further supported by the recent *Supreme Court* decision, *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, et al. The Court held that whenever a federal agency contemplates revoking or modifying an existing rule, it shoulders the same burden to justify its decision to revoke or modify the standard as if it were issuing it in the first place.

As noted above, the 1980 regulation provided for unrestricted employee and designated representative access to trade secret chemical identities conditioned solely upon signing a confidentiality agreement. Insufficient evidence was presented indicating the employee and designated representative access was unfairly jeopardizing

employees' trade secrets. Therefore, the evidence does not justify restricting access to trade secrets to physicians or health professionals as contemplated by the proposal and advocated by several commenters.

However, OSHA has decided that *bona fide* trade secrets do deserve greater protection than provided in the 1980 regulation, and has therefore established the more stringent access procedures noted above.

H. X-ray Microfilming

Paragraph (d)(2) of the 1980 regulation stated that "nothing in this section is intended to mandate the form, manner, or process by which an employer preserves a record so long as the information contained in the record is preserved and retrievable, except that X-ray films shall be preserved in their original state." The X-ray preservation requirement resulted from a finding by OSHA at that time that the diagnostic detail of certain X-rays could be lost when the original X-ray is microfilmed. X-rays related to a possible diagnosis of pneumoconiosis are particularly susceptible to this loss of detail. Pneumoconiosis is the accumulation of dust in the lungs and the tissue reaction to its presence. Inhalation of the dusts of coal, aluminum, beryllium, asbestos, aluminum oxide, silica, hematite (iron oxide), talc, kaolin, mica and cement are commonly associated with the development of pneumoconiosis. The earliest diagnostic indications of pneumoconiosis are often barely perceptible changes in the chest X-ray.

Following promulgation of the 1980 rule, OSHA received comments from a number of interested parties concerning the requirement that X-rays be kept in their original state (Exs. 3-3, 3-5, 3-8, 3-10, 3-15). They argued in general that modern microfilm processes can reduce X-rays for storage without an appreciable loss of diagnostic detail. Also, they maintained that microfilm storage is preferable for long-term X-ray preservation due to the fact that microfilm processes use archival materials which are specially resistant to fading and decay. By contrast, original X-rays can fade and crack over time to the possible detriment of their diagnostic value.

In response, OSHA proposed allowing the microfilm storage of X-rays if performed under the supervision of a licensed radiologist who is a diplomate of the American Board of Radiology. In addition, for the microfilm storage of a chest X-ray where the subject worker has been exposed to a substance known to cause pneumoconiosis, the proposal

required that the supervising radiologist consult with and obtain the written approval of the microfilm process from both: (a) A licensed physician who is a diplomate of the American Board of Internal Medicine certified in the subspecialty of pulmonary disease, and (b) a "B" reader certified by the National Institute for Occupational Safety and Health (NIOSH). OSHA stated in the proposal its belief that the microfilming of chest X-rays of workers exposed to toxic substances known to cause pneumoconiosis deserves separate consideration. In this case extremely fine shadings of image density are often required for proper analysis and diagnosis. Therefore there is an increased risk that diagnostic detail could be lost if current standard microfilm processes are used.

At the public hearing, Dr. William S. Cole, M.D., appeared on behalf of the Task Force on Pneumoconiosis of the American College of Radiology. He testified that the Task Force recommends that OSHA not permit the microfilming or other minification of chest X-rays, but could allow the minification of other X-rays provided that any original and subsequent interpretations of the X-rays are also microfilmed. Dr. Cole testified that:

The Task Force advanced three compelling reasons against optical minification techniques.

1. A loss of image detail inherent in any copying method;
2. An absence of medically accepted standards for minification quality; and
3. The presence of unavoidable variables introduced into viewing by dependence upon projectors and screens. (Tr. 254)

Dr. Cole summarized the Task Force recommendations as follows:

1. Require that chest radiographs be retained in their original form along with copies of original and subsequent interpretations;
2. Allow the copying of other radiologic images, subject to this first regulation, by any optical or electronic copying method acceptable to the institution or organization retaining custody, but only under the supervision of a radiologist to ensure that integrity of the image;
3. Expand the definition of a radiologist to include a physician appropriately credentialed by the American Osteopathic Board of Radiology; and
4. Require that the written interpretive reports accompanying the images also be copied and retained. (Tr. 256)

NIOSH and the American Lung Association also took the position that the microfilming of chest X-rays should not be permitted (Ex. 4-48; Tr. 108).

