DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Access to Employee Exposure and Medical Records

AGENCY: The Occupational Safety and Health Administration of the United States Department of Labor (OSHA).

ACTION: Final rule.

SUMMARY: This final occupational safety and health standard, 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. Access is also assured to employer analyses using exposure and medical records. The final standard requires long term preservation of these records, contains provisions concerning informing employees of their rights under the standard, and includes provisions protective of trade secret information.

EFFECTIVE DATE: August 21, 1980.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Department of Labor, OSHA, Office of Public Affairs, Third Street and Constitution Avenue, N.W., Room N–3641, Washington, D.C. 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:

I. Introduction

A. The format of this statement of reasons (the preamble)

The statement of reasons accompanying this final standard (the preamble) is divided into eight parts, numbered I through VIII. The following is a table of contents for the preamble:

Part VII is a provision-by-provision discussion of the standard in lettered paragraphs corresponding to the lettered paragraphs of the standard. It provides a brief summary of each provision and the evidence and rationale supporting it. Part VIII follows with a reference to the authority for the standard, the signature of the Assistant Secretary, and then the standard itself. References to the rulemaking record in the text of the preamble are in parentheses, and the following abbreviations have been used:

1. Ex. : Exhibit number to Docket H–112.

2. Tr. : Transcript page number.

This occupational safety and health standard is issued pursuant to sections 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 ("The Act") (84 Stat. 1593, 1599, 29 U.S.C. 655, 657), the Secretary of Labor's Order 8–76 (41 FR 25059) and Title 29 of the Code of Federal Regulations (CFR), Part 1911. It amends Part 1910 of 29 CFR by revising 1910.20, to be entitled "Access to employee exposure and medical records," and by making conforming amendments to existing occupational safety and health standards in sections 1910.440, 1910.1001–.1046, and 1990.151–.152. The standard applies to employment in all industries covered by the Act except agriculture.

The agency has reviewed the provisions of this action pursuant to the National Environmental Policy Act of 1969 and the Council on Environmental Quality Regulations (40 CFR Part 1500), and has determined that no significant environmental impact will result from the implementation of this standard.

B. History of proceedings

1. *The interim final rule.* On July 19, 1978, OSHA published in the **Federal Register** an interim final rule entitled "Preservation of Records" (29 CFR 1910.20; 43 FR 31019) which required employers to preserve all employee exposure and medical records, and to make them available, upon request, to OSHA and the National Institute for Occupational Safety and Health (NIOSH). OSHA indicated that the interim final rule would be superseded by a final rule promulgated after informal rulemaking. The final standard published today, when it goes into effect, will supersede the interim final rule.

2. *The proposal.* On July 21, 1978, a proposed rule entitled "Access to Employee Exposure and Medical Records" was published by OSHA in the **Federal Register** (43 FR 31371). The proposal provided for employees and their designated representatives to have access, upon request, to all relevant exposure records and all medical records of which the requesting employee was the subject or for which written consent had been obtained from the subject of the records. The proposal further provided OSHA and NIOSH with access upon request to employee exposure and medical records. In addition, it included a retention period for employee exposure and medical records of at least the duration of employment with the employer plus five (5) years. There was also a requirement for employers to instruct employees annually of their rights of access under the proposed rule.

The proposal included within its scope all "employee exposure records" and "employee medical records," regardless of whether they were subject to specific occupational safety and health standards. It did not mandate, however, the creation of new records or reports, nor impose any new obligations

on employers to monitor or measure employee exposures, or provide medical surveillance or examinations. Neither did it establish mandatory requirements on the format or content of employee exposure records or medical records. The proposal reflected a recognition that exposure monitoring and medical surveillance are conducted by many employers at their own initiative and expense, and that employers keep records of the results of such monitoring and surveillance.

The purpose of the proposal was to make the data contained in these records available to employees, their representatives, NIOSH, and OSHA in order to promote the recognition of workplace hazards and the subsequent reduction of occupational disease. As stated in the July 21 notice (at 31371):

> The goals of occupational safety and health are not adequately served if employers do not fully share the available information on toxic materials and harmful physical agents with employees. Until now, lack of this information has too often meant that occupational diseases and methods for reducing exposure have been ignored and employees have been unable to protect themselves or obtain adequate information from their employers. By giving employees and their designated representatives the right to see relevant exposure and medical information, this proposal will make it easier for employees to identify worksite hazards, particularly workplace exposures which impair their health or functional capacity. Increased awareness of workplace hazards will also make it more likely that prescribed work and personal hygiene practices will be followed.

The July 21 proposal gave interested persons until September 22, 1978 to submit comments, views, and arguments on any issue raised by the proposal. Comments were specifically invited on: (a) whether any types of information in the medical records should be excluded either partially or totally from the disclosure requirements of the final rule, and (b) whether the proposed retention period for records was too long or too short. Docket H–112 was established to receive all evidence concerning the proposal, and a total of 211 initial comments were received.

3. *The hearings.* Based on the widespread interest expressed in the proposal, OSHA announced in the **Federal Register** on October 6, 1978 (43 FR 46322) a schedule of informal public hearings. Public hearings were conducted under OSHA's procedural regulations for rulemaking (29 CFR Part 1911). They were presided over by Administrative Law Judge J. F. Greene, and all participants were afforded the opportunity to present oral testimony and to question other witnesses. The hearings were held from December 5–8, 1978, and January 3–5, 1979, in Washington, D.C.; from December 12–13, 1978, and January 9–10, 1979, in Chicago, Illinois; and on December 15, 1978, in San Francisco, California. A total of 88 interested individuals and organizations testified at these hearings. Hearing participants were given until February 9, 1979, to submit additional evidence and factual material, and until March 1, 1979, to submit post-hearing comments or arguments. This final deadline was later extended to March 30, 1979 by notice given in the **Federal Register** on February 27, 1979 (44 FR 11096).

4. *The administrative regulations.* In conjunction with this rulemaking a separate docket, Docket No. H–112A (Ex. 167 to Docket H–112), was created for materials and comments relating to OSHA's proposed administrative regulations concerning its own access to and handling of employee medical records. These regulations were initially developed as proposed administrative guidelines, and were entered into the public record prior to the public hearings on the records access proposal. These regulations have been revised and published today in the **Federal Register** as a companion document to this standard.

5. *The record.* The public record to the proposed rule was certified by Judge Greene on May 1, 1979. The record consists of all material submitted to the OSHA Docket Office, Docket No. H–112, by either OSHA or the public, including: (a) comments on the July 21 proposal, (b) background materials collected by OSHA, (c) notices of intent to appear at the public hearings, (d) pre-hearing submissions of testimony and evidence, (e) verbatim transcripts of the public hearings, (f) hearing exhibits, and (g) post-hearing comments. The views of a wide range of employees, businesses, trade and medical associations, international and local labor unions, physicians and other health professionals, legal experts, and public interest groups are represented in the public record. Additional information referenced in this preamble has been added to the record. 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 Nos. H–112 and H–112A, Room S–6212, U.S. Department of Labor, 3rd Street and Constitution Avenue, N.W., Washington, D.C. 20210; telephone (202) 523–7895.

II. Summary

A. Overview of the Purposes of the Standard

The fundamental reasons for this standard are the agency's judgments, based on experience, expertise, and the rulemaking record, that employee exposure and medical records are critically important to the detection, treatment, and prevention of occupational disease, and workers and their representatives need direct access to this information as well as to analyses of these records. Representatives of OSHA also need access to this information to fulfill responsibilities under the Occupational Safety and Health Act. The terms "employee exposure record" and "employee medical record" are defined and discussed at length in the Summary and Explanation portion of the preamble, but the core concepts of these terms are simple. Employee exposure records reveal the identity of, and extent of exposure to, toxic substances or harmful physical agents. Employee medical records contain individual health status information which may indicate whether or not an employee's health is being or has been impaired by exposure to toxic chemicals or harmful physical agents. If workers and their representatives are to play a meaningful role in detecting, treating, and preventing occupational disease, they must have the right and opportunity to learn: (1) what they are or were exposed to on the job, (2) what are or were the levels of exposure, and (3) what are or were the health consequences of these exposures. This standard simply establishes rights of access to this basic information by employees, designated representatives, and OSHA representatives, while at the same time affording appropriate privacy and confidentiality protection against uninvolved third parties.

The most immediate purpose behind this standard is to enable workers to play a meaningful role in their own health management. The individual worker has the greatest self-interest in maintaining his or her life and well-being. Sound public policy dictates that workers be afforded a central role in the detection and solution of health problems, as there are no assurances that anyone else will protect their health with equal vigor or determination.

Access to exposure and medical information will enable workers and their representatives to become directly involved in the discovery and control of occupational health hazards. Access will enable workers to uncover patterns of health impairment and disease.

Workers will be able to link specific adverse health effects with exposures to specific toxic substances, and investigate the possible causes of known patterns of disease. Once an occupational health problem is discovered, access to records can assist workers in their efforts to hasten control of the problem. This worker involvement to implement controls can take many forms, such as discussions with employers, collective bargaining remedies such as grievances or new contract provisions, or complaints to agencies such as OSHA and NIOSH.

Direct access to exposure and medical data will also enable an employee's personal physician to diagnose, treat, and possibly prevent permanent health impairment. Exposure and medical information can substantially assist a physician's evaluation, such as where previously recorded baseline medical information can be compared to current health status to ascertain whether and how health has declined over time.

Where the dangers of exposure to a toxic substance or harmful physical agent are known, worker access to information will also serve to decrease the incidence of occupational health problems. An individual worker's personal actions can greatly affect the extent of exposure to a toxic substance. Efforts are often made to control worker exposure to toxic agents through the use of respirators, protective work clothing, and careful personal hygiene (showers, washing hands and face before eating, etc.). Work practices which strive to minimize dispersal of toxic substances (e.g., immediately storing dust laden scrap material in closed containers) are also important. All of these control techniques depend on worker cooperation—cooperation which will best be assured when a worker knows the identity of hazardous substances he or she faces on the job, the magnitude of exposure, and the potential health consequences of this exposure.

Access to exposure and medical records, and long term preservation of these records, will also facilitate formal occupational health research. Groups of employees and unions can use the access rights of this standard to make medical and exposure information available to university and private organization researchers.

In addition, it is important to observe that worker access to exposure and medical information is important to the effectiveness of six explicit employee rights established by the Occupational Safety and Health Act. It is the agency's judgment that substantial occupational health benefits will result from improving the ability of workers to make beneficial use of these statutory rights. Access to information is first of all crucial to the effectiveness of the section 8(f)(1) right of employees and their representatives (29 U.S.C. 657(f)(1)) to complain to OSHA about perceived safety and health problems and obtain a prompt inspection of the worksite. Access gives meaning to the section 8(c) right of employees and their representatives to accompany OSHA during plant inspections (29 U.S.C. 657(e)) in order to identify where and how various toxic substances are used, which plant operations generate the greatest exposures, and otherwise help OSHA conduct a thorough inspection. Access will enable workers to better exercise their twin rights under section 10(c) to contest the reasonableness of abatement periods proposed by OSHA, and to participate as parties in Occupational Safety and Health Review Commission adjudicatory proceedings (29 U.S.C. 659(c)). A fifth statutory right enhanced by worker access to record is the section 20(a)(6) right of workers to request a workplace Health Hazard Evaluation (HHE) by NIOSH (29 U.S.C. 669(a)(6)). Lastly, the knowledge learned by workers due to access to medical and exposure records will also heighten the impact of the employee training and education programs currently being funded by OSHA pursuant to section 21(c) of the Act (29 U.S.C. 670(c)).

Having highlighted the benefits of direct worker access to medical and exposure records, it is appropriate to consider the kinds of records that employers generate, and the current practices concerning employee access to these records. Medical records relevant to potential occupational disease are generated in a variety of contexts. Occupational medicine is practiced in a wide variety of settings and encompasses a wide range of medical services. The range of experience includes company-owned hospitals capable of performing most primary care, sophisticated in-house medical departments with epidemiological, toxicological, and medical expertise, medical programs consisting only of an on-site occupational health nurse, and contractual arrangements with industrial health clinics or outside physicians (either on a retainer or fee-for-service basis). There is a high degree of variation in the medical services provided by employers, and as a result, employee medical records can contain a variety of items relevant to occupational disease issues.

With respect to environmental monitoring records, approximately 22% of all industrial employees are employed in plants where monitoring is regularly performed, with the percentage being approximately 40% for all manufacturing employees. There is a wide fluctuation in the extent of regular monitoring depending on employer size and SIC code. It is to be expected that far greater percentages of employees are covered by infrequent, if not by regular, exposure monitoring. For example, 52% of manufacturing industry employees work in plants which receive industrial hygiene services. Irrespective of the exact percentages involved, it is clear that a substantial portion of American workers work on jobs for which exposure monitoring is being conducted.

Industrial recordkeeping practices also appear to vary widely as to the extent to which employees are provided direct access to medical and exposure records. OSHA concluded on the basis of the record and its own experience that denial of direct, unrestricted employee access to exposure and medical information is commonplace, if not the universal practice of industry. This standard is necessary in those many situations where access is routinely denied.

The final standard also reaffirms OSHA's right of access to employee exposure and medical records. OSHA is a public health agency with regulatory responsibility "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions. . ." (Section 2(b) of the Act, 29 U.S.C. 651). Access to employee exposure and medical records will at times be necessary for the agency to accomplish numerous statutory responsibilities, and all comprehensive occupational health standards promulgated under the Act to date have included provisions guaranteeing OSHA access to exposure and medical records.

B. Summary of the Standard

The "Purpose" paragraph of the final standard creates no substantive requirements, but expresses the agency's intentions in promulgating the standard. The final rule assures access by employees and their representatives, and codifies OSHA access to relevant employee medical and exposure records. The goal behind access is to yield both direct and indirect improvements in the detection, treatment and prevention of occupational disease. This is articulated as a guide to application and interpretation of the entire standard, and reflects the many ways in which employees, their representatives, and OSHA are likely to use access rights.

The final standard applies to employers having employees exposed to toxic substances or harmful physical

agents. Since the rule seeks to yield benefits in the detection, treatment and prevention of occupational disease, coverage is appropriately limited to records relevant to employees currently or previously exposed to toxic substances or harmful physical agents.

The final standard applies to all relevant exposure, medical, and analysis records whether or not they are related to specific occupational safety and health standards. In so providing, the agency rejected suggestions that there be an exclusion for exposure and medical records created prior to the effective date of the standard.

The standard applies to records generated or maintained by contractors of the employer as well as by in-house employees. The final standard also applies to each employer who "makes, maintains, contracts for, or has access to" exposure or medical records, and it is the agency's intention that the standard be given a broad application in this respect.

The final standard applies to each "general industry, maritime, and construction employer" of employees exposed to toxic substances or harmful physical agents. Having considered the evidence provided, the agency concluded that there was no rational basis for categorically excluding any broad class of employers from coverage by the final standard, such as small businesses or employers with multiple or transient worksites or transient workforces. The final standard does not apply to agricultural employment, but OSHA is proposing in a separate **Federal Register** notice to extend the scope of the final standard to these workplaces.

The definitions paragraph of the final standard defines eleven key terms. "Access" means the right and opportunity to examine and copy. The term "analysis using exposure or medical records" is defined as "any compilation of data, or any research, statistical or other 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."

In order to enable each worker to utilize his or her rights of access to records, the final standard permits an employee to designate representatives to exercise access rights. Enabling an employee to designate anybody he or she desires to entrust with access rights will most effectively achieve the purposes of the Act and this standard. The employee should ultimately be the judge of who can make a positive contribution to his or her well-being by access to records. As a result, no limitation is placed on who the employee may choose to act as a "designated representative." Recognized or certified collective bargaining agents, who have the statutory authority to represent the interests of employees within the bargaining unit on health and safety matters, are automatically considered to be "designated representatives" by virtue of their special bargaining status. Under the standard, this gives them the right of access without individual employee consent to employee exposure records and analyses using exposure or medical records, but requires that they obtain specific written consent before gaining access to medical records.

The final standard defines "employee" 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. The term "employer" means a current employer, a former employer, or a successor employer.

"Employee exposure record" is defined as encompassing four kinds of records. First are environmental (workplace) monitoring or measurement records along with associated collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained. Second are those biological monitoring results which directly access the absorption of a substance or agent by body systems. Third are material safety data sheets. Fourth, in the absence of the above, is any other record which reveals the identity of a toxic substance or harmful physical agent.

The term "employee medical record" means the entire contents of a record concerning the health status of an employee which is made or maintained by health care personnel or a technician. Information generated by medical personnel is covered irrespective of how and where the information is presently maintained. The use of "made" is intended to assure access in situations where medical information is held by non-medical management departments or personnel. The use of "maintained by" medical personnel is intended to assure access to the entire contents of medical files, not just to information created by medical personnel. Once information from any source gains enough importance to be included in the medical file, that information becomes subject to the retention and access provisions of this rule. The use of "technician" is meant to cover situations where, for example, occupational health questionnaires or biological monitoring tests such as pulmonary function or audiometric testing are conducted by persons who, strictly speaking, may not be considered as health care personnel.

In defining "employee medical record," the agency decided that no meaningful distinction could be made between "occupational" and "non-occupational" information. The symptoms of occupational disease often closely mimic those of non-occupational diseases. The human body is limited in the number of ways it can react to chemical insults, and many of these responses parallel symptoms associated with a variety of other insults and disorders. This, plus our limited knowledge of occupational disease, makes it impossible to classify in advance what pieces of information may or may not be of "occupational" significance.

The final rule does, however, specifically exclude three kinds of information from the definition of "employee medical record": Certain physical specimens, certain records concerning health insurance claims, and certain records concerning voluntary employee assistance programs.

The phrase "exposure to toxic substances or harmful physical agents" is defined in two parts. "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. Exposure does not, however, 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 term "toxic substance or harmful physical agent" is defined as any chemical substance, biological agent or physical stress (noise, heat, cold, vibration, repetitive motion, ionizing and non-ionizing radiation, hypo- or hyperbaric pressure, etc.) for which there is evidence of harmful health effects. Four general criteria are established for determining whether evidence of harmful health effects exist. First, the standard applies to any chemical substance, biological agent, or physical stress which is regulated by any Federal law or rule due to a hazard

to health. Second, the standard applies to any chemical, biological agent, or physical stress which is listed in the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS), an annual compilation of all known toxic substances by chemical name and common synonym, along with the concentrations at which toxicity is known to occur. Third, the standard applies to any chemical, biological agent, or physical stress 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." Finally, the standard applies to any chemical, biological agent, or physical stress which has a material safety data sheet indicating that the material may pose a hazard to human health. This document generally accompanies the purchase of a chemical used in industrial processes, and serves to warn users of toxic properties of the product.

In addition to the preceding terms, "record" is defined to encompass any item of information regardless of the form or process by which it is maintained. Finally, since the standard enables designated representatives to obtain access to an employee's medical records only upon the specific written consent of the employee, the term "specific written consent" is carefully defined. This definition minimizes the possibility of invasion of an employee's privacy by precluding blanket and perpetual authorizations. To give specific written consent, an employee will have to indicate in writing who is being authorized to disclose record information, who may have access to it, and the general nature of the information to be disclosed. If the employee wishes, he or she may specify information which is not authorized to be disclosed and may place conditions on its use or redisclosure. In this way, it will be the employee who controls the amount and kinds of information available to the designated representative, and what the representative can do with it. A sample authorization letter is included as an Appendix to the standard.

The "Preservation of records" paragraph of the final standard provides that employee exposure records and analyses based on exposure or medical records must generally be preserved and maintained for at least thirty years, while employee medical records must be retained for at least the duration of employment plus thirty years. A minimal overall retention period of thirty years was adopted due to the very long latency periods characteristic of chronic occupational diseases. Not all records subject to the rule, however, must be retained for the thirty year period. Health insurance claims records which are maintained separately from the employer's medical program and its records need not be retained for any period of time. In addition, certain background information to employee exposure records must be maintained for only one year. Also, with the exception of x-rays, employers are provided maximum flexibility to microfiche, microfilm, computerize, or otherwise retain records in whatever fashion is most desirable to the employer.

The "Access to records" paragraph of the final standard governs the mechanics and nature of access to records. Employee and designated representative access must be provided in a reasonable time, place, and manner, but in no event later than fifteen (15) days after the request for access is made.

This permits employers to establish orderly procedures for providing access so that work schedules are not unduly disrupted and workers not unduly inconvenienced. Employers are also provided flexibility in responding to requests for copies of records. On the first occasion that an employee or designated representative requests a copy of a record, the employer has three choices. The employer can assure the (1) a copy is provided without cost, (2) the necessary mechanical copying facilities (e.g., photocopying) are made available without cost so that the employee or representative can make an exact copy, or (3) the record is loaned for a reasonable time to enable an exact copy to be made. Administrative costs can generally be charged for subsequent requests for a copy of a record.

As to the nature of access rights, employees and their designated representative (including collective bargaining agents) are provided access to "relevant" employee exposure records. An employee first is assured access to records of the employee's past or present exposure to toxic substances or harmful physical agents. Second, an employee is assured access to "records of other exposed employees with past or present job duties or working conditions related to or similar to those of the employee." Access to records of other employees is provided in recognition of the fact that most environmental monitoring using personal samples is conducted on a representative sample basis. The third kind of "relevant" employee exposure records are records containing exposure information concerning the employee's workplace or working conditions. These records would include area, grab, or wipe samples which would not specifically characterize the exact exposure of any one employee. The fourth kind of "relevant" records are records pertaining to workplaces or working conditions to which the employee is being assigned or transferred.

With respect to employee medical records, employees are afforded direct access to their own medical records, subject to one limited exception applicable to potentially harmful information involving terminal illnesses or psychiatric conditions. Access of an employee is provided only to medical records of which the employee is the subject; in all other cases specific written consent must be obtained. A designated representative of an employee may gain access to an employee's medical records only through the specific written consent of the employee. This restriction applies to all designated representatives including collective bargaining agents.

The final standard encourages physicians on behalf of employers to make recommendations to employees and designated representatives in connection with the exercise of access rights. The physician may recommend a consultation for the purposes of reviewing and discussing requested records, or may urge that a summary of material facts and opinions be accepted in lieu of the records requested. Other possible recommendations would include the physician urging that requested records be provided only to a physician or other designated representative.

The final standard also gives physicians limited discretion to deny direct employee access to portions of medical records. In the narrow situation where a specific diagnosis of a terminal illness or psychiatric condition is involved, there may be some cases where direct employee/patient access to this information could possibly prove harmful to the employee's health. In recognition of this possibility, the final rule adopts the recommendation made by the Privacy Commission. If a physician representing the employer believes the direct access to this information could be detrimental to the employee's health, the employer may deny the employee's request for direct access to this information. The employer must, however, inform the employee that access will be provided to a

designated representative having specific written consent.

In additon, the final standard authorizes the deletion from requested medical records of the identity of a family member, personal friend, or fellow employee who has provided confidential information concerning an employee's health status.

Employees and designated representatives are also provided access to analyses using exposure or medical records. As to an analysis using employee medical records, however, access without specific written consent is provided only to the extent that the analysis does not report the contents of employee medical records in a personally identifiable form. The employer must, where feasible, delete personally identifiable information from the analysis before providing access. Once aggregate medical information (as well as exposure information) is reported in a non-identifiable form such as in most research studies, there are no substantial privacy interests to be served by preventing direct access by those most interested in the analyses. Accordingly, the final standard provides for access to analyses without any prior showing of written consent by each employee whose records are part of the analyses.

The final standard also reaffirms OSHA's access to employee exposure records, medical records, and analyses of these records. OSHA access to records must be provided immediately upon request, and this access is not conditioned upon employee consent. Due to the strong personal privacy interests associated with employee medical records, however, the agency is simultaneously promulgating strict rules of practice and procedure governing OSHA access to employee medical records (and any analyses using employee medical records which report the contents of medical records in a personally identifiable form). These administrative regulations specify the mechanisms by which the agency will seek access to medical records, and how the records will be protected once in the agency's possession.

The "Trade secrets" paragraph of the final standard addresses industry concerns about worker and designated representative access to records containing trade secrets. On the basis of the total record, the agency concluded that workers have a fundamental need to know the identity of and extent of exposure to toxic substances and harmful physical agents, and any resulting health effects, regardless of whether or not the information is a trade secret. The final standard is founded in part on the judgment that employers must not as a matter of public health policy be permitted to deny worker access to this information which is needed for the purposes of detecting, treating, and preventing occupational disease. Under the final standard, access is afforded to chemical and physical agent identity, level of exposure, and health status information regardless of employer trade secret claims. The final standard, however, has been structured to accommodate trade secret concerns where protection of this information does not conflict with the overriding purposes of the standard. Although identities, levels of exposure, and health status data may not be withheld, the employer may delete any other trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in a mixture, as long as the employee or designated representative is notified of the deletion. In addition, the provisions of the final standard minimize possible abuse by permitting employers to condition access to trade secrets upon written agreements not to misuse this information.

Other paragraphs of the final standard contain requirements for employers to: (1) inform employees of their rights under the standard, (2) transfer records to successor employers when employers cease business operations, and (3) notify NIOSH of the impending destruction of records covered by the standard.

C. Major Factual/Policy/Legal Issues

In promulgating this final standard, OSHA not only determined that broad worker and designated representative access to records would serve important occupational health purposes, but also carefully evaluated the various arguments which were raised for and against OSHA's proposed means for achieving these objectives. Most employer participants, for example, opposed the standard's access principles on a variety of grounds. Concerns were voiced about potential harm to employees and the occupational physician-patient relationship should direct employee and designated representative access be provided to medical records. Arguments were made that direct access could prove to be genuinely harmful in certain cases; thus the employer's physician should retain discretion as to what information is released, and to whom. On the basis of the record and its own judgments, OSHA concluded that reliance on physician discretion to disclose information to an employee, or reliance solely on physician-to-physician transfers of medical records, were inadequate responses to the needs for direct worker access.

Unrestricted patient access to medical records has been a major public policy issue during the past decade, and the trend throughout the nation both on the State and Federal level has been to provide direct patient access to medical records. The final standard's access principles draw support from the recommendations of such bodies as the 1976 Privacy Protection Study Commission, the National Commission on the Confidentiality of Health Records, and the American Medical Records Association. It is OSHA's judgment that there is no basis for anticipating harm to an employee from direct access to medical information as provided in the final standard. The rare occasion where direct access may possibly be harmful can adequately be dealt with by the standard's provisions concerning physician consultations and access through a designated representative.

Employee and designated representative access to both medical and exposure records were also opposed on the grounds that these records would often be misinterpreted and misunderstood. Statements were made that most employees are incapable of understanding the highly technical language, abbreviated shorthand and illegible writing that is often found in medical records. The likelihood of misinterpretation leading to unnecessary anxiety or inappropriate action was therefore considered great. OSHA agrees that professional evaluation and interpretation will often be important, but does not agree that the possibility of occasional misunderstanding should enable employers to deny access to either medical or exposure records. The solution reflected in the final rule is to provide full worker access to the records, while at the same time encouraging the employer to offer whatever professional interpretation the employer feels is necessary. The worker, however, retains the right to personally evaluate the record, and have independent analysis conducted by professionals and non-professionals alike. If a worker is incapable of understanding something in a medical or exposure record, OSHA expects that the worker will naturally seek the assistance of someone more knowledgeable whom he or she trusts.

Arguments were also made that provisions allowing designated representative access to medical records would seriously interfere with the physician-patient relationship due to the

open-ended nature of the proposal's written consent process. Objections to the proposal focused on potential invasions of an employees's privacy expectations from unrestrained third party access to identifiable medical records. To preclude unrestrained third party access, the final standard conditions the access of designated representatives to employee medical records upon the specific written consent of the employee. The elements of specific written consent are a reflection of recommendations in the record, including those of the Privacy Commission and the American Medical Records Association.

As to who can be a designated representative, the final standard embodies the view that once specific written consent is obtained, no additional restrictions are needed, such as limiting access to physicians or industrial hygienists. Since it is the employee's right to have access to the complete record, the employee should, by the consent procedure, control the conditions of disclosure and redisclosure.

Arguments were also made that broadened access to medical records would inevitably impair the creation, expansion and effectiveness of occupational medical programs. It is OSHA's judgment that these predictions are exaggerated, since no concrete evidence was presented which indicated that the standard would have a negative impact on corporate efforts to provide occupational health programs. Corporate witnesses stated that, in fact, there would likely be no reduction in their occupational medical efforts. In addition, the record supports the view that direct patient access to medical records actually promotes the therapeutic relationship between physician and patient.

The most significant issue posed by OSHA access to employee records concerns a potential clash with the right of privacy vis-a-vis employee medical records. Employee medical records subject to this standard may sometimes contain intimate details concerning a person's life; e.g., disease experience, psychiatric disorders, venereal disease, abortion, alcohol or drug abuse, sexual preferences, family medical problems, etc. OSHA access to complete medical records was felt by numerous participants to raise the threat of misuse since harmful medical information could be disseminated in a way that would adversely affect the employee. It was also argued that governmental access to personal medical information threatens to destroy expectations of confidentiality and severely impair medical programs.

There was universal agreement that if OSHA obtained access to employee medical records, this access should be accompanied by stringent internal agency procedures to preclude abuse of personally identifiable medical information. Provided these procedures were established, many participants, including all union and employee participants, endorsed unconsented OSHA access to employee medical records for occupational safety and health purposes.

Having considered the record, and analyzed the legal issues involved, the agency decided to include a requirement in the final standard providing for unconsented OSHA access to employee medical records. As recognized by numerous participants, acquiring consent is not always a realistic possibility. Large numbers of people may be involved, emergency situations may not permit delay, the residences of terminated employees may be unknown, or an absence of consent may decrease the statistical validity of a study. In so providing for unconsented agency access, OSHA also agrees with the views of several participants that strong public health considerations must weigh heavily when balanced against the privacy interest in precluding unconsented access.

Even though OSHA has legal authority to seek unconsented access to identifiable medical records, the agency concluded that this authority should, as a matter of sound public policy, be exercised with great care. To protect the employee's privacy interests, OSHA recognizes the need for stringent internal procedures to: (1) limit the circumstances in which identifiable medical records are examined or obtained by OSHA personnel, and (2) control use of identifiable medical information once in the agency's possession. In order to effectuate these decisions, the agency is simultaneously promulgating detailed procedural regulations governing all aspects of OSHA examination and use of personally identifiable medical records.

In promulgating the final standard, OSHA also carefully considered the relevant legal authority issues. The Occupational Safety and Health Act provides ample legal authority for employee, designated representative, and OSHA access to medical and exposure records. The Act created OSHA as an expert administrative agency with broad regulatory powers to fashion protective regulations concerning occupational injury and disease. This final standard substantially advances the central purpose of the Act articulated in Section 2(b)—"to assure so far as possible every working man and woman in the Nation safe and healthful working conditions" (29 U.S.C. 651). The standard furthermore flows directly from, and is fully consistent with, the Act's express language.

By this rule, OSHA has adopted a generic approach to remedying the problems of access to exposure and medical records. Sections 6(b), 3(8), 2(b)(3) and (9), 8(c)(1), and 8(g)(2) of the Act provide for the promulgation of such occupational safety and health standards. Employee, designated representative, and OSHA access to records directly builds upon several express provisions of sections 6(b) and 8(c). The Secretary believes that a generic approach to rulemaking in this situation is a necessary and reasonable approach. The problems of access to information are common to a wide array of toxic substance exposures and industrial settings. The agency therefore rejects contentions that have been made by some in industry that the Act limits the Secretary to substance-by-substance rulemakings as to access issues.

The standard's resolution of the trade secret issue as it pertains to employee and designated representative access to records has also been made with appreciation for the role of trade secrets in American law. Based on careful analysis of the legal issues involved, the agency concluded that its authority to promulgate this standard can serve to pre-empt state law trade secret interests if necessary or appropriate to promote occupational safety and health. However, rather than totally pre-empt state law trade secret interests, the agency chose to seek means to accommodate the competing interests. But, where the competing interests irreconcilably clash, the interest in employee safety and health prevails.

The agency also analyzed the legal right of privacy issues posed by OSHA access to employee medical records. Having considered the relevant case law, OSHA is confident that agency access to personally identifable employee medical records is constitutionally and statutorily permissible when accompanied by strict protective measures such as the administrative regulations OSHA is promulgating simultaneously with this standard. It is also appropriate to point out that the physician's traditional duty of confidentiality owed to medical information, deriving from the patient's right of privacy in the information, is never absolute and may be overridden

by a supervening public interest such as the one asserted in this standard.

Numerous employers complained of the perceived economic burdens of the standard, but economic concerns were not a major issue in the rulemaking. No participant argued that the administrative costs involved rendered the standard economically infeasible, nor is there any evidence in the rulemaking record which could support such a suggestion. The final standard has been carefully drafted to provide employers substantial flexibility as to how they preserve records subject to the standard, and how these records are made available to employees and their designated representatives. The final rule neither mandates the creation of new records or reports, nor imposes independent obligations on employers to monitor or measure employee exposures. The standard does not require employers to provide medical surveillance or examinations, nor does it establish other mandatory requirements as to the format or content of exposure and medical records. Therefore, while administrative costs will be incurred in preserving records and in providing access to them over and above current practices, there is no basis for concluding that the standard will pose substantial economic burdens on industry.

III. Purposes and Need for the Standard

A. Introduction

The fundamental reasons for this standard are the agency's judgments, based on experience, expertise, and the rulemaking record, that employee exposure and medical records are critically important to the detection, treatment, and prevention of occupational disease, and workers and their representatives need direct access to this information and to analyses of these records. Representatives of OSHA also need access to this information to fulfill responsibilities under the Occupational Safety and Health Act. The terms "employee exposure record" and "employee medical record" are defined and discussed at length in the Summary and Explanation portion of the preamble (VII.C, *infra*), but the core concepts of these terms are simple. Employee exposure records reveal the identity of, and extent of exposure to, toxic substances or harmful physical agents. Employee medical records contain individual health status information which may indicate whether or not an employee's health is being or has been impaired by exposure to toxic chemicals or harmful physical agents. If workers and their representatives are to play a meaningful role in detecting, treating, and preventing occupational disease, they must have the right and opportunity to learn: (1) what they are or were exposed to on the job, (2) what are or were the levels of exposure, and (3) what are or were the health consequences of these exposures. This standard simply establishes rights of access to this basic information by employees, designated representatives, and OSHA representatives, while at the same time affording appropriate privacy and confidentiality protection against uninvolved third parties.

Due to the importance of this standard and the controversy that has been generated, it is appropriate to discuss at the outset the occupational safety and health purposes and need for this rule.

B. Worker Participation in Personal Health Management

The most immediate purpose behind this standard is to enable workers to play a meaningful role in their own health management. It is the individual worker who has the greatest self-interest in maintaining his or her life and well-being. The problems presented by occupational disease are enormous and are complicated by such factors as our limited medical knowledge, the typically long latency periods between exposure and the onset of disease, the finite resources available to correct even recognized problems, and the institutional and societal forces which impede and delay changes in traditional industrial practices (*See,* Weiner, Ex. 9A, pp. 1–2, 5–6). As a result, many workers continue to be exposed to toxic substances and harmful physical agents to an extent which may severely impair their health.

Sound public policy dictates that workers be afforded a central role in the detection and solution of health problems, as there are no assurances that anyone else will protect their health with equal vigor or determination. Employers have a legal and moral obligation to protect the health of their employees, but the problems which led to passage of the Occupational Safety and Health Act, and the high rates of occupational disease and death among groups such as former asbestos workers, are reflections of the fact that, by itself, industry on the whole does not adequately protect worker health. Governmental agencies such as OSHA and NIOSH were created to improve occupational safety and health, but due to limited resources and other institutional constraints, these agencies have just begun to have a significant impact on the massive problem of occupational disease. Workers thus have a vital interest in becoming directly and actively involved in occupational health matters. This standard serves to assure that workers who seek to become involved will at least be able to learn basic exposure and medical information.

Several participants in the rulemaking proceeding highlighted the fundamental interest of workers in access to exposure and medical information. As voiced by one employee from an electronics plant:

> It is the workers who are interested in monitoring the workplace. We are the ones who have a stake in what happens to us. the board of directors doesn't work with those chemicals. And I can't see why you would want to keep that kind of information out of the hands of the people who have got a lifelong interest in keeping their workplace safe. And with that I want to say that I know that—and our committee we receive a lot of requests from workers saying they want to understand and investigate their workplaces; they don't want to be in the dark; they want to find out what these symptoms are caused by. And they are more than serious and they are pretty up front, right?—and they want to live. They are working to live, not die. They are working to support families that are healthy, not children that are born with any kind of problems related to what their parents worked with. And this kind of ruling could really make a difference for workers. (Lamborn (Electronics Safety and Health Project), Tr. 1603–4)

Dr. David Wegman of the Harvard School of Public Health and University of Massachusetts Medical School observed:

> The access of the worker to his or her medical records is especially important. This is true because the worker ultimately is responsible for his or her own health. They need the information that is contained in medical records to fulfill this responsibility to themselves. This is consistent with the preamble to the constitution of the World Health Organization which defines health as a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity. For any individual to try to promote his or her own health requires sufficient information that he or she can act to build toward improved growth and health, not simply act in the presence of illness. The individual's right to control his or her own destiny is really the foundation upon which the principles of preventive medicine are based. (Dr. Wegman, Ex. 10, p. 8)
>
> In the absence of having a full understanding of the condition of health and disease in an individual, I think the individual plays a very little, small role in promoting their own health. And I think that the medical record provides a [route] to this knowledge that just isn't available in any other way. (Dr. Wegman, Tr. 203)

Peter Weiner, Chief Counsel of the California Department of Industrial Relations, also stressed this fundamental worker need to know:

Whatever we in government are able to accomplish, experience in the workplace will be the touchstone of occupational health action for some time to come. In giving workers the right to accompany OSHA inspectors on walkarounds, Congress recognized that workers often have the most practical knowledge of the hazards they face. Yet in the uncertain world of predicting occupational health hazards, the worker has all too often been kept in the dark. . . . Miners of yesteryear at least had canaries to warn them of dangers in the mine. Today, all too often, workers are themselves the canaries. . . . *It is time we recognized generally that workers have a right to know the hazards they face on the job.* They have a right to all information that may be relevant to protecting themselves, their fellow workers, and their families. As a DBCP worker told us, "the competitors ain't our worry. Our lives is what we're worried about." Workers have an absolute need to know this information in order to bargain collectively to reduce exposures, and to assure compliance with stringent safety and health rules in the workplace. (Ex. 9A, pp. 2–4) (emphasis in original; footnote omitted)

This standard will enable workers to play a major role in their personal health management.

C. Worker Discovery of, and Efforts to Control, Occupational Health Hazards

Access to exposure and medical information will also enable workers and their representatives to become directly involved in the discovery and control of occupational health hazards. Access to exposure and medical records will better enable workers to uncover unknown patterns of health impairment and disease. Workers will be able to link specific adverse health effects with exposures to specific toxic substances, and investigate the possible causes of known patterns of disease. Once an occupational health problem is discovered, access to records can assist workers in their efforts to hasten control of the problem. This worker involvement to implement controls can take many forms, such as discussions with employers, collective bargaining remedies such as grievances, new contract provisions, or complaints to agencies such as OSHA and NIOSH.

Experience has shown that direct worker involvement has often played a major role in discovering occupational health problems. Three very concrete examples concern the discovery of the occupational health hazards posed by bischloromethyl ether (BCME), dibromochloropropane (DBCP), and NIAX catalyst ESN.

I think it is rather interesting in the extreme case where Robert Pontius, who worked at Rohm and Haas, was aware of 13 fellow workers who had died of lung cancer following coughing up blood, brought this to the attention of a physician who was investigating the 14 cases, including Robert Pontius, [and] made the first determination that bischloromethyl ether was a human carcinogen in the circumstances of exposure. Now Pontius had to rely on rather finite and endstage results; that is, the death from cancer, in order to make these associations. There are much earlier stages where these associations could be made if workers are in detail aware of their own work history and can share that knowledge with other workers as they see fit. (Dr. Wegman, Tr. 203–4)

* * * * *

With DBCP, we were able to trace the cause of worker sterility only after workers became aware of the common pattern among them. It is possible that some of the tragic and irreversible sterility among DBCP workers could have been avoided had this pattern been evident earlier. (Weiner, Ex. 9A, pp. 3–4, 24)

In DBCP indeed the problem was perceived by the workers, and had it not been for their perceptions and discussions the problem would still be undiscovered. (Dr. Whorton, Tr. 273–274)

* * * * *

Another problem we [OSHA] are particularly concerned about is the tendency to introduce new chemicals without sufficient toxicological pretesting for acute and chronic effects. A dramatic example of a chemical without such testing happened just recently with the Union Carbide product NIAX catalyst ESN. I must say that while Union Carbide did not have toxicological data beyond the customary acute data, they did act responsibly by undertaking additional toxicological studies. Unfortunately, this occurred after the fact of workers becoming ill due to exposure in two different sites, one in Marblehead, Massachusetts and the other in Jessup, Maryland . . . Soon after the catalyst was introduced in a Massachusetts plastics plant a number of workers complained of bladder problems, weakness and tingling in their legs and impotency. When these workers went to their private physicians, their symptoms were diagnosed as prostate problems, bladder infections, or other diseases. By talking to one another at the plant, some of the workers became convinced that their health problems were work related. Finally, eleven employees went together to the Salem Hospital emergency room, to demand treatment and recognition of the problem as an occupational exposure. The hospital called Dr. David Wegman, an occupational health physician at the Harvard School of Public Health, who began investigating the problem.

At just about the same time, similar symptoms began appearing at a Baltimore plant using the same catalyst.

A Baltimore physician who began seeing patients from the plant, knew of the toxic effects of one chemical used there—TDI—and called Dr. Wegman, an authority on that chemical, and so, by chance, it was discovered that the two groups of workers were both exhibiting the same problems . . . NIOSH and OSHA were called in and it was determined that ESN was the causative agent—and a few weeks ago we [OSHA & NIOSH] issued a joint hazard alert. Union Carbide voluntarily stopped production of the catalyst and recalled existing stocks. (Statement of Assistant Secretary Bingham before the American Chemical Society, Ex. 170, p. 5–6; *See,* Dr. Wegman, Tr. 220–22)

(*See also,* Dr. Wegman, Ex. 10, pp. 9–10).

Access to records will not only facilitate the discovery of previously unrecognized patterns of occupational disease, but will enable workers to investigate potential occupational causes of clear patterns of disease.

Psychological problems resulting from the neurological effects of chemicals may be the common link uncovering a job-related hazard. In one benzene plant in Baltimore three workers in one department were diagnosed as having severe psychological disorders. Without the ability to obtain full medical records, workers would be hampered in their ability to follow up the possibility that a work exposure caused these symptoms. (Eller (ICWU), Tr. 732)

Access to exposure and medical records will enable workers to hasten the control of health problems as well as discover that problems exist.

In the presence of the adequate collection of environmental and personal exposure data and medical testing associated with such exposures, workers' access to the information would provide reasonably early the knowledge of the development of abnormalities and provide the workers the information to act on independent of any other person's action. (Dr. Wegman, Ex. 10, p. 6)

Dr. Wegman also gave this testimony:

It is my experience in my work, both with the Division of Occupational Hygiene [of the State of Massachusetts] and my research and teaching capacities at the Harvard School of Public Health, that when people know about the exposures that they have and know the risks associated with those exposures, they take much greater care in trying to control those exposures to the extent that their individual actions have some role . . . than they do if the material is presented to them as being not of significant health impact or if the material is not even described to them. An example of this was the case where I worked with [asbestos]. A local union working with the manufacturing of brake linings were not aware that asbestos was in the brake lining, and once it was brought to their attention the union leadership informed the membership. The membership recognizing the possible health effects became quite concerned about appropriate ventilation control, made it a major issue in discussions with management and as a result of this led to control of the asbestos exposures that were existing in that workplace which previously had been left uncorrected. (Dr. Wegman, Tr. 201)

(*See also,* Dr. Wegman, Ex. 10, pp.7–8).

Testimony in this proceding shows the numerous ways in which workers will use access rights under this standard to hasten the correction of occupational health hazards. Indeed, the active participation and testimony of the

many workers and local and international union officials who appeared at the public hearings is in itself strong evidence of worker desire and ability to obtain information and put it to good use. Several passages of the hearing transcript reflect the nature of worker testimony:

After just being on the union committee itself, we saw in an area that is called the drying room that men were having problems and had to get out of the area. And the company had told us there was no problems in the area. So from that point on it seemed like we had to check it out for ourselves because the company said there wasn't no problems. . . . I got a list of people, how long they were on the job, and then I started to interview to see what problems they were having. The people were having bleeding noses, holes in their noses, eye irritations and other problems. And at that point the company still hadn't done nothing. So from them I had to get more information to find out what was causing the problem. So I asked our international to help us and other technical people. At that point they told me we had problems with fluorides . . . If I would have had access to the information sooner as far as the materials being used and the medical records of some of the people affected in the area, we probably could have gotten action a lot sooner . . . (Herbst (ICWU), Tr. 721–22, 725; *See also* Tr. 722–25)

* * * * *

For instance, in International Harvester's Melrose Park plant workers in high noise areas in the plant are given annual hearing tests. Analysis by the union of this audiometric data could provide important insights concerning hearing loss in our plant. This would allow us, the union safety committee, working hopefully in cooperation with management to reduce noise levels or expedite temporary administrative controls in these departments where major hearing loss problems are occurring. We don't have that information and the company will not let us review the hearing test information. (Gaffney (UAW), Tr. 1323)

* * * * *

Well, upon receiving the sampling information, it would give me an idea of what spots are most hazardous and what to concentrate on first, and be able to inform the people, educate them, which I have taken steps already to do so by calling in the international safety department to educate people on what these types of exposures can lead to, and then if it be their will to go ahead with a grievance procedure and take steps to get this corrected. And if the grievance procedure, you know, if we failed there, then we [inaudible] OSHA. (Bergs (USWA), Tr. 1119–20)

* * * * *

Exposure records must not be permitted to become mere historical artifacts, sitting unattended in dusty archives while the hazards they document go uncontrolled. They have usefulness as tools and as with any tool they will be put to the best use by those who want to get the job done. It is employees, with their first hand experience with workplace conditions and their personal stake in the identification of danger, who are the driving force behind safety and health programs. It has become a truism to point out that the workers on the shop floor are often the ones with the most accurate sense of where the potential hazards exist . . . To deny workers the data necessary to distinguish between mere suspicion and accurate hazard recognition is a serious error. It has been our experience as a union with a particularly active health and safety program that employees who have gained access to exposure data have used it productively and aggressively to identify and control hazards. (Dr. Silverstein (UAW), Ex. 63, p. 12)

* * * * *

With regard to the need for ready access by individual workers or union representatives to exposure data, suffice it to say that such access will inevitably serve to motivate workers and their representatives to investigate and eliminate workplace hazards. OSHA will never have sufficient inspectors, nor the ability to immediately set standards, to protect workers from all hazards. The provision of exposure records will allow workers themselves, however, to protect themselves more completely than ever before. (ACTWU, Ex. 2(201), p. 5)

Based on the extensive worker testimony, the Steelworkers stated that: "In summary, the employees who testified do not pretend to be industrial hygienists or physicians, but they have demonstrated the ability to deal with technical material and seek help when needed;" and that "most unions have safety and health departments and consultants to provide advice in these areas" (Ex. 160, pp. 8–9) (*See also,* USWA, Ex. 160, pp. 2–4; Spatz (Cement, Lime and Gypsum Workers), Tr. 1200–01; Annas, Ex. 56, p. 7; Dr. Wegman, Ex. 10B (article on project to train industrial workers in health hazards surveillance); AFL–CIO, Ex. 152, p. 51). OSHA is convinced that workers and their representatives can and will obtain medical and exposure records and use this information to detect and help control occupational health hazards.

D. Improved Ability to Diagnose and Treat Occupational Disease

Direct access to exposure and medical data will also better enable an employee's personal physician to diagnose, treat, and possibly prevent permanent health impairment. Private physicians are extremely important to the proper diagnosis and treatment of occupational disease since there are currently very few trained and experienced occupational physicians (*See,* Dr. Wegman, Tr. 215–18). Dr. Teitelbaum discussed the importance of medical and exposure records in this context:

Day-to-day problems are raised for me as a practicing occupational toxicologist by the present situation in which employee medical records are not available for my study, are incomplete, or are submitted in a format which is obscure. My practice includes consultation in occupational health and toxicology. . . .

Some patients are self-referred and some are referred to me through their own primary physicians. These patients often consult their family practitioners, who are puzzled by the disease syndrome which they see but do not recognize. The practitioner carries out a traditional medical work up and detects abnormalities but does not have the knowledge required to arrive at a definitive diagnosis [which] links the disease to the individual's occupational activity, although he may strongly suspect an occupational connection . . . .

Typically, the information available to me is a classical medical record obtained from some other medical practitioner at the patient's request, a history which is obtained from the patient, and a small amount of information on the materials with which the patient has worked, which may be given graciously or grudgingly by the employer. Some employers collect and maintain important medical information regarding individual employees from preemployment examinations and regular medical monitoring. . . .

Some companies, even large employers, may have relatively little information on many of the chemicals which come into their plant, although they may have substantial information about the processes with which they work. Often, however, these companies are reluctant or resistant to provide copies of this information to the patient because of the medical-legal implications from a worker's compensation point of view. When such information is not provided to a consultant, diagnostic difficulties often occur. Patients usually do not know the health effects, the level of their exposure, or the chemistry of the material itself. They are usually unable to provide to me enough information for development of a definitive diagnostic and treatment program. (Dr. Teitelbaum, Tr. 114–116)

Dr. Wegman also stated the importance of exposure data to an examining physician faced with a patient experiencing a disease of unknown etiology (Ex. 10, pp. 7–8; Tr. 224; *See,* Dr. Parkinson, Ex. 43, p. 5; Samuels (AFL–CIO IUD), Tr. 972–73).

Physician access to medical and exposure data will help facilitate a prompt and accurate diagnosis, thus enabling appropriate treatment. Because the human body can react to various insults in only a limited number of ways, it is often difficult to distinguish between occupationally and non-occupationally related problems (*See,* VII.C.6, *infra*). Exposure and medical information can substantially assist a physician's evaluation, such as where previously recorded baseline medical information can be compared to current health status to ascertain whether and

how health has declined over time (*See*, Dr. Swartz, Tr. 2363, 2369–70). Access, by increasing the likelihood of discovering a connection between occupational exposure and a disease, will also enable a physician, where appropriate, to recommend a temporary or permanent end to exposure to the agent in question. Timely removal from exposure in some cases will serve to prevent the early manifestation of a disease process from progressing to permanent and irreversible health impairment. Timely removal from exposure in other cases will prevent further aggravation of whatever permanent impairment has already occurred. At the same time, a prompt diagnosis of an occupational disease can also serve to alert an employer of the need to reduce the exposures of other workers.

E. Employee Awareness and Improved Work Practices

Where the dangers of exposure to a toxic substance or harmful physical agent are known, worker access to information will also serve to decrease the incidence of occupational health problems. An individual worker's personal actions can greatly affect the extent of exposure to a toxic substance. These personal actions will be shaped by a worker's knowledge and appreciation of the health hazards he or she faces. Grover Wrenn, OSHA's official spokesperson at the public hearings, discussed this factor in his opening statement:

> Increased awareness of workplace hazards on the part of employees will also make it more likely that prescribed safety and health practices will be followed. During OSHA's hearings for the dibromochloropropane standard, one worker testified to the following, and I quote:
>
> We had no warning that DBCP exposure might cause sterility, testicular atrophy, and perhaps cancer. If we had known that these fumes could possibly cause the damage that we have found out it probably does cause, we would have worn equipment to protect ourselves. As it was, we didn't have enough knowledge to give us the proper respect for DBCP. Had we been warned of these dangers, some may not have accepted employment in the first place, and others, myself included, would certainly have handled this material more carefully.
>
> That is the end of that worker's quotation, but it is representative of comments delivered not only in that rulemaking hearing but others that OSHA has conducted on a number of toxic substances . . . . (Wrenn, Tr. 9–10)

Efforts are often made to control worker exposure to toxic agents through the use of respirators, protective work clothing, and careful personal hygiene (showers, washing hands and face before eating, etc.). Work practices which strive to minimize dispersal of toxic substances (e.g., immediately storing dust laden scrap material in closed containers) are also important. All of these control techniques depend on worker cooperation—cooperation which will best be assured when a worker knows the identity of hazardous substances he or she faces on the job, the magnitude of exposure, and the potential health consequences of this exposure (*See*, Dr. Wegman, Ex. 10, p. 7; Dawson (Electronics Safety and Health Project), Tr. 1600; Zebel, Ex. 2(91), p. 1).

F. Occupational Health Research

Access to exposure and medical records and analyses based on these records, as well as long term preservation of these records, will also facilitate formal occupational health research. Groups of employees and unions can use the access rights of this standard to make medical and exposure information available to university and private organization researchers (*See*, Dr. Enterline, Ex. 2(60)). Prof. Joel Swartz of the University of Illinois School of Public Health, Department of Occupational and Environmental Medicine, explained the importance of medical and exposure records to occupational health researchers:

> I think that the availability of medical records is important to detecting occupational disease and in being able to correct the situation which causes the disease. I want to bring out three main points. One, in the past, standards have been set too high for many substances, and the data from careful occupational and epidemiological study have been used to develop lower standards. In the same way, data from medical records and from monitoring could be used to provide information that standards for many other substances, the approximately 500 other regulated chemicals and many other unregulated chemicals, may be too high, and that therefore, the standard should be set lower.
>
> Second, the data from medical records is needed as a baseline to establish the presence of occupational disease because of individual variations in the population. In other words, many biological parameters vary from individual to individual, and a person may have substantial occupational disease, but this may be masked because of the normal variation in the population. And especially in the case of the working population, we generally find that the working population is healthier than the general population and that superficially it may look like there are no occupational diseases in the population, but if we have records that can show progressive changes, we may be able to find such occupational disease.
>
> A third point—it has been argued by industry that workers in their organizations and in some cases, NIOSH and OSHA, are not competent to interpret medical data. I'd like to argue exactly the opposite, that in many cases when data was left in the hands of industry, it has been systematically distorted and manipulated to mask the presence of occupational disease. And only when this data has gotten into the hands of representatives of unions or of NIOSH and OSHA has it been correctly interpreted and have we been able to find instances of occupational disease. (Tr. 2362–63).

Prof. Swartz gave a number of examples to illustrate these points (Tr. 2363–73). NIOSH also indicated that:

> Exposure, demographic and medical data provide valuable information in determining the effects of occupational exposures on workers, developing standards and establishing preventive measures. As has been shown in recent years, reliance on animal studies alone does not always provide the necessary information for evaluating or improving work or environmental conditions. . . . Since it would not be ethical to purposely expose humans to substances for research purposes, researchers must study those individuals who, as part of their everyday lives, may have been exposed to toxic substances. Specifically, information is needed to conduct various types of epidemiologic investigations, such as cross-sectional medical and reproductive studies, retrospective cohort mortality and morbidity studies and case control studies. The data needed for these studies include exposure data, medical information, work history information, and demographic data collected by employers. (Ex. 16, p. 2).

(*See also*, Weiner, Tr. 181–82; Dr. Wegman, Ex. 10A; NCCHR, Ex. 58, pp. 33–40, 46; Spatz (Cement, Lime and Gypsum Workers), Tr. 1205–06).

Although NIOSH and other federal agencies are likely to conduct a large portion of the non-employer-sponsored occupational health research in this country, there is a definite role for individuals such as union-sponsored researchers, university scientists, and doctoral candidates in occupational health or biostatistics. The designated representative provisions of the final standard will facilitate this kind of research.

G. Importance of Access To Explicit Statutory Rights

In addition, it is important to observe that worker access to exposure and medical information is important to the effectiveness of at least six explicit employee rights established by the Occupational Safety and Health Act. These statutory rights are discussed in greater detail in the Legal Authority portion of the preamble (V.A, *infra*). They are mentioned here because it is the agency's judgment that substantial occupational health benefits will result from improving the ability of workers to

make beneficial use of these statutory rights.

Access to information is first of all crucial to the effectiveness of the section 8(f)(1) right of employees and their representatives (29 U.S.C. 657(f)(1)) to complain to OSHA concerning perceived safety and health problems and obtain a prompt inspection of the worksite at issue. Access gives meaning to the section 8(e) right of employees and their representatives to accompany OSHA during plant inspections (29 U.S.C. 657(e)) in order to identify where and how various toxic substances are used, which plant operations generate the greatest exposures, and otherwise help OSHA conduct a thorough inspection. Access will enable workers to better exercise their twin rights under section 10(c) to contest the reasonableness of abatement periods proposed by OSHA, and to participate as parties in Occupational Safety and Health Review Commission adjudicatory proceedings (29 U.S.C. 659(c)). A fifth statutory right enhanced by worker access to records is the section 20(a)(6) right of workers to request a workplace Health Hazard Evaluation (HHE) by NIOSH (29 U.S.C. 669(a)(6)). Lastly, the knowledge learned by workers due to access to medical and exposure records will also heighten the impact of the employee training and education programs currently being funded by OSHA pursuant to section 21(c) of the Act (29 U.S.C. 670(c)).

By promoting the effective use of the foregoing employee rights, the final standard will substantially advance the statutory scheme created by Congress for the solution of occupational health problems.

H. Lack of Worker Access to Existing Medical and Exposure Records

Having discussed the benefits of direct worker access to medical and exposure records, it is appropriate to consider the kinds of records that employers generate, and the current practices concerning employee access to these records. As will be seen, the presence of records and the existing general lack of direct access establish the necessity for this standard.

Medical records relevant to potential occupational disease are generated in a variety of contexts. Occupational medicine is practiced in a wide variety of settings and encompasses a wide range of medical services. The range of experience includes company-owned hospitals capable of performing most primary care (Skiba (Magma Copper), Tr. 1446–8), sophisticated in-house medical departments with epidemiological, toxicological, and medical expertise (DuPont, Ex. 12, pp. 2–3), medical programs consisting only of an on-site occupational health nurse (Garry (Cal. Occ. Health Nurses), Tr. 1727), and contractual arrangements with industrial health clinics or outside physicians (either on a retainer or fee-for-service basis) (Dr. Jacknow (Chamber of Commerce), Tr. 981). Contractual arrangements with outside physicians or clinics constitute the major organizational form of occupational medicine practiced in this country (Dr. Wegman, Tr. 216–17; Dr. Jacknow (Chamber of Commerce). Tr. 981; Garry (Cal. Occ. Health Nurses), Tr. 1727; Dr. Hockwald (AOMA), Tr. 1531). There are approximately 10–15,000 physicians who are engaged in the practice of occupational medicine and many of these physicians practice only on a part-time basis. Approximately 500 of these physicians are board certified in occupational medicine (Dr. McLean (AOMA), Tr. 1536–7).

NIOSH, in its National Occupational Hazards (NOH) Survey found that only four percent of all industrial plants have a formally established health unit, only half of which were headed by a physician. The larger plants (500 or more employees) tend to have in-house medical facilities, accounting for 80% of the employees in plants which have a formal unit. The survey also found that whether a plant had and established health unit varied significantly according to industry type (Ex. 107; *See also,* Cal. Health Action Coalition, Ex. 95).

The NIOSH NOH Survey found a high degree of variation in the medical services provided by employers. Survey results indicated that 48% of all employees are given pre-placement physical examinations and 78% of all employees work in plants which regularly record some health information about new employees (Ex. 107; *See also,* Samuels (AFL–CIO IUD), Tr. 949). Some form of periodic medical examinations are provided to 34% of all industrial workers (Ex. 171, Table 11). Medical services provided by employers may include first aid, periodic comprehensive examinations, on-site treatment of injuries and illnesses, medical screening for occupational illnesses, medical examinations for workers' compensation and group health insurance purposes, and medical surveillance to comply with mandated OSHA requirements (NCCHR, Ex. 58, p. 30). As a result, and employee medical record can contain information concerning a variety of items: (a) a pre-employment questionnaire and/or medical history, with or without a physical examination; (b) laboratory tests; (c) chronology or episodic visits; (d) scheduled periodic examinations; (e) notes or letters from the employee's treating physician; (f) summaries of hospital records, other outside treatment records or consultations; (g) substance abuse problems; (h) psychiatric problems; (i) non-occupational medical problems; and (j) family records. (Dr. Whorton, Tr. 257).

The NIOSH NOH Survey also determined the extent to which employers regularly monitor the environmental conditions in their plants and receive some form of industrial hygiene services. In general, less than 5% of employers with fewer than 250 employees regularly perform monitoring (Ex. 171, Table 27). Approximately 16% of medium size manufacturing employers (250–500 employees), and 51% of large manufacturing employers (over 500 employees) regularly conduct monitoring *(Id.).* Overall, approximately 22% of all industrial employees are employed in plants where monitoring is regularly performed, with the percentage being approximately 40% for all manufacturing employees *(Id.).* The NIOSH NOH Survey shows a wide fluctuation in the extent of regular monitoring, depending on employer size and SIC code. In addition, it is to be expected that far greater percentages of employees are covered by infrequent monitoring than by regular exposure monitoring. For example, 52% of manufacturing industry employees work in plants which receive industrial hygiene services (Ex. 171, Table 2). Irrespective of the exact percentages involved, it is clear that a substantial portion of American workers work on jobs for which exposure monitoring is being conducted.

Industrial recordkeeping practices appear to vary widely as to the extent to which employees are provided direct access to medical and exposure records. Many occupational physicians subscribe to the "Code of Ethical Conduct for Physicians Providing Occupational Medical Services" adopted in 1976 by the American Occupational Medical Association (AOMA) (Tr. 1538; Ex. 2(59)). While members of the AOMA may be penalized for violations of the AOMA Code, including censure, suspension, or expulsion from the organization (Dr. McLean (AOMA), Tr. 1541), to date, no member physician has been disciplined for violating any part of the Code (Dr. McLean (AOMA), Tr. 1543). Moreover, one personnel manager, not himself a physician but nevertheless responsible for a large medical program, testified that he had

never heard of the AOMA or its code of conduct (Skiba (Magma Copper), Tr. 1501). In addition to the AOMA, the American Academy of Occupational Medicine (AAOM) (Ex. 2(101)), the American Medical Association (AMA) (Ex. 105), and the American Association of Occupational Health Nurses (Ex. 123) have similar codes of ethical conduct, and have similar sanctioning powers (Dr. Steen (AMA), Tr. 2398). License revocation by the state is also a potential penalty for ethical misconduct (Dr. Steen (AMA), Tr. 2398–99; API, Ex. 158, p. 19).

As part of its ethical code, the AOMA prescribes conduct with respect to informing workers about their health. It obligates occupational physicians to "communicate information about health hazards in timely and effective fashion to individuals or groups potentially affected" and to "communicate understandably to those they serve any significant observations about their health, recommending further study, counsel or treatment when indicated" (Ex. 2(59), Standards 8 and 9; *See also,* Council on Occupational Health, American Medical Association, *Scope, Objectives, and Functions of Occupational Health Programs* (1971), Ex. 93C, p. 8).

By its terms, this policy does not grant employees rights of full access to medical records. The rulemaking record indicates that in practice the AOMA policy has been subject to divergent interpretations, ranging from routinely giving employees copies of all documents generated in medical examinations (Dr. Dietz (Goodrich), Tr. 1221) to providing only an oral consultation if information is requested (Dr. Johnson (Goodyear), Tr. 1219–20). In general, occupational physicians familiar with industry practice depicted a broad middle ground in which "the occupational physician has an obligation to discuss in detail the results of his physical examination, laboratory studies and exposure data with the employee-patient" and "to provide factual information" (API, Ex. 68, p. 1). At the same time, they indicate that the occupational physician often retains broad discretion "as to how to release the information, and is required to divulge only information which is in the patient's best interest" (API, Ex. 158, p. 26 (footnotes omitted)). According to the AOMA,

> [U]sual occupational medical practice is to disclose an employee's records to him or her upon request. The physician, however, should be granted the right to withhold information contained in the record which may be harmful if divulged to the employee. An employee's designated physician should have the right, however, to review all medical information contained in the record. (Dr. McLean, Tr. 1530.)

In contrast, employees and their union representatives universally testified that lack of worker access to medical and exposure information was the rule rather than the exception. Numerous specific examples of employer refusals of information were given by employees, union officials, and independent physicians (Dr. Teitelbaum, Tr. 116, 118; Dr. Wegman, Tr. 231–34; Dr. Parkinson (USWA), Ex. 43, p. 5, Tr. 1145; Dr. Silverstein (UAW), Ex. 63, pp. 3, 4, 12–13, Dr. Ziem, Ex. 2(69), p. 2; AFL–CIO, Ex. 152, pp. 2–7, 9–11, 30, Ex. 39, p. 1, Tr. 640–42; Laden (USWA), Tr. 666–68; Wilson (USWA), Tr. 674–78, 683–84, 687; Wright (USWA), Tr. 871–72, 874–75; Becker (USWA), Tr. 2380–86; USWA Panels, Tr. 1116–24, 1150–52, 1157–61; Wodka (OCAW), Ex. 2(124), pp. 1–2, Attach., Ex. 26, Ex. 26a, Tr. 694–98; Eller (ICWU), Tr. 727–32, 745–46; Meyer (OCAW), Tr. 787–90; Clanigan (PHILAPOSH), Tr. 791–95; Walker (PHILAPOSH), Tr. 799–802; Frumin (ACTWU), Tr. 826–28; Keel (ACTWU), Tr. 843–48; Simonski (UAW), Tr. 1294; Klein (UAW), Tr. 1291–93; Mattillion (UAW), Tr. 1313–17; McDougall (IBT), Tr. 922–23; Howe (CACOSH), Tr. 1096, 1104–05; Spatz (Cement, Lime and Gypsum Workers), Tr. 1204–05; Electronics Safety and Health Project Panel, Tr. 1584–1605; LOHP Panel, Tr. 1679–83, 1685–90; HRG, Ex. 161, pp. 3–4; Ex. 161d, pp. 4–8; *See also,* Weiner, Ex. 9A, pp. 3–4, 13–14, Tr. 175–76; Castleman, Ex. 104; ACTWU, Ex. 2(201), pp. 1–3). The following passages are typical of the extensive worker testimony on this issue:

> The classic case that we are developing now concerns asbestos. It concerns bricklayers. Bricklayers in the steel mill, not the classic type of bricklayers that you are familiar with, but they reline furnaces and part of the substances that they use in relining furnaces are silicones and asbestos. When they tear them out, they are subject to heavy doses of very fine particles of asbestos. So asbestos has been recognized as a problem substance for a long time—not necessarily always connected with cancer but sometimes with asbestosis.
>
> So in 1952, the company agreed to examine the workers exposed to asbestos on a yearly or an every 18-month basis, and so from 1952 until today they have been doing that. But all that time—I have to give you a little background on the company dispensary. It is a very well-equipped dispensary. They have 16 medical doctors on staff, so they know what they are doing.
>
> Now, all the time from 1952 to date, they have not [found] a case of occupational illness among the bricklayers. Just six months ago we took a list of the bricklayers that were off sick and out of the 15 that were off sick, seven of them had over 30 years seniority, which is significant because of the latency period of asbestos in relation to problems. Out of the seven, four of them had a lung removed or a part of a lung removed. Two of them had congestive lung disease, and all of them had been examined by the company dispensary not less than seven months prior to the last time that they worked. All of them had been told by the company that you have no problem, with the exception of one, who was told by the company that 'Your pulmonary function tests have been getting worse for the last five years, and we think it is time that you saw a doctor.' None of them have been told by the company that 'We think you ought to get out of the area. Your pulmonary function tests are showing up worse. For your own benefit, get out of the area, stop getting exposed to the silicones and the asbestos.'
>
> Now you ask yourself why that would be the case and the answer is kind of obvious to the workers, anyway, that if the companies examine an employee for exposure to a specific agent that is harmful to his health, and then they admit that his health has been damaged and move him to another area, they are immediately subjected to a Workman's Compensation Claim, which is an expense item. That is because employers—specifically now, we are talking about Bethlehem Steel—refuse, blatantly refuse, to give employees any information in spite of the fact, in the case of the bricklayers, . . ., we have a document signed by the employee designating his personal physician, signed by a witness, requesting his records to be sent to his own doctor. The company has refused to supply those records to the doctors. (Wilson (USWA), Tr. 676–78)
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> * * * * *
>
> The union has also had difficulty receiving medical data. In these cases, despite a medical testing program which yields critical information the union is prevented from receiving the data. Workers at one ICWU local in New Jersey have been requesting but not receiving relevant work-related exposure records in a plant with an extremely high incidence of lung and bladder abnormalities. Another local demanded that sputum cytology results be forwarded to a doctor of the worker's choice. Workers were forced to picket and work without a contract for several months over this issue. In Waukegan, Illinois the ICWU was unable to obtain the results of [X-ray tests] and had to request that OSHA obtain these records. (Eller (ICWU), Tr. 731–32)
>
> * * * * *
>
> I personally wrote a letter to the head of the Employees Relations Department of our plant site and one to the doctor requesting my complete medical file. I had a problem a few years back with acute bronchitis. I was working in an area called the aflare area. . . .
>
> What it is for are these pearl cosmetics, some of the eye shadow that the ladies wear, but it is made with a really super fine mica. I worked in that area for almost nine years and I had continuous bronchitis all the time. It was acute. I finally got out of the area, and two years later my bronchitis started to clear up, but I wanted my medical records to see

for what reason I had this acute bronchitis all the time.

I got a letter back from the Employees Relations Department that said that medical records were confidential, the personal property of the company, and I was not allowed to have them. I could come down to the Employees Relations Department with my immediate supervisor and look over my medical records. I didn't get any of the medical records at all. The only way I ever got medical records through the DuPont Company is through an arbitration case and the medical records had to be subpoenaed. (Walker (PHILAPOSH), Tr. 799–800)

* * * * *

For example, in the welding areas we have periodically in the past requested tests be performed in the area where heavy concentrations of welding operations are performed. Specifically, . . . for exposure to such things as ozone or iron oxide. After the tests were made, after approximately three months for a team of hygienists to come from Detroit, we were told that all areas checked were in compliance. Exact results of the tests, however, were never disclosed to me. Nor were they disclosed to the particular employees who were tested. By simply stating that the test showed the corporation in compliance, in my opinion, does not mean the operation is healthful or particularly safe. Their results, for example, could have been on the high end of permissible exposure limits, making them far more harmful than had they been on the low end. Without this precise data our local safety committee is at a loss as to what to demand in the way of personal protective equipment or proper ventilation or whatever the case may be. Results of pulmonary function tests performed on these individuals and administered to many other employees have not as yet been disclosed to me or the employees despite repeated requests.

Another example is in the area of noise. We have known for a long time that many areas of the plant were out of compliance inasmuch as noise was concerned. As a result of an OSHA inspection and subsequent citation, the corporation instituted a large-scale noise survey in the plant. This survey was started approximately one and a half years ago and was completed in April of this year. Again, when we asked for exact results of the survey, we were told that most areas were in compliance but there were some definite problem areas. However, it was becoming [clear] to us that a serious problem was developing in certain areas of the shop with regard to possible noise-induced hearing loss. When the employees in these high noise areas requested copies of their audiograms that were being administered to them and were denied these copies, they became concerned because the simple fact was that they were having trouble hearing. This prompted the local union to set up at the union hall an audiologist to give preliminary hearing tests to anyone who wanted them.

As a result of this preliminary hearing testing and subsequent testing, approximately 500 employees were found to have noise-induced hearing loss of one degree or another. Five hundred cases, the severity of some which may have been lessened had the employees had access to their records and took necessary measures sooner. (Mattillion (UAW), Tr. 1313–14)

* * * * *

On the other hand, workers are often forced to turn to the grievance procedure, including arbitration and strike action, to obtain vital medical or exposure data. I personally have been involved in numerous occasions where we have or I have assisted through our union or myself directly in such endeavors . . . [G]oing back four years ago in Borg Warner Mechanics Division in Rockford, where we had a worker who had already been diagnosed as overexposed to maganese, the consequences of which I am sure the medical professional can articulate much better than I, but certainly it can destroy the central nervous system and do great damage to the individual if the amounts are excessive enough. He had already been diagnosed. We had to go to grievance procedure, we had to go to arbitration on contract language, and we had to take the initial steps of strike action to finally get the medical information and data that was in those records all the time. And it took us over two years of maneuvering and delay and frustration on the part of this individual to achieve that. And the only thing that is uncommon about that is the length of time. It is more common than not to have to resort to these kind of tactics and pressures to obtain medical information and data on these individuals. (Klein (UAW), Tr. 1291–92)

Employee and union testimony also indicated that when some form of access to exposure or medical information is provided by management, this is often given orally with only a general indication that the employer is or is not in compliance with prescribed standards, or the employee does or does not have a problem. Precise quantitative results are not released to either the employee or the union. In the light of its experience the AFL–CIO concluded,

To date, gaining access to exposure and medical information has been an uphill battle. While some unions have negotiated and gained the right to exposure information, most have had to resort to grievances, arbitration, unfair labor practices [claims], and in some cases strikes to secure information necessary to represent and protect their membership. These procedures are long and costly but the record shows only when required by law or ordered by an arbitrator or the NLRB will many employers turn over the requested information. (Ex. 152, p. 9; citations omitted)

OSHA's considerable experience from other rulemaking and enforcement proceedings corroborates the testimony from workers and their unions that they are often denied access to basic data in exposure and medical records. The statements of facts in several recent judges' decisions in NLRB cases involving access to exposure and medical records also provide corroborating evidence that access to such information is not routinely given. *Colgate-Palmolive Co.*, Case No. 17–CA–8331, ——. NLRB —— (March 27, 1979); *Minnesota Mining and Manufacturing Co.*, Case Nos., 18–CA–5710–11, —— NLRB —— (March 13, 1979); *Borden Chemical, A Divison of Borden, Inc.*, Case No. 32–CA–551, —— NLRB —— (April 25, 1979). Moreover, industry witnesses, while maintaining that in their view employees are provided adequate exposure and medical information, emphasized that broad discretion is exercised by management or the corporate physician over the manner and extent of disclosure.

OSHA concludes on the basis of the record and its own experience that denial of direct, unrestricted access to exposure and medical information is commonplace, if not the universal practice of industry. In those plants where direct access is freely granted, this standard will not significantly alter current practice. This standard is, however, necessary in those many situations where access is routinely denied. By making vital exposure and medical information available to workers and their representatives as a matter of a legally enforceable right, this standard will directly and indirectly contribute substantially to the detection, treatment, and prevention of occupational disease.

I. Designated Representative Access to Records

In order to enable each worker to utilize his or her rights of access to records, the final standard permits an employee to designate representatives to exercise access rights. OSHA believes that enabling an employee to designate anybody he or she desires to entrust with access rights will most effectively achieve the purposes of the Act and this standard. The employee should ultimately be the judge of who can make a positive contribution to his or her well-being by access to records. As a result, no limitation is placed on who the employee may choose to act as a designated representative (*See*, Weiner, Ex. 9A, pp. 36–40; Dr. Silvertein (UAW), Ex. 63, pp. 7, 10; Dr. Parkinson, Ex. 43, p. 4; Annas, Ex. 56, Tr. 1748–49, 1751–52; AFL-CIO, Ex. 152, pp. 51–3, 55–6; USWA, Ex. 160, pp. 10, 20; Wodka (OCAW), Tr. 701–02).

Provisions in the final standard concerning designated representative access serve to facilitate the manner in which employees will often exercise access rights in practice. Workers in various situations will inevitably desire that their records be reviewed by private physicians, union officials and technical staff, family members,

attorneys, or others. Designated representative access simply enables workers to avoid having to personally obtain information which they will then provide to a third party; rather, the desired third party can get direct access with worker consent. Many labor unions, in particular, have become increasingly active in occupational safety and health matters (Ex. 172), and have either employed or developed professional relationships with physicians, industrial hygienists, epidemiologists, and toxicologists. OSHA is accelerating this trend through its "New Directions Grants Program" (Ex. 173). Designated representative access will facilitate union access for health and safety purposes, as well as access by professionals serving the occupational health needs of non-union workers. (*See*, Electronics Safety and Health Project, Tr. 1585).

Experience under the National Labor Relations Act is also relevant to the role of unions as designated representatives of employees. That Act gives collective bargaining representatives statutory rights to information relevant or necessary to the collective bargaining process or to their responsibilities under a collective bargaining agreement. This may include access to exposure and medical records. In *Detroit Edison Co.* v. *NLRB*, 440 U.S. 301 (1979), the Supreme Court recently stated that the interests of the employer in the manner and extent of disclosure must be balanced against the interest of the union. The Court held that the employer in that case had not breached its duty to bargain in good faith when it refused to release personally identifiable scores of psychological tests without the employees' consent. With employee consent, however, the union would have been entitled to that data.

In other contexts, the courts have generally rejected claims of confidentiality as a basis for withholding relevant information from the union. See *General Electric Co.* v. *NLRB*, 466 F.2d 1177 (6th Cir. 1972) (wage data); *NLRB* v. *Frontier Homes Corp.*, 371 F.2d 974 (8th Cir. 1967) (selling price lists); *Curtiss-Wright Corp.* v. *NLRB*, 347 F.2d 61 (3rd Cir. 1965) (job evaluation and wage data); *NLRB* v. *Item Co.*, 220 F.2d 956 (5th Cir. 1955), cert. denied, 350 U.S. 836 (1955), 352 U.S. 917 (1956) (wage data); cf. *United Aircraft Corp.*, 192 N.L.R.B. 382, 390 (1971) (company physician's records not discloseable without employee's permission unless needed for a particular grievance), modified on other issues sub nom. *Lodges 743 and 1746* v. *United Aircraft Corp.*, 534 F.2d 422 (2nd Cir. 1975), cert. denied, 429 U.S. 825 (1976); *Shell Oil Co.* v. *NLRB*, 457 F.2d 615, 619 (9th Cir. 1975) (refusal to furnish employees' names without consent was proper when it was "establish(ed) beyond cavil that there was a clear and present danger of harassment and violence"). Cf. *Detroit Edison Co.* v. *NLRB*, 440 U.S. 301 (1979) (dissent). A number of arbitration decisions have also been reported resulting in access to exposure or medical information by grieving employees or their representatives (e.g. Ex. 2 (124); Ex. 122).

J. OSHA Access to Exposure and Medical Records

The final standard reaffirms OSHA's right of access to employee exposure and medical records. OSHA is a public health agency with regulatory responsibility "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions . . ." (Section 2(b) of the Act, 29 U.S.C. 651). Access to employee exposure and medical records is necessary to accomplish numerous statutory responsibilities, and all comprehensive occupational health standards promulgated under the Act to date have included provisions requiring OSHA access to exposure and medical records (*See*, 29 CFR 1910.1001–.1046).

Employee exposure records are crucial to the performance of many of the agency's investigatory, enforcement, and other regulatory functions. Compliance personnel routinely review employer-generated exposure records. Air monitoring data can pinpoint the problem areas within a plant and enable OSHA industrial hygienists to focus their investigatory energies on these problems. All OSHA health standards are structured in a fashion such that many employer obligations are tied to the results of initial exposure monitoring. For example, under OSHA's inorganic lead standard, an employer need only provide complete medical surveillance to employees "who are or may be exposed above the action level (30 micrograms of lead per cubic meter of air) for more than 30 days per year" (29 CFR 1910.1025(j)(1)(i)). Exposure records are thus scrutinized to verify that an employer has properly complied with its responsibilities. Exposure records are also routinely used in rulemaking proceedings for such purposes as defining the universe of employees at risk and analyzing the extent to which current technology has achieved a desired level of protection (Wrenn, Tr. 51–52).

Employee medical records are less frequently used by OSHA than employee exposure records, but are equally important to the agency's performance of its statutory functions. Prior to this rulemaking, the agency had no written instructions to its personnel on the use of employee medical records. Medical records have been only sporadically sought and used depending on the circumstances of particular compliance cases, and the expertise of the agency personnel involved. In recent years the national office has acquired full time staff physicians, and some OSHA field offices have established relationships with private physicians who are available when needed in specific cases. The agency's use of employee medical records will likely increase in the future with expanding medical resources and expertise, and with the development of additional comprehensive health standards. It is appropriate to outline some of the specific situations in which employee medical records have been or could be relevant to OSHA statutory functions:

1. All comprehensive OSHA health standards contain medical surveillance programs and associated recordkeeping requirements. Access to required employee medical records is necessary to verify employer compliance (AFL–CIO, Ex. 152, pp. 58–59). Field personnel might, for example, check a sample of records to verify that required biological monitoring tests were performed and results recorded, and that written medical opinions are preserved. In these situations, no substantive review is made of the medical content of required records.

2. OSHA enforces Section 11(c) of the Act (29 U.S.C. 660(c)) which prohibits employment discrimination against any employee for the exercise of rights afforded by the Act; e.g., the right to complain of unsafe working conditions. There have been cases where an employer has altered a worker's job status for purported medical reasons, and the worker then complained to OSHA that this action resulted from a retaliatory or other discriminatory intent. To investigate these situations it is necessary to obtain all relevant employee medical records to ascertain the legitimacy of the employer's actions. A summary of three recent cases of this nature has been added to the record (Ex. 174).

3. The substantive content of employee medical records may at times be relevant to the type of enforcement action OSHA initiates against an employer, or to proof of the appropriateness of an enforcement action. Serious violations under Section 17(k) of the Act (29 U.S.C. 666(j)) require an element of actual or constructive

employer knowledge. Section 17(k) provides:

> For purposes of this section, a serious violation shall be deemed to exist in a place of employment if there is a substantial probability that death or serious physical harm could result from a condition which exists, or from one or more practices, means, methods, operations, or processes which have been adopted or are in use, in such place of employment unless the employer did not, and could not with the exercise of reasonable diligence, know of the presence of the violation.

This "knowledge" element may be satisfied by a variety of forms of proof (*See,* Rothstein, Safety and Health Law, ss76–79(1978)). The content of employee medical records could document a pattern of disease sufficient to give an employer actual knowledge of the hazard involved (Wrenn, Tr. 61; Frumin (ACTWU), Tr. 851–2; USWA, Ex. 160, pp. 24–25).

4. The question of whether or not an employer willfully violated an OSHA standard may also be influenced by the content of employee medical records. Willful violations under Section 17(a) of the Act (29 U.S.C. 666(a)) carry up to a $10,000 penalty as opposed to potential $1,000 penalties for serious or non-serious violations (sections 17 (b) & (c), 29 U.S.C. 666 (b) & (c)). Willful violations may involve evidence of an employer's knowledge of both the requirements of an OSHA regulation and the factual circumstances underlying the hazardous working condition. This latter element may be satisfied by a pattern of disease related to occupational exposure to a toxic substance which is documented by employee medical records (USWA, Ex. 160, pp. 24–25).

5. In narrow situations, employee medical records could similarly influence whether or not a "general duty clause" violation occurred. Section 5(a)(1) of the Act (29 U.S.C. 654(a)(1)) provides that each employer:

> [S]hall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

In addition to the knowledge element being traced either to industry or common sense recognition of a hazard, the "recognized hazard" element of this general duty clause can be proved by actual employer knowledge of a hazard (*Brennan v. OSHRC (Vy Lactos Laboratories, Inc.),* 494 F.2d 460 (8th Cir. 1974); *See,* Rothstein, Health and Safety Law, s124(1978)). Again, employee medical records could document a pattern of disease constituting actual knowledge of a hazardous working condition (AFL–CIO, Ex. 152, pp. 58–9; USWA, Ex. 160, pp. 24–25).

6. In some situations a medical practice itself constitutes a violation of an OSHA standard. OSHA's lead standard prohibits prophylactic chelation, a medical procedure involving periodic use of a drug having serious side effects to extract lead from a worker's blood stream (29 CFR 1910.1025(j)(4), *See* 43 FR 53001–004 (Nov. 14, 1978)). Employee medical records could help document instances where this unlawful medical procedure was used (Wrenn, Ex. 7, p. 20).

7. Employee medical records are also relevant to the rulemaking process whereby OSHA health standards are established (Wrenn, Tr. 58). Human epidemiological studies are often at the heart of rulemaking medical controversies, and employers often present studies concerning the disease experience of their employees. Although the agency has not generally attempted to analyze independently the raw data for these studies, such analyses may well be performed in the future to better assess the significance of employer-generated studies (*See,* NCCHR, Ex. 58, p. 35). Also, OSHA intends to assess periodically the adequacy of its health standards. This could involve analysis of medical records of employees consistently exposed at or below the permissible exposure limit (*See,* Schwartz, Tr. 2362–63).

8. Employer medical records could be highly relevant to imminent danger situations. Medical records could demonstrate that a particular worker (or group of workers), in light of the worker's current health status, faces an imminent danger of disease or death from present working conditions. For example, presence of a toxic chemical in the worker's body may be close to a threshold for disease, and current workplace exposures are such that the threshold will soon be exceeded. Section 13(a) of the Act (29 U.S.C. 662(a)) and agency procedures provide for formal imminent danger proceedings (29 CFR 1910.13; Ex. 113, Field Operations Manual, Chpt. IX), and the content of employee medical records could precipitate initiation of these procedures.

9. Employee medical records can be relevant in situations where concern arises over the etiology of a newly discovered pattern of disease (AFL–CIO, Ex, 152, pp. 58–9). In these potential emergency situations a team of OSHA experts (sometimes in concert with NIOSH) can often act in close cooperation with an employer to investigate all possible causes of the disease. Immediate corrective action would then be taken if necessary to protect currently exposed employees. Medical records can be crucial sources of information in these situations. The result of these emergency investigations can be a variety of regulatory and non-regulatory responses. Examples include voluntary employer action which ends the need for governmental action, a formal OSHA/NIOSH Health Hazard Alert to all employers using a toxic chemical, or the initiation of Emergency Temporary Standard proceedings pursuant to Section 6(c) of the Act (29 U.S.C. 655(c)).

10. Employee medical records can be relevant to compliance investigations of the efficacy of controls on worker exposure to toxic chemicals. For example, the efficacy of a respirator program can be assessed by its success in preventing undesirable changes in employee biochemical status such as blood lead level elevations. Medical record proof could buttress citations based on the inadequacies of a respiratory program.

11. Access to employee medical records
is also necessary in very limited situations where an employer conducts medical surveillance, but fails to either evaluate the medical data, take corrective action vis-a-vis employees when disease arises, or even inform employees of diagnoses of disease. In these cases, agency physicians could independently evaluate the substantive content of the medical records in order to direct these problems.

The preceding paragraphs discuss some of the many situations where employee exposure and medical records can be extremely relevant, and sometimes crucial, to the performance of OSHA's statutory functions. Section IV.G of the preamble, *infra,* discusses the most significant policy issue involved with OSHA access to these records, i.e., OSHA access to employee medical records and the common law and Constitutional right of privacy.

IV. Central Factual and Policy Issues Concerning Access to Records

A. Introduction

In promulgating this final standard, OSHA not only determined that broad worker and designated representative access to records would serve important occupational health purposes, but also carefully evaluated the various arguments which were raised for and against OSHA's proposed means for achieving these objectives. Workers, union representatives, and several physicians and experts endorsed the concepts of direct, unrestricted employee access to medical and

exposure records plus an employee's additional right to designate representatives to gain access to these records. Most employer participants, however, opposed these access principles on a variety of grounds. Concerns were voiced about potential harm to employees and the occupational physician-patient relationship should direct employee and designated representative access be provided to medical records. Similar concerns were raised as to OSHA access to employee medical records. Arguments were raised that this rule would impair the ability of employers to attract occupational physicians and otherwise conduct effective occupational medical programs. Employee and designated representative access to both medical and exposure records was opposed on the grounds that these records would often be misinterpreted and misunderstood. Unqualified access to exposure records was opposed due to the possibility of trade secret information being revealed to competitors.

OSHA carefully considered these arguments in light of the record, the agency's expertise and experience, and the legal and practical context in which this standard will operate. The proposed rule has been modified in a number of respects to assure that: (1) the direct release of medical records to an employee is accomplished in a professional manner which minimizes any potential for harm or misinterpretation; (2) access to medical records by a designated representative is the result of specific written employee consent rather than a blanket release; and (3) the potential for competitive harm resulting from an unauthorized release of trade secret information is minimized. Administrative regulations are also being issued simultaneously with this standard in order to govern OSHA's access to employee medical records. These modifications to the proposed rule partially meet concerns expressed during the rulemaking proceeding. In other respects, however, the agency has concluded that employer fears concerning the standard's consequences are ill-founded, and that the central access provisions of the final standard represent sound public policies which are fully supported by the record. The discussion which follows explores in detail the agency's decisions on these matters.

B. Arguments of Potential Harm to the Employee Due to Direct, Unrestricted Access to Personal Medical Records

The concept of direct and unrestricted employee/patient access to his or her medical record generated considerable controversy during the rulemaking proceeding. Arguments were made that direct access could prove to be genuinely harmful in certain cases; thus the employer's physician should retain discretion as to what information is released, and to whom. Statements were made that medical records may contain sensitive information, such as subjective notes or a listing of possible diagnoses which the physician should consider but about which he or she has no firm opinion (i.e., differential diagnoses), or diagnoses of psychiatric disorders or terminal illnesses. Some physicians expressed the fear that revelation of sensitive information to a possibly unstable employee may provoke severe anxiety or a worsening of the employee/patient's physical condition (Dr. Dixon (SOCMA), Tr. 525; Dr. McLean (AOMA), Tr. 1557–58; Jensen (EEI), Tr. 1781–82; Dr. Spraul (Monsanto), Tr. 1909–10; Dr. Joyner, (Shell), Tr. 2226–27, Ex. 2(61), pp. 1–2).

This statement by Dr. Dinman of ALCOA is representative:

> Where medical record entries represent written notes of physicians which are needed to adequately manage the health needs to a patient, prudent exercise of non-disclosure is occasionally in the best interest of the patient and the therapeutic relationship. For example, tentative suspicions of fatal conditions or emotional aberrations; tentative propositions that such might be the case are necessary for the record of the physician seeing many patients and who will see this patient some time in the future.
>
> In the future, these considerations, these differential diagnostic possibilities may prove either unproven or still open to consideration and not established at some future juncture. Disclosure of such working diagnoses is rarely in the patient's interest and can, indeed, create physical and emotional problems which are wholly unnecessary. (Ex. 15, p. 5)

Another example of information which some physicians testified they would hestiate to disclose to patients/employees is information provided confidentially by a third party, whose identity may be indicated in the record (e.g., spouse, fellow employee). In their opinion, disclosure of this information, which is often sensitive in nature (e.g., substance abuse or behavioral problems), would violate the informant's expectation of confidentiality and may possibly even provoke violence (United Technologies Corp., Ex. 2(6); NAM, Ex. 2(135), p. 10; AISI, Ex. 2(142), p. 16; DuPont, Ex. 2(148), pp. 29–30; Dr. Hockwald (AOMA), Tr. 1529–30, 1554, 1556; Dr. Reilly (EEI), Tr. 1769, 1772–3; Dr. Joyner (Shell), Tr. 2227; cf., Dr. Teitelbaum, Tr. 137–140).

While instances where direct access to medical information may cause harm are generally acknowledged by physicians expressing these concerns to be rare, they nevertheless consider them to be sufficient reason to deny providing patients/employees with absolute rights of access (Dr. Hockwald (AOMA), Tr. 1554; API, Ex. 158, p. 28).

These arguments concerning recorded information on tentative or differential disgnoses, terminal illnesses, psychological disorders, and information supplied by informants have been presented as reasons for retaining broad physician discretion over the disclosure of medical records. Those witnesses advocating reliance on professional judgment and discretion in the disclosure of medical information usually recommended that release be only to the employee's designated physician on the grounds that, unlike others, a physician has an ethical duty of confidentiality and is uniquely qualified to interpret medical data (New Jersey Dept., of Labor, Ex. 2(58), Attach. (Hercules Corp.); Sherwin-Williams Co., Ex. 2(76); Batchelor (MCA), Tr. 396–7, 403; Dr. Hine (ASARCO), Tr. 1619; Dr. Bernacki (NAM), Tr. 2189–90, Ex. 2(135), pp. 5–6, 9). Physician-to-physician transfer of medical records with the consent of the patient is recognized as an ethical obligation by the medical profession (AMA, *Principles of Medical Ethics* (Rule 5.61), Ex. 105, p. 27).

Based on the record and its own policy judgments, OSHA concluded that reliance on physician discretion to disclose information to an employee, or solely on physician-to-physician transfers of medical records, are inadequate responses to the needs for direct worker access. Unrestricted patient access to medical records has been a major public policy issue during the past decade, and the evolving trend throughout the nation has been to provide direct patient access to medical records. Professor George Annas, Associate Professor of Law and Medicine at Boston University School of Medicine, and a member of the Massachusetts Board of Registration and Discipline in Medicine (Ex. 56 at 1), testified at the hearings as to this trend:

> Access to hospital and private physician records has traditionally been governed by state law, and until the 1970's, few states provided for direct patient access, the vast majority requiring commencement of a legal proceeding before records could be made legally available. Currently, however, a significant number of states, including California, Colorado, Florida, Hawaii, Illinois, Indiana, Massachusetts, Minnesota, Nevada, New Jersey, Oklahoma, Oregon, and Virginia have statutes that provided direct patient

access to physician or hospital medical records. In addition, access is guaranteed by case law in other states, such as Illinois, Nebraska, New York and Texas. The general theory of the case law is that "the fiducial qualities of the physician-patient relationship require the disclosure of medical data to a patient or his agent on request . . . ;" and that patients have a right to access to their own records based on a "common law right of inspection."