Several commenters opposed the Task Force recommendations (Ex. 4-4, 4-6, 4-60). In opposing the ban on microfilming

X-rays, Mr. Stephen Fisher (Radiological Systems Microfilm Association) stated in his post-hearing comments that:

If in fact OSHA adopts a ruling which disallows the microfilming of chest x-rays * * * OSHA will have done a great disservice to the people that they are trying to protect—the potentially exposed industrial worker. His radiographs will then be left to deteriorate beyond the point of any medical value. (Ex. 53, p. 1)

However, when questioned about the potential degradation of X-rays, Dr. Cole stated:

The old acetate emulsions that were used years ago did degrade. But the ones that are being made available today, I haven't seen it and I have seen films that are 20, 25 years old and I have not seen any degradation of the image, no. (Tr. 262)

Based primarily on the testimony of Dr. Cole and the American College of Radiology, OSHA has decided to permit the microfilming of all X-rays except for chest X-rays, which must continue to be retained in their original form. However, all permitted X-ray microfilming must be performed in accordance with generally accepted medical practice.

I. Duty to Inform Employees

The 1980 regulation required in paragraph (g)(1) that "upon an employee's first entering into employment, and at least annually thereafter, each employer shall inform employees exposed to toxic substances or harmful physical agents of (the regulation)." "Employees" was defined under paragraph (c)(4) as including former employees. Therefore the regulation was susceptible to the interpretation that employers were required to inform former employees of the provisions of the regulation (see Ex. 3-62). This was not OSHA's original intent. To clarify OSHA's intent, the proposal inserted the word "current" into paragraphs (g)(1) and (g)(2) to indicate that the employer's notification responsibility extends only to employees currently employed. No comments in opposition to this proposed modification were received and it has been adopted for the final rule.

J. Federal Employees

This regulation applies to Federal agencies under Executive Order 12196. However, the retention of records of Federal employees is regulated by the National Archives and Records Service, General Services Administration (GSA) under 44 U.S.C. 3303a (Ex. 57), which supersedes the OSHA access standard. GSA Bulletin FPMR B-117 (Ex. 57, Att. 1) contains guidelines designed to ensure agency compliance with the records

disposition provisions of the Federal Records Act.

IV. Regulatory Impact Assessment and Regulatory Flexibility Certification

A. Introduction

Executive Order 12291 (46 FR 13197, February 19, 1981) provides for the development of a "regulatory analysis" when a regulation has major economic consequences for the general economy, individual industries, geographical regions or levels of government. E.O. 12291 replaced Executive Order 12044, which also had provided for regulatory analyses of major standards.

OSHA issued the original access to exposure and medical records rule on May 23, 1980 (45 FR 35212-35303). At that time, OSHA concluded that this regulation would impose compliance costs below the Executive Order 12044 threshold of \$100 million in annual costs for the economy. This assessment was based on the determination that the rule would not require the creation of new records or reports, nor would it impose any additional environmental or employee monitoring or medical surveillance requirements. Finally, the rule was performance-oriented, in that the content of exposure and medical records was left to the employer. As a result, OSHA determined that a formal regulatory analysis under E.O. 12044 was unnecessary.

On July 13, 1982, OSHA issued the proposed modifications to the access to employee exposure and medical records regulation (47 FR 30420-30438).

At that time OSHA concluded that the proposed revisions would further lower compliance costs while causing no significant impact on competition, productivity, domestic investment, employment, innovation, or foreign competition—the criteria required to be considered under the current Executive Order. For these reasons, the proposed regulation was not considered major under the new E.O. 12291.

The final regulation will also impose less than \$100 million in annual costs to the economy. This is because the final rule leaves intact most of the provisions of the current rule. The sections of the final regulation that differ from the current regulation (e.g., allowing the minification of X-rays other than chest X-rays, providing greater trade secret protection, and excluding first aid records, and elimination of record retention for short-term employees) will reduce the costs of the current rule with no diminution of the rule's benefits.

The final regulation will also not have a disproportionate economic impact on

small entities. Likewise, the Regulatory Flexibility Act of 1980 (Pub. L. 96-353, 94 Stat. 1164 (5. U.S.C. 601 *et seq.*)) requires that OSHA give special consideration to the economic impact of the proposed rule on small entities. Such consideration should include a description of regulatory alternatives and estimates of the impacts of reporting, recordkeeping, and other compliance requirements in order to minimize any significant impact of the proposed regulation on small entities.

B. Summary of Costs

Several provisions of the modified rule will significantly reduce compliance costs of the regulation when compared to the 1980 rule. Major cost-saving modifications include: (1) Exempting medical records of short-term employees from the regulation's long-term retention requirements; (2) exempting most first aid records from the regulation's retention requirements; (3) modifying the broad-based rights of designated representatives to gain unconsented access to employee exposure records; and (4) modifying the absolute prohibition on the microfilm storage of employee X-rays.