State medical licensing boards are also beginning to take cognizance of the importance of patient access to medical records. New York in 1977 and Massachusetts in 1978 have required their licensees to make such records available to patients upon request. On the federal level, the Privacy Act of 1974 requires direct access under most circumstances, and the Privacy Protection Study Commission, set up under that act, has recommended that:

Upon request, an individual who is the subject of a medical record maintained by a medical-care provider, or another responsible person designated by the individual, be allowed access to that medical record including an opportunity to see and copy it (at p. 298 of their report).

This recommendation reinforces one made more than five years ago by HEW's Malpractice Commission which recommended that "states enact legislation enabling patients to obtain access to the information contained in their medical records through their legal representatives, public or private, without having to file a suit." (Ex. 56, pp. 2–3) (cases omitted)

In addition, California, Oregon, Maine, and Michigan have statutes giving employees access to personnel records, including medical records, used to make employment decisions (NCCHR, Ex. 125, p. 5).

The 1976 Privacy Protection Study Commission ("Privacy Commission") devoted a chapter of its final report to the many issues presented by recordkeeping practices in the medical-care setting (Ex. 101, Chpt. 7). The Commission fully reviewed the ramifications of direct patient access to medical records and recommended:

Upon request, an individual who is the subject of a medical record maintained by a medical-care provider, or another responsible person designated by the individual, be allowed access to that medical record including the opportunity to see and copy it. (Ex. 101, p. 98)

This basic right of patient/employee access to one's own medical records was also generally endorsed in the rulemaking proceeding by the National Commission on the Confidentiality of Health Records (NCCHR), a coalition of 23 health care organizations (Tr. 1867), and the American Medical Records Association (AMRA), a professional organization representing 22,000 members involved in medical records administration (Tr. 2456).

A variety of public policies support patient access to medical records, but the Privacy Commission based its recommendation on the fundamental personal privacy principle that an individual should have a "right of access to records about himself for the purposes of reviewing, copying, and correcting or amending them as necessary plus some control over the collection and disclosure of information about him" (Ex. 101, pp. 17–18). This fairness principle was explicitly extended by the Commission to medical records in general (Ex. 101, pp. 300–03), and to employer-maintained medical records in particular (Ex. 101, pp. 258–9). Moreover, in the Commission's opinion, the need for patient/employee access to medical records was inextricably tied to the patient/employee's need to authorize disclosure of his/her medical record in a variety of situations.

Indeed, in the final analysis, the most persuasive line of reasoning favoring access turned on the concept of authorization. So long as it is thought acceptable, or even necessary, for an individual's past or present medical condition to be taken into account in making non-medical decisions about him, he will be asked to allow others to have access to his medical records or at least some of the information in them. As a practical matter, however, his authorization allowing such access to a third party will be meaningless so long as he does not know, and cannot find out, what is in the records. Both theoretically and practically, authorization is a meaningless procedure unless the individual knows what he is authorizing to be disclosed. (Ex. 101, p. 289)

Although numerous organizations and individuals favor direct patient/employee access and oppose relying on physician discretion as to the release of medical records, there is recognition that disclosure to an intermediary, not necessarily a physician, may sometimes be appropriate. The Privacy Commission recommended that some provision should be made for indirect access to a designated person, provided it was clear that there would be no restriction on the ability of that person to disclose all the information to the patient (Ex. 101, pp. 259, 297–8).

* * * [N]o solution would be acceptable in the long run so long as it risks leaving the ultimate discretion to release or not to release in the hands of the patient's physician. In situations where the keeper of the medical record believes that allowing the patient to see and copy it may be injurious to the patient, the Commission concluded that it would be reasonable for the record to be given to a responsible person designated by the patient, with that person being the ultimate judge of whether the patient should have full access to it. In no case, however, should the physician or other keeper of the record be able to refuse to disclose the record to the designated responsible person, even where it is known in advance that the designated person will give the patient full access to it. (Ex. 101, pp. 297–98)

Several participants expressed general support for this approach, at least when highly sensitive information concerning psychiatric or terminal illness diagnoses were involved (Weiner, Ex. 9A, p. 35; Belair (NCCHR), Tr. 1867–71). Other participants, however, discounted the possibility that the direct release of even psychiatric or terminal illness information could prove harmful:

There is also, I think it worth noting, no evidence at all in the literature * * *, nor has there been any evidence brought forth in any hearings on this subject to indicate any negative impact at all of access to medical records on the part of individual patients.

We have heard that assertion made, and it is made commonly, that should patients get access or employees get access to their records this will have a detrimental effect on their medical condition, that they will become anxious, they will become upset, and they will become worse off. This is another way of arguing that this is opposed to the traditional doctor-patient relationship.

The fact of the matter is of course that—well not necessarily of course—but the fact of the matter is that there is no evidence to support this, and indeed all the evidence is on the other side, that since no one has ever been able to come up with any example where this has happened, one has to assume the opposite, that this hasn't happened and that in fact the studies on the other side which show that medical records in fact improve and not hinder the doctor-patient relationship, should be given more credence.

The Privacy Commission, for example, took testimony from all the Federal agencies about their experience under the Privacy Act since 1974 and not one agency could point to one case in which access to medical records had been detrimental to a patient. (Prof. Annas, Tr. 1745–46)

* * * * *

There is of course always the issue raised that there is a danger of misinterpretation and adverse emotional impact of the patient's reading his or her own medical record. Although I cannot promise that this would not happen, to my mind, the idea of frightening an individual by frankly informing them is absurd. An individual who does not wish to know that he has a terminal disease will choose not to know it. In fact, I would suggest the medical profession has more experience with individuals denying terminal disease even when informed about it than with having people adversely affected by chance discovery of terminal disease. In any event the individual should have the right to make that decision, not have some other third party make that decision for him or her. (Dr. Wegman, Ex. 10, p. 10)

* * * * *

Although there are numerous abbreviations, shortcuts, and jargon utilized in medical records, and, although physicians

frequently include early diagnostic opinions which are not substantiated by objective information, records are still readily capable of interpretation by a competent, intelligent physician to a concerned patient. Certainly failure to use the English language should not disqualify the patient from information about himself. (Dr. Teitelbaum, Ex. 8, p. 7)

* * * * *

OSHA regulations should certainly not exempt terminal illness from disclosure since there is evidence that diagnoses of occupational cancer have been completely withheld in the past and workers do not necessarily have their own physicians who would seek this information. (Laden (USWA), Tr. 668)

* * * * *

My personal custom has always been, while the patient's waiting, to give the patient their record. It keeps them busy when I fall behind, and it allows them to ask me questions about the things I've written there. And my instruction to my house staff and the attendants there at Cook County Hospital is that the patient should be given his record.

There's a very small marginal group of patients, so small as to not be important for our discussion, who cannot handle or might misunderstand serious diagnoses or phraseology. This is a bug bear as far as I'm concerned. It's not a serious issue. . . . But for the issue before us, working people, and a knowledge of what's going on in the world around them, I don't think [the problem of psychiatric diagnoses] has any relevance at all. (Dr. Young (CACOSH), Tr. 1107, 1109)

In addition, experience under the access provisions of the Privacy Act (5 U.S.C. 552a) is relevant. The Privacy Act governs access to medical records kept by the Federal government, and authorizes Federal agencies to develop special procedures which permit indirect access via a designated person when direct access would be considered harmful to the subject of the medical record (552a(f)(3)). Agency implementing procedures vary from providing indirect access through any responsible person designated by the patient (45 CFR 56.6) (HEW) to limiting access to a physician of the patient's choice (32 CFR 286a.7) (Defense). The Department of Labor took the more restrictive designated physician approach (29 CFR 70a.6(d)). In practice, however, most access under the Privacy Act throughout the government has been directly to the patient, and no harm from direct access has apparently ever occurred (Ex. 101, pp. 296–97). In the words of the Privacy Commission:

The Commission's hearings failed to produce evidence that one procedure was more effective than another in protecting patients from any adverse consequences that might result from obtaining their medical records. Not one witness was able to identify an instance where access to records has had an untoward effect on a patient's medical condition. While the Department of Defense special procedure is clearly the most restrictive, DOD representatives estimated that the Department had released a record to a physician, rather than to the individual directly, in less than one percent of the cases where access had been requested. (Ex. 101, p. 297)

The agency reached several conclusions from the preceding considerations. First, OSHA concluded that direct worker access to medical records was sound public policy as a general matter even without regard to the occupational health benefits to be gained by access. Second, due to the divergence of views as to whether access should always be available directly to the patient/employee, or whether in certain situations access should be through the employee's physician or non-medical representative, OSHA decided to structure the final standard so as to provide the physician representing the employer with a limited opportunity to release an employee's medical record to a third party rather than directly to the employee.

Under the final standard, the employee may request direct access to his or her records, or give the specific written consent for a designated representative to get access. The standard, however, explicitly encourages the physician maintaining the records to explain the records to the employee when the direct access is sought, and to suggest alternative forms of disclosure if that is felt necessary.

In addition, the final rule adopts the Privacy Commission's designated representative approach in cases of specific diagnoses of terminal illness or psychiatric conditions. Direct employee access to this narrow category of information may be denied if a physician representing the employer has evaluated the circumstances of the request and formed a good faith belief that direct access to this information could prove detrimental to the employee's health. Direct access may only be denied, however, to information directly related to the specific diagnosis that the employee actually has a terminal illness or psychiatric condition. It is OSHA's judgment that there is no basis for anticipating harm to an employee from direct access to other kinds of information, such as tentative differential diagnostic possibilities, or biological monitoring data unrelated to a specific finding of a terminal illness. A concerned physican can fully explain the significance of this information to a worker.

The rare occasion where direct access may possibly be harmful can adequately be dealt with by these provisions concerning physician consultations and access through a designated representative. Where the physician and the patient/employee have previously established a traditional medical relationship of trust and confidence, the employee will undoubtedly seriously consider and probably accede to recommendations of the physician as to what information should be disclosed, and how. Where trust and confidence does not exist or the employee persists in seeking access, then the desire of the employee should normally prevail.

As part of the foregoing decisionmaking, the agency considered and rejected suggestions that the employer or its physician be given discretion to disclose a medical record only to an employee's designated physician. In rejecting so restrictive a suggestion, the agency agreed with the approach of the Privacy Commission. The Privacy Commission was careful to indicate that, even where indirect access was considered appropriate, this intermediary function could be fulfilled by any "responsible person," including family members or friends (Ex. 101, p. 298). OSHA also attaches significance to the likelihood that limiting access to only employee physicians would undoubtedly pose a substantial practical barrier to worker access (*See*, Wrenn, Tr. 40–42; Weiner, Tr. 176–77). Dr. Whorton noted that approximately 20 percent of individuals do not have a primary physician to whom records could easily be transferred (Ex. 11, p. 11). Having a personal physician review medical records could prove costly to an employee. An employee would also have to make arrangements for a personal physician to review the records without any advance knowledge as to whether the record contained anything worth reviewing. These impediments are substantial, and would minimize the use of medical records in the discovery and control of occupational health hazards. Under the final standard, the employee can easily, and likely often will, transfer his or her medical records to a personal physician. Direct access coupled with a broad designated representative provision, however, provides the worker with a better opportunity to judge whether this is in his or her best interests and worth the effort and expense involved.

The one situation where the final standard permits information to be withheld altogether from an employee concerns confidential informants. As noted at the outset of this section, several participants argued that information provided by confidential informants should not be disclosed to an

employee due to confidentiality expectations and the possibility of violence. Confidential informants could include family members and friends of the employee, fellow workers, and management or medical personnel. Dr. Young expressed strong doubts that company physicians often receive confidential information from a worker's family (Tr. 1109), and it is probably also rare that friends of an employee engage in these communications. Where such communications do occur, Dr. Teitelbaum described in some detail how he as a responsible physician would disclose to the patient the identity of the informant and the content of his or her communication (Tr. 137–140). This is a sensitive area, however, in which OSHA recognizes that competing privacy interests are at stake.

In this exception situation, OSHA decided that the identities of fellow employees, personal friends, and family members who may have provided confidential information may be deleted prior to disclosure. This is the one area where OSHA believes that legitimate expections of confidentiality have been created which override whatever marginal occupational safety and health purpose would be served if disclosure of the informants' identities were provided. This provision, however, is limited to the identities of "fellow employees, personal friends, and family members" in the belief that those who stand outside this personal relationship, such as the employer (i.e., supervisory and managerial employees) or another physician or medical person, are not justified in any expectation of confidentiality and should not be protected from disclosure. Moreover, the information provided by the family member, friend, or fellow employee must be disclosed to the extent that this would not clearly identify the informat. Observations of a worker's behavior or health status could be highly relevant concerning occupational disease, particularly since toxic exposures can be the cause of an otherwise unrecognized central nervous system disorder which mimics non-specific behavioral disorders or alcoholism (*See,* VII.C.6, *infra*).

Finally, it is appropriate to stress that this standard is consistent with and builds upon existing principles of occupational medical ethics and developments in the law. Under the common law, the legal obligations of employer-selected physicians depend largely on whether a physician-patient relationship exists as a matter of law. The most important factor in determining whether such a relationship exists is the mutual expectations of the parties, i.e., what kind of understanding exists between the physician and the patient. Other factors which courts have considered include: (1) who is paying for the service; (2) who benefits from the service; (3) the degree of the physician's independence from the payor (if not the patient); and (4) the volitional quality of the patient's decision to consult with the doctor. Each situation thus turns on its particular set of facts (NCCHR, Ex. 125).

The physician-patient relationship imposes on the doctor three basic legal duties: (1) to treat the patient in a manner consistent with acceptable professional standards of care; (2) to disclose to the patient facts and diagnoses pertinent to the patient's medical condition; and (3) to protect the confidentiality of information obtained in the course of the relationship, subject to certain recognized exceptions (61 Am Jur 2d, Physicians, Surgeons, and other Healers, § 100). The duty of disclosure of pertinent facts and diagnoses is particularly relevant to the issue of employee access to medical records.

Traditionally, the courts have indicated that there is no physician-patient relationship between an employer-provided physician and the prospective or actual employee, or at least that there is not the usual physician-patient relationship (Ex. 145; NCCHR, Ex. 125). As a consequence, the case law varies significantly as to what duty of care, if any, the physician owes to the employee (*Lotspeich v. Chance Vought Aircraft,* (1963, Tex. Civ. App.) 369 SW 2d 705; *Riste v. General Elec. Co.,* (1955, Wash.) 289 P. 2d 338; *Beadling v. Sirotta,* (1964, N.J.) 197 A.2d 857; *Hoover v. Williamson,* (1964, Md.) 203 A. 2d 861; *Rogers v. Horvath* (1975, Mich. App.) 237 NW 2d 595; *See also,* Weiner, Ex. 9A, p. 16n.28). In general, the cases which do not acknowledge a physician-patient relationship in the occupational setting involve pre-employment or periodic examinations required by the employer. In all likelihood, a physician-patient relationship is established when an employee voluntarily goes to the company physician with a medical problem and the physician treats the condition (Annas, Ex. 56A, p. 539).

In recent years, the traditional rule of there being no physician-patient relationship, and thus no broad legal duty of disclosure to the employee/patient, has been scrutinized and found to be unacceptable as a matter of professional ethics. The American Occupational Medical Association (AOMA) in its Code of Ethical Conduct for Physicians Providing Occupational Medical Services (Ex. 2(59)), together with various medical and legal commentors on the subject, have taken the position that an occupational physician's primary obligation is to the employee, and the physician should generally be bound by traditional professional obligations (Weiner, Ex. 9A, p. 17 n. 30 (articles cited); Annas, Ex. 56A; NCCHR, Ex. 125). The American Association of Occupational Health Nurses has adopted an identical position (California Occupational Health Nurses, Ex. 123).

This view is also finding acceptance as a matter of law. The judicial trend appears to be in favor of finding a physician-patient relationship in the occupational setting. For example, in *Vella v. Wise,* (1976 Cal.) Contra Costa County Superior Ct., No. 116083, an asbestors worker recovered $350,000 because the physician failed to disclose that an x-ray examination showed the worker had asbestosis. The counsel for the National Commission on Confidentiality of Health Records (NCCHR) has observed that this finding of a fully developed physician-patient relationship is likely to be reflected in future decisions (NCCHR, Ex. 125, p. 11).

A board and virtually discretionless obligation to disclose information to the patient/employee accompanies this growing recognition of the physician-patient relationship in the occupational setting. The physician-patient relationship imposes on the doctor the duty of disclosing to the patient significant information concerning the patient's medical condition, including diagnoses and the hazards of proposed treatments (Ex. 149, § 4 (cases cited)). In the past, some courts recognized a "therapeutic privilege" to withhold information when such non-disclosure is determined by the physician to be in the best interests of the patient. The various factors considered included the mental and emotional makeup of the patient, the prognosis of his/her condition, and the definite or tentative nature of the diagnosis (Ex. 149, § 5 (cases cited)). The duty to disclose has traditionally been judged by the standard of the reasonable medical practitioner in the same or similar locality and under the same conditions (*id.*).

The "modern" trend, however, appears to be a shift towards to patient's right of access to medical information regardless of the doctor's concerns or the local standards of the medical profession. This view is expressed by the commentator to the *American Law Reports (ALR)* 1973 annotation on this issue (Ex. 149, p. 505);

It is submitted that the basic common-law principle that every man is the master of his own body, entitled to do with it as he will, is brought into question in those cases in which a physician who intentionally withholds an unfavorable diagnosis from his patient is judged by the standard of what the reasonable medical practitioner would disclose in the circumstances. Under such circumstances, the patient is denied important information of great potential usefulness in, at the minimum, winding up his affairs. It is suggested that, at least to some extent, the question of whether the patient should know of his condition is not a medical one, although some medical factors are present, but rather, it involves a philosophical issue: who should determine whether the patient is to be informed? Should the medical profession arrogate to itself this determination or should it be left to the patient or his family, or both? It would seem that, absent special circumstances [such as strong possibility of suicide], the determination should be made by the patient. . . . (Footnote omitted)

This modern trend is expressed in the state statutes and case law discussed by Professor Annas (Ex. 56), as well as the Federal Privacy Act (5 U.S.C. 552a(f)(3), as interpreted by OMB Privacy Act Guidelines, issued as a supplement to Circular A–10B, 40 FR 28957) and the deliberations of the Privacy Protection Study Commission (*See also,* Annas, Ex. 56A; Weiner, Ex. 9A, p. 30; HRG, Ex. 122E; NCCHR, Ex. 125, p. 5; PPSC, Ex. 101, p. 297; *Cobbs v. Grant,* 8 Cal. 3d 229, 242 (1972); *Canterbury v. Spence,* 464 F. 2d 772 (D.C. Cir. 1972)).

In addition to ethical and common law obligations to disclose information to employees, direct patient access to medical records has also been identified as basic to emerging notions of the constitutionally recognized right of privacy (Weiner, Ex. 9A, p. 6). The Supreme Court has indicated that the right of privacy involves at least two different kinds of interests: "one is the individual interest in avoiding disclosure of personal matters, and another is the interest of independence in making certain kinds of important decisions." *Whalen v. Roe,* 429 U.S. 589, 599–600 (1977). The first interest, the right to control disclosure of information to others, argues for patient access to information for which the patient is asked to authorize disclosure. As the Privacy Commission stated, ". . . authorization is a meaningless procedure unless the individual knows what he is authorizing to be disclosed" (Ex. 101, p. 289).

The second privacy interest in being able to maintain control over the making of certain highly personal decisions is also directly pertinent to the issue of access to medical records. As has been argued:

The right to know is thus an integral part of the right of people in a free society to have information in order to be able to determine for themselves what their actions will be. It is a personal right, and one with special relevance to the workplace. No right is more basic than the right to protect oneself from life-threatening harm. And it is only when one is armed with a basic knowledge of workplace hazards and how one's own medical record reflects one's reaction to that environment, that one can evaluate risks and act responsibly to protect oneself from those hazards. (Weiner, Ex. 9A, p. 11)

In addition to the physician's independent disclosure duties, the employer's legal responsibilities to employees must also be considered. Case law has traditionally recognized that an employer may be liable for the failure to inform an employee of a disease or phsyical condition disclosed in a medical examination where it is shown that the employer had knowledge, but the employee was unaware, of that disease or condition (Ex. 144). In addition, under the doctrine of *respondeat superior,* an employer may be held liable for a physician's malpractice where the employer was personally negligent in employing or retaining the services of an incompetent physician or surgeon (Ex. 146, s4(c)), or where the furnishing of such free medical attendance was for the employer's own benefit or purposes (Ex. 146, s4(d)). On the other hand, it has generally been held that where an employer gratuitously supplies medical treatment for his sick or injured employees, the *respondeat superior* doctrine is inapplicable and the employer is not liable for the malpractice of the physician or surgeon employed by him provided he exercised ordinary care to select a reasonably competent person to serve in that capacity (Ex. 146, ss3(a), 4(a)). This distinction found in early cases may be outdated, however, since "there should be little difficulty in convincing modern courts that regularly established medical service plans represent the assumption of a contractual obligation on the employer's part, bringing into play the rule that *respondeat superior* applies where such an undertaking is shown, especially where business benefits result" (Ex. 146, p. 564 (footnote omitted)).

Product liability law is also relevant. The manufacturer, in addition to his duty to test, inspect, and keep abreast of the latest developments in the field, also has a duty to effectively warn subsequent users of hazards associated with use of the product (*Borel* v. *Fibreboard Paper Prods. Corp.* 493 F. 2d 1076, 1089–1090 (5th Cir. 1973)). The *Borel* case, the leading products liability case involving occupational disease, upheld a claim brought by an asbestos insulation worker for failure to warn of the hazards of asbestos exposure. The Court held that "an insulation worker no less than any other product user, has a right to decide whether to expose himself to the risk" and must be fully apprised of the extent and gravity of the hazard faced, *id.* at 1089 (Weiner, Ex. 9A, p. 14 n. 24 (cases cited)). While workers' compensation statutes would normally bar such lawsuits against one's actual employer, some courts have allowed independent personal injury suits for breaches of this duty to disclose (Weiner, Ex. 9A, p. 12 n. 20 (cases cited); NCCHR, Ex. 125, p. 1; Ex. 148, s6 (cases cited)); BNA OSH Reporter, May 10, 1979, p. 1738).

The foregoing analysis of the relevant law and medical principles provides a solid foundation for OSHA's conclusions that direct worker access to medical records coupled with a broad designated representative provision is sound public policy. The promulation of this final standard to guarantee employees a quick and effective means of gaining access for occupational health purposes can thus be viewed as a logical outgrowth of a variety of legal and policy arguments which oppose maintaining employer and physician discretion and favor direct worker/patient access to medical records.

C. Potential Misinterpretation of Medical and Exposure Records

Employee and designated representative access to both medical and exposure records was also opposed on the grounds that these records would often be misinterpreted and misunderstood. Statements were made that most employees are incapable of understanding the highly technical language, abbreviated short-hand and illegible writing that is often found in medical records. The likelihood of misinterpretation leading to unnecessary anxiety or inappropriate action was therefore considered great.

We believe that the patient should have limited access, and the reason I say 'limited' is that there are many things in medical records that can be bewildering and misunderstood by patients, and I think the patient should have access to their medical record, but I think someone should be available at the time they review the medical record to be able to interpret any segment of the record that may not be clear to the patient or to explain to that patient some of the acronyms and abbreviations used which they might otherwise interpret as derogations. (Dr. Steen (AMA), Tr. 2403–4)

* * * * *

If OSHA truly believes that employee access will increase the employee's

recognition of hazards in the workplace, then OSHA must also believe that employees are capable of interpreting scientific test results and/or conducting epidemiological studies. And I think as physicians in industry we have tough enough problems with that ourselves. (Dr. Bernacki (NAM), Tr. 2190)

* * * * *

The correct interpretation of data pertaining to environmental hygiene, x-rays, functional capacity and laboratory tests is difficult even for the trained professional. Nothing would be accomplished by releasing this information to the employee, or to his nonprofessional "designated representative." (Dr. Hine (ASARCO), Tr. 1618–19)

* * * * *

The contents of the medical record are probably not understood by many of the people who would opt for practically unlimited access to such a record. . . . Many items in the record are written in the physician's jargon or in abbreviations or acronyms that can be misleading or cause unnecessary anxiety for the patient or others. To expose the patient to these written mental gymnastics of the physician is not in the best interest of the patient. (Dr. Spraul (Monsanto), Tr. 1909, 1910–11)

(*See also,* Kentucky Dept. of Labor, Ex. 2(5); Miles Laboratories, Inc., Ex. 2(146), pp. 1–2).

There was also testimony that exposure records can be as technical as medical records and are equally subject to misinterpretation. Thus, according to the API, which presented Tenneco's manager of industrial hygiene on this issue:

. . . [S]uch data will rarely provide reliable or useful information concerning an individual worker's exposure. . . . [T]he release of raw industrial hygiene data to workers who lack the training and experience necessary for proper interpretation would add little, if anything, to their knowledge of workplace hazards, and in some cases be unnecessarily alarming. Consequently, professional interpretation and review is an essential part of any program for releasing industrial hygiene data to workers. (Ex. 69, pp. 2,4; Ex. 158, pp. 31–2).

OSHA agrees that professional evaluation and interpretation will often be important, but does not agree that the possibility of occasional misunderstanding should enable employers to deny access to either medical or exposure records. The solution reflected in the final rule is to provide full worker access to the records, while at the same time encouraging the employer to offer whatever professional interpretation the employer feels is necessary. The worker, however, retains the right to personally evaluate the record, and have independent analysis conducted by professionals and non-professionals alike. If a worker is incapable of understanding something in a medical or exposure record, the worker will most likely seek the assistance of someone more knowledgeable whom he or she trusts (*See,* USWA, Ex. 160, pp. 8–9; Dr. Wegman, Ex. 10B (article on project to train industrial workers in health hazards surveillance); AFL–CIO, Ex. 152, p. 51; Dr. Ziem, Ex. 2(69), p. 2).

In considering the ability of workers to understand the contents of medical and exposure records, or to direct pertinent questions to those who do, it is important not to underestimate the intelligence and abilities of American workers. American workers, after all, have built and now operate and maintain the most technologically advanced and complex industrial society in the history of man. There is no basis for suggesting that exposure and medical records are somehow so inherently mysterious or complex that an informed adult cannot make beneficial use of them. Exposure records concern the identity of the chemical or physical agent measured, the quantity measured, and the circumstances under which the measurement was made. Workers can understand these matters, or be instructed as to their significance in specific situations. The same can be said with regard to medical records, particularly since the lay public is aware of many medical terms and medical conditions. Workers may also have received training and education as to disease processes known to be associated with the toxic substances to which they are exposed. Finally, a worker should understand much of the contents of his or her medical records before examining them if the physician who prepared the records fulfilled his or her ethical obligation to inform the worker of pertinent medical diagnoses and information.

Additional evidence in the record further convinced the agency that this issue of possible misinterpretation should not stand as an impediment to worker access to medical and exposure records. The comments of Dr. Teitelbaum, Professor Annas, and Mr. Spatz of the Cement, Lime and Gypsum Workers, were particularly on point:

If physicians cannot maintain records intelligible to a patient with appropriate assistance, then I suspect that they are incapable of maintaining medical records intelligible to themselves. Although there are numerous abbreviations, shortcuts and jargon utilized in medical records, and although physicians frequently include early diagnostic opinions which are not substantiated by objective information, records are still readily capable of interpretation by a competent, intelligent physician to a concerned patient.

Certainly our own failure to use the English language adequately should not disqualify the patient from information about himself. We cannot solve the problem of access by hiding behind a screen of confusion. A decision that the patient should not have access to his records or not be able to transmit them because he won't understand them is no decision at all. It merely immortalizes our own failure of communication.

Records should be intelligible to any individual who has competence in scientific disciplines. This person can then explain the record to the patient. (Dr. Teitelbaum, Tr. 121–122)

* * * * *

The patient should also have the right to have records submitted to others whom he feels will make a positive contribution to his health and safety. The former traditional requirement that the medical records be released only to other medical personnel must be viewed with a jaundiced eye. I have occasionally met physicians who were less capable of understanding industrial medical records which were generated about their patients than the patient himself was, because the physician had a weak education in chemistry, pharmacology or toxicology or lacked familiarity with plant working conditions. (Dr. Teitelbaum, Tr. 123)

* * * * *

It is my view that there should be no exceptions to direct patient access, and that none of the arguments that are set forth in support of limited access are persuasive. The primary one, that patients won't understand the information, can be answered in two ways. First, it is the legal and ethical duty of the physician to inform the patient about his condition and its implications, and this may further indicate a shortcoming of this particular relationship. Second, any patient who does not understand his records is likely [to] seek the aid of someone who does, and this will solve the problem. Finally, once access is general, physicians are more likely to write records that are understandable by their patients. (Annas, Ex. 56, p. 7a)

* * * * *

The issue of confidentiality which has been raised in opposition to this rule must be addressed. First, in our opinion, all information in an employee's medical file should be disclosable directly to that employee with absolutely no censorship. The members of our union are intelligent adults who have the ability to read, analyze and understand. If information in the medical records require medical interpretation, that employee has a chance to ask his personal physician for such an interpretation. To deny information on the basis that the company or the company doctor can determine best what an employee should know is demeaning paternalism.

(Spatz (Cement, Lime, Gypsum Workers), Tr. 1201–02). Comparable comments were made by other participants (Dr. Wegman, Tr. 204–05; Samuels (AFL–CIO IUD), Tr. 956–57; Dr.

Swartz, Tr. 2363, 2370–73; AFL–CIO, Ex. 152, p. 25–27; USWA, Ex. 160, p. 7–8).

Finally, it is relevant to consider how workers will likely exercise their access rights. Many workers will transfer their records directly to professionals such as personal physicians, or union physicians and industrial hygienists, and let them analyze the records. In other cases, workers will probably seek access out of interest and curiosity, and will ask their employer for an explanation of confusing information. Once this is forthcoming, that will be the end of the matter. In other cases, workers will have lingering questions and will consider their employer's responses to be unsatisfactory. These workers can be expected to question their personal physicians, union, friends, family, and agencies such as OSHA and NIOSH (*See,* Electronics Safety and Health Project, Tr. 1609–10). As a result, worker access to records will often lead to independent informed analysis of the record, even when the worker does not completely know what the record means.

In light of the foregoing considerations, OSHA concluded that arguments about the possibility of misinterpretation of records lacked merit, and should not affect promulgation of the final standard.

D. Designated Representative Access to Medical Records and Potential Harm to Employee Confidentiality Expectations

The final standard provides for the transfer of an employee's medical records to a designated representative upon the specific written consent of the employee. The Summary and Explanation portion of the preamble (VII.C.10, *infra*) discusses in detail all aspects of this specific written consent process. The standard closely follows the recommendations of the Privacy Commission and the AMRA, and seeks to minimize the possibility of blanket, perpetual, and ill-considered access of third parties to confidential medical records. The proposed standard provided for access by third parties upon the bare written consent of the employee, without the elements of this written consent being defined. This lack of a more formal consent process was criticized by numerous participants. Arguments were made that the proposal's designated representative access provisions would seriously interfere with the physician-patient relationship, and the proposed rule was significantly changed to avoid this potential problem.

Objections to the proposal focused on potential invasions of an employee's privacy expectations from unrestrained third party access to identifiable medical records. The medical directors who testified at the hearings on behalf of their companies or trade associations stated that confidentiality is an essential ingredient of effective medicine. Without assurances of confidentiality, they said it would be difficult for them to obtain the full cooperation of the worker in providing complete medical information or in following the medical advice given (Dr. Karrh (DuPont), Tr. 309; Dr. Dinman (ALCOA), Tr. 430; Dr. Hockwald (AOMA), Tr. 1527; Dr. Tetrick (National Steel Corp.), Tr. 1980–81; Dr. Duncan (NAM), Tr. 2180; Dr. Steen (AMA), Tr. 2392; Dr. Hilker (Ill. Med. Society), Tr. 2525–6; API, Ex. 66B, p. 2, Ex. 66D, p. 3; AMOCO, Ex. 76, p. 2). It was therefore said that the occupational physician-patient relationship is based on mutual trust and that information gathered in the course of this relationship is kept confidential. Accordingly, this information is protected from unconsented disclosure to management or anyone outside the medical department. While the existence of a few "bad actors" was acknowledged by industry (Dr. McLean (AOMA), Tr. 1524–5, 1529; Dr. Wolkonsky (AMOCO), Tr. 2246; API, Ex. 158, p. 24), it was stated that a duty of confidentiality is the ethical standard by which the occupational physician measures professional conduct. Standard No. 7 of the AOMA's Code of Ethical Conduct requires the occupational physician to:

> Treat as confidential whatever is learned about individuals served, releasing information only when required by law or by overriding public health considerations or to other physicians at the request of the individual according to traditional medical ethical practice, and recognize that employers are entitled to counsel about the medical fitness of an individual in relation to work but are not entitled to diagnoses or details of a specific nature. (Dr. Hockwald (AOMA), Tr. 1529; Ex. 2(59)).

The medical directors indicated that the AOMA code was the policy required of their medical staff.

Maintaining that the occupational physician-employee relationship is based on mutual trust and confidentiality, industry argued that the designated representative provision of the access rule would be harmful to that confidential relationship, and make it difficult, if not impossible, for physicians to adhere to their ethical duty of confidentiality. API's position is representative:

> Even in circumstances when third party access is lawful, OSHA's proposal to permit third party access merely upon obtaining a bare "written consent" would prove inadequate. OSHA's "written consent" procedure would not require a third party to particularize his purpose for access or specify the information he seeks. Nor would this "consent" have any expiration date. Thus, the proposal would permit a third party to obtain sensitive, personal information which he never needed to see, including information placed in the record long after a worker's "consent" was given. This is hardly the sort of procedure which will protect the confidentiality of doctor-patient exchanges. (Ex. 158, p. 33)

Industry witnesses said that if unconsented third party access to employee records was permitted, employees would be less candid during medical consultations, or perhaps even refuse to participate in voluntary medical programs altogether (Dr. Dixon (SOCMA), Tr. 520; Dr. Spraul (Monsanto), Tr. 1911; Dr. Tetrick (National Steel Corp.), Tr. 1979; Dr. Duncan (NAM), Tr. 2180; ALCOA, Ex. 15, pp. 2, 6; DuPont, Ex. 2(148), pp. 8–15). Several industry witnesses also maintained that unconsented third party access would cause physicians to engage in "defensive" recordkeeping practices, either by recording more information than is necessary or by not recording sensitive information which they would not want the employees themselves or third parties to see (Washington Legal Foundation, Ex. 2(96); AAOM, Ex. 2(101); Mayo Clinic, Ex. 2A(16), p. 2; Skiba (Magma Copper), Tr. 1455; Dr. Spraul (Monsanto), Tr. 1911–12; Dr. Joyner (Shell), Tr. 2228–9; MVMA, Ex. 153, pp. 6–7).

API suggested that the Privacy Commission's recommended model consent requirement should be developed as "a positive first step" toward informed consent (Ex. 158, p. 33; cf., Ex. 101, p. 315) (Privacy Commission). OSHA followed this suggestion, and further refined the specific written consent procedure in light of other evidence in the record (*See,* VII. C.10, *infra*). To give specific written consent, an employee will specifically have to indicate in writing who is being authorized to disclose record information, who may have access to it, the general nature of the information to be disclosed, and a general description of the purpose for the disclosure. If the employee wishes, he or she may specify information which is not authorized to be disclosed and may place conditions on its use or redisclosure. The authorization does not operate to authorize the release of medical information not in existence on the date of written authorization, unless this is expressly authorized, and does not operate for more than one year from the date of signature. The authorization

may be revoked prospectively at any time. These procedures will assure that the employee controls the amount and kinds of information available to the designated representative, and what the representative can do with it. OSHA is confident that these improvements to the standard will prevent any harm to an employee's legitimate expectations of confidentiality.

It is important to stress that in considering the issues of confidentiality and designated representative access to medical records, the only significant issues concern who can be a representative (with consent) and the nature and necessary elements for consent. The law has firmly established that there is no breach of the traditional duty of confidentiality when disclosure is made to a third party on the basis of the consent of the patient (Ex. 147; 70 C.J.S. Physicians and Surgeons, s36; Annas, Ex. 56B, pp. 148–9). The suggestion that designated representatives access to personally identifiable medical records should be conditioned on the specific written consent of the individual employee was endorsed by union and worker testimony (McDougall (IBT), Tr. 916; UAW, Ex. 63, pp. 4, 9–10; AFL–CIO, Ex. 152, pp. 52–53, 60, Appendix I; USWA, Ex. 160, pp. 17, 19). Virtually no one suggested that access to personally identifiable medical records should be provided to unions or other representatives without the consent of the individual employee (*But see*, ICWU, Ex. 106, p. 1).

As to who can be a designated representative, the final standard embodies the view that once specific written consent is obtained, no additional restrictions, such as limiting access to physicians or industrial hygienists, are needed. Since it is the employee's right to have access to the complete record, the employee should, by the consent procedure, control the conditions of disclosure and redisclosure. Access to an employee's own records should be as broad as the patient/employee desires (Dr. Wegman, Tr. 206–7; Annas, Tr. 1751–52; AFL–CIO, Ex. 152, p. 52).

There are some who would restrict access, even with consent, to another health professional. However, such a restriction flies in the face of the principle of independence in making basic life decisions, as discussed previously. Just as the individual should have access to his or her own record, or should be able to designate any other agent to receive that record, the individual should be able to consent to access by any other person whom the individual designates. It is up to the individual to decide whether such consent is in his or her own best interest. Rigid rules limiting this freedom of choice would not redound to the benefit of the worker. (Weiner, Ex. 9A, pp. 39–40).

In addition, independent of the specific written consent procedure of the final standard, potential harm to an employee's expectations of confidentiality must be viewed in light of the nature of the employee's expectations. If there is little expectation of true confidentiality, then there is little risk of harm, if any, by providing the employee broad discretion to give medical records to whomever the employee chooses. Although OSHA, employees, unions, employers, and occupational physicians alike all agree that the ethical principles of confidentiality should apply to the workplace, there is considerable evidence in the record that employees as a rule neither have, nor could be expected to have, reasonable expectations of confidentiality vis-a-vis their medical records.

The assertion that occupational medicine as currently practiced is normally marked by a confidential and trusting relationship between physician and patient was widely refuted by numerous participants (Morgan (PHILAPOSH), Tr. 821; Wilson (LOHP), Tr. 1707; Becker (USWA), Tr. 2379–82). Testimony from both labor and management indicated the existence of standard practices which tend to undermine the ability of the physician-patient relationship in industry to be based on mutual trust or the maintenance of confidentiality. Several witnesses testified that: (1) workers are often required to submit to pre-employment physicals and other examinations as a condition of employment with no choice of the physician who conducts these exams (Dr. Dinman (ALCOA), Tr. 441; Dr. Dixon (SOCMA), Tr. 537–8; Payne (ACTWU), Tr. 835; Samuels (AFL–CIO IUD), Tr. 948–9; Dr. Gresch (Allis-Chalmers), Tr. 2280; UAW, Ex. 63, p. 5); (2) company physicians commonly testify without the consent of the employee (and often favorably to the employer's interests) in arbitration and workers' compensation cases (Laden (USWA), Tr. 668; Mroczkowski (USWA), Tr. 1175; Electronics Safety and Health Project, Tr. 1614–15; Dr. Herrmann (Johnson & Johnson), Tr. 1843); (3) workers have often been required to sign releases for the blanket disclosure of medical information to employers in order to qualify for various benefits (Dr. Dinman (ALOCA), Tr. 443; Sheppard (PHILAPOSH), Tr. 809; Sheratt (Data General), Tr. 1997; USWA, Ex. 122A; Chamber of Commerce, Ex. 134, p. 4); and (4) to receive payment, employees typically must authorize the release of all information to the insurance company, who in turn may release the records to the employer's accounting or benefits department (Dr. Karrh (DuPont), Tr. 357; Dr. Jenkins (ICWU), Tr. 738; Becker (USWA), Tr. 2387; NCCHR, Ex. 58, pp. 32–3; Privacy Commission, Ex. 101, p. 268). These practices, while not common to every company, are sufficiently widespread to be considered inherent features of the industrial system.

The rulemaking record supports a further conclusion that breaches of confidentiality and denials of information which are contrary to established corporate policy occur at the local plant level to a greater extent than corporate management or the medical director perhaps realizes (USWA, Ex. 160, p. 5). This is consistent with the finding of the Privacy Commission that "among organizations that have adopted policies or practices to regulate the handling of records about employees, few have any way of checking to see if they are being carried out uniformly," and that "action taken at the corporate level is not always communicated to field offices" (Ex. 101, p. 234).

Moreover, the majority of companies do not have a full-time occupational physician in charge of their medical recordkeeping practices. The Privacy Commission has noted that personnel departments over the years have expanded to include, in many cases, the handling of occupational medicine and safety records, as well as insurance records and counseling records (Ex. 101, p. 225–6). This trend has placed more and more employee medical records in the hands of non-medically trained personnel. As a result, there is likely to be less sensitivity to confidentiality than when the medical records are under the exclusive control of a physician. For instance, two personnel managers who testified at the hearings, both responsible for the medical programs within large companies, indicated that they retained the authority to examine employee medical records even though they were not themselves physicians (Skiba (Magma Copper), Tr. 1459–60; Sheratt (Data General), Tr. 1996). One had never heard of the AOMA or its Code of Ethical Conduct (Skiba (Magma Copper), Tr. 1501).

This statement of facts from the National Labor Relations Board case of *Colgate-Palmolive Co.*, Case No. 17—CA—8331, —— NLRB —— (——) is also revealing:

Respondent (the Company) regards these medical files as highly confidential, and permits only limited access by authorized individuals, namely [the employee relations

manager], the company doctor and nurse, the plant manager, and certain employees within the personnel department (p. 8, sl. op.).

Similarly, in the CBS "60 Minutes" show on "Brown Lung," televised February 4, 1979, Dan Rather reported that, after being told of several workers who had contracted byssinosis ('brown lung disease') without having been told by the company that their respiratory problems were occupationally related, the president of West Point Pepperell "one hour later . . . had pulled the medical files of three workers . . ." (Ex. 117, p. 8).

In addition to the involvement of personnel departments and other non-medical company officials in medical records management, occupational medicine is often conducted primarily by either an on-site nurse, industrial health clinic, or a private practitioner. While occupational health nurses have their own code of ethics which is protective of patient confidentiality (Ex. 123), testimony indicated that nurses as a group are clearly more vulnerable than physicians to employer pressure for unauthorized disclosures of medical information (Dr. McLean (AOMA), Tr. 1562; Garry (Cal. Occupational Health Nurses), Tr. 1727, 1729).

The relationship between the employer and a contract physician may similarly result in medical information being supplied to the employer which constitutes a breach of confidentiality. Typically, the information is released to the employer based on a standard release form signed by the employee, but in some cases diagnostic information required by state law is disclosed without a release. In most cases the companies are small, and the information is received by the personnel or industrial relations manager (Dr. Jacknow (Chamber of Commerce), Tr. 1007–13; Malter (Health Evaluation Programs), Tr. 2315). Based on his experience and observations, Dr. Marvin Amdur, director of the Buffalo Industrial Medical Center and an independent witness with 40 years of experience in the private practice of occupational medicine, stated:

> I would regard the problem of so-called confidentiality to be almost a non-existent device used to deny accessibility of records.
>
> Every day such confidentiality is breached in a multitude of situations. We do not examine any applicant for employment or reinstatement who has not already indicated to his employer that pertinent records may be returned to that employer . . . I want you to remember also that in the industrial setting, the employee is not a patient of that physician. That contact is usually an arm's length one, certainly not comparable with the relationships that may exist between the same employee and his family physician. (Tr. 575–6)

Accordingly, industry's basic assumption concerning the physician-patient relationship and the protection of confidentiality was widely disputed. Given that there is little genuine employee expectation of true confidentiality as to employment medical records, whatever expectations exist cannot possibly be harmed by authorizing an employee to disclose medical records to third parties of the employee's choosing through a process of specific written consent (For further discussion on the issue of employer abuse of employee medical records, *See,* IV.H, *infra).*

E. Potential Harm to Occupational Medical Programs

Arguments were also made that broadened access to medical records would inevitably impair the creation, expansion and effectiveness of occupational medical programs. While no participant would identify itself or any particular company as a likely candidate for cutting back its medical program (Dr. Karrh (Dupont), Tr. 366, Ex. 2(148), pp. 8–15; Batchelor (Diamond Shamrock), Tr. 425; Dr. Dinman (ALCOA), Tr. 448; Kwon (ORC), TR. 1853; Blaiser (NAM), Tr. 2196–97), it was nevertheless stated that, due to the burdens of compliance, some companies may decide to do so (Dr. Dixon (SOCMA), Tr. 518–22; Ryan (RMA), Tr. 1212; Dr. Duncan (NAM), Tr. 2179; Drake (Maytag), Tr. 2475). Because of the requirement for providing access to studies based on exposure or medical records and the difficulty in getting employees to volunteer, it was said that there may be a detrimental effect on company-sponsored health research or epidemiology studies (Dr. Hine (ASARCO), Tr. 1619–20; Dr. Wolkonsky (AMOCO), Tr. 2251; MVMA, Ex. 153, p. 5; *See also,* Dr. Johson (Goodrich), Tr. 426; Dr. Dixon (SOCMA) Tr. 520; Dr. Duncan (NAM), Tr. 2180). The observation was also made that the standard could make it more difficult to attract private physicians to occupational medicine (Dr. Dixon (SOCMA), Tr. 521; NVMA, Ex. 153, pp. 6–7). Further suggestions were made that access to medical records might result in defensive medical practices where physicians either decline to place important information in medical records, or enter an overabundance of information (Skiba (Magma Copper), Tr. 1455; Dr. Joyner (Shell), Tr. 2228).

It is OSHA's judgment that these predictions are exaggerated, since no concrete evidence was presented which indicated the standard would have a negative impact on corporate efforts to provide occupational health programs. As previously noted, corporate witnesses stated that, in fact, there would likely be no reduction in their occupational medical efforts. This prompted the AFL–CIO to conclude that "the evidence in the record does not support the claims of a far reaching negative impact on occupational health programs" (Ex. 152, p. 25). In addition, Dr. Wegman remarked that, based on his experiences with the Division of Occupational Hygiene in Massachusetts:

> Some have stated that the emplyees' access to medical records will discourage medical surveillance programs, particularly because it punishes those most progressive employers who choose to institute programs beyond those required by the standards. . . . It is my opinion that employers who are committed to maximum protection of worker's health will find this proposed regulation consistent with their commitment. (Ex. 10, pp. 4, 6)

Dr. Wegman further argued that the broadest possible access to exposure records serves to improve employer-employee communication on health issues, rather than reduce data collection efforts (Dr. Wegman, Tr. 198–200). In addition, Dr. Silverstein saw no possible impairment to the operations of fee-for-service medical clinics due to the operation of the rule (Tr. 2022).

OSHA concedes that there may be some situations where employers reduce occupational health programs rather than permit employees to know the results of exposure monitoring and medical tests. Access will increase employee efforts for more healthful working conditions, and may well expand efforts to obtain workers' compensation, product liability and other legal remedies for harms inflicted. Some employers may conclude that it is wiser to have little or no occupational health program if employees are given the right to know what the employer knows about hazards in the workplace (*See,* Ritchie, Ex. 2(2); Fairfield Mfg. Co., Ex. 2(25); New Jersey Dept. of Labor, Ex. 2(58), Attach. (Hercules Corp.); Olin Corp., Ex. 2(71); Milwaukee Constr. Safety Council, Ex. 167(9–7), p. 1). OSHA is hopeful, however, that few employers respond in this fashion to the final rule, since the standard should be viewed as consistent with employers' commitment to occupational health. The compliance burdens of this standard are minimal, requiring only access to and retention of records the employer either voluntarily creates or must as a matter of law create. No good faith argument can thus be made that compliance burdens will

hinder the creation or expansion of occupational health programs.

OSHA also sees no genuine possibility that access to the results of health and safety studies by workers, their designated representatives, and their unions could impair voluntary participation of employees. Workers voluntarily participate in studies precisely because they want the studies to determine if problems exist so that the problems can be corrected. It is difficult in this context to understand how employees would be content for their employer to fully know the results of the study, but would not want their union, their designated representatives, or themselves to know the results of the study.

Similarly, OSHA sees no possibilty that this standard will deter physicians from entering the field of occupational medicine. As George Taylor of the AFL-CIO pointed out (Tr. 638–39), physicians presumably choose the field of occupational health because they recognize a challenging opportunity to serve the medical needs of employees. This motivation should not be affected by employee access to medical records—an obligation physicians are increasingly facing in private practice as governed by state law.

OSHA also sees no evidence that the standard will result in defensive or improper recordkeeping practices. The assertion that the access requirements would result in many physicians failing to put adequate reports in the medical records was disputed by statements that such action may constitute unethical behavior (Dr. Parkinson, Tr. 1098). In addition, the AMA spokesperson reported that there is no evidence that the existence of broad access rights by law in a number of states has resulted in overly conservative or defensive medical recordkeeping practices or a lowering of medical standards (Dr. Steen (AMA), Tr. 2406). Dr. Young, Director of the Department of Medicine (including a large occupational medicine section) at the Cook County (Ill.) Hospital further stated:

> I've come across testimony and I think it was enumerated in the initial remarks, that the impact of such regulations would result in occupational medicine doctors or company doctors' failure to put adequate reports in the patient's records, or perhaps even implying they would modify exposure records.
>
> I can't believe that's true. If it is true, it's unconscionable, and speaking for the doctors in training in my institution, the doctors who are teaching them, I will represent to you, Judge, that there will be no lowering of ethical standards should these regulations become part of the law of the land, and I really rather resent the implication coming from occupational medicine resources that their colleagues would ever be guilty of such chicanery. (Tr. 1098)

Dr. Parkinson also noted that access should not affect the content of the record since medical records are created for the ultimate benefit of the worker's health (Tr. 1141).

As a final matter, it is appropriate to state that the record supports a finding that patient access to medical records will actually serve to improve the effectiveness of occupational medical programs. Access will likely serve to "open up and further develop the relationship between doctors and patients so that maybe there would be a greater willingness on the part of patients to place some confidence in the doctor they were seeing" (Dr. Silverstein (UAW), Tr. 2022–24). As Prof. Annas indicated, "patients who ask to see their own medical records are not 'less anxious' when refused than they are if access is provided" (Annas, Ex. 56, p. 5). Prof. Annas also referred to a number of studies which indicated that:

> [I]ncreased access to patient records promotes a doctor-patient relationship and promotes patient education, permits patients to be less anxious and permits [them] to then be more ready to carry out doctor's recommendations and permits patients to be more active participants in their health care in general. (Tr. 1745; Ex. 56, pp. 5–6)

This also reflects the opinions and personal experiences of Dr. Whorton of the Labor Occupational Health Program (U. of California, Berkeley) (Ex. 11, pp. 10–11), Dr. Parkinson, Professor of Occupational Medicine at the University of Pittsburgh and a medical consultant to the United Steelworkers Union (Tr. 1142, 1148), and Vicki Laden, a health consultant to Steelworkers locals in Baltimore (Tr. 682). Finally, Dr. Young described the practice at the Cook County Hospital as follows:

> If the patient asks for the record, they of course get it.
>
> I'm encouraging them [staff physicians] to have the patients read their charts while they're being taken to x-ray and so on. It enhances patients' understanding of their condition. It improves the patient's ability to ask the right questions about their illness. And I think it's something that should become more widespread.
>
> MR. SPILLER: You say in your experience greater access improves relationships with the patients and physicians?
>
> DR. YOUNG: Absolutely. It can only improve because the patient sees there's a correspondence between what you're telling him and what you're writing down. It allows him in a deliberate way to ask questions about a particular test or works you're using. It only enhances. (Tr. 1108)

It was also suggested that "once access is general, physicians are more likely to write records that are understandable to their patients" (Annas, Ex. 56, p. 7a; cf., Dr. Teitelbaum, Ex. 8, pp. 6–7). Moreover, the spokespersons for the AOMA were unable to cite any studies which would indicate that greater access will erode the physician-patient relationship (Dr. McLean and Dr. Hockwald, Tr. 1561). Therefore, the record supports the view that direct patient access to medical records actually promotes the therapeutic relationship between physician and patient.

F. Trade Secrets and Records Subject to this Standard

The next major access issue concerns employer fears that the exercise of access rights could serve to impair or destroy the competitive value of trade secrets. These fears were not directed toward OSHA access to records, but rather toward worker and designated representative access. The proposed rule contained no provisions specifically addressed to trade secrets, and several employers and employer organizations, who commented on the proposal prior to the hearings, criticized this lack of protection. At the outset of the hearings on the proposal, OSHA acknowledged this issue, and solicited comments on how employer concerns over proprietary information could be accommodated with the need for workers to know the nature, extent, and consequences of exposure to toxic substances (Wrenn, Ex. 7, p. 13; Tr. 29–31). While recognizing the legitimacy of trade secret concerns, the agency indicated its preliminary intention that access rights would prevail over employer desires to maintain complete secrecy (Wrenn, Tr. 29–31, 65–67).

Considerable additional argument and testimony were received on this issue. On the basis of the total record, the agency concluded that workers have a fundamental need to know the identity of, and extent of exposure to, toxic substances and harmful physical agents, and any resulting health effects, regardless of whether or not the information is a trade secret. The final standard is founded in part on the judgment that, as a matter of public health policy, employers must not be permitted to deny worker access to this information which is needed for the purposes of detecting, treating, and preventing occupational disease. Access is afforded to chemical and physical agent identity, level of exposure, and health status information regardless of employer trade secret claims. The final standard, however, has been structured to accommodate trade secret concerns where protection of trade secret information does not conflict with the

overriding purposes of the standard. The provisions of the final standard minimize possible misuse of this information, and the agency is confident that a reasonable balance has been struck between the potentially conflicting goals. The legal analysis supporting the agency's decisionmaking is discussed at V.B., *infra*, and the standard's provisions concerning trade secrets are discussed further in the Summary and Explanation portion of the preamble (VII.F, *infra*).

Industry comments and testimony expressed a wide variety of potential trade secret problems with the language of the proposal. Several comments raised general concern over a lack of protection for trade secrets, without specifying what kinds of trade secrets would likely be contained in records subject to this rule (Chamber of Commerce, Ex. 2(162), p. 9; Mobay Chemical Co., Ex. 2(97), p. 5; Allied Chemical Co., Ex. 2(107), p. 3; Union Carbide Corp., Ex. 2(104), p. 2). Other participants were more definite as to the types of trade secret information which might be contained in requested records. The greatest concern was expressed over secret manufacturing processes and technology (Blaiser (NAM), Tr. 2192–95, 2173–75; Sheratt (Data General Corp.), Tr. 1999–2003, 1991–94; SOCMA, Ex. 2(163), p. 4, Tr. 524; National Constructors' Association, Ex. 2(98), pp. 3–4; MCA, Ex. 2(125), pp. 7–9; Minnesota Mining and Manufacturing Co., Ex. 2(129), pp. 6–7; Ex. 98, pp. 2–3; Dow Corning Co., Ex. 2(176), pp. 1–2; General Electric Co., Ex. 2(178), pp. 2–3). Concern was expressed that the precise percentages of chemicals in a mixture, which can be a trade secret, could be disclosed (SOCMA, Ex. 2(163), p. 4, Tr. 524; MCA, Ex. 2(125), p. 8). It was argued that the mere identity of a chemical could be a trade secret, particularly with respect to secret catalysts and intermediates which could not be discovered by chemical analysis of the end product (Bernacki (NAM), Tr. 2193–95; Batchelor (MCA), Tr. 407–13, Ex. 2(125), pp. 7–9; Dixon (SOCMA), Tr. 531–32, Ex. 156, pp. 27–29; Dupont, Ex. 150, pp. 12–16; General Foods Corp., Ex. 2(99), pp. 3–4; Sangamo Capacitor Div., Ex. 2(100), pp. 1–3; Polaroid Corp., Ex. 2(187), p. 2). A recent OSHA enforcement case indicated that even in situations where the identity of a chemical was not a trade secret, levels of exposure to the chemical could possibly be a trade secret (*Secretary of Labor* v. *Olin Corp. & OCAW*, OSHRC Docket No. 77–4369, Ex. 26C). Finally, although the content of employee exposure records was the focus of employer trade secret concerns, several participants indicated that employee medical records could also contain trade secret information (Dixon (SOCMA), Tr. 524; Mobay Chemical Co., Ex. 2(97), p. 5; Union Carbide Corp., Ex. 2(104), p. 2; Chamber of Commerce, Ex. 2(162), p. 9; Dow Corning Co., Ex. 2(176), p. 2; Polaroid Corp., Ex. 2(187), p. 2).

In contrast to these expressions of concern, several participants generally rejected the possibility that access to records would lead to competitive harm to employers. First, there was skepticism that exposure records would reveal process or percentage mixture information beyond what could be gathered from analysis of the end product (AFL–CIO, Ex. 39, p. 4; ICWU, Ex. 28, p. 7). For instance, arguments were made that competitors using sophisticated chemical analytical techniques could already determine the identities of end product constituents (Weiner, Ex. 9A, p. 25; AFL–CIO, Ex. 152, p. 28; ICWU, Ex. 28, p. 7). Secondly, arguments were made that exposure records would often not disclose information about secret processes beyond what workers already see or know (AFL–CIO, Ex. 152, p. 28).

Further arguments were made that even where access to records might reveal to workers previously unknown trade secrets, there was no reason to expect that the information would be abused.

> Many management employees—chemical engineers, supervisors, etc.—are privy to complete confidential information about trade secret products. Thus, given the scope of information available to management employees and the existing potential for abuse by these individuals, there can be little merit given to claims that worker access to much more limited information will threaten trade secret confidentiality. Taylor (AFL–CIO), Ex. 39, p. 4)
>
> * * * * *
>
> Claims that disgruntled employees will reveal this information to competitors have no basis in fact or in logic. Workers have access to trade secret information in the absence of this regulation and as a matter of routine practice are required to sign pledges of confidentiality (Tr. 410). No evidence has been introduced into the record of this rulemaking showing isolated incidences or a history of abuse of that information. Moreover, workers want to keep their jobs, not lose them to a competing firm. Unions represent workers and their interests, not the interests of industry competitors. (AFC–CIO, Ex. 152, p. 28)
>
> * * * * *
>
> Additionally I would just like to say that trade secrets are a spurious argument, particularly in relationship to labor unions because I don't think you can document any situation where the trade secrets are more likely to be released by the employees in the bargaining unit than they are in any other portion of management. The other thing is that it works to the advantage, particularly of an organized worker, to have his plant expand because of trade secrets; and I think that to suggest that an employee is going to give away that information which might ultimately cost him or her their jobs is clearly a spurious argument in this situation. (Eller (ICWU), Tr. 754)

In addition, no employer participant in this proceeding either gave concrete examples of past abuse of trade secrets by workers or representatives such as unions, or even suggested that there had been any pattern of past worker or worker representative abuse of trade secrets.

In view of the conflicting comments and testimony, the agency concluded that the final standard should clearly address how trade secret information would be handled. While it is likely that employers sometimes err on the side of caution and assert unwarranted trade secret claims, such as where reverse engineering could easily determine the chemical components of a product, or where professionals in an industry are fully familiar with "secret" process information that workers do not know, the agency believes on the basis of the record that raw exposure and medical records may at times reveal secret manufacturing processes and technology or secret percentages of a chemical in a mixture. This could occur not so much because the trade secret information is integrally tied to the identity and level of exposure to a chemical, but rather because process or mixture information was added to the total exposure file without an expectation that workers would gain access to the total file.

The agency believes also that the mere identity of a toxic chemical (which clearly would be revealed by an exposure record) might at times be a bona fide trade secret which workers do not already know. The NIOSH NOH Survey found that manufacturers asserted trade secret claims as to the chemical composition of approximately one third of the trade name products surveyed which contained OSHA regulated substances (NIOSH, Ex. 19, Chpt. III). It is likely that sophisticated chemical analytical techniques can often determine the identity of end product constituents, thereby ending trade secret protections, but this may not always be so (e.g., catalysts and intermediates). It is also conceivable that in rare situations the level of exposure to a toxic chemical, not its identity, could be a trade secret.

Having concluded that exposure and medical records may at times contain various forms of trade secret

information, the agency considered a variety of regulatory approaches. At the extremes, two options existed: (1) attempt to override all potential trade secret claims as in conflict with the purposes of this standard; and (2) give employers complete discretion to deny worker access to whatever information they perceive to be trade secrets. The agency rejected both of these approaches. As a legal matter (*See,* V.B, *infra*), and as a matter of sound public policy, the agency decided to accommodate legitimate employer trade secret claims, but only where the claims would not undermine the purposes of this rule. Workers have a fundamental need to know the identity, extent, and health consequences of exposure to toxic substances and harmful physical agents, regardless of whether or not the information is a trade secret. The final rule is therefore founded in part on the judgment that, as a matter of public health policy, employers must not be permitted to deny worker access to this information which is needed for the purposes of detecting, treating, and preventing occupational disease. As a result, the agency declined suggestions that the standard provide employers with unchecked discretion to deny access to asserted trade secrets. This could in practice render this rule virtually useless, since recalcitrant employers could easily use trade secret claims as a pretext for denying access to records. Access to records would then result only after protracted and complex administrative litigation demonstrated that a particular trade secret claim was not legitimate.

In striking a balance between preserving trade secrets and guaranteeing worker access to information, the agency considered the various employer suggestions that did not give employers unilateral discretion to deny access to trade secrets. Suggestions were made to: (1) inform the worker's doctor of the trade secret, but not the worker (Batchelor (NAM), Tr. 408–09; MCA, Ex. 156, pp. 28–29); (2) permit employers to delete trade secrets and substitute common names (SOCMA, Ex. 2(163), p. 4; MCA, Ex. 2(125), pp. 8–9); (3) permit employers to delete proprietary information "which is not relevant to either the exposure of or the medical impact of the exposure on the individual" (Dow Corning Co., Ex. 2(176), p. 2); (4) inform employees of the hazards of a chemical but not its identity (SOCMA, Ex. 156, p. 28); (5) permit employers to summarize monitoring results so as to avoid disclosure of proprietary processes or chemical formulations (Minnesota Mining and Manufacturing Co., Ex. 2(129), p. 7); and, (6) expressly permit employers to condition access on the formation of binding pledges of confidentiality (Polaroid Corp., Ex. 2(187), p. 4).

The final standard adopted several of these suggestions. First, employers are explicitly given the option to delete "any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in a mixture." It is OSHA's judgment that worker access to this process or mixture information is not crucial to the effectuation of this standard's limited goals. Union representatives also expressed acceptance of the deletion of this kind of trade secret information (Wodka (OCAW), Tr. 709–10; Eller (ICWU), Tr. 754).

OSHA decided to provide employers an opportunity to delete this legitimate trade secret information even where the deletion could substantially impair evaluation of where and when exposure to a toxic substance or harmful physical agent occurred. The location from which samples were collected might, for instance, be identified on a record in terms of proximity to the technical name for a secret machine. In these situations, however, the employer must provide alternative information which the employee can meaningfully use to identify where and when exposure occurred. This alternative information must be in a form employees can understand in light of their knowledge of the way their workplaces are laid out and what steps are followed in manufacturing processes. In this fashion, exposure and medical records will have true meaning to workers while employers are given flexibility to minimize disclosure of trade secrets previously unknown to workers.

While the final standard attempts to avoid unnecessary disclosure of trade secrets, the agency has decided that access must be provided to information concerning "chemical or physical agent identities including chemical names, levels of exposure, and employee health status data." In the agency's judgment, the need for worker access and the benefits of direct worker access to these basic data are compelling. Workers must, in all cases, at least have a right to know exactly what they are exposed to on the job, what is the magnitude of this exposure, and what are the resulting adverse health effects. Upon careful consideration the agency has declined to accept suggestions that employers be permitted to filter, summarize, substitute for, or interpret this fundamental information, or limit access to a narrow class such as physicians. Further, in assuring access to the identities of toxic substances and harmful physical agents, the standard covers the chemical name as well as any trade names or common names used for a chemical substance or agent. Medical and toxicological literature is generally indexed only by the chemical name of a chemical; thus employers may not obscure the known identity of a chemical by substituting a 'common' or 'trade' name.

Although the final standard compels access to data which may at times be trade secrets, the agency has not neglected the potential consequences of this access. To prevent misuse of this information, the standard provides that "whenever trade secret information is provided to an employee or designated representative, the employer may require, as a condition of access, that the employee or designated representative agree in writing not to use the trade secret information for the purpose of commercial gain and not to permit misuse of the trade secret information by a competitor or potential competitor of the employer." Polaroid Corporation endorsed the value of such agreements:

> Trade secret status and the right to judicial protection of it may be lost by an employer's failure to limit disclosure to employees with a need to know and to require a pledge of confidentiality as a condition of disclosure. See 2 Callman, *Unfair Competition* s53.3(d). Polaroid believes that the Proposed Rule should be amended to take this rule of law into account. In those cases where employees do have a need to know trade secret information contained in medical and exposure records, employers should be expressly permitted to require any employee to enter into a confidentiality agreement as a condition of obtaining access to it. (Ex. 2(187), p. 4)

Although a Manufacturing Chemists Association (MCA) representative questioned the value of these agreements (Schall, Tr. 410–11), it is clear that these agreements are widely used in industry (Schall (MCA), Tr. 410–11; Duncan (NAM), Tr. 2194; AFL–CIO, Ex. 152, p. 28). It is also clear that they can serve to establish judicially enforceable rights (Cavitch, Business Organizations s23.4.02(5)(1975)).

The agency is confident that simple pledges of confidentiality in the specific context of this standard can serve to prevent abuse of whatever limited trade secrets are made accessible. These simple written agreements are provided for in the standard because in this situation they are appropriate. Their inclusion, however, does not represent an agency determination that trade secrets should only be disclosed upon

the formation of such agreements; and there may be other regulatory contexts in which these kinds of agreements are neither practical nor appropriate.

There is no evidence in this record that workers or unions have previously abused trade secrets of which they were aware, and employers have not even suggested that abuses occur by these kinds of individuals. Written agreements will focus attention on the serious consequences that could result from abusing trade secrets. There is, of course, some chance that specific agreements will be violated by a few individuals, but this possibility appears no greater than the current potential for abuse of trade secrets already known by workers or management personnel. Written agreements, by manifesting expectations of continued secrecy, will also maximize the ability of a harmed employer to get meaningful injunctive and compensatory judicial relief against a competitor who unfairly attempts to utilize trade secrets.

As a final matter, it is appropriate to note that the main, if not sole, concern of some employers was with potential abuse of trade secrets by designated representatives, not by employees (Dupont Corp., Ex. 150, p. 12–13; Capitol Associated Industries, Inc., Ex. 2(123), pp. 1–5, 17–21; General Electric Co., Ex. 2(178), p. 2; Sheratt (Data General Corp.), Tr. 1991–94, 2001–03). Concern was expressed that an employee would name a competitor as a designated representative, thereby guaranteeing abuse. The final standard treats designated representatives in the same manner as employees; that is, they both may be subject to written pledges of confidentiality. Designated representatives as a class essentially stand in the shoes of employees. They are provided access in order to avoid the burdens of forcing employees to personally collect records that they intend to have reviewed by representatives of their choosing. There is no more likelihood that an employee will designate a competitor as a designated representative than that the employee will copy records and then deliver them to a competitor. It is OSHA's expectation that in the vast majority of situations an employee will designate a physician, union official, lawyer, family member, or independent professional to be a designated representative. In these cases there is no genuine likelihood of competitive abuse. Whatever abuse possibly arises can be protected against by means of written agreements not to abuse trade secrets.

G. OSHA Access to Medical Records and the Right of Privacy

The most significant issue posed by OSHA access to employee records concerns a potential clash with the right of privacy vis-a-vis employee medical records. As discussed in the Legal Authority section of the preamble (V.C, D, *infra*), employee medical records are protected against unjustified governmental intrusions by the United States Constitution. Employee medical records subject to this rule will sometimes contain the most intimate details concerning a person's life, e.g., disease experience, psychiatric disorders, venereal disease, abortion, alcohol or drug abuse, sexual preferences, family medical problems, etc. OSHA access to complete medical records was felt by numerous participants to raise two major problems. First, it was argued that indiscriminate examination and use of employee medical records poses the threat of misuse. Harmful medical information could be disseminated in a way that would adversely affect the employee, e.g., loss of employment or insurance opportunities, impairment of personal reputation, damage to family relationships, etc. Second, it was argued that governmental access to personal medical information threatens to destroy expectations of confidentiality and severely impair medical programs.

The following comment by Shell Oil Co. illustrates these concerns:

> OSHA states that it believes the benefits derived from employees and public access to these medical records outweighs the disadvantages and therefore proposes to overturn the confidential physician/patient relationship that has always existed. We believe OSHA's attempt to make suddenly public an historically confidential relationship is revolutionary and will harm the relationships that currently exist between physicians and patient-employees. Future interactions between physicians and patients will be damaged because it will become more difficult for physicians to obtain complete and correct medical histories and even more difficult to persuade employees to take medical examinations. The resulting difficulties will affect society and will likely lead to poorer medical care in the private as well as the public and industrial sectors. (Ex. 2(105), p. 7)

(*See also,* AOMA, Ex. 2(59); General Foods Corp., Ex. 2(99)).

As a result of these two potential problems, several participants opposed any form of OSHA access to employee medical records (Phipps Construction, Inc., Ex. 2(7); Gypsum Assn., Ex. 2(94); Terrence Reed, Ex. 167(9–1); Harold Ritchie, Ex. 167(9–2); Milwaukee Constr. Ind. Safety Council, Ex. 167(9–7), p. 1–2; General Telephone Co. of Indiana, Inc., Ex. 167(9–13); Union Electric Co., Ex. 167(9–19)). Numerous other participants argued that OSHA access to an employee's medical record should only occur through informed consent of the employee or pursuant to a court order (United Technologies Corp., Ex. 2(6); Olin Corp., Ex. 2(71); The Sherwin-Williams Co., Ex. 2(76); Mobay Chemical Corp., Ex. 2(97); Sangamo Capacitor Div., Ex. 2(100); AMA, Ex. 2(200), p. 3; Frances Mahon Deaconess Hospital, Ex. 167(9–4); Continental Oil Co., Ex. 167(9–10); Columbus Hospital, Ex. 167(9–11); Montana Hospital Assn., Ex. 167(9–16); Indianapolis Rubber Co., Ex. 167(9–20); Phillips Petroleum Co., Ex. 167(9–24); Hillenbrand Industries, Inc., Ex. 167(9–24)). Several participants focused their concern on OSHA access to personally identifiable medical information, as opposed to medical information *per se.* These participants argued that OSHA access should be conditioned on informed consent in cases where personally identifiable medical records were involved (Grumman Corp., Ex. 2(55); AMRA, Ex. 82, pp. 3–4; Dr. Hockwald (AOMA), Tr. 1530; Dr. Herrmann (Johnson & Johnson), Tr. 1831; Dr. Wolkonsky (AMOCO), Tr. 2253, 2259; Dr. Steen (AMA), Tr. 2395; Borg Warner Chemicals, Ex. 167(9–22), p. 2).

In contrast to the preceding comments, numerous other participants were supportive of unconsented OSHA access to employee medical records, provided that misuse of personally identifiable information was prevented. Recognition was given to the fact that the right of privacy is not absolute, but must often be balanced against competing interests (Weiner, Ex. 9A, pp. 8–9). As noted by the American Medical Association:

> The privileged nature of patient-physician communications is not absolute, however. Often the disclosure of such confidential information is at the patient's request or is otherwise in his or the public's best interests. There is a constant tension between confidentiality and accessibility. Legislators and regulators should be cognizant of this tension and provide for an appropriate balance between protection and disclosure. The AMA recognizes the need to retain and to provide appropriate access to pertinent data relating to the exposure and potential exposure of employees to toxic or other hazardous materials in the work place so that on-the-job risks may be assessed. However, the employee has a right to expect that information which has been collected, stored, and managed by others on his behalf will remain confidential except under limited and controlled circumstances. (Ex. 2(200), p. 2)

Chapter 7 of the Privacy Protection Study Commission's report focuses on the many competing societal interests which intrude on the medical-care

relationship, and recommends how to best accommodate valid interests at minimal risk to personal privacy (Ex. 101). The Commission explicitly struck the balance in favor of unconsented access to medical records for health research purposes (Ex. 101, pp. 305–10; *See also*, Belair (NCCHR), Tr. 1859, 1872–74)).

Other participants recognized the need for unconsented access for legitimate occupational safety and health purposes. As discussed earlier in the preamble (III.J, *supra*), the consent of employee medical records can be highly relevant to, and sometimes crucial to, OSHA efforts to further the goals of the Act. The life and death interest of workers in governmental efforts to guarantee safe and healthful working conditions is a substantial interest, and to the extent necessary should supersede individual privacy concerns (Dr. Wegman, Tr. 234–35; Dr. Whorton, Ex. 11, pp. 17–18, Tr. 289; Fanning (HEW), Ex. 126, pp. 16–17).

There was universal agreement that OSHA access should be accompanied by stringent internal agency procedures to preclude abuse of personally identifiable medical information. Provided these procedures were established, many participants, including all union and employee participants, endorsed unconsented OSHA access to employee medical records for occupational safety and health purposes (Dr. Wegman, Ex. 10, p. 13, Tr. 208; Dr. Young, Tr. 1111; Dr. Parkinson, Tr. 1142–44; Dr. Silverstein (UAW), Ex. 63, p. 9; Annas, Tr. 1752–56; Weiner, Ex. 9A, pp. 4–6, 40–46; AFL–CIO, Ex. 152, pp. 56–61, Ex. 39, p. Tr. 644–45; Samuels (AFL–CIO IUD), Ex. 36, pp. 2–3; USWA, Ex. 160, p. 10; Wilson (USWA), Tr. 684–85; Becker (USWA), Tr. 2390; OCAW, Ex. 2(124), Tr. 698; ICWU, Ex. 28, pp. 10–12, Ex. 106, p. 1; Spatz (Cement, Lime and Gypsum Workers), Tr. 1206–07; Howe (CACOSH), Tr. 1094–95; HRG, Ex. 2(161), p. 3; NIOSH, Ex. 16, p. 3). The attitude of those participants in favor of OSHA access was expressed by Dr. Silverstein of the UAW:

> The third piece, access by government agencies, has justifiably raised the most concern and controversy. At first glance, the issue is simple. The protection of the public welfare may legitimately supersede the normally protected individual right to privacy. There is so much legal and public health precedent for this that the rights of OSHA and NIOSH in this area might almost go without question. However, a more careful look reveals that this issue is actually quite complex and must be approached with the care of an appraiser viewing a precious diamond: Unless each facet is studied and evaluated we cannot be sure we are being sold an attractive replica of little ultimate value. (Ex. 63, p. 4)
>
> It is sometimes necessary and appropriate that sizeable amounts of information from medical files, with personal identifying information, be made available to enable epidemiologic investigation which may be of enormous benefit to large numbers of people. It is not always practical or possible to get individual permission for the release of this information. It is our belief that allowance should be made to permit such release to agencies which are charged with the responsibility to protect the public health. For this reason we support section (d)(3) of the rule which allows OSHA and NIOSH these records. We are not insensitive, however, to the fact that there has been an alarming and largely unregulated growth of data banks in recent years by government and various private agencies (notably insurance companies and credit agencies). The potential for abuse is high and we are not so naive to place blind trust in NIOSH and OSHA to use the medical reports wisely in all instances. The proposed rule is incomplete as long as it permits broad disclosure to NIOSH and OSHA without an accompanying regulatory framework which defines and limits the use of this information. (Ex. 63, p. 9)

Having considered the record, and analyzed the legal issues involved (V.A, C, D, *infra*), the agency decided to include a requirement in the final standard providing for unconsented OSHA access to employee medical records. As recognized by numerous participants, acquiring consent is not always a realistic possibility. Large numbers of people may be involved, emergency situations may not permit delay, the residence of terminated employees may be unknown, or an absence of consent may decrease the statistical validity of a study (Privacy Commission, Ex. 101, p. 309; Belair (NCCHR), Tr. 1859, Ex. 58, p. 46; Fanning (HEW) Ex. 126; Weiner, Ex. 9A, pp. 43–44; NIOSH, Ex. 16, p. 3; AFL–CIO, Ex. 152, p. 58; HRG, Ex. 2(161), Attach.). The time and expense involved in soliciting and waiting for consent by numerous employees is also a formidable impediment for a public health agency like OSHA with limited resources.

Even though OSHA has legal authority to seek unconsented access to identifiable medical records, the agency concluded that this authority should, as a matter of law and sound public policy, be exercised with great care. To protect the employees' privacy interests, OSHA recognizes the need for stringent internal procedures to: (1) limit the circumstances in which identifiable medical records are examined or obtained by OSHA personnel, and (2) control use of identifiable medical information once in the agency's possession. In order to effectuate these decisions, the agency is today simultaneously promulgating detailed procedural regulations governing all aspects of OSHA examination and use of personally identifiable medical records (29 CFR 1913.10). As suggested by numerous participants, these internal administrative requirements are being promulgated as a rule rather than as internal guidelines in order to give them the permanence and status accorded to published regulations (*See*, 44 FR 3995 (Jan. 19, 1979); Dr. Hockwald (AOMA), Tr. 1532; Swanson (API), Tr. 2063; Shell Oil Co., Ex. 167(9–28), p. 4; Phillips Petroleum Co., Ex. 167(9–23), p. 2; Rubber Mfgrs. Assn., Ex. 164, p. 2; Dr. Herrmann (Johnson & Johnson), Tr. 1833; UAW, Ex. 63. p. 10; AFL–CIO, Ex. 152, p. 61).

Several key considerations influenced OSHA's decision to provide for unconsented agency access to identifiable medical records. The agency foresees a need to seek access on occasion to personally identificable medical records. The administrative regulations are structured around the principle that personally identifiable information is not to be collected unless there is a clear need to do so. Many purposes for OSHA access can be satisfied without any access to personal identifers, but this will not always be so. Some purposes for OSHA access involve limited on-site review of medical records such as biological monitoring results to detect instances of occupational health problems. Once specific instances of problems are discovered, OSHA would investigate conditions in the workplace to discover causes of the problems, and then ensure that protective measures are provided to the employees involved. These kinds of inquiries necessarily involve personally identifiable information, as would Section 11(c) discrimination investigations and other inquiries directed to the problems of specific employees. OSHA anticipates that access to employee medical records will generally involve limited on-site review, with minimal personally identifiable information being recorded and taken off-site. Access can be accomplished at minimal burden to all concerned by access to the relevant portions of identifiable records. Due to the variety of reasons for OSHA access, and the practicalities involved, OSHA concluded that the final standard could not reasonably require OSHA to obtain employee consent in order to gain access to personally identifiable medical information.

The final standard provides for such OSHA access to personally identifiable medical records without requiring

individual employee consent. In so doing, OSHA agrees with the personal comments of John Fanning of HEW's Office of Health Policy, Research, and Statistics, to the effect that strong public health considerations must weigh heavily when balanced against the privacy interest in precluding unconsented access:

> My basic principle would be that the health of people and the prevention of suffering caused by ill health are very important values, that they are more important than the privacy interests normally involved in records needed for health research. I don't think I have to outline here the contributions of epidemiological research, to the preservation of health and the relief of suffering. Through the use of records, science has come to important conclusions about the causation of illness and the effects of various therapies. Through this knowledge, we've been able to in many instances interrupt this causation by quarantine measures, by the prevention of the use of toxic substances, by warnings in education programs. In other instances, helpful therapies have been confirmed in their use and harmful therapies have been stopped or limited. Much of this research requires the use of records that are identifiable to the individual and that are compiled for other purposes. And it is typically needed, without the consent of the individual. In most instances, consent is impracticable and will spoil the research. (Ex. 126, pp. 16–17)

> When the rather minor intrusion involved in the use of records in epidemiological research is balanced against the possibility of reducing disease and suffering for future generations, it seems difficult to justify a policy that will prohibit or seriously restrict the use of the record. The individuals whose records are used can be seen as having an obligation to the wider society to contribute to the elucidation of the causes, course and treatment of illness. . . .
>
> The possibility of learning something significant about illness is of such importance to the wellbeing of future generations and even in some instances the individuals involved in present generations, is of such importance that it surely justifies access by researchers when this is done in a way that does not interfere with the present wellbeing of the subjects. Unnecessary constraints on research in the name of privacy represent a balancing which gives privacy an obstructive position in human affairs, rather than a liberating position, which it ought to have. Illnesses are dehumanizing to its victims and the insignificant invasions of privacy attendant to research uses of records truly do not reach the level of dehumanizing those individuals that illness does for its victims. (Ex 126, pp. 17–18)

The preceding comments, though directed to epidemiological research, apply equally to other OSHA needs for access, where information contained in employee medical records is being directly utilized to ensure safe and healthful working conditions for employees.

The final standard and its accompanying procedural regulations are of necessity flexible as to when the agency will seek unconsented access to personally identifiable medical information. A very firm regulatory structure is established, however, to preclude abuse of any personal information obtained. Access is narrowly focused to only that information needed to accomplish the reason for access, and approval must be obtained from top OSHA officials. Notice of access by means of posting and in some cases by individual notice is afforded to employees. Direct personal identifiers may not be obtained unless needed, and are to be removed and maintained separately from the medical record once in the agency's possession. Use, security, and inter-agency and public disclosure of medical records are strictly controlled. This combination of procedures established by OSHA tracks many of the recommendations made by participants in the rulemaking and by organizations who have studied medical record privacy issues.

OSHA is confident that the protections established will avoid impermissible interference with the right of privacy, while at the same time enable medical record information to play a constructive role in preventing occupational injury and disease. All aspects of the procedural regulations are discussed in a separate **Federal Register** notice issued today. No evidence was entered into the record of past OSHA abuses of employee medical records (*See,* Wodka (OCAW), Tr. 698; Samuels (AFL–CIO IUD), Ex. 36, pp. 2–3), nor did any participant in this proceeding even suggest that there had been instances of abuse by OSHA. The procedural regulations adopted will build on this foundation. In addition, several participants firmly rejected suggestions that well-controlled OSHA access to medical records would undermine corporate medical programs.

> Virtually every corporate witness who testified claimed that access by government agencies without consent would interfere with the heretofore confidential doctor/patient relationship and destroy the basis of trust in that relationship. While expressed corporate concern over patient's welfare was great, not one worker or worker representative voiced the opinion that government access would undermine the workers' relationship with the company physician. On the contrary, the testimony of every worker and worker representative clearly and strongly supported OSHA and NIOSH access to individual records without consent.AFL–CIO, Ex. 152,

(*See also,* Wilson (USWA), Tr. 684–5; Bergs (USWA), Tr. 1127–8; Tutrow (USWA), Tr. 1130; Gaffney (UAW), Tr. 1324–5; LOHP Panel, Tr. 1706–09).

H. Non-medical Corporate Access to Employee Medical Records

As discussed in the preamble (IV.D, *supra*), workers have little genuine expectation of true confidentiality as to employment medical records. A variety of standard practices tend to undermine the ability of the physcian-patient relationship in industry to be based on mutual trust or the maintenance of confidentiality. Workers are often required to submit to pre-employment physicals and other examinations as a condition of employment with no choice as to the physician who conducts these exams. Company physicians commonly testify without the consent of the employee (and often favorably to the employer's interests) in arbitration and workers' compensation cases. Workers have often been required to sign releases for the blanket disclosure of medical information to employers in order to qualify for various benefits. And typically, employees must authorize the release of all medical information to an insurance company to assure the payment of claims, with the insurance company in turn releasing the records to the employer's accounting or benefits department.

In addition, the rulemaking record contains substantial evidence that non-medical management personnel often have access to employee medical records beyond what is considered ethically permissible by the occupational medical profession. Although the AOMA Code of Ethical Conduct provides that ". . . employers are entitled to counsel about the medical fitness of an individual in relation to work but are not entitled to diagnoses or details of a specific nature" (Ex. 2(59)), the record indicates that management access to the contents of employee medical records is often much more extensive (Weiner, Ex. 9A, pp. 34–35, Tr. 177–78, 180; Dr. Whorton, Ex. 11, pp. 6–8, Tr. 271–3; Taylor (AFL–CIO IUD), Ex. 39, pp. 5–6, Tr. 640–3; Samuels (AFL–CIO), Ex. 35 (Attach.), Tr. 949–53, 961–2, 964–5, Ex. 93A, Ex. 93H, pp. 14–16; ICWU, Ex. 28, pp. 1, 10–12, App.; Eller (ICWU), Tr. 727–9, 738–40, 747–8, 759–61; Dr. Silverstein (UAW), Ex. 63, pp. 3–6, 7, Tr. 2020–22, Ex. 165, pp. 2–3; NCCHR, Ex. 58, pp. 30, 32–3; HRG, Ex. 161d, p. 7; AFL–CIO, Ex. 152, pp. 7–8, 19–22; USWA, Ex. 160, pp. 4–7; Wilson (USWA), Tr. 678–9, 687–8; Wodka (OCAW), Tr. 703–05; McDougall (IBT), Tr. 915; Howe (CACOSH), Tr. 1093–4, 1096, 1102–04; Dr. Young (CACOSH), Tr. 1098–9; Becker

(USWA), Tr. 2381–2, 2384, 2387; Toland (PHILAPOSH), Tr. 884–5; Mattillion (UAW), Tr. 1319; Fenn (OCAW), Tr. 1362). The following testimony is representative:

I will say for the record that there is absolutely no privacy in our workplace on medical records. Anyone can get, any member of management can get access to the records any day of the week, any hour of the day. It's as easy as picking up any phone and calling the medical department or the doctor and asking any question you want and getting the information. (Howe (CACOSH), Tr. 1096)

* * * * *

But as far as the lack of confidentiality of records, yes, I can attest to that. I have been in medical, you know investigating an incident or whatever, trying to talk to the company doctor. A member of labor relations would come down and just, you know, hi, doc, and then go through the records, the medical records, and pull a particular individual's medical record and without even consulting the doctor first or a nurse or anybody as far as that goes, just directly [go] to the cabinet and pull an individual's record. I know it happens with personnel and I know it happens with different individuals in management during the course of a grievance procedure, you know, in regard to promotion or something, to see if a man has any kind of physical handicap. They will just go directly down and pull the file themselves. So there is no confidentiality. (Mattillion (UAW), Tr. 1319)

* * * * *

But when we talk about the small companies, the small chemical company with 40 or 50 employees or 25 or 30 employees, they normally employ either a doctor locally or a clinic in the nearby area that works for half a dozen or 25, maybe as many as 200 companies. And there the right of privacy, which we continue to hear companies talk about, protecting the physician-patient relationship, evidently has a real tendency to go astray, because the man is sent there for a physical, the physical comes back, the company secretary or receptionist who opens the mail, she scans it first. Then the office manager scans it. Then from the office manager it usually goes to the general foreman and it may [go] further away from him [or] it may stay confidential; it may go just to the company benefit person or it is mailed downtown to Toledo or Philadelphia, wherever their main headquarters and they are sent there for the benefit people. So a lot of people have access to his medical records except him. So I think that the part of the saying that it is just a matter of relationship between the patient or the employee and the doctor is so sacred in this case I wonder how all those other people got into the sacred act. (Fenn (OCAW), Tr. 1362)

* * * * *

The examples are great in number, and I will just give you one from my own experience that is an illustration, I think, that is representative. I had the opportunity to tour a plant where we represent members a number of months ago because of some health problems that our members were experiencing and during the course of this investigation, I spoke with the company physician at that plant and I asked at that time about the measures taken in the plant to protect the privacy of the individual employees and to preserve the medical records and the physician told me that the records were kept in a locked file cabinet and that they were available only to that physician alone and to nobody else and that the physician was assured that, because of the way the records were maintained, that there were no current abuses.

However, the physician described to me what had happened when he initially took employment with that company and said that during the first weeks of his employment there he was approached on a number of occasions by industrial relations personnel, by foremen, by supervisors and a variety of others, asking to see medical files and he said to these people, no, I can't show you those. These are private medical records and I keep them confidential. And he was told, look, you don't understand. We've had these records available to us for years. You just don't understand. You've been hired by the company; you're part of the team now, and this is the way we handle this kind of information.

Well, it required an apparently sizable struggle on the part of the physician to gain control of those records and to protect them from abuse, but these abuses did exist in that plant for a number of years and I am convinced that they continue to exist, uncontrolled, in a large number of institutions. (Dr. Silverstein (UAW), Tr. 2021–22)

On the basis of the record, the agency is convinced that significant abuses of employee medical records occur. Several participants urged that the final rule contain provisions to limit corporate access to employee medical records. The UAW recommended that:

(1) All employee medical records as defined in this rule should be required to be kept in locked files under the direct control of medical professional personnel.

(2) A written log should be maintained which would document all movement of material into and out of these files. This would include signed accounts of all releases and subsequent circulation of material from the files. (Ex. 165, pp. 2–3)

The AFL–CIO similarly recommended a provision requiring that "Medical records shall be maintained in a secure fashion, separate from other non-confidential records so as to prevent access by non-authorized individuals" (Ex. 152, pp. 7–8, 19–22, 45–47, 53–54, A2). The USWA recommended more detailed provisions including the following elements: (1) retention of employee medical records under the exclusive control of a physician; (2) unrestricted employer access to opinions and recommendations of the physician, but employer access to specific diagnoses or details only with the written consent of the employee; (3) access by non-governmental researchers to medical records for epidemiological purposes only with the consent of the union; and (4) retention of a log for each medical record detailing the circumstances of releases of medical information (Ex. 160, pp. 4–7, 10–15).

Although the preceding recommendations are straightforward methods of minimizing corporate abuse of employee medical records, the final standard does not address this issue. The proposed rule was silent on the question of corporate access to employee medical records, and OSHA's opening statement to the rulemaking hearings stated that:

[T]he proposal does not limit to whom the employer may discretionarily disclose exposure and medical records. In particular, it is silent on the extent to which non-medical management employees or officers can rightfully gain access to, use, or disclose to third parties (such as insurers, health researches, or other employers) information that has been collected by the company's medical department.

. . . [O]ur silence on these broad questions of corporate medical and recordkeeping practices and privacy policies should not be construed as OSHA assent. Rather, it serves only to underscore the relative modesty of the current proposal. These broader issues not being issues in the current proceeding except insofar as they are relevant to issues which are raised, we leave them to future legislation or regulation, as appropriate. (Wrenn, Ex. 7, pp. 17–19)

In addition, since the issuance of the proposal, the Department of Labor has conducted extensive hearings on the whole question of employee privacy rights within the corporation, including the privacy of medical information (44 FR 57537 (Oct. 5, 1979)). In view of OSHA's initial expressed intention not to regulate corporate access to employee medical records as part of this rulemaking, and the overall Departmental initiative to address these questions, the agency has declined to promulgate final requirements at this time. The record has, however, convinced the agency that a serious problem exists, and consideration will be given to appropriate agency responses. The lack of provisions in the final rule concerning this topic should not be viewed either as implicit criticism of the specific recommendations made by various participants, or as an agency concession that the problem does not merit a response.

V. Legal Authority Issues

A. Statutory Authority for Access to Records

The Occupational Safety and Health Act provides ample legal authority for employee, designated representative

and OSHA access to medical and exposure records. The Act created an expert administrative agency with broad regulatory powers to fashion protective regulations concerning occupational injury and disease and to tailor administrative procedures in informal rulemakings to the needs of efficient regulatory actions. This final rule substantially advances the central purpose of the Act articulated in Section 2(b)—"to assure so far as possible every working man and woman in the Nation safe and healthful working conditions" (29 U.S.C. 651). This standard furthermore flows directly from, and is fully consistent with, the Act's express language.

By this rule, OSHA has adopted a generic approach to remedying the problems of access to exposure and medical records. Sections 6(b), 3(8), 2(b)(3) and (9), 8(c)(1), and 8(g)(2) provide for the promulgation of such occupational safety and health standards which the Secretary deems necessary to carry out his responsibilities. The Secretary believes that the generic approach to rulemaking is a necessary and reasonable approach to regulating occupational health problems which are universal to a wide array of toxic substance exposures and industrial settings in view of the large number of such substances and settings and the weaknesses of the substance-by-substance approach. OSHA therefore explicitly rejects contentions that have been made by some in industry that the Act limits the Secretary to substance-by-substance rulemaking.

Access to records will yield both direct and indirect improvements in the detection, treatment, and prevention of occupational disease (III, *supra*), thereby advancing the remedial purposes of the Act. Access to vital exposure and medical information is an innovative method of promoting occupational health consistent with the Congressional directive in Section 2(b)(5) that healthful working conditions be provided "by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems" (29 U.S.C. 651(5)). Access to exposure and medical information will advance the Congressional goal in Section 2(b)(1) of:

> [E]ncouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions. (29 U.S.C. 651(1))

Access also furthers the section 2(b)(6) goals of "exploring ways to discover latent diseases, (and) establishing causal connections between diseases and work in environmental conditions . . ." (29 U.S.C. 651(6)). As such, this rule squarely falls within the definition of 'occupational safety and health standard,' which is defined by Section 3(8) as:

> [A] standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment. (29 U.S.C. 652(8))

Because this rule comes within the terms of Section 3(8), Section 6(b) (29 U.S.C. 654(b)) authorizes the Secretary to issue it in accordance with the procedures prescribed in that section.