Exempting the medical records of short-term employees from the long-term preservation requirements of the regulation should result in significant savings. Based on employment levels in the affected industries and on the National Institute for Occupational Safety and Health (NIOSH) National Occupational Health Survey OSHA has estimated that about 10.1 million medical records would be generated annually. Of those 10.1 million medical records, approximately 20 percent (2 million) medical records per year would be exempted from the requirement to retain medical records for the duration of employment plus thirty years. These records would be given to the employee, enabling the construction of a work life medical history for that employee.

Records of first aid treatment for minor scratches, cuts, burns, splinters, etc. have also been exempted from the regulation's retention requirements. OSHA has not estimated the volume of records covered by this exemption. Testimony of construction industry employers indicates that savings would be significant since the majority of medical records generated in this industry are first aid records.

The modified rule also requires designated representatives seeking unconsented access to employee exposure records to state with reasonable particularity the records requested, the specific occupational health need for these records. This

provision would permit employers to respond to a request with only those records needed. This provision therefore provides a specific alternative to blanket requests for records far in excess of what is needed to satisfy a particular occupational health concern.

Finally, the regulation permits the microfilm storage of all employee X-rays except chest X-rays. This provision reduces compliance costs by allowing less expensive storage of X-rays other than chest X-rays.

OSHA estimated in 1980 that the costs of the records access regulation would not exceed \$100 million annually. This estimate was little contested in the rulemaking record. OSHA's review of the cost-saving provisions of the modified rule supports the conclusion that compliance costs with the modified rule will also be less than \$100 million annually. No modifications have been made to the rule which would increase compliance costs.

C. Summary of Benefits

Employee medical and exposure records are potentially important to the detection, treatment, and prevention of occupational disease. If workers and their representatives are to play a meaningful role in their own health management they must have an opportunity to review their medical and exposure records. Access will enable workers and their personal physicians to uncover patterns of health impairment and disease. Access to exposure and medical records and long-term preservation of these records may also facilitate formal occupational health research on substances for which little scientific health data presently exist.

The trade secret modifications allow employers adequate trade secret protections while providing requesting parties access to the necessary information without the requirement for bonding and liquidated damages. Also, the final rule will provide employee protection equivalent to that provided in the 1980 standard while lowering costs to employers.

D. Regulatory Flexibility Analysis

The impact of the 1980 access rule on small businesses was determined to be insignificant. According to the 1972 NOH survey, only 1.4 percent of all small firms (8-250 employees) regularly monitored workplace environmental conditions. Only 2.3 percent of these firms had a formally established health unit. Approximately one-half of all small firms collected some preemployment health information on new employees, but less than 10 percent provided

periodic medical exams to workers. The U.S. Department of Commerce County Business Patterns 1977 (Ex. 81) estimates that more than 68 percent of all employees work in firms of less than 250 employees.

To summarize the results of the NOH survey as it pertains to small entities.

(1) Most small firms do not collect health information beyond that on new employees.

(2) Few small firms provide formal or periodic health care, and

(3) Few small firms regularly monitor workplace environmental conditions.

Although these percentages cited above have probably increased in the last decade, the vast majority of small entities will not be affected by the regulation because medical surveillance and environmental monitoring are not required. The regulation does require that firms creating medical and exposure records must keep them and grant employee access to them. Since few small entities create or store such records, the economic impact of the regulation on these firms is small.

List of Subjects in 29 CFR Part 1910

Occupational safety and health, Health, Health records.

V. Authority And Signature

This document was prepared under the direction of John A. Pendergrass, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210. Pursuant to sections 8(c) and 8(g) of the Occupational Safety and Health Act of 1970.

Pursuant to 29 U.S.C., 657; 29 CFR Part 1911; and Secretary of Labor's Order No. 9-83 (48 FR 35736), 29 CFR 1910 is amended as set forth below.

Signed at Washington, DC this 20th day of September, 1988.

John A. Pendergrass,
Assistant Secretary for Occupational Safety and Health.

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended as follows:

PART 1910—[AMENDED]

1. The authority citation for Subpart C of Part 1910 is revised to read as set forth below:

Authority: Section 8 of the Occupational Safety and Health Act, 29 U.S.C. 657; Secretary of Labor's Order No. 9-83 (48 FR 35736) and 29 CFR Part 1911.

2. Section 1910.20 is revised to read as follows:

§ 1910.20 Access to employee exposure and medical records.