This application of 6(b) is a means of strengthening and broadening the participation of employees and their representatives in occupational health matters. The Senate Committee on Labor and Public Welfare, in recommending passage of the Senate version of the Act, placed great importance on this participation:

> It has been made clear to the committee that the most successful plant safety programs are those which emphasize employee participation in their formation and administration; every effort should therefore be made to maximize such participation throughout industry (Sen. Comm. on Labor and Public Welfare, *Legislative History of the Occupational Safety and Health Act of 1970* ("Legislative History"), 92d Cong., 1st Sess. 150 (Comm. Print 1971))

The House Committee on Education and Labor, in its report recommending passage of the House bill, attached comparable importance to employee awareness of hazards:

> Basically, the worker needs to have adequate advance knowledge of hazards in order to protect himself from damaging exposures. . . . Since inadvertent exposure to unknown products or processes often causes severe and immediate reactions, the exposed worker must know what type of exposure he has suffered in order to use proper treatment. The worker especially needs this information in cases of toxic substances which have delayed or latent ill effects. (Legislative History at 859)

This final occupational safety and health standard gives meaning to these Congessional findings.

Employee and designated representative access to records directly builds upon several express provisions of sections 6(b) and 8(c). Section 6(b)(5) (29 U.S.C. 655(b)(5)) provides that "the Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard, which most adequately assures, to the extent feasible, on the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." This standard is viewed as necessary and appropriate to protecting employees from material impairment as a result of exposure to toxic substances and harmful physical agents, including with respect to those substances and agents which have not otherwise been the subjects of specific occupational safety and health standards. This standard therefore will contribute significantly to achieving the statutory goal stated in section 6(b)(5), as well as aid employees in the fulfillment of other rights under the Act.

In addition, Section 8(c)(3) (29 U.S.C. 657(c)(3)) provides that when a toxic substance is being regulated comprehensively pursuant to section 6(b), exposure monitoring where appropriate shall be conducted by the employer, and employees and their representatives shall be afforded access to the resulting records. Section 6(b)(7) further provides in this context that employees shall be apprised of all hazards to which they are exposed, and that medical examinations where appropriate shall be afforded to employees. Access to the results of these medical examinations must be provided to an employee's physician upon request. These provisions contemplate basic requirements to be included in each standard regulating a toxic substance, and, contrary to the narrow interpretation offered by several industry participants, should not be viewed as imposing substantive limitations on OSHA's authority to issue general rules effectuating all the purposes of the Act.

As has been stated, it is the agency's judgment, based on a decade's experience, that a substance-by-substance implementation of sections 6(b)(5), 6(b)(7) and 8(c)(3) is impractical due to the large number of unregulated toxic substances and the long periods necessary to conduct thorough rulemaking proceedings on each substance (*See,* 45 FR 5011–15 (Jan. 22, 1980)). Section 6(b), however, is flexible, and authorizes broad OSHA discretion in the format and content of each occupational safety and health standard. The many benefits of worker and designated representative access to exposure and medical information can be achieved even before all toxic substances and harmful physical agents are fully regulated. Congress intended

that OSHA have broad flexibility in mandating protective measures and setting regulatory priorities. OSHA's judgment that all workers at risk should have access to available information now as opposed to in the indefinite and possibly distant future is well within the scope of the flexibility Congress afforded.

The Occupational Safety and Health Act also contains ample legal authority for providing OSHA with its own access to employee exposure and medical records. Section III.J of the preamble, *supra*, discusses the variety of agency investigatory, rulemaking, and other functions which can depend on access to employee exposure and medical records. The statutory provision which principally authorizes OSHA access to these records is Section 8(c)(1) of the Act [29 U.S.C. 657(c)(1)], which states:

> Each employer shall make, keep and preserve, and make available to the Secretary * * * such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health, Education, and Welfare, may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses.

By its terms, Section 8(c)(1) applies to employer activities "relating to this Act" and not just to records required pursuant to Section 6 of the Act, as is provided by section 8(c)(3). The phrase "relating to this Act" must be liberally interpreted in light of the broad remedial purposes of the Act to extend to all employer records which are determined to be "necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and diseases."

The employee exposure and medical records addressed by the final rule clearly come within this scope of section 8(c)(1). As stated by the House Committee on Eudcation and Labor in discussing recordkeeping and agency investigatory powers of the House bill:

> Adequate information is the precondition for responsive administration of practically all sections of this bill. (Legislative History at 860)
>
> Since the Federal Government is moving for the first time into an area of broad national responsibility, corresponding authority must be delegated to the Secretary in order that he may carry out this responsibility. (Legislative History at 852)

The amended Senate bill adopted the broad "relating to * * *" phrase found in the Act even though earlier versions of various bills applied the recordkeeping requirements only to records "concerning the requirements of the Act" (Legislative History at 13, 93, 736). Congress, therefore, opted for the broadest possible application of section 8(c)(1). *Marshall* v. *American Olean Tile Co.*, —— F. Supp. —— (E.D. Pa., No. 79-597) (p. 4 n. 3, sl. op.; Feb. 29, 1980).

Legal authority for OSHA access to exposure and medical records also arises from section 8(a)(2) [29 U.S.C. 657(a)(2)], which authorizes inspections and investigations of, among other things, employer "materials"; from Section 8(b) [29 U.S.C. 657(b)], authorizing the agency to require "the production of evidence under oath" (which both the House and Senate committees stated to include books and records (Legislative History at 152, 171, 852)); and from section 8(g)(1) [29 U.S.C. 657(g)(1)], which authorizes the compilation, analysis, and publishing of information obtained under Section 8.

The final standard is also authorized by section 8(g)(2) of the Act [29 U.S.C. 657(g)(2)]. Section 8(g)(2) empowers the Secretary to "prescribe such rules and regulations as he may deem necessary to carry out (his) responsibilities under this Act." In light of the remedial and ambitious nature of the Act, this general rulemaking section necessarily applies to all statutory responsiblities, and supplements specific grants of authority found elsewhere in the statute. In discerning the scope of its statutory responsibilities, OSHA looks to the entire Act, and not just to ss6 and 8. A more narrow application of s8(g)(2) would mean that its function was purely ornamental. Since there is nothing in the legislative history indicating that its inclusion in the enacted bill was meant to be more limiting than the overall statutory purposes, s8(g)(2)'s applicability must be commensurate with the agency's overriding responsibility of assuring healthful working conditions for every working man and woman(s2(b) of the Act).

Thus section 8(g)(2) also establishes legal authority for this rule, particularly because at least six important statutory provisions are substantially advanced by employee and designated representative access to medical and exposure records. These six provisions relate to employee rights under the Act—rights which OSHA has a responsibility to effectuate and preserve, especially since, as the Supreme Court has recently recognized, "OSHA inspectors cannot be present around the clock in every workplace." *Whirlpool Corp.* v. *Marshall*, —— U.S. ——, 100 S. Ct. 883 (1980), *at* p. 891.

Access to information is first of all crucial to the effectiveness of the section 8(f)(1) right of employees and their representatives [29 U.S.C. 657(f)(1)] to complain to OSHA concerning perceived safety and health problems and obtain a prompt inspection of the worksite at issue. The importance of this complaint procedure can be seen by the fact that, of 57,937 total FY 1979 (Oct. 1, 1978–Sept. 30, 1979) OSHA inspections throughout the country, approximately 22 percent were initiated by complaints from employees or their representatives (Ex. 175). Approximately 34 percent of these worker complaints concerned health issues (Ex. 175). Responding to worker complaints thus consumes a large portion of OSHA's inspection resources. Agency experience has demonstrated that the complaint mechanism is one of the most important means by which occupational health problems are brought to OSHA's attention for investigation and enforcement solutions. Worker access to records will significantly increase the impact of complaint inspections, since workers will be able to be more specific about the nature of their exposures, the job locations of greatest exposure, and any resulting health problems. Knowing this information in advance of an investigation will enable OSHA to respond immediately to severe problems, to better prepare itself for inspections, and to assure that the correct personnel and equipment are sent to investigate the problems complained of.

The second vital employee statutory right affected by this rule is the section 8(e) right of employees and their representatives to accompany OSHA during plant inspections [29 U.S.C. 657(e)]. This walkaround right helps OSHA identify where and how various toxic substances are used, which plant operations generate the greatest exposures, and in other ways helps OSHA conduct a thorough and effective inspection. The Senate Committee on Labor and Public Welfare, in reporting the Senate version of the Act, attached great importance to this right:

> During the field hearings held by the Subcommittee on Labor, the complaint was repeatedly voiced that under existing safety and health legislation, employees are generally not advised of the content and results of a Federal or State inspection. Indeed, they are often not even aware of the inspector's presence and are thereby deprived of an opportunity to inform him of alleged hazards. Much potential benefit of an inspection is therefore never realized, and workers tend to be cynical regarding the thoroughness and efficacy of such inspections. Consequently, in order to aid in the inspection and provide an appropriate degree of involvement of employees themselves in the physical inspections of their own places of employment, the

committee has concluded that an authorized representative of employees should be given an opportunity to accompany the person who is making the physical inspection of a place of employment * * * (Legislative History at 151)

Agency experience has demonstrated that, to the extent workers are aware of the hazards they face, they share this information with OSHA, and are valuable aides in the agency's efforts to maximize the effectiveness of our compliance resources. Worker access to medical and exposure records will make more meaningful the exercise of an important statutory right, and will also directly improve the quality of OSHA plant inspections.

Two other important statutory rights of employees are their section 10(c) rights to contest the reasonableness of abatement periods proposed by OSHA, and to participate as parties in Occupational Safety and Health Review Commission adjudicatory proceedings (29 U.S.C. 659(c)). Congress thus created a clear statutory framework by which workers could contribute to the just resolution of disputes over OSHA enforcement cases. Workers and their representatives have in recent years increasingly invoked these participatory rights. Our experience in Review Commission proceedings has been that worker participation often substantially affects the outcome of adjudications and can assist the Secretary in the exercise of his enforcement responsibilities. (*See, Kaiser Aluminum & Chemical Corp.*, 1978 CCH OSHD Para. 23,200; *Brown & Root*, 1978 CCH OSHD Para. 23,731; *United Parcel Services*, 1979 CCH OSHD Para. 23,837). As with other rights under the Act, however, the effectiveness with which workers invoke section 10(c) rights depends largely on the extent of their knowledge of the health hazards addressed by enforcement proceedings. Access to medical and exposure records will enable workers to decide more rationally whether to use section 10(c) rights. And, once workers have decided to participate, access to records will improve the quality of their participation.

A fifth statutory right enhanced by worker access to records is the section 20(a)(6) right of workers to request a workplace Health Hazard Evaluation (HHE) by NIOSH (29 U.S.C. 669(a)(6)). HHE's are performed by NIOSH to identify the nature and magnitude of existing workplace health hazards (Bierbaum (NIOSH), Tr. 480–83, 487; Ex. 20). NIOSH perceives its HHE program as a crucial means of discovering occupational disease—so much so that NIOSH is refocusing its resources in an attempt to triple the number of HHE's it conducts in 1980 over the number performed in 1979 (Testimony by NIOSH Director Anthony Robbins on September 20, 1979, before the National Advisory Committee on Occupational Safety and Health, Ex. 175, p. 9). Philip Bierbaum of NIOSH testified that approximately 60 to 70 percent of requests for HHE's come from workers or their representatives (Tr. 481). Worker access to medical and exposure records will thus increase the value of HHE's in two ways. First, access will enable workers to better detect health problems and seek the benefits of NIOSH's help. And second, access will enable employees to provide NIOSH with information on the potential magnitude of the health problems involved, so NIOSH can set priorities for its limited HHE resources.

Lastly, worker access to medical and exposure records will maximize the impact of employee training and education provided by OSHA pursuant to section 21(c) of the Act (29 U.S.C. 670(c)). OSHA realizes that it alone cannot solve occupational safety and health problems. Occupational disease is a societal problem and effective solutions require the combined efforts of employees, employers, government, the educational community and the technical community. Knowledge concerning the causes, nature, and prevention of disease is required, as well as the technical resources to effect solutions in practice. The House Committee on Education and Labor, in its favorable report of the House bill, emphasized these realities:

> American industry cannot be made safe and healthful solely by enacting a Federal law which emphasized punishment. (Legislative History at 856)
>
> The Committee judges that one of the key contributions Government can make to the occupational safety movement is through education by the dissemination of safety information and by the training of employers and employees * * *
>
> The Committee recognizes that a substantial increase in manpower with professional competence is needed to bring about a successful program. To remedy this situation, certain provisions in the bill are designed to expand significantly the number of properly trained personnel to work in the field of occupational safety and health * * *
>
> Special emphasis is to be placed on technical assistance to both labor and management for the adoption of sound safety and health practices. (Legislative History at 861)

The Committee Report of the Senate Committee on Labor and Public Welfare attached equal significance to education and training (Legislative History at 161).

To implement section 21(c) of the Act, OSHA has established a major program, its "New Directions Grant Program," which provides funds to labor unions, nonprofit trade associations, educational institutions, and other groups for the purposes of training, education, and acquisition of technical resources (Ex. 173). The New Directions Grant program is substantially improving worker knowledge of the causes and prevention of occupational disease, and is broadening the availability of technical resources to both union and non-union employees. Worker access to exposure and medical records is crucial so that workers can take full advantage of the knowledge and technical resources being made available by the New Directions Grant program.

The statutory authority for employee and designated representative access to medical and exposure records therefore arises from numerous provisions of the Act. The remedial purposes of the Act dictate that this statutory language be broadly applied. Recent court decisions have emphasized that the Act is a remedial statute, which requires a liberal construction and broad deference to the Secretary's definition of statutory authority. In *Whirlpool Corp.* v. *Marshall*, —— U.S. ——, 100 S. Ct. 883 (1980), the Supreme Court unanimously held (pp. 890–91):

> The (OSH) Act, in its preamble declares that its purpose and policy is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to *preserve* our human resource . . ." 29 U.S.C. 7651(b) (Court's emphasis).
>
> To accomplish this basic purpose, the legislation's remedial orientation is prophylactic in nature. See *Atlas Roofing Co.* v. *Occupational Safety Commission*, 430 U.S. 442, 444–445. The Act does not wait for an employee to die or become injured. It authorizes the promulgation of health and safety standards and the issuance of citations in the hope that these will act to prevent deaths or injuries from ever occurring . . . . In the absence of some contrary indication in the legal history, the Secretary's regulation must, therefore, be upheld, particularly when it is remembered that safety legislation is to be liberally construed to effectuate the congressional purpose. *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 798; *Lilly* v. *Grand Truck R. Co.*, 317 U.S. 481, 486.

Finding the requisite authority in ss8(g)(2) and 5(a)(1) (the "general duty clause"), the Court upheld OSHA's regulation protecting workers against discriminatory action if they refuse to work in the face of a perceived imminent danger.

Decisions upholding OSHA's authority to require "upstream" labeling of toxic substances, *American*

Petroleum Institute v. *OSHA*, 581 F.2d 493 (5th Cir. 1978), *cert. granted* with respect to a different issue, 440 U.S. 906 (1979), and walkaround pay for employees during inspections, *Chamber of Commerce* v. *OSHA*, No. 77–1842 (D.C.D.C. 1978), *appeal pending* C.A.D.C., have also expressly noted that the remedial nature of the Act warrants a liberal interpretation of the authority granted to carry out its purposes. In upholding the labeling requirement, the *American Petroleum Institute* Court approvingly quoted a prior Ninth Circuit statement that "Congress clearly intended to require employers to eliminate all foreseeable and preventable hazards" (581 F.2d *at* 509). Section 6(b) was also construed liberally in the United States Circuit Court of Appeals for the District of Columbia decision in *AFL–CIO* v. *Marshall*, —— F.2d —— (1979), 1979 CCH OSHD Para. 23,963, *petition for cert. filed* (No. 79–1429). This decision upheld most of OSHA's cotton dust standard, including the innovative medical transfer and wage retention provisions (1979 CCH OSHD Para. 23,963 at pp. 29,086–29,087).

Together, these cases support the concept that OSHA's rulemaking authority is as broad as the general purposes of the Act. The agency may thus fashion suitable remedies to meet particular problems standing in the way of a safe and healthful workplace provided the need for action can be demonstrated and the proposed remedy is feasible. Only explicit statutory prohibitions backed up by clear legislative history can overcome this presumption of authority. Notwithstanding the various rigid interpretations of ss6(b), 6(b)(7), 8(c)(3), 8(g) and 8(d) that have been suggested by several participants as barriers to this rule, none of the statutory sections contains such explicit prohibitions, and there is no legislative history to indicate the contrary. The Supreme Court has provided the appropriate canon of interpretation when faced with statutory provisions such as those relied on here. In *Mourning* v. *Family Publications Services*, 411 U.S. 356 (1973), the Court interpreted language in the Truth in Lending Act strikingly similar to s8(g)(2):

> Where the empowering provision of a statute states simply that the agency may "make . . . such rules and regulations as may be necessary to carry out the provisions of the Act," we have held that the validity of a regulation promulgated thereunder will be sustained so long as it is "reasonably related to the purposes of the enabling legislation," *Thorpe* v. *Housing Authority of City of Dupont*, 393 U.S. 268, 280–281 (1969) (quoting Housing Act of 1937, s81). (411 U.S. at 369)

Moreover, a broad delegation of rulemaking authority in the context of remedial legislation provides for reasonable over-inclusion. If over-inclusion is necessary to remedy the conduct the legislation was intended to deter or control, it will be upheld, for "(n)othing less will meet the demands of our complex economic system," *Mourning*, 411 U.S. at 374, citing *Village of Euclid* v. *Ambler Realty Co.*, 272 U.S. 365 (1926) (Accord *State of Fla.* v. *Mathews*, 526 F.2d 319 (5th Cir. 1976); *Environmental Defense Fund* v. *Costle*, 578 F.2d 337 (D.C. Cir. 1978); *American Frozen Food Inst.* v. *Mathews*, 413 F. Supp. 548 (D.C.D.C. 1976)). See also *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 786n.2, 791–92 (1969) ("(I)t is enough for us that the expert agency (FDA) charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health. . . ."); *FERC* v. *Pennzoil Producing Co.*, No. 77–648 (Jan. 16, 1979), slip op. 8; *FCC* v. *National Citizens Committee for Broadcasting*, 436 U.S. 775, 796–97 (1978); *FPC* v. *Texaco Inc.*, 417 U.S. 380, 394 (1974); *Permian Basin Area Rate Cases*, 390 U.S. 747, 776n.40 (1968); *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, 201–3 (1956); *American Trucking Associations* v. *United States*, 344 U.S. 298 (1953); *SEC* v. *Chenery Corp.*, 332 U.S. 194, 207 (1947); *Bowles* v. *Willingham*, 321 U.S. 503, 519 (1944).

The *Mourning* Court also addressed the question of whether specific, affirmative mandates in other sections of a statute carry with them an implied limitation on an agency's general rulemaking authority with respect to additional or alternative remedies the agency deems appropriate to effect. The Court first cited approvingly this statement from *Gemso, Inc.* v. *Walling*, 364 U.S. 244, 255 (1945):

> When command is so explicit and, moreover, is reinforced by necessity in order to make it operative, nothing short of express limitation or abuse of discretion in finding that the necessity exists should undermine the action taken to execute it. (411 U.S. at 370)

The Court went on to say (411 U.S. at 372–3):

> Respondent argues that, in requiring disclosure as to some transactions, Congress intended to preclude the Board from imposing similar requirements as to any other transactions.
>
> To accept respondent's argument would undermine the flexibility sought in vesting broad rulemaking authority in an administrative agency. In *American Trucking Assn. v. United States*, (344 U.S. 298 (1953)) we noted that it was not:
>
> 'a reasonable canon of interpretation that the draftsmen of acts delegating agency powers, as a practical and realistic matter, can or do include specific consideration of every evil sought to be corrected . . . [N]o great acquaintance with practical affairs is required to know that such prescience, either in fact or in the minds of Congress, does not exist. Its very absence, moreover, is precisely one of the reasons why regulatory agencies such as the Commission are created, for it is the fond hope of their authors that they bring to their work the expert's familiarity with industry conditions which members of the delegating legislatures cannot be expected to possess.' 344 U.S. at 309–310, 73 S. Ct. at 314 (citations omitted).

This judicial canon of interpretation should be of particular relevance in considerations of the OSH Act, which the Sixth Circuit in *Marshall v. Whirlpool Corp.*, 593 F. 2d 715 (1979), aff'd —— U.S. ——, 100 S. Ct. 883 (1980), emphasized was the subject of legislative focus on only four major issues: (1) which agency was to set safety and health standards, (2) whether an independent adjudicatory body should be established to administratively review violations, (3) whether employers should be subject to a general requirement to provide a safe and healthful work environment, and (4) whether the Secretary of Labor should have authority to order administrative shutdowns in cases of imminent danger (*Marshall v. Whirlpool Corp.*, 593 F. 2d at 728 n. 26). On other legal questions, such as the ones presented in this rulemaking, the presumption should be in favor of "the flexibility sought in vesting broad rulemaking authority in an administrative agency" *(Mourning, supra)*. In enumerating certain rights given to employees and employee representatives to various sections of the Act, it should not be supposed that Congress intended to deprive OSHA of the authority to establish other rights considered necessary to fulfill the statutory purposes. Rather, the requirements of ss8(c)(3), 6(b)(7), 8(d) and the like are properly to be construed as guideposts and not as ceilings on agency action.

OSHA also does not accept arguments based on s4(b)(1) of the Act (29 U.S.C. 653(b)(1)) that OSHA must yield jurisdiction to the National Labor Relations Board (NLRB) on all matters relating to employee or designated representative access to information pertinent to occupational safety and health. First, the Act and rules issued under it apply equally to employees who are represented by unions with collective bargaining status as well as employees who are not. The latter constitute approximately 80 percent of the workforce (Ex. 177). Second, s4(b)(1)

preemption arguments are clearly overbroad, since any safety or health problem which OSHA could address would also be an appropriate subject for collective bargaining. The failure to bargain in good faith on any health or safety problem would then be the subject of NLRB's adjudicatory and sanctioning powers. It may also be an appropriate matter for arbitration under a collective bargaining agreement. But when Congress added the OSH Act to Federal labor policy, OSHA was given rulemaking authority intended not only to fill gaps in existing labor-management relations and the collective bargaining process, but to place a solid foundation under that process. Worker safety and health was thought by Congress to be too important to be resolved solely by the interplay of private economic forces and the rules established for economic warfare. OSHA, therefore, may appropriately set standards and provide remedies which are independent from, and in addition to, any rights afforded by the National Labor Relations Act. Thus, as an NLRB Administrative Law Judge recently stated in *Colgate-Palmolive Co.*, Case No. 17–CA–8331 (March 27, 1979):

> Accommodation between the (NLRA) and OSHA is to be undertaken in a careful manner so as to preserve the objectives of each. See *Southern Steamship Company v. N.L.R.B.*, 316 U.S. 31, 47 (1942); *Western Addition Community Organization v. N.L.R.B.*, 485 F. 2d 917, 927–28 (C.A.D.C. 1973); *Alleluia Cushion Co.*, 221 N.L.R.B. 999; *Memorandum of Understanding Between Department of Labor, Occupational Safety and Health Administration and National Labor Relations Board*, 40 F.R. 26033 (June, 1975). (*Sl. op.*, p. 13, n. 9.)

OSHA agrees. *Cf. Brennen* v. *Western U. Tel. Co.*, 561 F. 2d 477 (3rd Cir. 1977).

Third, under the terms of s4(b)(1), OSHA's authority for this standard is not preempted because the NLRB has not exercised statutory authority "to prescribe or enforce standards or regulations affecting occupational safety or health" with respect to employees' working conditions. To the extent the NLRB has acted in this area, it has proceeded solely through adjudication, not through standard-setting or rulemaking of general applicability. The object of its adjudications has only been to assure a fair bargaining process, and not to assure safe and healthful working conditions for the workers affected. The triggering requirements of s4(b)(1) have therefore not been satisfied (*See* Rothstein, *Safety and Health Law*, ss18–21(1978)).

Accordingly, OSHA believes that it has ample authority under the Act to promulgate this rule.

B. Access to Records and the Law of Trade Secrets

Section IV.F of the preamble, *supra*, discusses the issue of employee and designated representative access to potential trade secret information. The final standard has been structured to eliminate access to unnecessary trade secret information, and maximize protection of trade secrets where access is provided. Access is provided, however, to chemical and physical agent identity, level of exposure, and health status information regardless of employer trade secret claims. The resolution of the trade secret issue as it pertains to employee and designated representative access to this information has been made with appreciation for the role of trade secrets in American law. Some of the relevant considerations are discussed below.

The law of trade secrets was introduced into American common law in the middle of the last century. *Peabody* v. *Norfolk*, 98 Mass. 452 (1862). It remains principally a matter of state decisional and statutory law. While state trade secret law varies, the description of a trade secret provided by the Restatement of Torts, s757, comment (b) (1939), is commonly accepted:

> A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do no know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

A slightly different definition was provided in *U.S. ex rel Norwegian Products Co.* v. *U.S. Tariff Commission*, 6 F.2d 491, 495 (D.C. Cir. 1925), rev'd other grounds 274 U.S. 106 (1927), and applied in some Federal cases. To be a trade secret, the subject matter must be at least substantially secret, minimally novel, and commercially valuable. The factor of cost in the development of a trade secret has also been identified as an element underlying judicial findings of trade secrets, Cavitch, *Business Organizations*, s232.01 (1975). Of these, the element of secrecy is probably the most significant.

But absolute secrecy beyond the knowledge of the holder is not required for information to constitute a trade secret. The corporate holder will necessarily have to divulge information to some employees and others in order to utilize the secret commercially. It may also license its use. Whether a disclosure destroys the element of secrecy depends on the extent, manner, and purpose of the disclosure. *Kewanee Oil Co.* v. *Bicron*, 416 U.S. 470, 477 (1974); Cavitch, *supra.*, s232.01(1). The broadly stated policies behind trade secret law are the maintenance of standards of commercial ethics and the encouragement of invention, *Kewanee Oil* v. *Bicron, supra*, at 481. Provided employees with a "need to know" are under an obligation not to use or disclose information revealed to them in confidence, and the holder of the information has taken measures to restrict access to the information, trade secret law affords the holder of the trade secret with judicial remedies for a breach of confidence or dispossession of the trade secret through improper or unethical means (industrial theft, spying, bribery, etc.). OSHA's treatment of trade secret information in this rule is not meant to deprive employers of these private law protections.

Although the protection of trade secrets is primarily a state-created right, it is necessary to note the existence of certain Federal policies which recognizes the legitimacy of this interest. Perhaps the most important of these, a Federal criminal statute, popularly known as the Trade Secret Act, makes it a criminal offense for a Federal officer to disclose a trade secret "to any extent not authorized by law" (18 U.S.C. 1905). The National Stolen Property Act, 18 U.S.C. 2311, 2314, has also been applied to theft of intangibles. Exemption (b)(4) of the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4), exempts trade secrets from mandatory disclosure by Federal agencies. Other "anti-disclosure" provisions have been written into various statutes, e.g., Sec. 15 of the OSHA Act (15 U.S.C. 651) and Sec. 14 of the Toxic Substances Control Act (15 U.S.C. 2601). Even in cases covered by the Federal statutes, however, the question of whether something is a trade secret must still be answered by the application of common law principles since, unlike patents and copyrights, there is no Federal statute establishing the law of trade secrets.

There is also relevant Supreme Court law evidencing favorable treatment of the trade secrets interest. In *Kewanee v. Bicron, supra*, the Court held that Ohio's trade secret law is not pre-empted by the Federal patent laws, since the Federal policy of encouraging invention is not disturbed by the existence of another form of incentive to invention such as trade secret protection. More recently, in *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979), the Court examined the interrelationship between 18 U.S.C. 1905 and exemption (b)(4) of the FOIA, holding that while the FOIA does not

prohibit disclosure of trade secrets or confidential business information by an agency, 18 U.S.C. 1905 does prohibit such disclosure if there is no other statute or validly promulgated regulation authorizing the particular disclosure. Therefore, release of trade secret information by an agency may be an actionable abuse of discretion under the Administrative Procedure Act. And in *Detroit Edison Co. v. NLRB,* 411 U.S. 301 (1979), the Court held that the NLRB exceeded its remedial discretion when it ordered the company to turn over to the union psychological aptitude tests and answer sheets, the continued secrecy of which was essential to the integrity of the testing process, rather than accept the company's suggestion that this information be provided only to a psychologist designated by the union. Essentially, the Court balanced the company's interest in test secrecy against the union's interest in access and found that the company's interest in this case was predominant.

These expressions of Federal policy, while suggestive, do not answer the precise question of the extent to which OSHA's policies on worker access to records, which are designed to advance the statutory purposes of promoting occupational safety and health so far as possible, must or should yield, or accommodate themselves, to employers' interests in maintaining the secrecy of trade secrets. This question requires closer examination of Federal pre-emption doctrine, the OSHA statutory scheme, and judicial treatment of trade secrets in analogous situations.

Under the Supremacy Clause of the Constitution (Art. VI, cl. 2), Federal law takes precedence over state law whenever they clash or conflict. The test which the Supreme Court has consistently followed in Federal pre-emption cases is two-fold: (1) whether the Federal and state regulatory schemes inescapably conflict, and (2) whether the Congressional intent was to oust the state from a particular field. Even absent an overt manifestation of such congressional intent, the Supremacy Clause requires the invalidation of any state law that burdens or conflicts in any manner with any Federal law. *Jones v. Rath Packing Co.,* 430 U.S. 519 (1977); *DeCanas v. Bica,* 424 U.S. 351 (1976); *Sears, Roebuck & Co. v. Stiffel,* 376 U.S. 225 (1964); *Florida Lime & Avocado Growers v. Paul,* 373 U.S. 132 (1963); *Sola Electric Co. v. Jefferson Electric Co.,* 317 U.S. 173 (1942); *Hines v. Davidowitz,* 312 U.S. 52 (1941); *Savage v. Jones,* 225 U.S. 501 (1911).

This statement from *Savage v. Jones, supra.,* remains valid (225 U.S. at 533):

> For when the question is whether a Federal act overrides a state law, the entire scheme of the statute must of course be considered and that which needs must be implied is of no less force than that which is expressed. If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field also must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power.

Consider also *Florida Lime & Avocado Growers, supra.,* (373 U.S. at 142):

> A holding of Federal exclusion of state law is inescapable and requires no inquiry into congressional design when compliance with both Federal and state regulations is a physical impossibility . . .

In promulgating this access rule, OSHA is implementing its mandate to afford employees safe and healthful working conditions by enabling them, among other things, to know what chemicals they are exposed to and what the hazards are to the extent such information is available in exposure and medical records which employers already maintain. Based on industry testimony, there may be an undetermined number of exposure records containing information involving the identities and exposure levels of chemicals which could be considered bona fide trade secrets (i.e., after taking into account the possibility of reverse engineering and other readily available analytical techniques). Yet, if employees are to be afforded safe and healthful working conditions, they must be fully informed of what chemicals they are exposed to, whether or not they are trade secrets. Knowledge of the chemical names of trade products is essential if one is to learn of the inherent hazards, particularly since indexes to the scientific literature are generally maintained only by chemical name. Accordingly, if OSHA were to exempt trade secrets altogether from the access provisions of this rule, its "operation . . . must be frustrated and its provisions . . . refused their natural effect."

Given the appearance of an inescapable conflict between this rule's health purposes and trade secret claims based on state law protection, a finding of express Congressional intent to override trade secrets is not necessary, since each of the two tests for pre-emption operates independently. Nevertheless, OSHA's statutory scheme as well as Congressional intent should be carefully considered if only to make sure that Congress did not express a contrary intent.

The only section of the OSHA Act concerned directly with trade secrets is section 15 (29 U.S.C. 664). It states:

> All information reported to or otherwise obtained by the Secretary or his representative in connection with any inspection or proceeding under this Act which contains or which might reveal a trade secret referred to in section 1905 of title 18 of the United States Code shall be considered confidential for the purpose of that section, except that such information may be disclosed to other officers or employees concerned with carrying out this act or when relevant in any proceeding under the Act. In any such proceeding the Secretary, the Commission, or the court shall issue such orders as may be appropriate to protect the confidentiality of trade secrets.

Section 15 plainly contemplates that OSHA should have access to trade secrets as necessary. This section adds nothing to the obligation already imposed upon federal employees by an existing criminal statute (18 U.S.C. 1905), except to indicate that such information may be disclosed to other officers or employees concerned with carrying out the Act or when relevant in any proceeding. In the latter situation, it provides for the possibility of appropriate protective orders. In interpreting this section, the Occupational Safety and Health Review Commission has said: "Hence, section 15 is in the nature of an exemption from 18 U.S.C. 1905 rather than a prohibition and clearly does not limit access to trade secrets only to federal employees." (Footnote omitted). *Secretary of Labor v. Owens-Illinois, Inc.,* 1978 CCH OSHD Para. 23,218, at pp. 28,072 (access to outside expert consultant in enforcement case). Cf. *Chrysler Corp. v. Brown, supra.*

As such, section 15 contemplates that OSHA might undertake proceedings or promulgate recordkeeping requirements resulting in the disclosure of trade secrets. In such cases, a general obligation is imposed on OSHA to keep confidential all information which the agency obtains via reports or otherwise and which contains or which might reveal a trade secret, although disclosure may be made "when relevant." To carry out its obligations, OSHA has already issued regulations and administrative directives addressing the special treatment of trade secrets (29 CFR 1903.9; Ex. 113; cf. *Sec. of Labor v. Owens-Illinois, Inc., supra*). These are in addition to the criminal penalties of 18 U.S.C. 1905 for unauthorized disclosure of trade secrets.

Section 15 reflects an apparent Congressional interest in balancing

competing interests based on providing protection to trade secrets to the extent consistent with carrying out the overall statutory purposes. The section does not define "trade secrets" or provide precise guidance beyond the "relevance" standard on how the necessary balance is to be struck; and the legislative history, which consists of different versions of the same provision contained in the different bills, does little to illuminate the section further. The section, however, is consistent with how Congress had addressed trade secrets in other statutes (e.g., 15 U.S.C. 1401(e) (the National Traffic and Motor Vehicle Act of 1966)).

More recently, however, Congress has expressed its intent in this area in the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 et seq.), a public health statute which in purpose and effect is in many respects analogous to OSHA's. Its section 14 (15 U.S.C. 2613) substantively parallels OSHA's section 15 except that it explicitly provides for public disclosure of trade secrets "if the Administrator of the Environmental Protection Agency determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment" and also for the disclosure of "health and safety studies" other than "data which disclose processes . . . or, in the case of a mixture, . . . data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture." See also, the 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136h). The Federal Mine Safety and Health Act of 1977, 30 U.S.C. 801 *et seq.*, is silent on the issue of trade secrets.

In addition, the House Committee on Government Operations has twice urged OSHA to exercise its rulemaking authority to insure that employers and workers alike are apprised of the kinds of toxic dangers present in workplaces notwithstanding the prevalence of trade name products (House Report No. 94–1688 (Sept. 1976); House Report No. 95–710 (Oct. 1977)).

Whatever the precise meaning of "trade secrets" intended in section 15, the section, by its terms, does not operate as a limitation on OSHA's rulemaking authority; that is, it does not address OSHA's ability to issue occupational safety and health standards or other rules which may incidentally affect trade secret interests by requiring information transfers from employers to employees or their representatives. Indeed, s6(b)(7) affirmatively requires any standard to "prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed," and s8(c)(3) requires that "such regulations shall also make appropriate provision for each employee or former employer to have access to such records as will indicate his own exposure to toxic materials or harmful physical agents." These sections reflect the Congressional determination that certain information must be given to employees, without regard to any possible trade secret interests of employers. The regulations issued today are consistent with this Congressional intent. The only express limitation on OSHA's rulemaking, other than a requirement that they be based on substantial evidence, is that rules be feasible (section 6(b)(5) of the Act; 29 U.S.C. 655(b)). Since the harm of trade secret disclosure is an economic one, it is possible to conclude that trade secrets should be considered as one element of the economic feasibility inquiry, and not as something which stands as an independent obstacle to the access rule regardless of its feasibility. But access to exposure records surely presents no problems of technical feasibility, and nothing in the record would support a finding that lack of special treatment for trade secret information would render the rule economically infeasible.

Based on the foregoing analysis, the agency concluded that its authority to promulgate this rule can serve to pre-empt state law trade secret interests if necessary or appropriate to promote occupational safety and health. However, rather than totally pre-empting state law trade secret interests, the agency chose to seek means to accommodate the competing interests to the extent possible. But, where the competing interests irreconcilably clash, the interest in employee safety and health prevails. This approach is consistent with the balancing approach expressed in section 15 and other Federal policies. It is also consistent with Federal pre-emption doctrine itself:

> [C]onflicting law, absent repealing or exclusivity provisions, should be pre-empted * * * "only to the extent necessary to protect the achievement of the aims of" the federal law since the proper approach is to reconcile "the operation of both statutory schemes with one another rather than holding [the state scheme] completely ousted."

DeCanas v. Bica, supra., 424 U.S. at 357 n.5, quoting *Merrill, Lynch v. Ware*, 414 U.S. 117, 127 (1973) quoting *Silver v. New York Stock Exchange*, 373 U.S. 341, 361, and 357 (1963).

The priority attached to safety and health concerns by this rule is also consistent with the law of trade secrets in analogous contexts. It is necessary to remember that the interest in trade secrets in never absolute. For instance, the law ordinarily protects a holder of a trade secret from a breach of confidence or dispossession of the trade secret by improper or unethical means, but not against independent discovery. *Kewanee v. Bicron, supra.* More significantly, the trade secrets interest is not considered to be an absolute right in the face of a strong countervailing public interest in the information. Thus, in the beginning of the century, the Federal courts considered a number of cases involving economic due process challenges to the state's authority to require disclosure of ingredient information in the regulation of foods and drugs to promote safety and health and to prevent fraud and deception of purchasers. In one such case, *Arbuckle v. Blackburn*, 113 Fed. Rep. 616 (6th Cir. 1902), *aff'd* 191 U.S. 405 (1903), the Court stated (at p. 627):

> The enactment of laws for the protection of health and safety and to prevent imposition in the sale of food products is within this [state police] power, and the fact that the process by which it is made is protected by a patent, while it may prevent others from using it during the life of the patent, does not deprive the state of the power of regulation for the general good.

Savage v. Jones, supra, involved an Indiana statute which, among other things, required ingredient labeling to prevent fraud in the sale of animal feed. The Supreme Count declined to consider the trade secrets issue, since the statute did not demand the disclosure of formulas or manner of combination but rather only a statement of the ingredients, "* * * a requirement of obvious propriety in connection with substances purveyed as feeding stuff" (225 U.S. at 524).

Moreover, in more recent times, judicial and administrative courts have similarly taken the position that, if the information is indispensable for ascertaining the facts, the evidentiary "privilege" for trade secrets must give way even when the possessor of the secret is a bystander who may be unfairly injured by broad dissemination of the information. This is particularly true when the public interest in disclosure stems from a safety or health rationale. *Uribe v. Howie*, App., 96 Cal. Rpt. 493 (1977) (pest control reports); *Carter Products, Inc. v. Eversharp, Inc.*, 360 F.2d 868 (7th Cir. 1966) (patent infringement); *Wilson v. Superior Ct.*, 225 P. 881 (1924) (chemical composition of explosive); *Secretary of Labor v. Owens-Illinois, supra.; U.S. v. 48 Jars More or Less*, 23 F.R.D. 192 (D.D.C. 1958)

(FDA suit for seizure and condemnation of misbranded article); Cf. *Jacobson v. Massachusetts*, 197 U.S. 11 (1904) (compulsory vaccinations). Significantly, this has also been the approach of the NLRB when faced with union requests for access to trade secret information. *Ingalls Shipbuilding Corp.*, 143 NLRB 712, 717 (1963); *Minnesota Mining & Manufacturing, Co., supra.; Borden Chemical, supra.*

Consequently, the law of trade secrets fully supports OSHA's treatment of trade secrets in this final rule, which reflects these two principles: (1) if there is a valid trade secret claim, means should be sought if possible to reconcile the trade secrets interest with the statutorily mandated interest in occupational safety and health, but where the two interests irreconcilably conflict, the safety and health interest must predominate; and (2) to the extent OSHA's regulatory policy favoring employee and employee representative access to exposure records results in the disclosure of trade secrets for safety and health purposes, this should not derogate from the employer's private law rights and remedies to protect the trade secret status of the information from rediscloure for non-safety and health purposes.

C. OSHA Access to Employee Medical Records and the Right of Privacy

The right of privacy, and the corresponding duty of confidentiality, have been recognized in both common law and Constitutional law. This section will discuss the constitutional considerations raised by OSHA access to medical records, while the section which follows will discuss the common law aspects of the duty of confidentiality.

Section IV.H of the preamble, *supra*, discusses the agency's decision to structure the final standard to provide for unconsented agency access to identifiable employee medical records. Because Federal action is involved, OSHA access to personally, identifiable medical records raises the legal question of whether the public interest in OSHA access overrides, or can be accommodated to, the employees' privacy interests. The right of privacy has been recognized as a constitutionally protected value. *Roe v. Wade*, 410 U.S. 113 (1973); *Griswold v. Connecticut*, 381 U.S. 479 (1965). In *Roe v. Wade*, the Court located the privacy interest in the Fourteenth Amendment's concept of personal liberty, 410 U.S. at 152–153; *Whalen v. Roe*, 429 U.S. 589n. 23 (1977). (Presumably, it is applicable to the Federal government via the Fifth Amendment). When recognized, the right of privacy has generally been invoked to protect against unreasonable governmental intrusions into certain zones of personal intimacy (e.g., contraception, abortion). As has already been stated, at least two separate interests have been identified as aspects of the concept of privacy: the individual interest in avoiding disclosure of personal matters, and the interest of independence in making certain kinds of important decisions, *Whalen v. Roe, supra.*, 429 U.S. at 599–600.

It is primarily the first interest—avoiding disclosure of personal matters—which is at stake when a public agency like OSHA seeks access to identifiable medical records without consent. To the extent such access deters employees from seeking treatment or confiding in company physicians, the second interest would also be implicated. *Whalen v. Roe* is the leading constitutional case with respect to the privacy of medical information. In that case, the Court denied a constitutional challenge alleging invasion of the patient's right to privacy by a New York statute requiring that a copy of prescriptions (including names of recipients) of certain dangerous but legitimate drugs be sent to the state health department and put on computer. The Court held that "the New York program does not, on its face, pose a sufficiently grievous threat to either interest to establish a constitutional violation." *Id.* at 600. It stated (at p. 602):

> Unquestionably, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention. Nevertheless, disclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice even where the disclosure may reflect unfavorably on the character of the patient. Requiring such disclosures to representatives of the State having responsibility for the health of the community, does not automatically amount to an impermissible invasion of privacy. (Footnote omitted.)

This holding is consistent with the common law principle that the public interest, such as that asserted by a public health agency to prevent illness, overrides the duty of confidentiality which otherwise would pertain (*See*, V.E, *infra.*). Also noteworthy was the *Whalen* Court's complete rejection of the physicians' claim that such data collection was an unconstitutional interference with a physician's right to practice medicine free of unwarranted state interference: "the doctors' claim is derivative from, and therefore no stronger than, the patients'." (at p. 604).

Of particular significance in the determination of the case was the fact that the state was taking reasonable steps to insure the confidentiality of the information reported to it, since "the right to collect and use such data for public purposes is typically accompanied by a concomitant statutory or regulatory duty to avoid unwarranted disclosures." (at p. 655). OSHA likewise recognizes such a duty and has taken steps comparable to those found constitutionally adequate by the Supreme Court in *Whalen v. Roe*. These steps can be found in the procedural regulations governing OSHA access to medical records, published today as s1913.10 of 29 CFR.

District court decisions upholding NIOSH's and OSHA's right to seek access to personally identifiable medical records are also highly relevant. In *DuPont v. Finklea*, 442 F. Supp. 821 (S.D. W. Va., 1977), *Whalen v. Roe* was explicitly applied to a NIOSH health hazard evaluation. The Court found that it was within NIOSH's statutory authority to request access to identifiable medical records for the purpose of conducting a cancer study, even though, in this case, the employees themselves had affirmatively withheld consent. Notwithstanding the fact that the information sought was determined to be within a constitutionally protected zone of privacy, the court held that this privacy right would not be abridged by NIOSH's access to the records. The fact that no evidence had been adduced which would show or even tend to show that the information sought to be gathered would be used improperly was of particular significance. The Court's detailed order was designed to assure that NIOSH would keep the information confidential, but employee consent was *not* made a condition of NIOSH's access.

NIOSH's right of access to personally identifiable medical records without consent has also been recently upheld in *United States v. Westinghouse Electric Corp.*, C.A. 79–774 (W.D. Pa., Jan. 31, 1980). Presented with essentially identical facts as in *DuPont*, the Court held:

> In our case, Westinghouse is the employer of a number of persons, and it seeks, as it asserts, to protect the privilege of its employees and prevent divulging of medical information taken by its doctors as of the time when they were employed. It is not for [this court] to determine what the respondent's interest is here. What matters is that the United States through Congress has expressed a serious concern for these same employees who might have been patients of the respondent's doctors. As such, it accordingly assumes a superior position and responsibility for protecting these same

employees than does the employer. This is a constitutional right in the Congress to do so for the purpose of preserving the health and welfare of the public, wherever such circumstances may exist. (p. 12, sl. op.)

* * * * *

NIOSH must have the entire medical records in personally identifiable form of the employees under study in order to properly conduct its Health Hazard Evaluation, to facilitate adequate record-keeping of the information and to prepare an adequate study of the matter. The function which the petitioner is exercising here is not only appropriate but is legally and authoritatively mandated. It is not within the power of the courts to thwart such statutory and constitutional functions, but to the contrary, the courts must lend their judicial authority to aid the petitioner to so function. (p. 14, sl. op.)

By so holding, *Westinghouse* all but rejects *General Motors v. Finklea*, 459 F. Supp. 235 (S.D. Ohio, 1978). The *GM* Court had held that while NIOSH has statutory authority to seek access to medical records, the individually identifying data could be withheld from the agency absent a showing of compelling need, and even then, every employee might be entitled to a due process hearing to determine whether or not identifiable records could be examined without the employee's consent. As *Westinghouse* properly points out, the *GM* decision was based upon Ohio's physician-patient privilege law and not upon general principles protecting the right of privacy itself; and in any event, the existence of such a state privilege is irrelevant since "no physician-patient privilege exists as a matter of Federal common law." (p. 9, sl. op.). To the extent that *GM*, which is being appealed by the Government, deviates from *Whalen v. Roe* in its analysis of legal principles, it cannot be considered controlling law.

Most recently, OSHA's own right to subpoena employer-generated exposure and medical records has been upheld in *Marshall v. American Olean Tile Co.*, No. 79–597 (E.D. Pa., Feb. 29, 1980). The court stated:

* * * the Secretary [of Labor] performs legislative as well as enforcement functions. He needs information to develop standards as well as to enforce compliance with these standards. Although he may obtain that information through recordkeeping requirements or investigations by the National Institute for Occupational Safety and Health (NIOSH), inspections and evidence subpoenaed may also provide useful data. Because the remedial purposes of the Act may be furthered by inspections and subpoenas designed to explore the causes and prevention of occupational illnesses, we decline to find that the authorization of inspections "to carry out the purposes of this chapter" extends only to enforcement. If the information requested is relevant to any of the Secretary's functions and its production is not unduly burdensome, the subpoena should be enforced.[2]

Having considered the relevant case law, therefore, OSHA is confident that OSHA access to personally identifiable employee medical records is constitutionally permissible when accompanied by strict protective measures such as the administrative regulations OSHA is promulgating today.

Finally, the separate constitutional right of employers to be free of unreasonable searches and seizures must also be taken into account. *Marshall* v. *Barlow's, Inc.*, 436 U.S. 307 (1978) held that the Fourth Amendment requires OSHA to get a warrant from a neutral magistrate before conducting an inspection of a workplace if an employer objects to entry. Footnote 22 of that decision states (at p. 324):

Delineating the scope of a search with some care is particularly important where documents are involved.

. . . It is the Secretary's position, which we reject, that an inspection of documents of this scope may be effected without a warrant.

Therefore, while OSHA anticipates voluntary employer acceptance of OSHA access to medical records in most cases, we recognize that the OSHA access requirement of this rule may not be self-enforcing. In the aftermath of *Barlow's*, this is a rapidly evolving area of the law, and the exact means OSHA will choose to gain access to records if an employer refuses to provide access voluntarily will depend on the particular circumstances of the case and future developments in the law.

D. OSHA Access to Employee Medical Records and the Common Law Duty of Confidentiality

The physician's traditional duty of confidentiality owed to medical information, which derives from the patient's right of privacy in that information, is never absolute and may be overridden by a supervening public interest such as the one asserted here by OSHA. The duty of the physician to maintain the confidentiality of information acquired in the course of a physician-patient relationship has always been recognized as an ethical requirement imposed by the profession. The Hippocratic Oath obliges physicians to keep secret whatever is learned in connection with their professional practice. In addition, the Principles of Medical Ethics of the American Medical Association prohibit a physician from revealing confidences learned in the course of medical attendance, *unless required to do so by law or if it becomes necessary to protect the welfare of the community or the individual* (Ex. 105). A physician may be disciplined by the local medical society for failure to abide by these ethical rules (Dr. Steen (AMA), Tr. 2398).

In common law, the physician-patient privilege was not traditionally recognized. This meant that, whatever the ethical obligations, the physician had no legal obligation to protect patient communications from disclosure to a third party (Ex. 147, p. 1117; *Horne* v. *Patton*, (1973, S. Ct. Ala.) 287 So. 2d 824, at 833 (J. McCall, dissent)). In the absence of testimonial privilege statutes, several courts have found that there was no liability for disclosure to third parties where the common law rule was applicable. *Collins* v. *Howard*, (1957, D. Ct. Ga.), 156 F. Supp. 322 (disclosure to plaintiff's employer); *Quarles* v. *Sutherland*, (1965 Tenn.), 389 SW 2d 249 (disclosure to store's attorney).

The modern rule, by contrast, appears to be that, in general, the duty of confidentiality is legally recognized and enforceable regardless of whether the state has enacted a physician-patient testimonial privilege. Most states have in fact created testimonial privileges which generally prohibit physicians from revealing confidential information in judicial proceedings unless the privilege is waived by the patient or by application of one of the recognized exceptions to the rule (HRG, Ex. 122E). Even in states without a testimonial privilege, or where the third party disclosure is outside a court proceeding and thus not directly covered by the privilege, courts tend to find grounds upon which a patient can hold a physician liable for unauthorized disclosure of confidential information.

Most frequently the courts have upheld the right of a patient to recover damages from a physician for unauthorized disclosure concerning the patient on the grounds that such disclosure constitutes an actionable tort under the state's common law or statutory privacy rights (Ex. 147, s3 (cases cited)). Recovery has also been granted on the grounds that: (1) disclosure by the physician constitutes a breach of a legally recognized confidential or privileged relationship between the patient and physician (Ex. 147, s4(a) (cases cited)); (2) violation of statutory requirements concerning the licensing or conduct of a physician gives rise to a tort action by the patient (Ex. 147, s5 (cases cited)); and (3)

[2] * * * Since the Secretary of Labor has ultimate responsibility for rulemaking under the Act, his authority under s657 should be at least commensurate with NIOSH's authority under that same section. * * * (pp. 3–4, sl. op.)

unauthorized disclosure constitutes a breach of an implied contractual obligation not to divulge confidences. *Horne* v. *Patton, supra,* 287 So. 2d at 831–2; *Hammonds* v. *Aetna Casualty and Surety Co.,* (1965, N.D. Ohio), 243 F. Supp. 793, at 801. Accord *Clark* v. *Geraci* (1960), 208 NYS 2d 564.

The duty of confidentiality, however, is not absolute. In the occupational setting, to the extent that the physician-patient relationship does not exist, the legal duty of confidentiality may not exist either or is at least attenuated. Thus, the *Beadling v. Sirotta* (disclosure to personnel department of applicant's condition) and *Quarles v. Sutherland* (disclosure to store's attorney of customer's condition) cases, *supra.,* both upheld unauthorized intra-corporate disclosures on the basis of there being no doctor-patient relationship. Also relevant is *Pitcher v. Iberia Parrish School Bd.* (1973, La. App.), 280 So. 2d 603, *cert den'd,* 416 U.S. 904 (1974), which held that a school board had the right to obtain the results of annual physical examinations required of teachers, without distinguishing whether the examinations were performed by the teachers' personal physicians or by the school board's physician. However, such disclosure of medical records to management or to others outside the company without the employee's consent would clearly be viewed today as a breach of professional ethics. Moreover, under existing law, unauthorized disclosure outside the company is of questionable legality and could be attacked on the grounds stated above: violation of a state privacy act (applicable in about three-quarters of the states), defamation, malicious misrepresentation, and possibly even breach of an implied contract of confidentiality (NCCHR, Ex. 125, pp. 7–8).

There are nevertheless numerous exceptions to the duty of confidentiality even when a physician-patient relationship clearly exists. The most obvious exception occurs when the patient consents to the disclosure of his medical records. Often, however, the patient may not realize the extent to which consent results in wide distribution of the medical records within the health care facility and to third party payers (Annas, Ex. 56B, pp. 148–149).

Even in the absence of consent, disclosure of confidential information is legally permitted in a number of situations. As provided in this standard, disclosure may be made for certain overriding competing interests to which the law affords greater protection than to the interest of the patient in keeping the information undisclosed, as where the public interest demands, for health reasons, the disclosure of such information (Ex. 147, s6(a) (cases cited)). A physician cannot be held liable if he or she was required by law to make such disclosure (Ex. 147, s7 (cases cite)). Almost all states have a wide variety of conditions and diseases (e.g., vital statistics, contagious and dangerous diseases, child neglect and abuse, drug abuse, and criminally inflicted injuries) which must be reported to the public authorities when discovered by the physician. These take precedence over privilege statutes and the physician's ethical obligation to maintain a patient's confidence (Annas, Ex. 56B, p. 148; *Whalen v. Roe, supra.; General Motors v. Finklea,* S.D. Ohio, C.A., C–3–77–339 (1978)).

Other exceptions exist as well. When an individual makes his or her own physicial condition an issue in a lawsuit (e.g., personal injury claim), most courts will permit examination of the physician under oath either before or during the trial. Even in states with privilege statutes, there are exceptions which permit bringing personal medical information into court without consent. For example, medical information is often available in criminal cases, and almost always in malpractice cases (Annas, Ex. 56B, p. 150).

The general rule is that courts will afford physicians wide latitude in making disclosures they believe are in the best interests of their patients, such as when disclosures are made to a spouse or near relative without the patient's consent (Annas, Ex. 56B, p. 149; Ex. 147, s6(b) (cases cited)). Moreover, in a number of jurisdictions liability against a physician will be denied unless it can be shown that the disclosure was made maliciously (Ex. 147, s8 (cases cited)). There have been no reported appellate decisions in the United States where any physician or hospital has ever had to pay money damages to any patient for the unauthorized disclosure of medical records (Annas, Ex. 56B, p. 148).

From the foregoing, OSHA concludes that its access to employee medical records, as provided for in this standard and as limited by the administrative regulations, is legally permissible and does not constitute an unwarranted interference with employee privacy.

VI. Feasibility Considerations

In promulgating an occupational safety and health standard pursuant to section 6(b) of the Act, the agency considers the question of feasibility. Feasibility analysis involves two inquiries: whether the rule is technologically feasibility, and whether the rule is economically feasible (*See,* 43 FR 54473–54476 (Nov. 21, 1978)). In this case, since the final standard simply requires the preservation and availability of records which employers for one or more reasons have already chosen to create, there can be no doubt that the standard is technologically feasible. No participant in the rulemaking proceeding argued otherwise.

Numerous industry participants objected to the perceived economic burdens that would allegedly result from the standard. No participant, however, argued that the administrative costs involved rendered the standard economically infeasible, nor is there any evidence in the rulemaking record which could support such a suggestion, regardless of the definition of "economic feasibility" applied. The final standard has been carefully drafted to provide employers substantial flexibility as to how they preserve records subject to the standard, and how these records are made available to employees and their designated representatives. It is OSHA's conclusion that the final standard does not pose substantial economic burdens on employers, and is a feasible standard.

OSHA rulemakings not only consider questions of economic feasibility, but, depending on the nature of the rule, analyze the broader issue of the overall impact of a rule on industry and the economy. Executive Order 12044 ("Improving Government Regulation," 43 FR 12660 (March 24, 1978)) provides for a "Regulatory Analysis" where a rule has major economic consequences for the general economy, individual industries, geographical regions or levels of government. When OSHA issued the proposed access rule, it determined that preparation of a formal Regulatory Analysis document in accordance with E.O. 12044 would not be necessary. OSHA based this determination on the fact that the final rule would neither mandate the creation of new records or reports, nor impose independent obligations on employers to monitor or measure employee exposures. The rule would not require employers to provide medical surveillance or examinations, nor would it establish other mandatory requirements as to the format or content of exposure and medical records. Therefore, while administrative costs would be incurred in preserving records and in providing access to them over and above current practices, there was no reason to believe that either of the two economic thresholds established in

E.O. 12044 (an annual effect on the economy of $100 million or a major increase in costs or prices for individual industries, levels of government or geographical regions) would be exceeded. (The Secretary of Labor's final guidelines for implementing E.O. 12044 were not issued until January 26, 1979 (44 FR 5570)).

In its notice of hearings (43 FR 46322, October 6, 1978), OSHA specifically invited comment on the economic impact of the proposal. OSHA's preliminary determinations on economic impact and its invitation for further comment on this issue were restated in its opening statement at the public hearings (Ex. 7, p. 28).

Both the decision not to do a Regulatory Analysis, and OSHA's underlying rationale that the economic impact of the rule would not be great or particularly burdensome, were criticized by industry groups. Participants who argued that a Regulatory Analysis should have been made included the National Association of Manufacturers (Ex. 2(135), p. 8), the Chamber of Commerce (Ex. 37, pp. 3–4), the American Petroleum Institute (Ex. 158, pp. 43–44), the Organization Resources Counselors (Ex. 159, p. 2), and the Edison Electric Institute (Ex. 162, p. 18). There was also considerable industry testimony that the proposal would place an undue administrative and economic burden on employers (Magma Copper, Tr. 1451; EEI, Tr. 1774; API, Tr. 2067; NAM, Tr. 2176–78; Refractories Inst., Tr. 2215–16). In particular, employers argued that the burdens of compliance would be particularly great for small business (Amdur, Tr. 572; Chamber of Commerce, Tr. 979; Crowley Maritime, Tr. 1578; NAM, Tr. 2177–78; Refractories Inst., Tr. 2216), companies with multiple work sites (Southern Cal. Edison, Tr. 1515), companies with mobile work sites (Steel Plate Fabricators, Tr. 2522), and companies with transient work forces (Fertilizer Inst., Tr. 2160–61).

Although numerous employers complained of the alleged "burdens of compliance," they presented no quantitative or specific information on how this standard would present anything other than incidental administrative expenses. The API was the only participant who introduced any quantitative information on costs. These were drawn from the estimates on total recordkeeping costs that had been made in several OSHA economic impact statements regarding the regulation of specific substances (Ex. 132a–f). While not intended to show the actual costs of this rule, API presented this data for the purpose of indicating that the likely costs would exceed $100 million, and therefore a Regulatory Analysis would be required (Tr. 2123). However, the cost estimates contained in these prior economic analyses pertained exclusively to the costs of creating and storing records which, in the absence of the regulation, would not be created or kept at all; and therefore the entire cost of recordkeeping was attributable to the proposed regulations (Tr. 2119–20). None of the costs pertained to the limited costs of providing access (Tr. 224). Consequently, these analyses are irrelevant to consideration of the economic impact of the current standard.

The economic burdens presented by the final standard are largely a function of three factors: (1) the extent to which records are actually created by employers, (2) the extent to which the preservation periods and access provisions of this rule go beyond current practices, and (3) the likelihood that employees will exercise their rights of access. Examination of these three factors supports the agency's conclusion that this standard will not present major compliance burdens to industry.

The impact of the final standard first of all depends on the extent to which exposure and medical records are actually created in industry. The NIOSH National Occupational Hazards (NOH) Survey examined several factors which bear on this issue. The NIOSH survey examined the extent to which businesses receive industrial hygiene services (Ex. 171, Table 2), regularly monitor environmental conditions (Ex. 171, Table 27), have formally established health units (Ex. 171, Table 4), regularly record health information about new employees (Ex. 171, Table 9), require preplacement physical examinations of employees (Ex. 171, Table 10), provide periodic medical examinations of some type to employees (Ex. 171, Table 11), and both receive industrial hygiene services and have a formally established health unit (Ex. 171, Table 38). Examination of the data in these tables yields several conclusions. Many employers generate neither exposure nor medical records, and thus will experience little or no impact from this rule. To the extent records exist (other than pertaining to pre-employment medical information), they are generated primarily by large employers (over 500 employees), who would be expected to have existing administrative staffs that could absorb the administrative burdens of this rule. Smaller employers (less than 250 employees) are likely to generate very few records, and thus will experience little impact (*See also*, Fertilizer Inst., Tr. 2163–65). When they do keep exposure records, it is likely because there is a potential hazard concerning the exposure being monitored (Duncan (NAM), Tr. 2200). And finally, records are generated primarily by basic manufacturing employers, including chemical and allied products employers, and rarely by contract construction employers who would be expected to have transient workforces and workplaces. The burdens of the final standard will thus fall most heavily on large employers in industry sectors with substantial use of toxic substances and harmful physical agents (*See*, NAM, Tr. 2200). Two tables which consolidate selected data from the NIOSH NOH Survey (Ex. 171, Tables 2, 4, 9, 10, 11, 27, 38, *supra*) are as follows:

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TABLE 1 - FACTORS RELEVANT TO THE EXISTENCE OF EXPOSURE AND MEDICAL RECORDS-- BY SIZE OF PLANT

	FACTORS RELEVANT TO THE EXISTENCE OF EXPOSURE AND MEDICAL RECORDS	PERCENTAGES OF PLANTS-ALL INDUSTRIES				TOTAL PERCENTAGES OF EMPLOYEES COVERED
		SMALL (8-250)	MEDIUM (250-500)	LARGE (OVER 500)	TOTAL	
1.	INDUSTRIAL HYGIENE SERVICES ARE USED	1.5	15.3	42.3	3.1	24.2
2.	ENVIRONMENTAL CONDITIONS ARE REGULARLY MONITORED	1.4	9.0	43.0	2.5	21.7
3.	A FORMALLY ESTABLISHED HEALTH UNIT EXISTS	2.3	13.6	70.0	4.0	31.5
4.	HEALTH INFORMATION ON NEW EMPLOYEES IS REGULARLY RECORDED	50.9	79.6	96.3	53.7	78.4
5.	PRE-PLACEMENT PHYSICAL EXAMINATIONS ARE REQUIRED	15.0	44.3	75.0	18.1	47.7
6.	PERIODIC MEDICAL EXAMINATIONS OF SOME TYPE ARE PROVIDED	8.9	26.2	54.9	10.8	33.7
7.	BOTH INDUSTRIAL HYGIENE SERVICES ARE USED AND A FORMALLY ESTABLISHED HEALTH UNIT EXISTS	0.1	4.2	34.2	0.8	17.9

TABLE 2 - FACTORS RELEVANT TO THE EXISTENCE OF EXPOSURE AND MEDICAL RECORDS-- BY TYPE OF INDUSTRY

	FACTORS RELEVANT TO THE EXISTENCE OF EXPOSURE AND MEDICAL RECORDS	PERCENTAGES OF PLANTS							
		ALL INDUSTRIES		MANUFACTURING		CHEMICALS AND ALLIED PRODUCTS		CONTRACT CONSTRUCTION	
		TOTAL	LARGE	TOTAL	LARGE	TOTAL	LARGE	TOTAL	LARGE
1.	INDUSTRIAL HYGIENE SERVICES ARE USED	3.1	42.3	12.4	70.0	29.0	89.1	1.4	43.6
2.	ENVIRONMENTAL CONDITIONS ARE REGULARLY MONITORED	2.5	43.0	6.1	51.1	21.3	71.9	1.5	0.0
3.	A FORMALLY ESTABLISHED HEALTH UNIT EXISTS	4.0	70.0	8.5	80.4	14.4	79.4	0.5	22.3
4.	HEALTH INFORMATION ON NEW EMPLOYEES IS REGULARLY RECORDED	53.7	96.3	61.5	99.0	80.2	100.0	29.2	64.9
5.	PRE-PLACEMENT PHYSICAL EXAMINATIONS ARE REQUIRED	18.1	75.0	25.9	87.3	49.4	89.1	5.6	0.0
6.	PERIODIC MEDICAL EXAMINATIONS OF SOME TYPE ARE PROVIDED	10.8	54.9	14.9	59.1	28.6	58.9	1.9	8.5
7.	BOTH INDUSTRIAL HYGIENE SERVICES ARE USED AND A FORMALLY ESTABLISHED HEALTH UNIT EXISTS	0.8	34.2	3.9	58.2	10.9	79.4	0.1	0.0

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The economic impact of this standard also depends on the extent to which the preservation and access provisions of the final rule go beyond current industrial practices. As discussed in Part VII.D, *infra*, medical records are currently generally maintained for extremely long periods of time. The record is less clear as to general retention practices regarding exposure records, but NIOSH indicated its experience that employers were increasingly maintaining exposure records for thirty or more years (Ex. 16, p. 7). The ongoing development of sophisticated information retrieval systems by corporations and hospitals will also serve to minimize the impact of the rule (*See*, AMRA, Tr. 2465; Illinois Bell, Tr. 2532; AMOCO, Ex. 133, p. 2; API, Ex. 158, p. 47n.99). Finally, numerous employers emphasized that they currently afford worker access to occupational exposure and medical information (Union Carbide Co., Ex. 2(104), p. 1; Shell Oil Co., Ex. 2(105), p. 2; API, Ex. 158, p. 18; Polaroid Corp., Ex. 2(187), pp. 1–2; Sheratt (Data Gen. Corp.), Tr. 2002–3; EEI, Tr. 1783–4; NAM, Tr. 2195).

The third major factor affecting the economic impact of this standard is the likelihood that employees and designated representatives will frequently invoke their access rights. While the record indicates that many employees and unions do intend to invoke their rights under this standard, there is no reason to expect a flood of either initial or periodic requests for access (*See*, Chamber of Commerce, Tr. 997; EEI, Tr. 1784; Privacy Commission, Ex. 101, pp. 288–9; Ex. 103; Annas, Tr. 1759–60; Weiner, Ex. 163).

In addition, the standard contains a number of provisions which should result in minimizing the final standard's burdens on industry. These include:

(1) Limiting the scope of the standard to records relevant to employees exposed to toxic substances or harmful physical agents;

(2) Defining "analyses using exposure and medical records" in a way which avoids requiring access to purely preliminary drafts;

(3) Excluding certain physical specimens, health insurance records, and employee assistance programs records from coverage by the standard;

(4) Reducing the required retention periods as to certain exposure records;

(5) Providing employers complete flexibility in the manner in which records are maintained (except for x-ray films);

(6) Specifying that access must be provided in a "reasonable time, place, and manner;"

(7) Providing employers a reasonable period of time to provide access;

(8) Authorizing the assessment of reasonable administrative costs for repeat requests for copies of records;

(9) Permitting alternatives to full or direct access to medical records if the employee is agreeable;

(10) Assuring protection for certain trade secret information; and

(11) Permitting employers to choose the most desirable means of informing employees of their rights under this rule.

Finally, in considering the economic burdens presented by this rule, it is important not to lose sight of the burdens posed by occupational disease. Occupational disease is extremely costly to our society, both in terms of human impact (premature death, pain and suffering, family anguish, etc.) and purely economic consequences (extended health care costs, increased workers' compensation expenses, lost productivity, absenteeism, larger welfare costs, etc.). The goal of this standard is to enable employees, their representatives, and OSHA to better detect, treat, and prevent occupational disease through access to employee exposure and medical records. By serving to reduce the human and economic impact of occupational disease, this rule will yield substantial benefits which fully justify promulgation of this rule notwithstanding the administrative costs that will be imposed on employers.

VII. Summary and Explanation of the Standard

The final standard is similar in structure and content to the proposed rule, but contains numerous refinements in light of the rulemaking record and the agency's evaluation of it. Significant refinements include: (1) a purpose paragraph to guide application of the standard; (2) more detailed definitions of key terms including the elements of "specific written consent"; (3) an extension of the retention period for basic exposure and medical records along with a reduction in the retention period for certain exposure data; (4) provisions governing the mechanics of access to records including authorizing the employer to charge reasonable fees for multiple requests for copies of records; (5) conditioning the access of all designated representatives to an employee's medical records upon the specific written consent of the employee; (6) permitting an employer's physician to release certain medical data only to a designated representative and not directly to the employee; (7) permitting the deletion of the identity of confidential sources from requested medical records; (8) combining OSHA access to employee medical records with strict administrative regulations; and (9) provisions governing the treatment of trade secret information.

The final standard also differs from the proposal in that NIOSH is not covered by the final rule. NIOSH has independent statutory authority under section 20 of the Act (29 U.S.C. 669) to seek access to records, and furthermore testified that it did not intend to rely upon this final rule to assure its access to necessary records (Tr. 460, 472). OSHA's access to employee medical records is tied to detailed administrative regulations (29 CFR 1913.10) which have been specifically tailored to OSHA's needs and methods of operations. These administrative regulations may in some respects be ill-suited to NIOSH operations. Accordingly, after consultation with NIOSH, the agency decided to exclude NIOSH from the final standard's access provisions.

A. Paragraph (a)—*Purpose*

The "Purpose" paragraph of the final standard creates no substantive requirements, but rather expresses the agency's intentions in promulgating the standard. The proposed rule contained no similar express language. The final rule assures access by employees and their representatives, and codifies OSHA access to relevant employee medical and exposure records. The goal behind access is to yield both direct and indirect improvements in the detection, treatment and prevention of occupational disease. This is articulated as a guide to application and interpretation of the entire standard, and reflects the many ways in which employees, their representatives, and OSHA are likely to use access rights. The Purposes and Need for the Regulation portion of the preamble, III, *supra*, discusses in great detail numerous means by which access to medical and exposure records will yield occupational health benefits. Additional benefits will likely arise from other uses of these records that we have not contemplated.

The "Purpose" paragraph contains several other statements in order to preclude possible misinterpretations of the standard. As with all OSHA regulations, employers are responsible for assuring compliance with the rule. Non-medical management personnel, however, generally have no right to unconsented access to the contents of employee medical records. Concern has been expressed that employers might construe the rule as giving them the right to unconsented access, which medical ethics now denies them (USWA, Ex. 43,

pp. 3–4; Ex. 160, p. 16). To preclude this interpretation, the rule states that "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." It is the agency's expectation that where medical personnel maintain the medical records, they will handle the mechanics of providing access on behalf of the employer. The standard embodies this expectation without attempting to regulate the manner in which employers maintain employee medical records (*See*, Wrenn, Tr. 99–100).

This standard is promulgated against a background of existing legal and ethical obligations concerning the medical-care relationship, especially the maintenance and confidentiality of employee medical information and the duty to disclose information to patients/employees. Legal obligations also exist with respect to trade secret information. These subjects are discussed at length elsewhere in the preamble. To foreclose arguments that OSHA has attempted to preempt existing obligations, the final rule states that "except as expressly provided, nothing in this section is intended to affect" these matters. For example, this standard is in no way intended to diminish the obligation of a physician to inform an employee of a diagnosis of disease immediately. This standard similarly does not override state legal remedies for the abuse of trade secret information.

B. Paragraph (b)—*Scope and application*

The language of this paragraph generally follows that of the proposed rule (43 FR 31374), but has been expanded to better express the intended coverage of the standard. As originally proposed, the final standard applies to general industry, maritime, and construction employers having employees exposed to toxic substances or harmful physical agents. Since the rule seeks to yield benefits in the detection, treatment and prevention of occupational disease, coverage is appropriately limited to records relevant to employees currently or previously exposed to toxic substances or harmful physical agents. The definitions paragraph of the rule (subparagraphs (c)(8) and (c)(11)) defines the phrases "exposure or exposed" and "toxic substance or harmful physical agent." The terms "employee exposure record," "employee medical record," and "analysis using employee exposure or medical records" are also defined in subparagraphs (c)(5), (c)(6), and (c)(2), respectively.

Subparagraph (b)(2) expresses the final standard's application to all relevant exposure, medical, and analysis records whether or not they are related to specific occupational safety and health standards. In so providing, the agency rejected suggestions that there be an exclusion for exposure and medical records created prior to the effective date of the regulation. The agency also rejected arguments that employee medical records could or should be separated into "occupational" and "non-occupational" components, with the standard applying solely to the "occupational" component. Lastly, subparagraph (b)(3) and the phrase "contracts for" in (b)(1) were added to express clearly the agency's intention that the standard apply to records generated or maintained by contractors of the employer as well as by in-house employees.

Before explaining in detail the agency's decisionmaking on these matters in light of the record, it is important to stress that this standard is limited both in its scope and the resulting burdens placed on employers. The standard does not mandate the creation of new records or reports. It does not impose any independent obligation on employers to monitor or measure employee exposures or to provide medical surveillance or examinations. Also, the standard does not establish mandatory requirements as to the format of exposure or medical records. The standard does, however, provide that once employee exposure and medical records are created for any reason, they must be preserved. In addition, persons vitally interested in the contents of these records—employees, their representatives and OSHA—must be provided, upon request, with access to them. This standard is written to assure that access will be consistent with appropriate personal privacy and data confidentiality protections.

The final standard applies to "each general industry, maritime, and construction employer" of employees exposed to toxic substances or harmful physical agents. During the rulemaking proceeding, several participants urged that certain classes of employers, most notably small businesses, and employers with multiple or transient work sites or transient workforces, be entirely excluded from the rule's coverage because of the anticipated excessive administrative and economic burdens of the final rule (Gen. Foods Corp., Ex. 2(99); Lavino Shipping Co., Ex. 2(144), p. 2; Dr. Amdur, Tr. 572; Chamber of Commerce, Tr. 979; So. Cal. Edison Co., Tr. 1575; Crowley Maritime Co., Tr. 1578; Fertilizer Inst., Tr. 2160–61; NAM, Tr. 2177–78; Refractories Inst., Tr. 2216; Steal Plate Fabricators, Tr. 2522). In addition, several participants argued that the rule should not apply to employers who only have safety, as opposed to health, hazards (Steel Plate Fabricators, Tr. 2449; Edison Electric Inst., Ex. 162, pp. 11–12).

Having considered the evidence provided, the agency concluded that there is no rational basis for categorically excluding any broad class of employers from coverage by the final standard. First, as discussed in the feasibility portion of the preamble, VI, *supra*, the agency is confident that the final standard does not impose burdensome or unreasonable administrative and economic costs on any class of employers. Second, the NIOSH National Occupational Hazards Survey (NOHS) documented the fact that exposures to toxic substances occur throughout industry among all types and sizes of employers (Ex. 178; *See also*, testimony of Edison Electric Institute concerning health hazards in the utility industry, Tr. 1917, 1825).

Third, there is no justification for excluding from this rule employees exposed to toxic substances for only a matter of weeks or months as opposed to years. The duration of exposure to a toxic substance may affect the rate of disease incidence, and perhaps the latency period for particular diseases, but the intensity of exposure is equally important. Even short term exposures to toxic substances may be associated with increased risks of chronic disease (as well as the various acute reactions to over-exposure). Research has demonstrated occupationally-related disease in asbestos workers exposed for a matter of months (Ex. 179), and similar results have been obtained for beryllium workers (Ex. 180), for pesticides workers (Ex. 181), for arsenic workers (Ex. 182; *See also*, 43 FR 19587), and for vinyl chloride workers (Ex. 183). It is OSHA's expert judgment that there is no safe level of exposure to a carcinogen; thus any exposure poses some incremental risk of disease (*See*, 29 CFR Part 1990, 45 FR 5002, 5023 (Jan. 22, 1980)). Animal research has, for example, demonstrated chemically-induced neoplasms long after administration of a single dose of vinyl chloride (Ex. 184) or asbestos (Ex. 185).

Although no exclusion from coverage is provided to specific classes of employers due to size, type of business, or nature of workforce, the final standard does exclude employers who have no employees exposed at any time

to toxic substances or harmful physical agents. Furthermore, the final standard only applies to records pertaining to exposed employees, and only to the extent that medical or exposure records exist with respect to these employees. As a result, records of employees who are exposed solely to typical safety hazards (e.g., trips, falls, traumatic injury, etc.) are not covered by this rule.

Subparagraph (b)(2) provides that the final standard applies to records "of employees exposed to toxic substances or harmful physical agents, whether or not the records are related to specific occupational safety and health standards." Numerous participants argued that this scope was too broad, and that the final standard should be limited to records mandated by specific OSHA standards (AAOM, Ex. 2(101), p. 2; Atlantic Richfield Co., Ex. 2(109), p. 1; Machinery and Allied Products Inst., Ex. 2(119), p. 3; RMA, Ex. 2(123), p. 2; Grumman Corp., Ex. 2(55); Shell Oil Co., Ex. 2(105)). However, limiting the scope of the standard only to those records which are created pursuant to the provisions of specific OSHA standards would clearly deny employees access to important job-related health information, and limit the discovery of previously unknown health hazards (Dr. Wegman, Tr. 220–2; Cal. Medical Ass'n, Tr. 1715–16; Ill. State Medical Society, Tr. 2529).

OSHA's limited resources and the time-consuming nature of the standard-setting process allow for the comprehensive regulation in the foreseeable future of only a very small percentage of the toxic chemicals found in the workplace. Since 1971, OSHA has to date promulgated 24 comprehensive toxic substances regulations, all of which contain records access provisions (29 CFR 1910.1001–.1045). Approximately 400 toxic substances are regulated by 29 CFR 1910.1000, which lacks specific access provisions. NIOSH has issued criteria documents recommending further regulation of some 90 substances or categories of substances (Ex. 169, pp. 1340–41). The 1978 NIOSH Registry of Toxic Effects of Chemicals covers some 33,929 distinct toxic substances (Ex. 169, p. xiii), although many of these substances may not currently be widely used. Approximately 1500 new toxic substances are added to the Registry each quarter (Ex. 169, p. 1362). This final standard has been promulgated to improve the ability of employees and their representatives to detect, treat, and prevent occupational diseases, and especially those associated with non-regulated or under-regulated substances. The greatest benefits of this standard may result from access to information contained in otherwise non-mandated records.

Neither paragraph (b) nor the (c)(6) definition of "employee medical record" makes any distinction between "occupational" and "non-occupational" medical information. The preamble to the proposal explicitly recognized that some information in a medical record might be irrelevant to occupational health concerns, and invited "comments on whether any types of information in the medical records should be excluded from the disclosure requirements of the final rule" (43 FR 31372). Several participants urged that "non-occupational" medical information be excluded from coverage by the final rule (AMRA, Tr. 2454; AAOM, Ex. 2(101), p. 2; VII.C.6, *infra*). As explained further in the discussion of the (c)(6) definition of "employee medical record," OSHA decided that any attempted segregation of "occupational" and "non-occupational" records would be both impractical and unwise. The rulemaking record indicates that physicians do not keep two sets of records and that there exist no reliable criteria by which one type of record could be distinguished in advance from the other. Because the symptoms of occupationally related diseases may be identical to diseases that are non-occupational in origin, it is necessary that the entire records of an exposed employee be available for examination and analysis with appropriate safeguards.

Just as the final standard makes no distinction between "occupational" and "non-occupational" records, no exclusion is provided for "historical records". Several employers argued that the standard should not apply to records created before the effective date of this standard, and certainly not to records created before the OSH Act itself went into effect (Shell Oil Co., Ex. 2(105), p. 3; Mobay Chemical Corp., Ex. 2(97); Nat. Agr. Chemicals Assn., Ex. 2(127), p. 1; NAM, Ex. 2(135), pp. 7–8). Some employers maintained that since these records were generated without the knowledge that they would become disclosable under this rule, they should not now be made disclosable (AISI, Ex. 2(142), pp. 8–9; Borg-Warner Corp., Ex. 2(177), p. 3). This argument complements the view held by some participants that since these records have been generated voluntarily by employers, it is unfair to subject the conscientious employer to the disclosure obligations of this standard, especially since employers who have not undertaken exposure surveillance programs are not so obligated.

This standard, however, is not meant to penalize conscientious employers, but is predicated on the judgment that invaluable exposure and medical records must be shared so as to minimize occupational disease. Employer arguments of unfairness must fail when balanced against the fact that continued secrecy will substantially impair the ability of workers, their representatives, and OSHA to detect, treat and prevent occupational disease. Due to the typically long latency periods associated with occupational disease (*See*, VII.D, Preservation of records, *infra*), even very old medical and exposure records can be vitally important to the interpretation of diseases which occur today. For example, thirty year old exposure records can suggest or refute a particular etiology for a disease, thereby dictating appropriate medical treatment. Similarly, a medical record that old may contain irreplaceable baseline health data on an individual to which current health status can be compared. The value of historical records for research purposes is self-evident. Indeed, our ability to interpret disease patterns today is often frustrated by the lack of prior exposure data and such medical data as prior medical histories, smoking habits, and baseline physiological data. The exclusion of "historical" records from coverage by this rule could delay for another 20 or 30 years the positive impact of this standard on the detection of occupational disease. Since medical and exposure records are invaluable regardless of when created, the final standard contains no exclusion for "historical" records.

The American Petroleum Institute (API) in part opposed employee access to historical exposure records on the grounds that these records are usually not meaningful to employees and may often be misunderstood (Ex. 158, pp. 30–31). OSHA disagrees with these statements. Section III of the preamble discusses in detail the numerous ways in which employees and their representatives are expected to make good use of this data, and section IV.E responds to arguments of potential misinterpretation. In making exposure data available to employees, employers are not prevented by this rule from explaining historical data to their employees. That is the appropriate response to potential misinterpretation. API further testified that data not collected with research in mind rarely provides useful information concerning an individual's exposure (Ex. 158, pp. 30–31). Dr. Joel Swartz testified in rebuttal that historical records are

indeed useful in assisting researchers in reconstructing the exposure history of an employee. Even partial or incomplete data "could still be very useful in showing that people were exposed as compared to not being exposed at all" (Tr. 2376). Similarly, Dr. Wegman stated that "all past data should be available; that is, not only data which is specifically prescribed by OSHA, but any health data which could conceivably lead to developing appropriate research conclusions from appropriately designed research data" (Tr. 207). If nothing else, historical records will reveal the identity of chemicals to which employees were exposed.

Lastly, OSHA agrees with the observation of Peter Weiner as to arguments for excluding records predating the OSH Act that "the term 'pre-Act' is misleading; these are presently maintained records, even though they contain records of past exposure" (Ex. 9A, p. 21). In addition, many of these "historical" records may have been created by employers prior to 1970 in order to monitor compliance with mandatory Federal occupational safety and health laws such as the Walsh-Healy Public Contracts Act (41 U.S.C. 35–45; *See,* 41 CFR 50–204.1–205.10; s4(b)(2) of the Act, 29 U.S.C. 653(b)(2)). Irrespective of this possibility, the data base of occupational health information which already exists should be made available immediately to those most directly concerned with the relationship between work and disease. To require waiting twenty or thirty years to partially recreate this data base would be unconscionable. The public health value of this information overrides all arguments that the continued secrecy of "historical" records is appropriate.

The final standard applies to each employer who "makes, maintains, contracts for, or has access to" exposure or medical records. The preamble to the proposed rule best expresses the agency's intention that the final rule be given a broad application in this respect:

> To come within the scope of this . . . rule, the records do not have to be within the employer's physical control as long as the employer has access to them. The concept of employer access encompasses situations in which any of the employer's officers, employees, agents, or contractors (including the corporate medical department) has physical control or access to records, even though they are not generally available to all officers, employees, agents, and contractors. (43 FR 31372)

Subparagraph (b)(3) and the phrase "contracts for" in (b)(1) were added to clearly express the agency's intent that the final standard apply to records generated or maintained by contractors, including records generated on a fee-for-service basis. Although the preamble to the proposal (41 FR 31372 (July 21, 1978)) and OSHA official Grover Wrenn's testimony at the outset of the hearings (Tr. 24–25) explicitly stated this intent, subparagraph (b)(3) and the phrase "contract for" in (b)(1) were added to the final standard to avoid any possible ambiguity (*See,* International Chemical Workers' Union, Ex. 28, p. 6; Weiner, Ex. 9A, p. 28). Coverage of contractor generated or maintained records is crucial since the hearing record indicates that many industrial medical services are performed through contractual arrangements, rather than done in-house by persons employed exclusively by the employer (Southern Gas Assn., Ex. 2(67); Cyanamid Co., Ex. 2(102), pp. 1–2; Dr. Wegman, Tr. 216–17; Chamber of Commerce, Tr. 981; AOMA, Tr. 1531; California Occupational Health Nurses, Tr. 1721; USWA, Ex. 160, p. 16; California Department of Industrial Relations, Ex. 2(132), p. 2; Mechanical Contractors Ass'n., Ex. 2(157)). To exempt contractor generated or maintained records from the final standard would deprive substantial numbers of workers of the benefits of this rule, and would also create a simple vehicle by which employers could in the future evade their obligations.

Subparagraph (b)(3) also provides that "Each employer shall assure that the preservation and access requirements of this section are complied with regardless of the manner in which records are made or maintained." This provision is intended to explicitly put employers on notice that, where necessary, relationships must be modified or created anew in order to assure that this rule is complied with. OSHA thus intends to provide employers maximum flexibility while at the same time emphasizing employer responsibility to assure compliance with the rule (*See,* Weiner, Ex. 9A, pp. 28–29).

A significant remaining matter is the final standard's exclusion of agricultural employers. The preamble to the proposed rule stated that it would apply to each employer in general industry, maritime, and construction who makes, maintains, or has access to employee exposure or medical records (43 FR 31372). Agricultural employers were implicitly excluded. The Migrant Legal Action Program, Inc., (MLAP) (Ex. 154) and the Health Research Group (HRG) (TR. 2032–4; Ex. 161) argued that agricultural workers should be included within the scope of the final rule, since there is no rational basis for not doing so. MLAP stated that "the burden on the agricultural employer would be no greater than it would be for any other employer," while "the value of the regulation for farmworkers would be great." (Ex. 154, p. 2). The AFL–CIO also supported this position (Ex. 152, p. 32).

Both MLAP and HRG observed that agricultural employment is one of the most hazardous occupations:

> Nationwide, in 1977, there were an estimated 1800 accidental work-related deaths in agriculture. Fourteen percent (14%) of all work-related deaths occur in agriculture, and the annual death rate in agriculture is 53 per 100,000 workers. In 1977 one of 20 farmworkers suffered a disabling injury. This makes agriculture the third most hazardous industry in the United States, surpassed only by construction and mining/quarrying. (MLAP, Ex. 154, p. 1)

HRG noted that farmworkers are often exposed to extremely toxic substances such as the many pesticides in current usage (Tr. 2033). HRG also stated:

> Rarely if ever do farmworkers know the nature or extent of these exposures. And if a farmworker were to ask a labor contractor or grower for records which shed light on those exposures, the records would likely be destroyed and the farmworkers fired.
>
> Without rules requiring agricultural employers to retain and disclose exposure and medical records, farmworkers will surely be denied the right to know about health hazards in their workplaces. (HRG. Tr. 2033)

MLAP further stated that the need for farmworker access to exposure and medical information is reinforced by the limited resources of OSHA to inspect agricultural worksites (Ex. 154, p. 2, 3).

OSHA finds MLAP's and HRG's comments to be persuasive. However, since the proposed rule implicitly excluded agricultural employers from coverage, and these employers did not participate in the proceedings, OSHA believes that a further comment period is appropriate before extending the scope of this standard. Accordingly, this final rule is being simultaneouly published as a proposed rule with regard to agricultural employers. The evidence provided during the comment period, in addition to the evidence gathered in this proceeding will be evaluated in determining whether to extend the scope of this standard to agriculture operations.

As a final matter, the agency would like to stress that the limited nature of this standard is not intended to detract from the potential occupational health importance of other information created or maintained by employers. This rule is limited in scope to available medical and exposure records, but other exisiting information may have

significance and the prevention of disease will at times require the creation of new records. Accordingly, OSHA compliance efforts, and public health activities of other agencies such as NIOSH, will at times necessitate access to records other than those covered by this standard. This rule is not intended to limit OSHA's or any other agency's authority to seek access to such employer information in particular circumstances.

C. Paragraph (c)— *Definitions*

1. *"Access."* The proposed rule used the term "access" in the sense of a right and opportunity to examine and copy records (43 FR 31373–74). The final standard makes this explicit in subparagraph (c)(1). Paragraph (e), Access to Records, governs the specifics of how access rights may be exercised.

2. *"Analysis using exposure or medical records."* The proposed rule defined "employee exposure record" and "employee medical record" as including "general research or statistical studies based on information collected from" either of these forms of individual records (43 FR 31372, 31374). The final standard removes studies from the definition of individual records, and creates a separate definition—"analysis using exposure or medical records." This change was made for four reasons. First, based on the manner in which exposure and medical records are created and maintained, it strains normal meaning to speak of an individual record as encompassing an aggregation of data from numerous records. Second, the phrase "general research or statistical studies" was correctly viewed as overly vague (AFL–CIO, Ex. 152, p. 39); thus there was a need to express the agency's intentions better. Third, subparagraph (e)(2)(iii) provides that analyses without personally identifiable information must be made available, upon request, to workers, collective bargaining representatives, and other designated representatives without requiring them to obtain the specific written consent of the individual subjects whose records underlie the analyses. Since these analyses should not be viewed as traditional medical records, the final rule created a separate definition (*See*, Deere & Co., Ex. 2(84), p. 2). Fourth, the final standard exempts purely preliminary work on analyses of records from the access requirements, and this was most easily accomplished by specifically defining what is meant by analyses based on individual records.

The term "analysis using exposure or medical records" is defined as "any compilation of data, or any research, statistical or other 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." This definition refines the proposal in several respects. 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 this definition (*See*, AFL–CIO, Ex. 39, p. 5, Ex. 152, p. 39; ICWU, Ex. 28, p. 13, Tr. 758–59; OCAW, Tr. 702; UAW, Ex. 35, pp. 11–12). Analyses "based at least in part on . . . information collected from health insurance claims records" were included since studies of the utilization of medical services covered by health insurance may reveal patterns of occupational disease. These analyses based on insurance claims records are covered by the final standard even though the individual records upon which the analyses were based may be held by an insurance company or otherwise not treated as employee medical records (and thus not subject to the access or preservation requirements of this rule).

The phrase, "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," has been added in response to employer concerns that premature access to studies could be misleading and hinder research. OSHA recognizes that researchers may go through several early revisions and drafts in the review and analysis of data and that this process deserves some insulation from close scrutiny. However, once the analysis has been sufficiently completed as to be reported to the employer—i.e., to someone in management beyond those individuals immediately involved in preparing the analysis—then the analysis should be accessible to workers, to their representatives, and to OSHA. Similarily, the analysis should be accessible if the persons preparing it have stopped working on the analysis even though no detailed report has been made to management. The wording of the definition also responds to concerns that providing access only to "final" studies could invite evasion through the devices of labeling analyses as "draft" or by purging earlier drafts of unfavorable findings. The language adopted should minimize these results while precluding premature access to ongoing studies and analyses.

3. *"Designated Representative."* The preamble to the proposed rule discussed the term "designated representative" as follows:

> This proposal does not provide a limiting definition of "designated representative." Rather, a designated representative could be anyone to whom an employee has given written permission to act on his or her behalf to obtain direct access to his or her records. For instance, a collective bargaining agent, physician, attorney, family member, fellow employee, or anyone else, could be a designated representative, provided the necessary consent were obtained. Access to employee exposure records and medical records by designated representatives is necessary so they can assist the employees they represent in making effective use of their records and in securing their rights under the OSHA Act. (43 FR 31373)

The final standard on subparagraph (c)(3) makes this explicit. Designated representatives include "any individual or organization to whom an employee gives written authorization to exercise a right of access." The final rule contains no rigid criteria as to what this written authorization must say. Any written statement which is signed and indicates that the designated representative is authorized to exercise the employee's right of access will suffice. The rule also singles out "a recognized or certified collective bargaining agent" as included within this (c)(3) definition for the purposes of access to employee exposure records and analyses using exposure or medical records. A "recognized or certified collective bargaining agent" is a labor union which has legal status under the National Labor Relations Act (29 U.S.C. 151 *et seq.*) as the exclusive agent for a particular collective bargaining unit.