(a) *Purpose.* The purpose of this section is to provide employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act. Access by employees, their representatives, and the Assistant Secretary is necessary to yield both direct and indirect improvements in the detection, treatment, and prevention of occupational disease. Each employer is responsible for assuring compliance with this section, but the activities involved in complying with the access to medical records provisions can be carried out, on behalf of the employer, by the physician or other health care personnel in charge of employee medical records. Except as expressly provided, nothing in this section is intended to affect existing legal and ethical obligations concerning the maintenance and confidentiality of employee medical information, the duty to disclose information to a patient/employee or any other aspect of the medical-care relationship, or affect existing legal obligations concerning the protection of trade secret information.

(b) *Scope and application.* (1) This section applies to each general industry, maritime, and construction employer who makes, maintains, contracts for, or has access to employee exposure or medical records, or analyses thereof, pertaining to employees exposed to toxic substances or harmful physical agents.

(2) This section applies to all employee exposure and medical records, and analyses thereof, of such employees, whether or not the records are mandated by specific occupational safety and health standards.

(3) This section applies to all employee exposure and medical records, and analyses thereof, made or maintained in any manner, including on an in-house of contractual (e.g., fee-for-service) basis. Each employer shall assure that the preservation and access requirements of this section are complied with regardless of the manner in which the records are made or maintained.

(c) *Definitions.* (1) "Access" means the right and opportunity to examine and copy.

(2) "Analysis using exposure or medical records" means any compilation of data or any statistical study based at least in part on information collected from individual

employee exposure or medical records or information collected from health insurance claims records, provided that either the analysis has been reported to the employer or no further work is currently being done by the person responsible for preparing the analysis.

(3) "Designated representative" means any individual or organization to whom an employee gives written authorization to exercise a right of access. For the purposes of access to employee exposure records and analyses using exposure or medical records, a recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

(4) "Employee" means a current employee, a former employee, or an employee being assigned or transferred to work where there will be exposure to toxic substances or harmful physical agents. In the case of a deceased or legally incapacitated employee, the employee's legal representative may directly exercise all the employee's rights under this section.

(5) "Employee exposure record" means a record containing any of the following kinds of information:

(i) Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained;

(ii) Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc.) but not including results which assess the biological effect of a substance or agent or which assess an employee's use of alcohol or drugs;

(iii) Material safety data sheets indicating that the material may pose a hazard to human health; or

(iv) In the absence of the above, a chemical inventory or any other record which reveals where and when used and the identity (e.g., chemical, common, or trade name) of a toxic substance or harmful physical agent.

(6)(i) "Employee medical record" means a record concerning the health status of an employee which is made or maintained by a physician, nurse, or other health care personnel or technician, including:

(A) Medical and employment questionnaires or histories (including job description and occupational exposures),

(B) The results of medical examinations (pre-employment, pre-assignment, periodic, or episodic) and laboratory tests (including chest and other X-ray examinations taken for the purposes of establishing a base-line or detecting occupational illness, and all biological monitoring not defined as an "employee exposure record"),

(C) Medical opinions, diagnoses, progress notes, and recommendations,

(D) First aid records,

(E) Descriptions of treatments and prescriptions, and

(F) Employee medical complaints.

(ii) "Employee medical record" does not include medical information in the form of:

(A) Physical specimens (e.g., blood or urine samples) which are routinely discarded as a part of normal medical practice; or

(B) Records concerning health insurance claims if maintained separately from the employer's medical program and its records, and not accessible to the employer by employee name or other direct personal identifier (e.g., social security number, payroll number, etc.); or

(C) Records created solely in preparation for litigation which are privileged from discovery under the applicable rules of procedure or evidence; or

(D) Records concerning voluntary employee assistance programs (alcohol, drug abuse, or personal counseling programs) if maintained separately from the employer's medical program and its records.

(7) "Employer" means a current employer, a former employer, or a successor employer.

(8) "Exposure" or "exposed" means that an employee is subjected to a toxic substance or harmful physical agent in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes past exposure and potential (e.g., accidental or possible) exposure, but does not include situations where the employer can demonstrate that the toxic substance or harmful physical agent is not used, handled, stored, generated, or present in the workplace in any manner different from typical non-occupational situations.

(9) "Health Professional" means a physician, occupational health nurse, industrial hygienist, toxicologist, or epidemiologist, providing medical or other occupational health services to exposed employees.

(10) "Record" means any item, collection, or grouping of information regardless of the form or process by

which it is maintained (e.g., paper document, microfiche, microfilm, X-ray film, or automated data processing).