OSHA believes that enabling an employee to designate anybody he or she desires to entrust with the access rights of this rule will most effectively achieve the purposes of the Act and this standard. At the same time, recognized or certified collective bargaining agents, who have the statutory authority to represent the enterests of employees within the bargaining unit on health and safety matters, are automatically considered to be "designated representatives" by virtue of their special bargaining status. Under the rule, this gives them the right of access to employee exposure records and analyses using exposure or medical records without individual employee consent. However, like any other

designated representatives, collective bargaining agents must have the specific written consent of an employee to get access to an employee's medical record.

4. "*Employee*." The term "employee" has a statutory definition (s3(6) of the Act, 29 U.S.C. 652(3)(6)) which governs this rule, but the final standard contains language to clarify the intended coverage. The proposed rule guaranteed access rights to former employees (43 FR 31374). The final rule makes this explicit in the definition of "employee" so as to avoid repetitive use of the phrase "and former employees" each time the standard created a right of access. Former employees have needs of access to records relevant to their current or future health status as compelling as the needs of current employees; thus the final rule makes no distinction between former and current employees.

The proposed rule also covered "exposure records of past and potential exposures" (*Id.*). The phrase "potential exposures" was the source of some concern, since it appeared to expand the class of employees who would be given access rights without clearly delimiting who they were (MCA, Ex. 2(125), p. 11; Rubber Mfgr. Assn., Ex. 2(128), p. 3; Dresser Industries, Inc., Ex. 2(130), p. 7; Beckman Instruments, Inc., Ex. 2A(6), p. 2; EEI, Ex. 2A(36), pp. 24–25). The final standard better expresses OSHA's intent by defining "employee" as including "an employee being assigned or transferred to work where there will be exposure to toxic substances or harmful physical agents." Mere job applicants and employees with only hypothetical future exposure are thus not entitled to any rights under this rule, but employees who are being offered or assigned to new jobs involving exposure to toxic substances or harmful physical agents are covered by the standard (*See*, Dr. Wegman, Tr. 202).

At the suggestion of the Xerox Corp., the final rule also contains language assuring that the legal representative of a deceased or legally encapacitated employee may exercise rights under this rule (Xerox Corp., Ex. 2(136), p. 2). OSHA believes that the goals of the Act are well served by facilitating attempts by such legal representatives to ascertain whether the deceased or legallly incapacitated employee was a victim of occupational disease, and to assist health research in discovering the causes of occupational disease. The records of deceased and incapacitated workers are obviously relevant to occupational health research. Therefore, the rule explicitly applies to records relevant to deceased and legally incapacitated employees.

5. "*Employee exposure record.*" The proposed rule defined this term as meaning "a record of monitoring or measuring which contains qualitative or quantitative information indicative of employee exposures to toxic materials or harmful physical agents" (43 FR 31373). The preamble to the proposal explained as follows:

> These records would include determinations of airborne concentrations of chemicals to which an employee is exposed, or would be exposed if not wearing a respirator. They would also include determinations of physical agents within the workplace environment which might impair an employee's health or functional capacity, for example, records of heat, noise, radiation, vibration, or hypo- or hyperbaric (i.e. nonatmospheric) pressure. Records of area sampling of workplace contaminant levels and representative or random employee sampling are covered by this definition. If a record contains information which is useful to determine employee exposure, the record would be covered by this rule even though the record was not created for occupational health purposes. (43 FR 31372)

This generalized definition, particularly the phrase "qualitative or quantitative information" gave rise to considerable discussion and debate during the rulemaking proceeding. In light of the record, the agency decided to specify more precisely the information covered by the final standard (*See*, Electronic Industries Assn., Ex. 2(93); Union Carbide Corp., Ex. 2(104), p. 1; Fla. Agricultural Research Inst., Ex. 2A(19), pp. 1–2). The language adopted focuses on the major issues raised during the proceeding, particularly sampling methodologies, calculations, background data, biological monitoring tests, and the types of other "qualitative and quantitative" information of greatest importance.

Subparagraph (c)(5)(i) covers "environmental (workplace) monitoring or measuring, 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." There was little disagreement that classical industrial hygiene monitoring or measurement results should be covered by the rule. The phrase "including personal, area, grab, wipe, or other form of sampling" was added to ensure that all forms of industrial hygiene sampling were embraced (Ex. 186). As expressed by OSHA official Grover Wrenn, the intention is to encompass data which "in any way characterizes the environment in which workers are working" (Tr. 89).

The issue of collection and analytical methodologies, calculations, and other background data was a matter subject to considerable difference of opinion. Some industry witnesses argued that complete background data and calculations should not be covered by this standard due to their possible misinterpretation by the employee (API, Ex. 158, p. 30–2). Since this kind of information can be voluminous, it was also stated that its inclusion within the definition of "employee exposure record" would be particularly burdensome (SOCMA, Tr. 523; DuPont, Ex. 12, p. 10). In contrast, there was testimony from the unions and others that such data would be useful over and above the basic results of monitoring and measuring and should be included within the "employee exposure record" definition.

> While it is true that some data contained in underlying calculations and laboratory notebooks might not be of great interest to workers (i.e. the carrier gas or temperature reading of a gas chromatograph), some information would be of direct interest and use. For example, the time over which a sample was taken, the date and the number of readings constitute information readily understood by workers and important to the interpretation of exposure readings. While a worker on the shop floor may not know (or care to know) the difference between a midget impinger or an activated charcoal absorbant, he or she can determine if measurements were taken during down time or reflect true exposure. Moreover, representatives of workers trained in industrial hygiene are fully capable of interpreting and utilizing technical documentation of exposure measurements (Tr. 891, 1165, 1167, 1194 (USWA)). (AFL–CIO, Ex. 152, p. 41)
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> * * * * *
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> A minicourse in medical science or industrial hygiene is not required for the ordinary worker, who is concerned principally with his or her own exposure readings. On the other hand, an industrial hygienist employed by a union would find the underlying data and calculations essential for the purpose of verifying the results obtained by the employer. (Weiner, Ex. 9A, p. 22).

In light of the record and the agency's expertise in industrial hygiene matters, OSHA concluded that the final standard should apply to collection and analytical methodologies, calculations and background data. The approach chosen by the final rule is to assure access to both the sampling results and information relevant to interpretation of the results. Sampling results often will be less meaningful unless one knows precisely where the sampling was done, at what time of day, for what period of time, and under what working conditions. The collection plan or methodology will provide this data. Analytical methodologies and mathematical calculation methods may

be of considerable importance to verify the statistical significance and accuracy of the results obtained. As Mr. Weiner and the AFL–CIO noted, some of these matters will be easily appreciated by workers; others will at times require evaluation by industrial hygienists. Subparagraph (d)(1)(ii) provides reduced retention requirements for some of this information, but subparagraph (c)(5)(i) appropriately includes it within the definition of "employee exposure record." In addition, the definition does not cover all sampling methodology, calculation and other background data, but only that information "relevant to interpretation of the results obtained." A rule of reason is intended to apply as dictated by sound industrial hygiene practice.

The next major issue concerns biological monitoring tests. Numerous participants urged that the final standard define "exposure records" as including biological minitoring results, but little comment was directed towards specifying which tests should be covered (Lovejoy, Ex. 2(90); Dr. Johnson (MCA), Tr. 417; Weiner, Ex. 9A, p. 24, Tr. 166–67, 195; Taylor (AFL–CIO), Tr. 636; AFL–CIO, Ex. 152, pp. 41–42; Eller (ICWU), Tr. 751; USWA, Ex. 160, pp. 21–22, Tr. 900; Dr. Parkinson, Tr. 1146–47). Biological monitoring tests involve the evaluation of a body system (e.g., pulmonary function) or a body fluid or tissue (e.g., blood, urine, breath, sputum, hair, fingernails). These tests generally measure either the fact or level of absorption of a substance (e.g., blood lead level), or the physiological or biochemical status of some body system (e.g., the efficiency with which the kidney is filtering the blood as reflected in the urinalysis or in the serum creatinine or blood urea nitrogen).

The final standard treats certain biological monitoring results as exposure records, but only those tests which "directly assess the absorption of a substance or agent by a body system." This limited coverage is consistent with comments made by Dr. Silverstein of the UAW:

> We believe, in general, that in the absence of written consent an employee should not have access to the medical records of fellow employees, even if those with related or comparable exposures. Reasonable exceptions to this guideline are necessary, however, for the unique and relatively infrequent situations that a piece of information has as much the characteristic of an industrial hygiene test result as a private medical test result. For example, the results of a biological monitoring test, like a blood lead analysis, often tell as much about the plant environment as the health of the individual. The availability of blood-lead tests results may be crucially important data to the fellow worker, the union representative or the industrial hygienist, who is trying to judge the extent of hazard and to design control mechanisms. (Ex. 63, pp. 10–11).

Several biological tests are currently used to assess directly whether and to what extent a worker has absorbed a toxic substance. Tests such as blood lead level, urine mercury, urine phenols, urine monoacetylbenzidine, exhaled carbon monoxide (USWA, Ex. 160, pp. 21–22), and hair or fingernail assays for arsenic are illustrative. These tests may be a valuable complement to traditional industrial hygiene personal sampling, since the actual absorption is measured rather than mere breathing zone exposure. Since these tests predominantly measure absorption as opposed to the biological effect of the absorption, the worker's unique health status is not directly assessed. The worker's unique physiology or metabolism may influence the level of absorption, but generally this cannot be assessed by examination of the biological monitoring result by itself. Furthermore, these kinds of biological monitoring tests have not traditionally been afforded the privacy protections given to medical records (Wrenn, Tr. 53–55; USWA, Ex. 160, pp. 21–22).

From the foregoing considerations, the agency, in defining "exposure record," included biological monitoring tests of absorption, but explicitly excluded tests which assess "the biological effect of a substance or agent." These latter tests, such as lung function, sputum cytology, male fertility tests (sperm number, motility, and morphology), kidney function tests (e.g., blood urea nitrogen, and serum creatinine), and hemoglobin levels, merit the privacy protection afforded to other medical information. These tests more directly measure some aspect of an individual's unique health status, and may reveal health problems caused by non-occupational factors. Accordingly, the final rule treats these biological monitoring results as medical records rather than exposure records.

The remaining issue concerns what if any additional kinds of quantitative or qualitative information should be included within the definition of "employee exposure record." The final standard includes two kinds of information. First, "Material safety data sheets" are included within the definition of "employee exposure record." Typically, these sheets contain information on the identity of the chemical, its physical characteristics, its known toxic properties, some of its possible health effects, and proper handling procedures. Several participants urged that access to these records be assured (United Paperworkers International Union, Tr. 940–41; AFL–CIO Industrial Union Department, Tr. 947–48, 962–63; AFL–CIO, Ex. 152, p. 40). As noted by the Paperworkers Union, access to these data sheets "would at least give some idea of what, if not how much, workers are being exposed to" (Tr. 940).

Finally, the definition of "employee exposure record" includes "any other record which reveals the identity (chemical, common, or trade name) of a toxic substance or harmful physical agent". Coverage of this last kind of record, however, only arises in situations where no other type of exposure record exists for the particular toxic substance or harmful physical agent (i.e., environmental monitoring, biological monitoring, or material safety data sheets). An example of this kind of exposure record would be a detailed manual concerning toxic substances which some employers develop for the benefit of their employees (Panhandle Eastern Pipeline Co., Ex. 51; Truckline Gas Co., Ex. 2(153), p. 1). Dr. Teitelbaum also pointed out that in the absence of other kinds of exposure records, a simple purchase record might reveal the nature of an employee's exposure (Tr. 134). These kinds of records are covered to the limited extent that the identity of the substance or agent is revealed—i.e., either its chemical, common, or trade name. Subparagraph (d)(1)(ii) provides that these fall-back 'qualitative' exposure records need not be retained for any period of time so long as some record is maintained of the identity (chemical name if known) of the substance or agent used, where it was used, and when it was used. The final standard, however, is founded on the judgment that access to these records is appropriate where no alternative means exists to identify what toxic substances or harmful physical agents employees are exposed to (*See*, NJCOSH, Ex. 2(58), Attach., p. 1).

It is appropriate to stress that OSHA defined "employee exposure record" so as to make the most important information available to employees and their representatives at a minimal burden to employers. Several participants argued that other forms of information should be included in the standard; e.g., system design information, engineering tests, and mechanical ventilation measurements (Weiner, Ex. 9A, pp. 20–21), and personnel records (NIOSH, Ex. 16, p. 5). These and other forms of information may well have occupational health importance and this rule is not meant to imply otherwise. Further rulemakings may cover other kinds of data. For the

time being, however, OSHA has declined to expand the scope of this final rule to encompass all types of employer-held information of possible relevance to occupational safety and health matters.

6. *"Employee medical record."* The definition contained in the final standard is similar to that of the proposal (43 FR 31374), but has been refined in light of the record. First, the final rule applies to information concerning an employee's health status which "is made or maintained by" medical personnel. Information generated by medical personnel should be accessible irrespective of how and where the information is presently maintained. The use of "made" is intended to assure access in situations where medical information is held by non-medical management departments or personnel. The use of "maintained by" medical personnel is intended to assure access to the entire contents of medical files, not just to information created by medical personnel. Once information from any source gains enough importance to be included in the medical file, that information becomes subject to the retention and access provisions of this rule.

The final standard also applies to health status information made or maintained by a "technician." This is meant to cover the results of situations where, for example, occupational health questionnaires or biological monitoring tests such as pulmonary function or audiometric testing are conducted by persons who, stricyly speaking, may not be considered as health care personnel. Records from these tests might not be made a part of the formal medical program; thus the final rule includes "technician" in the definition of "employee medical record" to assure that these health status records are covered.

An important effect of the phrase "is made or maintained by" is to exempt certain information from this rule. Miscellaneous personnel file and other information peripherally related to an employee's health status, but never included in the employee's medical file nor created by health care personnel or a technician, are excluded. Another example of information exempted would be minor injury statistics not made a part of the employee's medical file. (All employees are already entitled to access to illness and injury statistics required to be kept by 29 CFR Part 1904).

The final standard lists five categories of information explicitly treated as part of an employee medical record, all of which were mentioned in the preamble to the proposed standard (43 FR 31372). These five categories are not meant to be all-inclusive, but represent the types of information most likely to be found in a medical record and most relevant to occupational health issues. All health status information must be made accessible, however, limited only by the "made or maintained by" medical personnel or technician qualification. The wide variety of information that could be contained in employee medical records was discussed by numerous participants (*See*, Dr. Robinson, Ex. 2(95), pp. 1–3; Dr. Teitelbaum Tr. 143; Dr. Whorton, Ex. 11, pp. 4–5; Weiner, Ex. 9A, pp. 27–28; Samuels (AFL–CIO IUD), Tr. 973).

As just noted, the final standard broadly defines "employee medical record." During the rulemaking proceeding, discussion on the definition of "employee medical record" centered on whether a meaningful distinction could be made between 'occupational' and 'non-occupational' information. The preamble to the proposed rule noted that some medical information could be irrelevant to occupational health issues, and solicited information on what, if anything, should be excluded from coverage by the rule (43 FR 31372).

Several participants, who endorsed explicit exclusion of 'non-occupational' information, stated that medical records compiled by occupational physicians may contain data unrelated to workplace exposures, such as family problems, abortions, venereal disease, emotional and mental illness problems, and drug or alcohol abuse (Nat. Steel Co., Tr. 1978; DuPont Co., Ex. 12, p. 4; API, Ex. 66B, p. 3). It was even estimated that perhaps "only about 10 percent of employee consultations concern medical problems clearly defined as industrial injuries or illnesses" (API, Ex. 66B, p. 3). Other comments included:

> We recognized and agree that employees should have access to information about their occupational exposures and the condition of their health. We also recognize the need for OSHA and NIOSH to require certain exposure and medical records be kept and be available to OSHA and NIOSH. But it is unreasonable for OSHA to request *all* information contained in employee medical records be available to employees, their representatives, and Federal agencies. A medical record contains a variable amount of information because it is a record of an individual. Often there is very sensitive and personal information and sometimes employees don't know or don't remember just what is in the record. Much information in the record is not of valid interest to OSHA, NIOSH, or employee representatives. (AAOM, Ex. 2(101), p. 2)
>
> * * * * *
>
> We believe that only information related to conditions or hazards of the workplace constitute legitimate, pertinent information under these regulations, and that all other information relating to the employee's medical condition or communication with his physician should not be released from the employee medical record. (AMRA, Tr. 2454)

OSHA agrees that in particular situations some medical information may have no relevance to occupationally-related health problems. No general exclusion has been created, however, because the record indicates that such an exclusion would be impossible to define properly. The record indicates that the symptoms of occupational disease often closely mimic those of non-occupational diseases. The human body is limited in the number of ways it can react to chemical insults, and many of these responses parallel symptoms associated with a variety of other insults and disorders. The record makes it clear that occupational exposure to toxic substances can result in practically every form of apparent "non-occupational" health problem, including personality change, psychiatric disorder, minor cuts, falls, or bruises, dizziness, headache, reproductive disorders, common cold, flu or stomach-ache. This, plus our limited knowledge of occupational disease, makes it impossible to classify in advance what pieces of information may or may not be of "occupational" significance. Furthermore, even information concerning genuine non-occupational health problems may have later significance in assessing occupational health issues. For example, full understanding of an employee's pre-employment medical problems could possibly avoid unnecessary suspicion and investigation of a chemical where prior health problems recur. Numerous participants discussed these factors at length (Illinois Bell Co., Ex. 2(56); ACGIH, Ex. 2A(25), p. 3; Dr. Karrh (DuPont), Tr. 354–5; Dr. Johnson (MCA), Tr. 427; Dr. Teitelbaum, Tr. 120, 145–148; Dr. Wegman, Tr. 207–08, 211–14; Dr. Whorton, Tr. 304–05; Dr. Silverstein (UAW), Tr. 2025–26; Weiner, Tr. 171–73; AFL–CIO, Ex. 152, pp. 36–39).

On the basis of the foregoing, OSHA concluded that there is no sound way to exclude on an *a priori* basis any form of "non-occupational" information from this standard. In addition, permitting any form of "non-occupational" information exclusion could easily prove to be counterproductive. This rule's access provisions are designed to facilitate the detection of previously unrecognized occupational health problems; thus the broadest possible access with appropriate safeguards must

be provided or important information could be lost. As Dr. Wegman stated:

> . . . [I]f the associations are there it is our job to find them, and we must use any available medical records to find them. We cannot simply use records which are prescribed ahead of time as being associated with certain work exposures. Mostly the occupational diseases which exist are undescribed, and it is very difficult for us to predict what material in the medical record is going to be useful in determining new occupational diseases. (Tr. 207–08)
>
> I think the issue we in the research end of this profession need to address is what are the variety of symptoms associated with the variety of occupational exposures. Every single one of them can be, and if we don't maintain an open mind about that, we are going to close off certain series of occupationally related diseases. (Tr. 214)

Dr. Wegman further described in detail how easily even a broad pattern of occupationally related urinary dysfunction could go unrecognized (Tr. 220–22). The final rule contains no exclusion for "non-occupational" medical information in order to maximize the possibility that currently unrecognized occupational disease will be detected.

The record indicates that providing access to an employee's entire medical file will not prove to be burdensome, since existing recordkeeping practice has generally been to maintain both personal and job-related information in a single medical file (Dr. Whorton, Tr. 304; Dr. Spraul (Monsanto), Tr. 1909; Dr. Bernacki (NAM), Tr. 2186). Thus, Dr. Robert Hilker, past president of the AOMA, testified:

> [The AOMA] believe(s) that records should not be segregated. We believe that to practice good medicine, it is necessary to have a contemporary running record in order to evolve the thought process to decide what is happening to this patient. And when you separate them you deprive yourself of a lot of information that you need to arrive at a diagnosis and a possible cause, a possible occupational exposure, if you will. (Tr. 2529)

Dr. Givens of the California Medical Association provided similar testimony on recordkeeping practices:

> Using the DBCP sterility case as an example, it would seem that such a dual system might at times allow for the erroneous separation of medical data, leading possibly to unforeseen tragic consequences. (Tr. 1716)

Although no exemption is provided for "non-occupational" information, the final rule does specifically exclude three kinds of information from the definition of "employee medical record": certain physical specimens, certain records concerning health insurance claims, and certain records concerning voluntary employee assistance programs. First, OSHA does not desire to alter in any way existing medical practices as to the retention of physical specimens (e.g., blood or urine samples). In general, physical specimens are discarded after having been analyzed. There are exceptions to this, however, such as peripheral blood smears and permanent sputum cytology slides required under specific occupational safety and health standards (*See*, 29 CFR 1910.1029(j)(2)(vii) (coke oven emissions); 29 CFR 1910.1028(i)(2)(i)(*b*) (benzene), *vacated, API v. Marshall*, 581 F.2d 493 (5th Cir. 1978, *cert. granted*, 440 U.S. 906 (1979). Since there was some confusion as to the standard's application to physical specimens, the agency decided the best solution was to explicitly exclude physical specimens from the rule (*See*, Wrenn, Tr. 36–37). The final rule excludes from the definition of "employee medical record" physical specimens "which are routinely discarded as a part of normal medical practice, and are not required to be maintained by other legal requirements." Of course, the written results obtained from examining specimens are covered by the definition of "employee medical record."

Next, "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.)" are excluded from the final standard's definition of "employee medical record." Health insurance records are routinely generated in industry. These are often medical records created by a Health Maintenance Organization (HMO) or by the employee's private physician, although the employer may have access to the information in aggregate or individual form due to an "interest in claims administration." In "Dilemma: A Report of the National Conference on Health Records," published and submitted into the record by NCCHR, it was noted that:

> This structure of group insurance plans varies considerably from one employer to another. In some plans, the insurance company handles claims administration, and the employer receives only utilization data (sometimes in individually identifiable form), in others the employer virtually insures itself, and the insurance company plays little if any part in administering the plan. (Ex. 58, p. 33)

This report also indicated that group insurance claims in the industrial setting are normally handled by personnel departments rather than the medical department, and that such submitted claims may be screened by management on the way to the insurer (NCCHR, Ex. 58, p. 32). George Becker, of the United Steelworkers Union, further stated:

> . . . I[n] many small plants, the monitoring of group insurance is a clerical rather than a medical function. The clerk in charge as a matter of course checks with the employee's supervisor on any questions on a group claim.
>
> Often the employee's immediate supervisor is the one who determines the entitlement to sick and accident benefits and the duration of the sick and accident benefit. (Tr. 2387)

Recommendations were made by several employers to exclude insurance claims records from the definition of "employee medical record" (Steel Plate Fabricators, Tr. 2501; Dresser Ind., Ex. 2(130), p. 7; Biscuit and Cracker Mfgrs., Ex. 2(140), p. 3; Motorola Corp., Ex. 2A(26)). The final standard in part follows these recommendations. If the health insurance claims records are kept separate from medical program records and "not accessible to the employer by employee name or other direct personal identifier (e.g., social security number, payroll number, etc.)," then they are not treated as employee medical records. If, however, employee health insurance records are either integrated into medical program records or can otherwise be retrieved by the employer by direct personal identifier, then they are treated as employee medical records for the purpose of the access provisions of the rule (VII.E, *infra*), but not for the purpose of the preservation provisions of the rule (VII.D, *infra*). Access to identifiable insurance claims records containing health status information is appropriate for the same reasons applicable to employer-generated medical records—the employee health status information may be highly relevant to the detection, treatment, and prevention of occupational disease. OSHA does not believe, however, that it is appropriate to require long term preservation of all health insurance records maintained outside the context of an employer's medical program. The final rule thus establishes no preservation requirements as to these records. However, as discussed earlier, analyses based on insurance claims records are subject to both the access and preservation requirements of this standard.

The final exclusion from the definition of "employee medical record" concerns "records of voluntary employee assistance programs (alcohol, drug abuse, or personal counseling programs), if maintained separately from the employer's medical program and its records." Representatives of the Edison Electric Institute (EEI) took the lead in arguing that records of employee assistance programs should be exempt

from the scope of this rule (Ex. 2A(36), pp. 12–13). In its words:

> The Edison Electric Institute, almost exclusively among the participants at the hearings, raised substantial objections to the mandatory disclosure of records generated by employee assistance programs. These programs are operated on a voluntary basis by employers to assist their employees with personal problems such as alcoholism, drug abuse, psychological, marital and legal difficulties. OSHA's regulation, as proposed, would subject records generated in such programs to the same disclosure requirements contemplated for other employee records. The record evidence before OSHA demonstrates that even the possibility of such disclosures would chill employees' participation in such programs, create risks for third parties who provide confidential information about employees involved, and perhaps destroy the effectiveness of these programs which are so worthwhile. (Ex. 162, p. 13)

In addition to the testimony on the need for confidentiality (Tr. 1778–9) and the strict confidentiality policies that have been adopted as part of these programs (Tr. 1779, 1787, 1791–2), the EEI representatives indicated that these programs are often administered completely outside the medical program by clinical psychologists or counselors, and even when they are part of a medical program, the records are kept strictly separate from the medical records (Tr. 1785–6). Even the contract physician must have the consent of the employee to get access to them (Tr. 1786–7). (*See also*, Taylor (AFL–CIO), Tr. 648–55; Dr. Teitelbaum, Tr. 140–142).

On the basis of the foregoing, OSHA decided that records pertaining to voluntary employee assistance programs are apt to have limited significance to occupational health matters when these programs are structured and operated outside of the context of the employer's medical program. Application of this standard to these voluntary assistance programs would likely yield little benefits though imposing unnecessary burdens on employers. Accordingly, the final rule exempts the records of these programs from the definition of "employee medical record," but only to the extent that the records of these programs are maintained apart from the employer's medical program and its records. Where, however, these assistance programs are part of the employer's overall medical program and its records, they should be subject to this standard (*See*, Dr. Teitelbaum, Tr. 140–42). Similarly, information on substance abuse and behavioral disorders recorded as part of a medical history or medical examination is covered by this rule.

7. "*Employer.*" The word employer is defined by statute (s3(5) of the Act, 29 U.S.C. 652(3)(5)) and that definition will control. In addition to covering current and former employers, the final standard makes clear that successor employers must assume the obligations to retain and make available records of employers that they succeed. The agency chose to mention successor employers explicitly due to the extended periods medical and exposure records must be maintained under this rule.

8. *"Exposure" or "exposed."* The proposed rule was directed toward employees "exposed or potentially exposed to toxic materials or harmful physical agents." This phrase was not explicitly defined, although OSHA intended that it be construed in a traditional industrial hygiene sense (Wrenn, Tr. 102–03). The term "harmful physical agent" was described to include such well recognized exposures as heat, noise, radiation, vibration, and hypo- and hyperbaric pressure (43 FR 31372; Wrenn, Tr. 92–93). The overall phrase, however, due to its generality and breadth, was the subject of some comment and confusion during the rulemaking proceeding (Ball Corp., Ex. 2(122), p. 2; Motorola, Inc., Ex. 2A(26), p. 4; EEI, Ex. 2A(36), p. 24; API, Ex. 158, p. 2n.2). Words like "toxic" and "exposure" are subject to numerous interpretations; thus the final standard clarifies what is intended by the phrase "exposed to toxic substances or harmful physical agents." Subparagraph (c)(8) defines "exposure" or "exposed" while subparagraph (c)(11) defines "toxic substance or harmful physical agent." The goal of this expanded definition is to avoid confusion on the part of employers as to whether their employee medical and exposure records are covered by this standard.

Subparagraph (c)(8) defines "exposure" or "exposed" as meaning "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 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.

The final rule applies when an employee has "potential (e.g., accidental or possible) exposure" to a toxic substance or harmful physical agent. This phrase was included to indicate that the standard covers situations where exposure could reasonably have occurred and not only situations where exposure has definitely occurred or been measured. An example would be workers handling electrical transformers containing poly-chlorinated biphenyls (PCBs). Exposure is not a certainty since the toxic chemical should be maintained within a closed system. However, seals sometimes leak and accidents occur which disperse the chemical; the final rule is therefore intended to apply to these types of potential exposure situations.

9. *"Record."* The preamble to the proposed rule stated that "the term 'record' as used in this proposed rule, is intended to cover any recorded information regardless of its physical form or character" (43 FR 31372). Questions were raised as to the intended scope of "record" (Wrenn, Tr. 39–37); thus the agency decided to define "record" explicitly in the final standard. The definition provided, "any item, collection or grouping of information regardless of the form or process by which it is maintained (e.g., paper document, microfiche, microfilm, or automated data processing)" is meant to be all-encompassing. This is consistent with the flexibility provided to employers by paragraph (d), Preservation of Records, to maintain medical and exposure records in whatever form the employer chooses (with the exception of X-ray films).

10. *Specific written consent."* As discussed in Chapter IV.D, *supra*, the proposed rule was criticized in that employee medical records were to be released upon the mere "written consent" of the employee, but the proposal did not define what was meant by "written consent." There was

widespread agreement that medical records should only be disclosed to non-governmental third parties through a process of carefully designed written consent so as to minimize the possibility of invasion of an employee's legitimate privacy expectations. Invasion of privacy could have significant adverse consequences to the employee (loss of job, friends, insurance, etc.) and impair the physician-patient relationship. OSHA recognizes these potential problems, and thus has incorporated a thorough "specific written consent" definition in the final standard. The components of "specific written consent" are a reflection of the record comments on this issue (*See*, Privacy Commission, Ex. 101, pp. 314–15; AMRA, Ex. 83, p. 12; Dr. Teitelbaum, Tr. 124–26, 157; Dr. Whorton, Ex. 11, pp. 19–20; Dr. Wegman, Tr. 206–07; NIOSH, Ex. 16, pp. 7–8; Dr. Parkinson, Ex. 43 p. 4; Weiner, Ex. 9A, pp. 36–40, Tr. 180–81; Taylor (AFL–CIO), Ex. 39, p. 5; AFL–CIO, Ex. 152, pp. 52–53; USWA, Ex. 160, p. 19; Wodka (OCAW), Tr. 708–09; Health Research Group, Tr. 2045–46).

The essence of "specific written consent" is assuring that the employee knows what is being disclosed, to whom, and for what purpose. Consent which is "blanket" (i.e., a general release of all records to whoever requests them) or "perpetual" (i.e., lacking a time limit or the possibility of revocation) would clearly be unacceptable (AMRA, Ex. 83, p. 7) and arguably legally unenforceable (Annas, Ex. 56B, p. 149). The Privacy Commission recommended an authorization procedure along the lines prescribed in the HEW regulations on the "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 CFR Part 2 (Ex. 129). This working model of consent is contained in Recommendation (13) of the Commission's chapter on medical records:

> That whenever an individual's authorization is required before a medical-care provider may disclose information it collects or maintains about him, the medical-care provider should not accept as valid any authorization which is not:
>
> (a) in writing;
>
> (b) signed by the individual on a date specified or by some one authorized in fact to act in his behalf;
>
> (c) clear as to the fact that the medical-care provider is among those either specifically named or generally designated by the individual as being authorized to disclose information about him;
>
> (d) specific as to the nature of the information the individual is authorizing to be disclosed;
>
> (e) specific as to the institutions or other persons to whom the individual is authorizing information to be disclosed;
>
> (f) specific as to the purpose(s) for which the information may be used by any of the parties named in (e) both at the time of the disclosure and at any time in the future;
>
> (g) specific as to its expiration date, which should be for a reasonable period of time not to exceed one year, except where an authorization is presented in connection with a life or non-cancellable or guaranteed renewable health insurance policy, in which case the expiration date should not exceed two years from the date the authorization was signed. (Ex. 101, p. 315)

The American Medical Records Association recommended a similar model authorization procedure (AMRA, Ex. 83, p. 12).

The final standard's definition of "specific written consent" adopts the substance of these elements. To give consent, an employee will specifically have to indicate in writing who is being authorized to disclose record information, who may have access to it, and the general nature of the information to be disclosed. If the employee wishes, he or she may specify information which is not authorized to be disclosed and may place conditions on its use or redisclosure. In this way, it will be the employee who controls the amount and kinds of information available to the designated representative, and what the representative can do with it.

In addition, the final standard provides for limited prospective authorization by the employee. The AMRA recommendations do not accept prospective authorization for the release of information not yet in existence (AMRA, Ex. 83, pp. 7, 12 (*at* 3.8(h))), while the Privacy Commission's recommendations permit prospective authorizations. The policy argument raised against prospective authorization is that "consent to the release of information prior to treatment" precludes "intelligent decisionmaking on the part of the patient" (AMRA, Ex. 83, p. 7). In general this is a good policy, but there are notable exceptions applicable to the occupational setting. For example, periodic biological monitoring of exposed employees, perhaps on a monthly basis, would generate predictable kinds of medical information outside of a treatment context. If an employee desired for his personal physician, or a union industrial hygienist or physician, to receive biological monitoring results regularly, it is reasonable to permit authorization for the release of future results, as long as the authorization is subject to revocation. Requiring the employee to re-execute a "specific written consent" each month would be burdensome and serve no useful function. Accordingly, the final standard states that "A written authorization does not operate to authorize the release of medical information not in existence on the date of written authorization, unless this is expressly authorized. . . ." and for no more than one year even when expressly authorized. The presumption, therefore, is against "prospective consent," but the employee may expressly override this presumption for up to one year. Furthermore, the employee may revoke the consent at any time.

The remaining components of the definition of "specific written consent" are straightforward and need no further elaboration. The definition, however, stops short of some recommendations presented in the rulemaking proceeding. Several employers felt the recommendations of the Privacy Commission were inadequate because an employee may give consent without being fully cognizant of the potential consequences of disclosure, or may be coerced or feel pressured into signing a consent form (Dr. Spraul (Monsanto), Tr. 1915; API, Ex. 158, p. 34). The API proposed these additional safeguards:

> No third party should have an access privilege unless he has a program which provides for (i) a clear and specific statement of an occupational health purpose for access to medical records; (ii) the exclusion of information—particularly personal identifiers—which is unnecessary to the stated purpose; and (iii) security and administrative precautions to prevent access by unauthorized persons. (Ex. 158, p. 35)

OSHA recognizes that it is possible for third parties to abuse specific written consent, but does not believe this merits numerous further provisions in the final standard. The Privacy Commission recognized that its recommendation "provides assurance that an individual will understand what he is allowing to be disclosed, and why, but does not require that the voluntariness of his action be verifiable, nor does it assume that he can recognize every possible consequence of signing it" (Privacy Commission, Ex. 101, p. 315). In the Privacy Commission's view, that is all that one can reasonably expect from a consent requirement, even where an element of coercion is clearly involved in demands for medical records by medical facilities, employers, insurance carriers, or social service organizations (Ex. 101, p. 314). Employers and groups such as the API are apparently concerned about possible coercion by labor unions to gain access, but the record contains no evidence to support this concern or to refute the observation of Peter Weiner that:

> An often silent but present theme is the danger that a labor organization might coerce

its members to give such consent. It is time to recognize that this undercurrent is built on bias without foundation, and that this type of pressure for disclosure is the least of our worries where third parties are concerned. (Ex. 9A, p. 40)

OSHA recognizes, however, that there may be situations where an employee desires to specify additional conditions or restrictions on the use or re-disclosure of medical information released to a designated representative. An opportunity to do this is provided in Appendix A to the standard, which is a model authorization letter meeting the definition of "specific written consent."

11. *Toxic substance or harmful physical agent.* Subparagraph (c)(11) provides that the final rule applies whenever there is exposure to 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.)" for which there is evidence of harmful health effects. This definition excludes traumatic safety hazards such as trips, fall, cuts, etc., but includes repetitive motion (ergonomic) stresses due to their subtle and chronic nature (Ex. 187).

Although no comprehensive list of substances or hazards is possible since our knowledge and appreciation of occupational health problems are constantly expanding, OSHA felt it was important to limit the rule to those chemicals, biological agents, and physical stresses for which there is some evidence of toxicity or harmfulness. To do this, the final rule establishes four general criteria for determining when to apply this rule. First, the standard applies to any chemical substance, biological agent, or physical stress which "is regulated by any Federal law or rule due to a hazard to health." The term "chemical substance" is used in the broadest possible sense (e.g., dust, mist, fume, liquid, solid, mineral, etc.). Health regulations of a hazard by any Federal agency, such as OSHA, EPA, FDA, CPSC, NRC, etc., should clearly be sufficient for coverage of exposure and medical records of employees exposed to that hazard. Employers should already be well aware of the hazards associated with these substances and agents.

Second, the standard applies to any chemical, biological agent, or physical stress which "is listed in the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS)." NIOSH is mandated under section 20(a)(6) of the Act (29 U.S.C. 669(a)(6)) to publish on at least an annual basis "a list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur." Excerpts from the RTECS 1978 edition Foreword and Introduction demonstrate that this document is an appropriate source for defining chemicals covered by this rule:

> The annual publication of a list of known toxic substances is a NIOSH mandate under the Occupational Safety and Health Act of 1970. It is intended to provide basic information on the known toxic and biological effects of chemical substances for the use of employers, employees, physicians, industrial hygienists, toxicologists, researchers, and, in general, anyone concerned with the proper and safe handling of chemicals. In turn, this information may contribute to a better understanding of potential occupational hazards by everyone involved and ultimately may help to bring about a more healthful workplace environment. (Ex. 169, p. iii)
>
> This Registry contains 124,247 listings of chemical substances: 33,929 are names of different chemicals with their associated toxicity data and 90,318 are synonyms. This edition includes approximately 7,500 new chemical compounds that did not appear in the 1977 Registry. (Ex. 169, p. xiii)
>
> 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 alternate processes which may be less hazardous. (Ex. 169, p. xiii)
>
> 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. Data may be used for the evaluation of chemical hazards in the environment, whether they be in the workplace, recreation area, or living quarters. (Ex. 169, p. xiii)
>
> 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. (Ex. 169, p. xiv)

In addition to an annual printed edition, the RTECS is continuously updated on a quarterly basis (Ex. 169, p. 1362). The RTECS 1978 printed edition may be purchased for $13.00 (GPO Stock No. 017–033–00346–7) from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, D.C. 20402 (202–783–3238). The 1979 printed edition is anticipated to be issued in the summer of 1980. An annual subscription to the quarterly microfiche which revises the RTECS may also be purchased from the GPO for $14.00 (Order the "Microfiche Edition, Registry of Toxic Effects of Chemical Substances"). Appendix B to the standard contains additional information on where RTECS may be examined or purchased.

Third, the standard applies to any chemical, biological agent, or physical stress 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." This criterion is intended to cover the situation where the employer is aware that a particular chemical, etc., poses a hazard, even though the chemical may not yet have been identified in RTECS or regulated by any of the health regulatory agencies. OSHA believes that it would be inappropriate to expect that each employer be familiar with the entire body of evolving scientific knowledge concerning the toxicity of chemicals used in its workplaces. Many employers do, however, subscribe to the quarterly microfiche edition of RTECS, review the published literature, receive knowledge of unpublished studies or pre-publication copies of studies, or conduct biological evaluations on their own initiative. Some health hazards, such as extremes of heat and cold, are obvious. Where an employer is aware of evidence suggesting that health risks are posed by the use of a chemical, biological agent, or physical stress, then this rule applies to whatever employee medical and exposure records exist with respect to exposed workers. This provision is crucial as to new chemicals, and will be increasingly important as employers implement the testing requirements of the Toxic Substances Control Act of 1976 (15 U.S.C. 2601 *et seq.*).

Finally, the standard applies to any chemical, biological agent, or physical stress which "has a material safety data sheet indicating that the material may pose a hazard to human health." This document generally accompanies the

purchase of a chemical used in industrial processes, and serves to warn users of toxic properties of the product. Employers of employees exposed to such a chemical are properly covered by this standard, even where the employer may have no knowledge of the precise ingredients, or chemical name, of trade name products.

The foregoing overall definition of "toxic substance or harmful physical agent" is flexible enough to incorporate advances in scientific knowledge, while definite enough to place employers on notice of what their obligations are under this rule. This definition will minimize compliance and enforcement difficulties, and will avoid both unnecessary record retention requirements and the inadvertant destruction of important occupational health information.

D. Paragraph (d)—*Preservation of records*

The proposed regulation provided that:

> Each employer who makes, maintains, or has access to employee exposure records or employee medical records shall preserve and retain them for at least the duration of the affected employee's employment with the employer plus five (5) years, except where a specific occupational safety and health standard provides a different retention period. (43 FR 31374)

This proposal of a "duration of employment plus five years" retention period was explained as follows:

> There may be situations where this retention period may be longer than absolutely necessary, and others where it is too short to ensure the preservation of the record throughout the latency period of an occupational illness arising from an earlier exposure to toxic materials. OSHA believes that the general retention period of this proposed rule strikes a reasonable balance between these two situations.
>
> Nevertheless, because it recognizes that the longer the retention period, the greater the risk of infringement upon employees' privacy interest and the greater the administrative burden on employers, OSHA invites comments on whether a lesser or longer period should be adopted in the final rule for some or all kinds of records covered by the regulation. (43 FR 31373)

Numerous initial comments argued that this retention period was either too long or too short, while others indicated it was just about the correct length of time. On the basis of these comments, OSHA explained at the outset of the public hearings on the proposal that the evidence appeared to dictate a retention period of at least thirty years (Wrenn, Ex. 7, p. 27). Considerable additional testimony and post-hearing comments were submitted on this issue. On the basis of the total record, the agency decided to extend the retention period as to basic exposure and medical information and shorten it as to some background exposure information, while assuring employers maximum flexibility as to the manner in which records are retained.

The final standard provides that employee exposure records and analyses based on exposure or medical records must generally be preserved and maintained for at least thirty years, while employee medical records must be retained for at least the duration of employment plus thirty years. A minimal overall retention period of thirty years was adopted due to the very long latency periods characteristic of chronic occupational diseases. This period is consistent with the recordkeeping requirements of existing OSHA health standards, and with the thirty year retention period for records of significant adverse employee health reactions established by section 8(c) of the Toxic Substances Control Act, 15 U.S.C. 2607(c).

The "duration of employment plus thirty years" retention period for employee medical records takes into account three factors in addition to the long latency periods of occupational disease. First, existing medical record retention practices are such that a running medical record would in any event be maintained for at least the duration of employment. Second, an employee's first exposure to a toxic substance or harmful physical agent could occcur at any point during the course of employment. Third, the entire medical record is of importance even where first exposure to a toxic substance occurs near the end of an employee's employment. This results from the likelihood that important baseline medical information was recorded at the outset of an employee's employment and not recorded thereafter. For ease of administration and certainty the agency chose the duration of employment plus thirty years retention period instead of some more complicated formula. Once an employee becomes exposed to toxic substances or harmful physical agents, his or her entire medical record becomes subject to the standard, including medical information collected prior to initial exposure.

The agency's choice of a minimal retention period of thirty years for exposure and medical records, and analyses thereof, took into consideration the wide variety of suggestions made during the rulemaking proceeding. Recommendations ranged from retention periods of 25 to 40 years: (25 Years.) Dr. Swartz, Tr. 2362; (20–25 yrs.) Dr. Young, Tr. 1099; (30 yrs.) Wodka (OCAW), Tr. 702; (40 yrs.) Dr. Thorpe (API), Tr. 2074; (40 yrs.) AFL–CIO, Ex. 152, p. A2; (40 yrs.) Dr. Wegman, Tr. 208; (up to permanent retention) Dr. Teitelbaum, Tr. 126–27; Dr. Whorton, Ex. 11, p. 21). A variety of intermediate suggestions were made tied to other factors such as the duration of the employee's employment (duration plus 25 yrs.) CACOSH, Tr. 1095; (duration plus 30 yrs.) Laden (USWA), Tr. 668–69; (duration plus 35 yrs.) Dr. Parkinson, Tr. 1142; (duration plus 40 yrs.) HRG, Tr. 2034–36; (duration plus 40 yrs.) ICWU, Tr. 735–36; (30 yrs. or duration plus 10 yrs., whichever is longer) Cement, Lime, and Gypsum Workers, Tr. 1203–04; (40 yrs. or duration plus 20 yrs., whichever is longer) USWA, Ex. 160, p. 22; (40 yrs. from onset of exposure) Dr. Wegman, Ex. 10, pp. 14–15; (30 yrs. from cessation of exposure) NIOSH, Ex. 16, pp. 5–7). More recent OSHA health standards generally provide for retention periods of 40 years or the duration of employment plus 20 years, whichever is longer. This wide variety of possible provisions indicates that no one perfect choice exists. The thirty year retention periods chosen, however, are reasonable in light of the suggestions made and existing evidence concerning the latency period of occupational disease.