(11) "Specific chemical identity" means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

(12)(i) "Specific written consent" means a written authorization containing the following:

(A) The name and signature of the employee authorizing the release of medical information,

(B) The date of the written authorization,

(C) The name of the individual or organization that is authorized to release the medical information,

(D) The name of the designated representative (individual or organization) that is authorized to receive the released information,

(E) A general description of the medical information that is authorized to be released,

(F) A general description of the purpose for the release of the medical information, and

(G) A date or condition upon which the written authorization will expire (if less than one year).

(ii) A written authorization does not operate to authorize the release of medical information not in existence on the date of written authorization, unless the release of future information is expressly authorized, and does not operate for more than one year from the date of written authorization.

(iii) A written authorization may be revoked in writing prospectively at any time.

(13) "Toxic substance or harmful physical agent" means any chemical substance, biological agent (bacteria, virus, fungus, etc.), or physical stress (noise, heat, cold, vibration, repetitive motion, ionizing and non-ionizing radiation, hypo- or hyperbaric pressure, etc.) which:

(i) Is listed in the least printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS); or

(ii) Has yielded positive evidence of an acute or chronic health hazard in testing conducted by, or known to, the employer; or

(iii) Is the subject of a material safety data sheet kept by or known to the employer indicating that the material may pose a hazard to human health.

(14) "Trade secret" means any confidential formula, pattern, process, device, or information or compilation of information that is used in an

employer's business and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it.

(d) *Preservation of records.* (1) Unless a specific occupational safety and health standard provides a different period of time, each employer shall assure the preservation and retention of records as follows:

(i) *Employee medical records.* The medical record for each employee shall be preserved and maintained for at least the duration of employment plus thirty (30) years, except that the following types of records need not be retained for any specified period:

(A) Health insurance claims records maintained separately from the employer's medical program and its records,

(B) First aid records (not including medical histories) of one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters, and the like which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job, if made on-site by a non-physician and if maintained separately from the employer's medical program and its records, and

(C) The medical records of employees who have worked for less than (1) year for the employer need not be retained beyond the term of employment if they are provided to the employee upon the termination of employment.

(ii) *Employee exposure records.* Each employee exposure record shall be preserved and maintained for at least thirty (30) years, except that:

(A) Background data to environmental (workplace) monitoring or measuring, such as laboratory reports and worksheets, need only be retained for one (1) year as long as the sampling results, the collection methodology (sampling plan), a description of the analytical and mathematical methods used, and a summary of other background data relevant to interpretation of the results obtained, are retained for at least thirty (30) years; and

(B) Material safety data sheets and paragraph (c)(5)(iv) records concerning the identity of a substance or agent need not be retained for any specified period as long as some record of the identity (chemical name if known) of the substance or agent, where it was used, and when it was used is retained for at least thirty (30) years;¹ and

¹ Material safety data sheets must be kept for those chemicals currently in use that are effected by the Hazard Communication Standard in accordance with 29 CFR 1910.1200(g).

(C) Biological monitoring results designated as exposure records by specific occupational safety and health standards shall be preserved and maintained as required by the specific standard.

(iii) *Analyses using exposure or medical records.* Each analysis using exposure or medical records shall be preserved and maintained for at least thirty (30) years.

(2) Nothing in this section is intended to mandate the form, manner, or process by which an employer preserves a record as long as the information contained in the record is preserved and retrievable, except that chest X-ray films shall be preserved in their original state.

(e) *Access to records.*—(1) *General.* (i) Whenever an employee or designated representative requests access to a record, the employer shall assure that access is provided in a reasonable time, place, and manner. If the employer cannot reasonably provide access to the record within fifteen (15) working days, the employer shall within the fifteen (15) working days apprise the employee or designated representative requesting the record of the reason for the delay and the earliest date when the record can be made available.

(ii) The employer may require of the requester only such information as should be readily known to the requester and which may be necessary to locate or identify the records being requested (e.g. dates and locations where the employee worked during the time period in question).

(iii) Whenever an employee or designated representative requests a copy of a record, the employer shall assure that either:

(A) A copy of the record is provided without cost to the employee or representative,

(B) The necessary mechanical copying facilities (e.g., photocopying) are made available without cost to the employee or representative for copying the record, or

(C) The record is loaned to the employee or representative for a reasonable time to enable a copy to be made.

(iv) In the case of an original X-ray, the employer may restrict access to on-site examination or make other suitable arrangements for the temporary loan of the X-ray.

(v) Whenever a record has been previously provided without cost to an employee or designated representative, the employer may charge reasonable, non-discriminatory administrative costs (i.e., search and copying expenses but not including overhead expenses) for a

request by the employee or designated representative for additional copies of the record, except that

(A) An employer shall not charge for an initial request for a copy of new information that has been added to a record which was previously provided; and

(B) An employer shall not charge for an initial request by a recognized or certified collective bargaining agent for a copy of an employee exposure record or an analysis using exposure or medical records.

(vi) Nothing in this section is intended to preclude employees and collective bargaining agents from collectively bargaining to obtain access to information in addition to that available under this section.

(2) *Employee and designated representative access*—(i) *Employee exposure records.* (A) Except as limited by paragraph (f) of this section, each employer shall, upon request, assure the access to each employee and designated representative to employee exposure records relevant to the employee. For the purpose of this section, an exposure record relevant to the employee consists of:

(1) A record which measures or monitors the amount of a toxic substance or harmful physical agent to which the employee is or has been exposed;

(2) In the absence of such directly relevant records, such records of other employees with past or present job duties or working conditions related to or similar to those of the employee to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents to which the employee is or has been subjected, and

(3) Exposure records to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents at workplaces or under working conditions to which the employee is being assigned or transferred.

(B) Requests by designated representatives for unconsented access to employee exposure records shall be in writing and shall specify with reasonable particularity:

(1) The records requested to be disclosed; and

(2) The occupational health need for gaining access to these records.

(ii) *Employee medical records.* (A) Each employer shall, upon request, assure the access of each employee to employee medical records of which the employee is the subject, except as provided in paragraph (e)(2)(ii)(D) of this section.

(B) Each employer shall, upon request, assure the access of each designated representative to the employee medical records of any employee who has given the designated representative specific written consent. Appendix A to this section contains a sample form which may be used to establish specific written consent for access to employee medical records.

(C) Whenever access to employee medical records is requested, a physician representing the employer may recommend that the employee or designated representative:

(1) Consult with the physician for the purposes of reviewing and discussing the records requested,

(2) Accept a summary of material facts and opinions in lieu of the records requested, or

(3) Accept release of the requested records only to a physician or other designated representative.

(D) Whenever an employee requests access to his or her employee medical records, and a physician representing the employer believes that direct employee access to information contained in the records regarding a specific diagnosis of a terminal illness or a psychiatric condition could be detrimental to the employee's health, the employer may inform the employee that access will only be provided to a designated representative of the employee having specific written consent, and deny the employee's request for direct access to this information only. Where a designated representative with specific written consent requests access to information so withheld, the employer shall assure the access of the designated representative to this information, even when it is known that the designated representative will give the information to the employee.

(E) A physician, nurse, or other responsible health care personnel maintaining medical records may delete from requested medical records the identity of a family member, personal friend, or fellow employee who has provided confidential information concerning an employee's health status.

(iii) *Analyses using exposure or medical records.* (A) Each employee shall, upon request, assure the access of each employee and designated representative to each analysis using exposure or medical records concerning the employee's working conditions or workplace.

(B) Whenever access is requested to an analysis which reports the contents of employee medical records by either direct identifier (name, address, social security number, payroll number, etc.) or

by information which could reasonably be used under the circumstances indirectly to identify specific employees (exact age, height, weight, race, sex, date of initial employment, job title, etc.), the employer shall assure that personal identifiers are removed before access is provided. If the employer can demonstrate that removal of personal identifiers from an analysis is not feasible, access to the personally identifiable portions of the analysis need not be provided.

(3) *OSHA access.* (i) Each employer shall, upon request, and without derogation of any rights under the Constitution or the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*, that the employer chooses to exercise, assure the prompt access of representatives of the Assistant Secretary of Labor for Occupational Safety and Health to employee exposure and medical records and to analyses using exposure or medical records. Rules of agency practice and procedure governing OSHA access to employee medical records are contained in 29 CFR 1913.10.

(ii) Whenever OSHA seeks access to personally identifiable employee medical information by presenting to the employer a written access order pursuant to 29 CFR 1913.10(d), the employer shall prominently post a copy of the written access order and its accompanying cover letter for at least fifteen (15) working days.

(f) *Trade secrets.* (1) Except as provided in paragraph (f)(2) of this section, nothing in this section precludes an employer from deleting from records requested by a health professional, employee, or designated representative any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in mixture, as long as the health professional, employee, or designated representative is notified that information has been deleted. Whenever deletion of trade secret information substantially impairs evaluation of the place where or the time when exposure to a toxic substance or harmful physical agent occurred, the employer shall provide alternative information which is sufficient to permit the requesting party to identify where and when exposure occurred.

(2) The employer may withhold the specific chemical identity, including the chemical name and other specific identification of a toxic substance from a disclosable record provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) All other available information on the properties and effects of the toxic substance is disclosed;

(iii) The employer informs the requesting party that the specific chemical identity is being withheld as a trade secret; and

(iv) The specific chemical identity is made available to health professionals, employees and designated representatives in accordance with the specific applicable provisions of this paragraph.

(3) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a toxic substance is necessary for emergency or first-aid treatment, the employer shall immediately disclose the specific chemical identity of a trade secret chemical to the treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (f)(4) and (f)(5), as soon as circumstances permit.

(4) In non-emergency situations, an employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (f)(2) of this section, to a health professional, employee, or designated representative if:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information would not enable the health professional, employee or designated representative to provide the

occupational health services described in paragraph (f)(4)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, employee, or designated representative and the employer or contractor of the services of the health professional or designated representative agree in a written confidentiality agreement that the health professional, employee or designated representative will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (f)(9) of this section, except as authorized by the terms of the agreement or by the employer.

(5) The confidentiality agreement authorized by paragraph (f)(4)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(6) Nothing in this section is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(7) If the health professional, employee or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the employer who provided the information shall be informed by the health professional prior to, or at the same time as, such disclosure.

(8) If the employer denies a written request for disclosure of a specific chemical identity, the denial must:

(i) Be provided to the health professional, employee or designated representative within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

(9) The health professional, employee, or designated representative whose request for information is denied under paragraph (f)(4) of this section may refer the request and the written denial of the request to OSHA for consideration.

(10) When a health professional, employee, or designated representative refers a denial to OSHA under paragraph (f)(9) of this section, OSHA shall consider the evidence to determine if:

(i) The employer has supported the claim that the specific chemical identity is a trade secret;

(ii) The health professional, employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and

(iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

(11)(i) If OSHA determines that the specific chemical identity requested under paragraph (f)(4) of this section is not a *bona fide* trade secret, or that it is a trade secret but the requesting health professional, employee or designated representatives has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means for complying with the terms of such agreement, the employer will be subject to citation by OSHA.

(ii) If an employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health needs are met without an undue risk of harm to the employer.

(12) Notwithstanding the existence of a trade secret claim, an employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is

provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is trade secret.

(g) *Employee information.* (1) Upon an employee's first entering into employment, and at least annually thereafter, each employer shall inform current employees covered by this section of the following:

(i) The existence, location, and availability of any records covered by this section;

(ii) The person responsible for maintaining and providing access to records; and

(iii) Each employee's rights of access to these records.

(2) Each employer shall keep a copy of this section and its appendices, and make copies readily available, upon request, to employees. The employer shall also distribute to current employees any informational materials concerning this section which are made available to the employer by the Assistant Secretary of Labor for Occupational Safety and Health.

(h) *Transfer of records.* (1) Whenever an employer is ceasing to do business, the employer shall transfer all records subject to this section to the successor employer. The successor employer shall receive and maintain these records.

(2) Whenever an employer is ceasing to do business and there is no successor employer to receive and maintain the records subject to this standard, the employer shall notify affected current employees of their rights of access to records at least three (3) months prior to the cessation of the employer's business.

(3) Whenever an employer either is ceasing to do business and there is no successor employer to receive and maintain the records, or intends to dispose of any records required to be preserved for at least thirty (30) years, the employer shall:

(i) Transfer the records to the Director of the National Institute for Occupational Safety and Health (NIOSH) if so required by a specific occupational safety and health standard; or

(ii) Notify the Director of NIOSH in writing of the impending disposal of records at least three (3) months prior to the disposal of the records.

(4) Where an employer regularly disposes of records required to be preserved for at least thirty (30) years, the employer may, with at least (3)

months notice, notify the Director of NIOSH on an annual basis of the records intended to be disposed of in the coming year.

(i) *Appendices.* The information contained in appendices A and B to this section is not intended, by itself, to create any additional obligations not otherwise imposed by this section nor detract from any existing obligation.

Appendix A to § 1910.20—Sample Authorization Letter for the Release of Employee Medical Record Information to a Designated Representative (Non-Mandatory)

I, _____ (full name of worker/patient), hereby authorize _____ (individual or organization holding the medical records) to release to _____ (individual or organization authorized to receive the medical information), the following medical information from my personal medical records:

(Describe generally the information desired to be released)

I give my permission for this medical information to be used for the following purpose:

but I do not give permission for any other use or re-disclosure of this information.

(Note: Several extra lines are provided below so that you can place additional restrictions on this authorization letter if you want to. You may, however, leave these lines blank. On the other hand, you may want to (1) specify a particular expiration date for this letter (if less than one year); (2) describe medical information to be created in the future that you intend to be covered by this authorization letter; or (3) describe portions of the medical information in your records which you do not intend to be released as a result of this letter.)

Full name of Employee or Legal Representative

Signature of Employee or Legal Representative

Date of Signature

Appendix B to § 1910.20—Availability of NIOSH Registry of Toxic Effects of Chemical Substances (RTECS) (Non-Mandatory)

The final regulation, 29 CFR 1910.20, applies to all employee exposure and medical records, and analyses thereof, of employees exposed to toxic substances or harmful physical agents (paragraph (b)(2)). The term "toxic substance or harmful physical agent" is defined by paragraph (c)(13) to encompass chemical substances, biological agents, and physical stresses for which there is evidence

of harmful health effects. The regulation uses the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS) as one of the chief sources of information as to whether evidence of harmful health effects exists. If a substance is listed in the latest printed RTECS, the regulation applies to exposure and medical records (and analyses of these records) relevant to employees exposed to the substance.

It is appropriate to note that the final regulation does not require that employers purchase a copy of RTECS, and many employers need not consult RTECS to ascertain whether their employee exposure or medical records are subject to the rule. Employers who do not currently have the latest printed edition of the NIOSH RTECS, however, may desire to obtain a copy. The RTECS is issued in an annual printed edition as mandated by section 20(a)(6) of the Occupational Safety and Health Act (29 U.S.C. 669(a)(6)).

The Introduction to the 1980 printed edition describes the RTECS as follows:

"The 1980 edition of the Registry of Toxic Effects of Chemical Substances, formerly known as the Toxic Substances list, is the ninth revision prepared in compliance with the requirements of Section 20(a)(6) of the Occupational Safety and Health Act of 1970 (Public Law 91-596). The original list was completed on June 28, 1971, and has been updated annually in book format. Beginning in October 1977, quarterly revisions have been provided in microfiche. This edition of the Registry contains 168,096 listings of chemical substances; 45,156 are names of different chemicals with their associated toxicity data and 122,940 are synonyms. This edition includes approximately 5,900 new chemical compounds that did not appear in the 1979 Registry. (p. xi)

"The Registry's purposes are many, and it serves a variety of users. It is a single source document for basic toxicity information and for other data, such as chemical identifiers and information necessary for the preparation of safety directives and hazard evaluations for chemical substances. The various types of toxic effects linked to literature citations provide researchers and occupational health scientists with an introduction to the toxicological literature, making their own review of the toxic hazards of a given substance easier. By presenting data on the lowest reported doses that produce effects by several routes of entry in various species, the Registry furnishes valuable information to those responsible for preparing safety data sheets for chemical substances in the workplace. Chemical and production engineers can use the Registry to identify the hazards which may be associated with chemical intermediates in the development of final products, and thus can more readily select substitutes or alternative processes which may be less hazardous. Some organizations, including health agencies and chemical companies, have included the NIOSH Registry accession numbers with the listing of chemicals in their files to reference toxicity information associated with those

chemicals. By including foreign language chemical names, a start has been made toward providing rapid identification of substances produced in other countries. (p. xi)

"In this edition of the Registry, the editors intend to identify 'all known toxic substances' which may exist in the environment and to provide pertinent data on the toxic effects from known doses entering an organism by any route described. (p. xi)

"It must be reemphasized that the entry of a substance in the Registry does not automatically mean that it must be avoided. A listing does mean, however, that the substance has the documented potential of being harmful if misused, and care must be exercised to prevent tragic consequences. Thus, the Registry lists many substances that

are common in everyday life and are in nearly every household in the United States. One can name a variety of such dangerous substances: prescription and non-prescription drugs; food additives; pesticide concentrates, sprays, and dusts; fungicides; herbicides; paints; glazes, dyes; bleaches and other household cleaning agents; alkalies; and various solvents and diluents. The list is extensive because chemicals have become an integral part of our existence."

The RTECS printed edition may be purchased from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402 (202-783-3238).

Some employers may desire to subscribe to the quarterly update to the RTECS which is published in a microfiche edition. An annual subscription to the quarterly microfiche may

be purchased from the GPO (Order the "Microfiche Edition, Registry of Toxic Effects of Chemical Substances"). Both the printed edition and the microfiche edition of RTECS are available for review at many university and public libraries throughout the country. The latest RTECS editions may also be examined at the OSHA Technical Data Center, Room N2439—Rear, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (202-523-9700), or at any OSHA Regional or Area Office (See, major city telephone directories under United States Government-Labor Department).

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