There was wide agreement among participants that the long latency periods associated with occupational diseases, especially cancer, dictate the retention of records for decades (Dr. Teitelbaum, Tr. 126–27; Dr. Wegman, Tr. 208; Dr. Swartz, Tr. 2362; HRG, Tr. 2034–36, 2046–49, Ex. 161, pp. 1–3; CACOSH, Tr. 1095; Dr. Parkinson, Tr. 1142; Laden (USWA), Tr. 668–69; ICWU, Tr. 735–36, Ex. 28, p.. 8; USWA, Ex. 160, p. 22; Cement, Lime, Gypsum Workers, Tr. 1203–04; AFL–CIO, Ex. 152, pp. 42–43, Ex. 39, pp. 2–3; Dr. Silverstein (UAW), Ex. 63, pp. 13–14; NIOSH, Ex. 16, pp. 5–7; Dr. Whorton, Ex. 11, p. 21). The following passage and tables from the well-respected text-book, *Chemical Carcinogenesis and Cancers (1964)* by Drs. W. C. Hueper and W. D. Conway of the National Cancer Institute, demonstrate the necessity for long term retention of records:

> The onset of a carcinogenic exposure may antedate by many years or even decades, the appearance of the first symptoms of a cancer causally related to it. The establishment of direct associations between such events is not infrequently obscured by the fact that the critical exposure to a carcinogen may have ceased months-to-decades before the cancer becomes manifest, i.e., an exposure-free and

symptom-free lag period may intervene (Hueper; Williams; Henry; Browning). During this period all traces of the causative carcinogenic agent have often disappeared from the exposed organism. The definite demonstration of causal relations to specific chemical factors encounters for these reasons, considerable difficulties in many cases of environmental carcinogenesis. In assessing the role which chemical carcinogens play in the production of human cancers, due consideration must be given to the fact that, as a rule, some ten years will elapse after the introduction of a new carcinogen into the human environment before its carcinogenic effects upon an exposed and well circumscribed population become epidemiologically demonstrable, that some additional twenty to thirty years may go by before the peak of such a development is reached, and that again a period of similar length will pass before the last carcinogenic manifestations attributable to an environmental carcinogen will disappear after a particular carcinogen has been removed from the human environment. (Ex. 161a)

Table 8.—*Latent Periods of Occupational Cancers*

Organ and agent	Average latent period (years)	Range of latent period (years)
Skin:		
Arsenic:		
Medicinal	18	3–40
Occupational	25	4–46
Tar	20–24	1–50
Creosote oil	25	15–40
Mineral oil	50–54	4–75
Crude paraffin oil	15–18	3–35
Solar radiaton	20–30	15–40
X-radiation	7	1–12
Lung:		
Asbestos	18	15–21
Chromates	15	5–47
Nickel	22	6–30
Tar fumes	16	9–23
Ionizing radiation	25–35	7–50
Bladder:		
Aromatic amines	11–15	2–40

(Source: Ex. 161a)

Table 9.—*Ranges of Latent Periods Following Exposure to Different Aromatic Amines (M. W. Goldblatt)*

Chemical	Maximum period		Minimum period	
	Years	Months	Years	Months
Beta-naphthylamine	16		1	8
Benzidine	33	8	6	10
Toluidine	32		10	
Aniline	36		7	
m-Phenylendiamine				
Dimethylaniline	19–20			

(Source: Ex. 161a)

Very long latency periods are not only associated with occupational cancer, but with occupational disease in general. As Dr. Wegman stated, "we are talking about diseases which are predominantly chronic in nature, * * *" (Tr. 208). Concrete examples include the two non-carcinogens for which OSHA has to date issued comprehensive health standards—cotton dust and inorganic lead. Exposure measurements and medical surveillance records generated under the cotton dust standard must be maintained for at least twenty years (29 CFR 1910.1043(k)(1)(iii) and (k)(2)(iii); 43 FR 27398 (June 23, (1978)). The reason for this period was explained in the preamble to the final rule:

> * * * OSHA feels that this retention period is necessary in order to develop sufficient longitudinal dose-response data and to determine the effectiveness of the selected permissible exposure limits in reducing the prevalence of respiratory diseases, particularly irreversible chronic obstructive pulmonary diseases, in each of the covered industries. 43 FR 27393 (June 23, 1978)

Exposure measurements and medical surveillance records generated under the inorganic lead standard must be maintained for at least forty years, or for the duration of employment plus twenty years, whichever is longer (29 CFR 1910.1025 (n)(1)(iii) and (n)(2)(iv), 43 FR 53013 (Nov. 14, 1978)). The preamble to the final standard explained:

> Lead is known to have both acute and chronic effects, depending on the level and duration of exposure. The onset of clinical symptoms may occur many years after exposure. OSHA requires these records be maintained to document the medical and exposure history of the worker in order to assist the physician in determining whether lead was an etiologic agent in a disease progression. For example, renal and neurological disease do not necessarily have early warning indicators which physicians might use for evaluation. The records will serve to aid the physician in determining the dose to the worker over his work tenure.
>
> OSHA is also concerned that the physician be able to follow asymptomatic workers who have been exposed to low lead levels over long periods of time, in order to ascertain the long term effects of low level exposure. In this regard, another important function the combined records serve is to provide a data base for much needed scientific and epidemiological research into the effects of chronic low level lead exposure. (43 FR 53006, Nov. 14, 1978)

Dr. Silverstein of the UAW highlighted the need for preservation of records for all potential forms of occupational disease:

> Cancer is not our only concern. We have only begun to look at the relationship between workplace exposures and other chronic disease. Medical and exposure records are likely to prove valuable in uncovering the presently hidden links between the workplace and cardiovascular, renal, endocrine, and musculosketetal disease.
>
> There are many current examples of workers who are now exposed to chemicals whose long term effect is unknown but potentially serious. Examples include workers exposed to mixtures of solvent vapors, diesel exhaust, or welding fumes. In other instances workers sustained exposure to substances which are now controlled or removed from the workplace because of suspected but largely unknown long term consequences. Examples include Tris and PCB exposure. Workers in these situations, and unfortunately the National Occupational Hazard Survey would suggest that this applies to an overwhelming number, certainly have the right to expect a diligent effort to determine whether health effects are becoming apparent over the years. Giving sanction to the wholesale destruction of records at five years may prove to be one of the most disastrous public health mistakes we could make. (Ex. 63, pp. 13–14)

The preceding comment by Dr. Silverstein properly emphasizes the limited scope of our knowledge concerning occupational disease in general. Few of the thousands of chemicals in the workplace have been thoroughly tested in animals for chronic toxicity, and systematic human epidemiological investigations of exposed workers have only sporadically been conducted. The history of governmental responses to occupational disease has largely been one of responding to demonstrated disease rather than establishing protective mechanisms before known disease arises. One purpose of this standard is to preserve and make accessible the existing data base of medical and exposure information concerning employee exposure to toxic substances and harmful physical agents so that workers, their representatives and the government can better detect and respond to previously unrecognized associations between exposure and disease. The state of our limited knowledge dictates that records be preserved for long periods of time so these unforeseen associations can be made (Dr. Teitelbaum, Tr. 208). Dr. Young also endorsed this reason for long term retention of records:

> We cannot tell now, just as we could not tell 20 years ago, what new dread diseases would become manifest after lengthy latent periods, and I think we would all view with chagrin if not horror a decade or two down the line if important records that would uncover new patterns of risk were not available simply because of an all-too-short five-year retention period. It seems to me the burden on any company is trivial. A few file cases well protected is all we're talking about. (Dr. Young, Tr. 1099)

The preservation requirements of the final standard will enable records to be used in the many fashions envisioned by Section III of the preamble, Purposes and Need for the Standard (*supra*). Both exposure and medical records must be preserved for at least thirty years since they will be critical to understanding and responding to occupational health

problems. For example, prior exposure records can suggest the cause of current disease experience; prior medical records can supply vital baseline health status information to which a patient's current health status can be compared.

The thirty year retention period is reasonable in light of the latency periods associated with occupational diseases, but OSHA recognizes that specific toxic substances may merit longer or shorter retention periods. The final standard explicitly addresses this in two provisions. First, if a specific occupational safety and health standard sets a retention period for exposure and medical records different from that of this rule, the specific standard's provision controls. This is appropriate since the provisions of specific health standards are based on rulemaking evidence of the consequences of employee exposure to the toxic substances being controlled. Second, the standard envisions situations where records may have occupational health value beyond the retention periods of this rule. To deal with this, the stardard provides that whenever an employer intends to dispose of records required to be kept at least thirty years, the employer shall notify the Director of NIOSH of this intention. The required three months advance notice will enable NIOSH to assess the value of the records and take steps, if appropriate, to prevent destruction of the records. NIOSH and OSHA will communicate with each other so that notice to NIOSH will also notify OSHA of the impending destruction of covered records.

The final standard has been structured so that only certain records subject to the rule must be retained for the thirty year period. Analyses using exposure and medical records must be maintained for at least thirty years since these records will likely be most useful in analyzing patterns of disease. Similarly, employee medical records must be preserved for at least the duration of employment plus thirty years since there is no rational way to determine in advance which portions of a medical record may or may not become important in the future. Health insurance claims records which are maintained separately from the employer's medical program and its records, however, need not be retained for any period of time.

In addition, not all employee exposure records must be maintained for at least thirty years. Exposure records describe the identity of, and possibly the level of exposure to, a toxic substance or harmful physical agent. These two elements—identity and level of exposure—are the critical data which must be preserved for at least thirty years.

The definitions paragraph of the rule defines "employee exposure record" as encompassing four kinds of records. The first kind, environmental (workplace) monitoring or measuring, can contain a wide variety of information which is critical to the evaluation of occupational exposures. Industrial hygiene surveys will often involve detailed laboratory reports, worksheets containing mathematical calculations and other background information, documentation of collection (sampling) methodology (where, when, how, and under what working conditions samples were collected), and other assorted documents. Not all of this information is of lasting importance, and several participants offered varied opinions as to how long the background data should be retained (USWA, Ex. 160, pp. 22; AFL–CIO, Ex. 152, p. 45). The final rule provides that "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" must be retained for at least thirty years. Permitting analytical and mathematical methods to be described, and other relevant background data to be summarized, will enable bulky records such as laboratory reports and worksheets to be discarded. This background information, however, must be maintained for at least one year to allow workers, their representatives, and OSHA a reasonable opportunity to evaluate the exposure calculations and thoroughly examine the employer's methodologies.

The second type of "employee exposure record," certain biological monitoring results, must under the final standard be maintained for at least thirty years (and employment plus thirty years if made part of an employee's medical record) for the same reasons applicable to environmental monitoring.

However, the third and fourth types of employee exposure records, material safety data sheets and other records which reveal the identity of a toxic substance or harmful physical agent, need not be retained for any specific period of time. The final rule provides that these records "need not be retained for any specified period so long as some record is retained of the identity (chemical name if known) of the substance or agent, where it was used, and when it was used." This provision will assure retention of the basic exposure information for at least thirty years while enabling employers to avoid burdensome record retention obligations.

The agency believes that the retention requirements of the final standard are necessary and appropriate, and sufficiently flexible to avoid burdening employers with unjustified obligations. We recognize that several employers urged that shorter retention periods be established than the one proposed (North Car. Nat. Gas Corp., Ex. 2(134); Wash. Legal Foundation, Ex. 2(96); Magma Copper, Tr. 1451; Fertilizer Inst., Tr. 2160; Steel Plate Fabricators, Tr. 2520), but the long latency periods associated with occupational disease and the limited extent of our knowledge dictate the periods chosen.

The agency recognizes the possibility that in specific narrow factual settings requirements other than those established by this standard may provide equivalent protection. Employers or their trade associations are free to file applications for variances under section 6(d) of the Act (29 U.S.C. 665(d); *See*, 29 CFR Part 1905) in situations where equally effective or better means exist to achieve the goals of this rule. As with other standards, variance proceedings will enable case-by-case consideration of specialized factual circumstances, and will add flexibility to the application of the standard. In addition, this standard itself may, of course, be subject to modification in the future, either in response to a petition to modify or to other developments.

Although the final standard establishes long retention requirements for some records, the agency is confident that the burdens imposed will not prove to be significant. First, the final rule states that "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 x-ray films shall be preserved in their original state." As a result, with the exception of x-rays, employers are provided maximum flexibility to microfiche, microfilm, computerize, or otherwise retain records in whatever fashion is most desirable to the employer (*See*, Truckline Gas Co., Ex. 2(153), p. 2; Beckman Instruments, Inc., Ex. 2A(6), p. 1; Motorola, Inc., Ex. 2A(26), p. 10). The agency has previously studied the issue of microfilming x-ray films and has reached the conclusion that in view of currently available technology, this practice should not be permitted (Ex. 188). The analysis of x-ray films is highly dependent upon the

quality of the film, and appreciable detail is clearly lost when an original film is microfilmed or otherwise copied. As a result, the final rule provides that "x-ray films shall be preserved in their original state."

Second, the record suggest that many employers and medical establishments already maintain medical and exposure records for lengthy periods of time.

> We, Illinois Bell Telephone Company now-have now adopted a policy of microfilming [medical records] and keeping them for an indeterminate period of time. (Dr. Hilker, Illinois and Chicago Medical Societies, Tr. 2532)
>
> * * * * *
>
> Most hospitals retain the medical record or the most pertinent parts of that record in some reproducible form such as microfilm or microfiche for literally ever, indefinitely. (ARMA, Tr. 2466)
>
> * * * * *
>
> NIOSH believes the employer burden for keeping records of terminated employees is probably not that great since it just involves space and minimal maintenance and logistics. In fact, through the use of techniques such as microfilming, space is no longer a problem.
>
> It is NIOSH's opinion that by far the largest burden upon the employer is creating the records initially rather than maintaining them after they are created. Also, it should be noted that NIOSH experiences during the conduct of field studies is that industry is recognizing the importance of maintaining records for longer periods of time (i.e., 30–40 years) and a retention requirement in the OSHA regulation will not be as if industry is starting from point zero. (Bierbaum (NIOSH), Ex. 16, p. 7)
>
> * * * * *
>
> If exposure and medical records are to be useful in advancing our knowledge of [occupational] diseases (an avowed purpose of the proposed rule), records must be kept for longer than five years, and perhaps for fifty years or more. It is common practice in the medical world to retain medical records almost permanently or at least for some years after the death of the individual concerned. (Dr. Goldwater, Chief of Occ. Med., Duke U. Med. Center, Ex. 2(87))
>
> * * * * *
>
> Mr. Spiller: Okay, would you say that medical training generally encourages doctors to keep their medical records almost indefinitely or at least for the lifetime of the patient or certainly for very long periods of time?
>
> Dr. Thorpe: Yes, I believe so. I have always had the feeling—I know that there are statutes of limitations, but most physicians and I think most hospitals don't abide by that. They may reduce or prune or convert medical records into manageable storage space, but most physicians have a horror of destroying medical records. (Dr. Thorpe, (Exxon Corp.), Tr. 2122)

(See also, Deere & Co., Ex. 2(84), p. 2 (at least the lifetime of the employee); Eller (ICWU), Tr. 735–36 (employment plus 10 yrs. in Dow Chemical Co.); RCA, Ex. 2(75) (employment plus 10 yrs.); DuPont, Ex. 114A, p. 1 (employment plus 40 yrs.); Dr. Thorpe (Exxon Corp.), Tr. 2121–22 (at least 40 yrs.)). Also, the importance of medical and exposure records to potential legal proceedings such as workers' compensation and medical malpractice suits is a strong inducement for long term retention of records. As noted by Dr. Hanks, Medical Director of the Personnel Department of the City of Los Angeles:

> With respect to retention of records, at least some States have laws extending statute-of-limitations for filing of workers' compensation claims to within a year following the employee's awareness of an occupational illness. This makes for indefinite retention of records on large classes of employees, since decades may pass between alleged exposures and illnesses related or alleged to be related to such exposure. In other words, employer self-interest and potential liability call for indefinite retention, even to the post-mortem period in which claims are apt to be filed by survivors. Thus a federal regulation would be superfluous in such States and possibly superfluous in any case, since self-interest would indicate retention well-beyond a five-year post-termination date in view of evolving laws in employees' favor. (Ex. 2A(35))

This is further supported by a recent article in *Malpractice Digest,* a bi-monthly newsletter to medical malpractice insurance policyholders, which is published by the St. Paul Fire & Marine Insurance Co., the leading carrier of medical malpractice insurance:

> The need for accurate medical records goes beyond the efficient day-to-day practice of medicine. Medical records have become legal documents which play a major role in many matters, including medical malpractice. The responsibility of the physician to properly document the care provided to patients also turns up in personal injury suits, workers compensation disputes, pension eligibility investigations and contests of wills.
>
> The best defense in any action involving the practice of medicine is accurate, legible and complete records. (Ex. 189 p. 1).

As a result of the foregoing, it is clear that the preservation requirements of the final standard are promulgated against a backdrop of existing widespread long term retention of records, and thus pose little additional burden.

E. Paragraph (e)—*Access to records*

Paragraph (e) of the final standard significantly refines the language previously contained in the proposal's paragraph (d), Availability of records. Subparagraph (e)(1), *General,* specifies the mechanics of access to avoid possible confusion and abuse of the rule's access rights. Subparagraph (e)(2), *Employee and designated representative access,* is little different from the proposal as to exposure records and analyses using exposure or medical records. As to medical records, however, subparagraph (e)(2) is changed from the proposal in two respects. Designated representatives obtain access only through a process of specific written consent, and physicians are provided limited discretion to release certain medical information to designated representatives rather than to the employee directly. Subparagraph (e)(3), *OSHA access,* varies from the proposal in that administrative regulations established at section 1913.10 of 29 CFR are incorporated by reference as to employee medical records, and NIOSH access is no longer directly addressed by this rule.

Subparagraph (e)(1) of the final standard addresses the mechanics of access to records. First, the rule in (e)(1), as well as elsewhere in paragraph (e), provides that "the employer shall assure that" various obligations are met. The use of "assure" was chosen instead of providing that the employer directly perform various obligations since the mechanics of access often will be performed by medical personnel not directly supervised by the employer. Several participants urged that the final rule not be worded in a manner which implicitly expands employer access to confidential employee medical records (AFL–CIO, Ex. 152, p. 54; USWA, Ex. 160, p. 16; Dr. Parkinson, Tr. 1138–39). The use of "assure" avoids this result.

Subparagraph (e)(1) next states that employee and designated representative access must "be provided in a reasonable time, place, and manner, but in no event later than fifteen (15) days after the request for access is made." This language permits employers to establish orderly procedures for providing access so that work schedules are not unduly disrupted and workers not unduly inconvenienced (NAM, Tr. 2180–81, 2197; Ohio Bldg. Chpt., Ex. 2(29); Bofors Lakeway, Inc., Ex. 2(156), p. 3; Motorola, Inc., Ex. 2A(26), p. 10). An employer, for example, need not pay an employee during the time a requested record is being reviewed, if the record is made available before or after the worker's normal working hours. It also recognizes that records may be stored in several locations or in centralized storage, and thus not immediately accessible at the place of employment (Southern Cal. Edison, Tr. 1515, 1518). The use of "reasonable time" and "in no event later than fifteen days after the request for access is made" also

responds to recommendations that definite time limits be established to preclude inordinate delay by employers (OCAW, Ex. 2(124), p. 3; ACTWU, Ex. 2(201), p. 5; AFL–CIO, Ex. 152, p. 56; USWA, Ex. 160, p. 23, Tr. 669; ICWU, Ex. 28, p. 9; NIOSH, Ex. 16, p. 8; Right to Know Coalition, Ex. 2(103), p. 1). What is a "reasonable" time will vary from situation to situation.

Immediate access will be required where records are readily available, whereas the maximum fifteen calendar days provided may be necessary where records must be photocopied and mailed across the country. The use of the phrase "reasonable time, place, and manner" is also intended to preclude unjustified barriers to access, such as limiting access to clearly inconvenient times or places (e.g., requiring workers to sacrifice worktime in order to exercise access rights).

Subparagraph (e)(1) also contains language specifying what happens when an employee or designated representative desires an exact copy of a requested record. The proposed rule was unclear on this issue (*See*, Wrenn, Tr. 37) although it was intended that employers, as with other compliance obligations, would have to bear the costs of making requested records available. Several participants urged that employers explicitly be required to bear the expense of providing copies of requested records (Right to Know Coalition, Ex. 2(103), p. 1; USWA, Ex. 160, p. 23, Tr. 669; ICWU, Ex. 28, p. 9). Other participants complained that the proposal was open-ended and provided no disincentive for employees and designated representatives who might abuse access rights through the submission of large numbers of superfluous requests, the costs of which would presumably be borne by employers (Shell Oil Co., Ex. 2(105), p. 8; Xerox Corp., Ex. 2(136), pp. 1–2; Am. Trucking Assn., Ex. 2A(1), pp. 6–7; NAM, Tr. 2180–83; API, Ex. 158, pp. 46–47). The language adopted in the final standard is responsive to all of these concerns.

It is OSHA's intention that should an employee or designated representative simply desire to examine and possibly hand copy a record, then the employer must bear all administrative costs associated with this opportunity. Abuse of this opportunity is unlikely since access will normally be on an employee's own time. Should the employee or representative desire an exact copy of a record, the standard enables the copying to occur at minimal cost to the employee, while also providing the employer the flexibility to minimize costs and prevent abuse. On the first occasion that an employee or designated representative requests a copy of the record, the employer has three choices. The employer can assure that (1) a copy is provided without cost, (2) the necessary mechanical copying facilities (e.g., photocopying) are made available without cost so that the employee or representative can make an exact copy at the employer's site, or (3) the record is loaned for a reasonable time to enable an exact copy to be made. An employer can avoid abuse through use of the latter two alternatives, and minimize costs by copying records once and loaning out the copy when requested. The most an employee or representative would ever have to pay would be what it costs to have records copied at one's own initiative.

In addition, the standard provides that "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." "Administrative" costs are not meant to encompass overhead or capital costs. Two other limiting phrases are added. First, "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." Second, "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." Collective bargaining agents are given special status as designated representatives under this rule, and their ability to obtain a copy of records to use on behalf of all employees should not be encumbered by the fact that a copy of a record was previously provided to a specific employee. However, once a copy of a record has been provided to a collective bargaining agent, the employer may charge for subsequent requests by an employee, by the union, or by another designated representative. As a result, once a copy of an exposure record or an analysis of records has been provided to the union, the opportunity of the employer to charge for subsequent requests will prevent any possibility of abuse of the rule's access rights.

Subparagraph (e)(1) contains one more provision which was suggested during the rulemaking (USWA, Ex. 160, p. 21). The standard provides that "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." This language makes it clear that the final rule establishes only minimal obligations under the Act, and that collective bargaining agents may have or may bargain for additional access rights. Unions may, for example, desire to bargain for automatic provision of records to employees, for summaries and analyses of records to be prepared and made available to workers and the union, or for major epidemiological studies to be conducted using employee records. The agency's approach is in no way intended to impede innovative programs by employers, employees, and their unions.

Subparagraph (e)(2) of the final standard governs employee and designated representative access to records. Subparagraph (e)(2)(i) concerns employee exposure records. Employees are provided access to "relevant" employee exposure records, which consist of four kinds of employee exposure records. An employee first is assured access to "records of the employee's past or present exposure to toxic substances or harmful physical agents." The relevance of these records is obvious.

Second, an employee is assured 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." Access to records of other employees is provided in recognition of the fact that most environmental monitoring using personal samples is conducted on a representative sample basis. Therefore, to discover his or her own exposure, an employee may have to rely on measurements taken concerning other employees. Also, access to exposure records of other employees will enable analysis of the role of work practices and personal hygiene in minimizing exposure (Dr. Wegman, Ex. 10, p. 8). The Health Research Group was concerned over the privacy implications of an employee's knowing another employee's exact exposure and expressed the fear that disclosure of this information could lead to an employee's being discriminated against when seeking future employment or other benefits (HRG, Tr. 2043–45). The agency, however, agrees with other participants that the privacy interests involved in exposure records are minimal, and any risk of harm is clearly outweighed by the need for access (Weiner, Tr. 195;

AFL–CIO, Ex. 152, pp. 55–56; Samuels (AFL–CIO IUD), Ex. 36, pp. 3–4). It is OSHA's judgment that a potential employer, insurance company, or other person inclined to discriminate against an employee on the basis of prior exposure to toxic substances or harmful physical agents could easily discriminate simply by knowing what job an employee did and where; the employee's exact extent of exposure would not be needed.

The third kind of "relevant" employee exposure records covered by the final standard are "records containing exposure information concerning the employee's workplace or working conditions." These records would include area, grab, or wipe samples which would not specifically characterize the exact exposure of any one employee. Also included would be material safety data sheets and other records which simply reveal the identity of a toxic substance or harmful physical agent.

The fourth kind of "relevant" records are "exposure records pertaining to workplaces or working conditions to which the employee is being assigned or transferred." This substitutes for the phrase "potential exposure" in paragraph (d)(2) of the proposed rule (43 FR 31374), and will permit workers "to better understand the risks they might assume by bidding on a job, the specifics of which they are not well-acquainted with until they actually enter the job category" (Dr. Wegman, Ex. 10, p. 8). The use of "pertaining to" is meant to cover those exposure records the employee would have access to if actually working in the new job.

Subparagraph (e)(2)(i) provides designated representatives of an employee with access to employee exposure records equal to that of the employee. Given the definition of "designated representative," this will normally require some written authorization from the employee. The final standard contains no rigid criteria as to what this written authorization must say. Any written statement which is signed and indicates that the designated representative is authorized to exercise the employee's right of access will suffice. "Designated representative," however, is defined to automatically include recognized or certified collective bargaining agents for the purpose of exposure records and analyses of exposure or medical records. Collective bargaining agents thus do not have to obtain a written authorization to gain access to these records. Occupational safety and health matters are a well established subject for collective bargaining and union officials will undoubtedly frequently act on behalf of bargaining unit employees in exercising rights of access under this standard. Collective bargaining agents also have rights under several provisions of the Act to act on behalf of their members (*See, e.g.*, §§ 8(e), 8(f)(1), 8(f)(2), 10(c), 13(d) 20(a)(6) of the Act, 29 U.S.C. 657(e), 657(f)(1), 657(f)(2), 659(c), 662(d), 669(a)(6)). Requiring separate written authorization from each employee in the bargaining unit before a union could seek access to all relevant exposure records concerning the bargaining unit would pose unreasonable burdens and would be contrary to the status that is afforded to the union by law.

Subparagraph (e)(2)(ii) governs employee and designated representative access to employee medical records. The contents of this subparagraph have largely been discussed previously in Section IV of the preamble, Central Factual and Policy Issues Concerning Access to Records. First, employees are afforded direct access to their own medical records, subject to one limited exception applicable to potentially harmful information involving terminal illness, or psychiatric conditions. Access of an employee is provided only to medical records of which the employee is the subject; in all other cases specific written consent must be obtained. Second, a designated representative of an employee may gain access to an employee's medical records only through the specific written consent of the employee. This restriction applies to all designated representatives, including collective bargaining agents. Paragraph (c) defines "specific written consent" in detail, and Appendix A has been added as a sample form reflecting this definition. Appendix A satisfies the requirements of the standard but is offered as a sample form, not as a mandatory requirement.

Third, the final rule explicitly authorizes physicians on behalf of employers to make recommendations to employees and designated representatives in connection with the exercise of access rights under this section. The physician may recommend a consultation for the purposes of reviewing and discussing requested records, or may urge that a summary of material facts and opinions be accepted in lieu of the records requested. Other possible recommendations would include the physician urging that requested records be provided only to a physician or other designated representative. These provisions were added to the final standard to make it clear that physicians (not non-medical management personnel) could in their professional judgment recommend alternative or additional means of informing workers of the contents of their medical records other than by direct access to the records. The physician, however, may only make recommendations to the employee or designated representative; full access under the standard must be provided where the employee or designated representative chooses not to follow the recommendations, with the one exception noted below.

Fourth, the final standard does give physicians limited discretion to deny direct employee access to portions of medical records in certain circumstances. In the narrow situation where a specific diagnosis of a terminal illness or psychiatric condition is involved, there may be some cases where direct employee/patient access to this information could possibly prove harmful to the employee's health. In recognition of this possibility, the final rule adopts the recommendation made by the Privacy Commission. If a physician representing the employer believes that direct access to this information could be detrimental to the employee's health, the employer may deny the employee's request for direct access to this information. The employer must, however, inform the employee that access will be provided to a designated representative having specific written consent. Where the employee designates a representative to receive the medical information, the employer must assure that access is provided to the designated representative, even where it is known in advance that the designated representative will give the employee full access to the requested information. The designated representative will then be the ultimate judge of whether and in what manner the employee/patient should have full acess to the information.

Lastly, the final standard authorizes the deletion from requested medical records of the identity of a family member, personal friend, or fellow employee who has provided confidential information concerning an employee's health status. As noted in Chapter IV, Central Factual and Policy Issues Concerning Access to Records, several participants argued that information contained in medical records provided by confidential informants should not be disclosed to an employee due to confidentiality expectations and the possibility even of violence. Confidential informants could include

family members, personal friends, and fellow workers. Dr. Young expressed strong doubts that company physicians often receive confidential information from a worker's family (Tr. 1109), and it is probably also rare that friends of an employee engage in these communications. Where such communications do occur, Dr. Teitelbaum described in some detail how he as a physician would disclose to the patient the identity of the informant and the content of his or her communication (Tr. 137–140). This is a very sensitive area, however, and in this narrow situation, OSHA decided that the identities of personal friends, fellow employees, and family members who may have provided confidential information may be deleted prior to disclosure of the medical record. This is the one area where OSHA believes that legitimate expectations of confidentiality have been created which override whatever marginal occupational safety and health purpose would be served if disclosure of the informant's identity was provided. This provision, however, is limited to the identities of fellow employees, personal friends, and family members, on the basis that those who stand outside this personal relationship, such as the employer (i. e., supervisory and managerial employees) or another physician or medical person, are not justified in any expectation of confidentiality and should not be so insulated from disclosure. Moreover, the substance of the information provided by the family member, friend, or fellow employee must be disclosed to the extent that this would not clearly identify the informant. Observations of a worker's strange behavior or apparent poor health status could be highly relevant to occupational disease; for example, where unusual behavior is the consequence of an unrecognized central nervous system disorder.

Subparagraph (e)(2)(iii) governs employee and designated representative access to analyses using exposure of medical records. Access to these records was provided in the proposed rule (43 FR 31374), and several participants endorsed worker and designated representative access to these records (AFL–CIO, Ex. 152, pp. 54–55, Ex. 39, p. 5; USWA, Ex. 160, p.15; United Technologies Corp., Ex. 2(6), p. 1; Deere and Co. Ex. 2(84), p. 2; Union Carbide, Ex. 2(104), p. 4). These records will often be most valuable for efforts to detect, treat, and control occupational health problems. As a result, an employee or designated representative is assured direct access to analyses concerning the employee's working conditions or workplace. As to analyses using employee medical records, however, access without specific written consent is provided only where the analysis does not report the contents of employee medical records in a personally identifiable form. OSHA anticipates that in practice most analyses would not identify specific employees, but this will not necessarily always be the case. A listing of lung function results, for example, may list the employee names with the laboratory results. The final standard provides that the employer shall assure that personal identifiers are removed before access is provided. Personal identifiers are defined as either a "direct identifier (name, address, social security number, payroll number, etc.)" or "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.)." A reasonableness qualification was added since the number of employees involved and the manner in which the data is presented will affect whether or not factors such as age or job title can be used to identify specific employees. The final rule also provides that "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."

Once aggregate medical information is reported in a non-identifiable form such as in most research studies, there are no substantial privacy interests to be served by preventing direct access by those most interested in the analysis. Accordingly, the final rule provides for access to analyses without any prior showing of written consent by each employee whose records are part of the analyses.

Subparagraph (e)(3) of the final standard governs OSHA access to records. As was the case with the proposed rule, the final standard requires that employers assure OSHA access to all records subject to this section. This access is to be "immediate." As explained earlier in the preamble, this access is also not conditioned on employee consent. Due to the strong personal privacy interests associated with employee medical records, however, the agency is simultaneously promulgating strict rules of practice and procedure governing OSHA access to employee medical records (and any analyses using employee medical records which report the contents of employee medical records in personally identifiable form). These administrative regulations specify the mechanism by which the agency will seek access to medical records, and how the records will be handled once in the agency's possession.

One route by which the agency will seek access to personally identifiable employee medical information is by presenting to the employer a written access order approved by the Assistant Secretary. In order to inform employees of the contents of this order, the final standard provides that "the employer shall prominently post a copy of the written access order and its accompanying cover letter for at least fifteen (15) working days."

Finally, subparagraph (e)(3) unlike the proposal does not address NIOSH access to records. Due to the differences between NIOSH and OSHA's functions, responsibilities, and personnel, it was felt that no one set of administrative or substantive regulations was fully adequate for both agencies. NIOSH has independent legal authority to seek access to employee exposure and medical records; thus their exclusion from this rule will not affect NIOSH's operations.

F. Paragraph (f)—*Trade secrets*

Section IV.F of the preamble, *supra*, explains in detail the agency's decisionmaking as to trade secret issues. Section V.B, *supra*, explains the legal analysis which underlies and supports OSHA's policy determinations. The final standard accommodates trade secret concerns so far as possible, but where irreconcilable conflicts arise, the public health interest in access prevails. For example, employers may not delete from requested records "chemical or physical agent identities including chemical names, levels of exposure, or employee health status data." The use of "identities" is meant to preclude the withholding of chemical names as well as trade names. The use of "health status data" is meant to encompass any kind of medical information concerning an employee.

Although identities, levels of exposure, and health status data may not be withheld, the employer may delete "any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in a mixture, as long as the employee or designated representative is notified that information has been deleted." In addition, the final rule provides that an employer may require as a condition of access to trade secrets "that the employee or designated representative agree in writing not to use the trade secret information for the

purpose of commercial gain and not to permit misuse of the trade secret information by a competitor or potential competitor of the employer." This provision will assure that an employer's statutory or common law remedies are effectively brought to the recipient's attention. This will preserve an employer's rights even in the event that an employee or designated representative attempts to misuse protected trade secret information. This provision is intended to enable employers to establish a basic contractual obligation not to misuse trade secret information, but may not be used as a pretext for more onerous requirements such as the posting of penalty bonds, liquidated or punitive damages clauses, or other preconditions. The employer may, however, prominently label released documents as containing trade secret information so that anyone who misuses the documents does so with actual notice of its protected status.

The final standard contains one other provision addressed to situations where an employer may properly delete information from a record. OSHA can envision situations, for example, where exposure records contain specifications of where and when samples were collected such that the "where and when" possibly constitute or reveal trade secrets. The "where" might be five feet above a piece of confidential process equipment described by its technical name; the "when" might be ten minutes after a secret chemical reaction becomes evident by a specified temperature change. These kinds of trade secret information may be withheld, but doing so might eliminate any possibility of adequately interpreting the results obtained. Accordingly, the rule provides that "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 employee to identify where and when exposure occurred." The alternative information must be in a form employees will understand, such as "five feet above pump No. 7" or "the pump closest to the office." Employees already know the way that their workplaces are set up or designed and the steps followed in manufacturing processes. In some cases alternative information could itself be a trade secret, but it must nonetheless be provided since it is needed and employees already know it. This information, as with all other trade secret information provided, can be made the subject of a written agreement not to misuse the information.

G. Paragraph (g)—*Employee information*

Paragraph (g) of the final standard contains basic employee information requirements similar to those of the proposed rule (43 FR 31374). The final standard provides that employers must inform employees of "(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." Employers must complete this instruction within sixty (60) days of the standard's effective date for current employees, and annually thereafter. As recommended by Dr. Teitelbaum (Tr. 126), equivalent information must also be provided to new employees upon their first entering employment. These information requirements are intended to maximize employee awareness of their rights under this standard so that access will be utilized to help detect, treat, and prevent occupational disease. Several participants endorsed the importance of these basic requirements (Dr. Parkinson, Ex. 43, pp. 5–6; Dr. Wegman, Tr. 209; Spatz (Cement, Lime and Gypsum Workers), Tr. 1204).

Several industry participants argued that the employee instruction provisions of the proposal were too burdensome (Skiba (Magma Copper), Tr. 1455; Xerox Corp., Ex. 2(136), p. 1). Specifically, the obligation to inform "each" employee was challenged since it was thought to connote a duty to advise employees individually. It was suggested that alternative means exist to inform employees (bulletin board notice, etc.) which would both satisfy the intent of the provision to apprise employees of this regulation and place a minimal burden on the employer. The Xerox Corp. further suggested that the employee rights of access could be expressed on the annual Summary of Occupational Injuries and Illnesses which employers are currently required to post (Ex. 2(136), p. 1). Counter to these arguments were the comments of the Right to Know Coalition (Ex. 2(103), p. 2). The Coalition argued that to apprise employees adequately of their rights under this rule, the employer should provide written notice to each employee individually and assure that the records are legible and in a language understood by the employees.

The agency believes that employee information is crucial, but the final standard, in order to minimize unnecessary burdens on employers, is deliberately flexible. Employers may use any method which will effectively apprise employees of their rights, including posting, group discussions, or individual notification. The agency believes that a requirement of written notification to each employee is unnecessary in this case. Several other minor provisions have been added, however, to improve the ability of workers to exercise rights under this rule.

The final standard, as is the case with other OSHA health standards, provides that employers "shall make readily available to employees a copy of this standard and its appendices." Ready access to the standard itself will better enable employees to exercise their rights. In addition, the final rule provides that the employer "shall distribute to employees any informational materials concerning this standard which are made available to the employer" by OSHA. OSHA intends to develop specific training and educational materials concerning this standard for distribution and presentation to employees. The standard's provision will assure effective distribution of these materials when they are completed.

H. Paragraph (h)—*Transfer of records*

A remaining issue concerns the possible transfer of records when an employer goes out of business, or when the preservation periods of the standard expire. The preamble to the proposed rule invited comments on this issue (42 FR 31373). Several participants urged that successor employers assume the obligations of prior employers (HRG, Tr. 2035–36; AFL–CIO, Ex. 152; p. 47; ICWU, Ex. 28, p. 12), and the final rule so provides. The final standard also requires an employer who is going out of business in situations where there will be no successor employer to notify his employees of their access rights at least three months in advance of ceasing to do business. This notification requirement is considered appropriate to assure that employees in this situation are given the opportunity to exercise their rights before, as a practical matter, they may be lost to them forever.

Several other suggestions were made as to what to do when there is no successor employer. Direct transfer to NIOSH was recommended (AFL–CIO, Ex. 152, p. 47; ICWU, Ex. 28, p. 12) as was direct transfer to employees (Cement, Lime and Gypsum Workers, Tr. 1203). Recent OSHA health standards specify direct transfer to NIOSH ((inorganic lead) 29 CFR 1910.1025(n)(5)(ii), 43 FR 53014 (Nov. 14,

1978); (cotton dust) 29 CFR 1910.1043(k)(4)(ii), 43 FR 27398 (June 23, 1978)), as does the model standard contained in OSHA's recent cancer policy standard (29 CFR 1990.151(q)(4), 45 FR 5292 (Jan. 22, 1980). The final standard provides that, if a specific standard requires the transfer of records to NIOSH, its transfer requirement must be followed. NIOSH endorsed this mandatory transfer approach (NIOSH, Ex. 16, p. 11). Mandatory transfer will enable NIOSH to eventually assess the adequacy of the specific standard's protective provisions.

Where no specific health and safety standard applies to the records being disposed of, OSHA does not believe it is appropriate to mandate automatic transfer of the records to either NIOSH or OSHA. The records may or may not be valuable for future epidemiological investigations. Rather than mandate automatic transfer, the final rule provides a three months notification to NIOSH requirement. This notification will given NIOSH and OSHA an opportunity to initiate appropriate action based on the circumstances of each situation.

The final standard also recognizes that the thirty (30) year preservation requirements may continuously be expiring as to various records, such that records are disposed of quite frequently. Rather than require notice to NIOSH each time a record is discarded, the rule provides:

> Where an employer regularly disposes of records required to be preserved for at least thirty (30) years, the employer may, with at least three (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. Paragraph (i)—*Appendices*

The appendices included with the standard are intended to provide information and are not intended to create any additional obligations not otherwise imposed. This applies both to Appendix A and B and any other appendix that may subsequently be issued.

J. Paragraph (j)—*Effective date*

The effective date of this standard is ninety (90) days after the rule is published in the **Federal Register**. This three month period is intended to provide sufficient time for employers and employees to become informed of the existence of the standard and its requirements. With the exception of initial employee information requirements, all obligations of the rule commence on its effective date. An extra sixty (60) days are given for employers to provide the information required in subparagraph (g)(1) to employees employed on the effective date.

Any petitions for administrative relief from this final standard, including an administrative stay pending judicial review, must be filed with the Assistant Secretary of Labor for Occupational Safety and Health within 45 days of the publication of this standard in the **Federal Register**. Any petitions filed after this date will be considered untimely. This requirement is considered essential to permit the agency to give full consideration to each petition and respond in advance of the effective date of the standard.

K. Conforming amendments

The access proposal indicated OSHA's intention to make necessary conforming amendments to current OSHA standards such as those in subparts T and Z of Part 1910 so that their access provisions would be consistent with the final access standard (43 FR 31372). The terms of current OSHA records access requirements, such as those in the vinyl chloride standard (29 CFR 1910.1017(m)(4)—(m)(6)) and the cotton dust standard (29 CFR 1910.1043(k)(3)(ii)—(k)(3)(iv)), are less detailed than and in some respects inconsistent with the provisions of the new access standard. Also, existing provisions are in some cases not as effective as the provisions of the new rule in providing for employee and designated representative access to personal monitoring and medical data.

Furthermore, while specific standards all provide for OSHA access to mandated records, 29 CFR 1910.20, as set forth below, also affects OSHA's access to these records. As a companion document to 29 CFR 1910.20, OSHA has promulgated administrative regulations at 29 CFR 1913.10 entitled "Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records". By its terms, 29 CFR 1913.10 applies to OSHA access to personally identifiable employee medical information which is required to be kept by specific OSHA standards. Since 29 CFR 1910.20(e)(3) references 29 CFR 1913.10 as governing OSHA access to employee medical records, the conforming amendments serve to make section 1913.10 applicable to the many standards in Part 1910 which currently contain specific provisions for OSHA access to mandated medical records. On the other hand, since some specific standards provide for certain records such as equipment inspection records (commercial diving) and authorized personnel rosters (vinyl chloride) which are not covered by section 1910.20, general provisions which provide for OSHA and NIOSH access to all records under particular standards have been left unchanged by the conforming amendments.

The necessary conforming amendments which are being made to existing records access provisions of Part 1910 clarify that 29 CFR 1910.20 governs employee, designated representative, and OSHA access to exposure and medical records created pursuant to specific occupational safety and health standards. To avoid confusion, the definitions contained in paragraph (c) of section 1910.20 shall control in the amended provisions. For instance, the term "employee" in the amended provisions includes current employees, former employees, and employees being assigned or transferred to work where there will be exposure to a toxic substance or harmful physical agent (*See*, 29 CFR 1910.20(c)(4)). The term "designated representative" as defined in 29 CFR 1910.20(c)(3) includes individuals or organizations 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 is treated automatically as a designated representative without regard to written employee authorization.

Paragraph (f) of 29 CFR 1910.20 concerning trade secrets is not applied by the conforming amendments to these existing standards since records mandated by specific standards have not contained trade secrets and there has been no need to structure special protections for trade secrets in the context of these specific standards. The current provisions for NIOSH access to records also remain unchanged by these conforming amendments. Furthermore, the records preservation requirements of the specific standards are not affected by these conforming amendments. For example, medical records required by the vinyl chloride standard must still be maintained for the duration of the employment of each employee plus 20 years, or 30 years, whichever is longer (*See*, 29 CFR 1910.1017(m)(2)(iii)).

The following paragraphs are being amended to include the foregoing conforming amendments:

Section 1910.440 (b)(2)
Section 1910.1001 (i)(2), (j)(6)(ii)
Section 1910.1003 (g)(2)(ii)
Section 1910.1004 (g)(2)(ii)
Section 1910.1006 (g)(2)(ii)
Section 1910.1007 (g)(2)(ii)

Section 1910.1008 (g)(2)(ii)
Section 1910.1009 (g)(2)(ii)
Section 1910.1010 (g)(2)(ii)
Section 1910.1011 (g)(2)(ii)
Section 1910.1012 (g)(2)(ii)
Section 1910.1013(g)(2)(ii)
Section 1910.1014(g)(2)(ii)
Section 1910.1015(g)(2)(ii)
Section 1910.1016(g)(2)(ii)
Section 1910.1017(m)(2)–(m)(6)
Section 1910.1018(q)(3)(ii)–(q)(3)(iii);
Appendix A (Section VIII)
Section 1910.1025(n)(4)(ii)–(iii)
Section 1910.1028(l)(3)(ii)–(l)(3)(iv);
Appendix A (Section VII)
Section 1910.1029(m)(3)(ii)–(m)(3)(iv)
Section 1910.1043(k)(3)(ii)–(k)(3)(iv)
Section 1910.1044(p)(3)(ii)–(p)(3)(iv)
Section 1910.1045(q)(4)(ii)–(q)(4)(iii);
Appendix A (Section VII.D.)
Section 1910.1046(h)(2)(ii)
Section 1990.151(q)(3)(ii)–(q)(3)(iii)
Section 1990.152(q)(3)(i)–(q)(3)(iii)

Finally, these conforming amendments do not amend existing "transfer of records" provisions in specific standards; i.e., those provisions in existing standards which require employers to transfer certain mandated records to NIOSH either upon going out of business or upon the expiration of the standard's records preservation period. However, paragraph 1910.20(h), which is being incorporated into the specific standards by these conforming amendments, does contain some additional requirements, particularly involving notification of employees when an employer is going out of business. These requirements in paragraph 1910.20(h) are meant to apply to employers covered by the specific standards. Accordingly, the following sections of specific standards are being amended or added to best clarify this intent:

Section 1910.440(b)(4)
Section 1910.1017(m)(3)
Section 1910.1018(q)(4)(iv)
Section 1910.1025(n)(5)(iv)
Section 1910.1028(l)(4)(iv)
Section 1910.1029(m)(4)(iv)
Section 1910.1043(k)(4)(iv)
Section 1910.1044(p)(4)(iv)
Section 1910.1045(q)(5)(iv)
Section 1910.1046(h)(3)(iv)
Section 1990.151(q)(4)(iv)

All the above-referenced conforming amendments will go into effect when 29 CFR 1910.20 becomes legally effective.

VIII. Authority, Signature, and the Standard

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

The **Federal Register** has been requested to officially file this document at 1 p.m. E.D.T. on May 21, 1980, which shall be the time of issuance of this document as provided by 29 CFR 1911.18. The time of issuance is the earliest moment that petitions for judicial review may be filed.

Accordingly, pursuant to sections 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1599, 1600; 29 U.S.C. 655, 657), the Secretary of Labor's Order 8–76 (41 FR 25059) and 29 CFR Part 1911, Chapter XVII of Title 29, the Code of Federal Regulations is hereby amended by revising section 1910.20 and by adding Appendices A and B, and by making conforming amendments to existing occupational safety and health standards in Part 1910.

Signed at Washington, D.C., this 14th day of May 1980.

Eula Bingham,

Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations (CFR) is amended as follows:

Subpart C—General Safety and Health Provisions

1. Section 1910.20 is revised to read as follows, including the addition of Appendices A and B:

§ 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 employees exposed to toxic substances or harmful physical agents, whether or not the records are related to 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 or 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 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 research, statistical or other 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

concerning employee exposure to toxic substances or harmful physical agents:

(i) environmental (workplace) monitoring or measuring, 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 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;

(iii) material safety data sheets; or

(iv) in the absence of the above, any other record which reveals 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 X-ray examinations and all biological monitoring),

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

(D) descriptions of treatments and prescriptions, and

(E) employee medical complaints.

(ii) "Employee medical record" does not include the following:

(A) physical specimens (e.g., blood or urine samples) which are routinely discarded as a part of normal medical practice, and are not required to be maintained by other legal requirements,

(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 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) "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).

(10) "Specific written consent" (i) 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 this 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.

(11) "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 regulated by any Federal law or rule due to a hazard to health,

(ii) is listed in the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS) (*See* Appendix B),

(iii) 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, or

(iv) has a material safety data sheet available to the employer indicating that the material may pose a hazard to human health.

(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.* Each employee medical record shall be preserved and maintained for at least the duration of employment plus thirty (30) years, except that health insurance claims records maintained separately from the employer's medical program and its records need not be retained for any specified period;

(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 so long as the sampling results, the collection methodology (sampling plan), a description of the analytical and mathmematical 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; and

(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 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.

(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, but in no event later than fifteen (15) days after the request for access is made.

(ii) Whenever an employee or designated representative requests a copy of a record, the employer shall, within the period of time previously specified, 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.

(iii) 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.

(iv) 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.* Each employer shall, upon request, assure the access of each employee and designated representative to employee exposure records relevant to the employee. For the purpose of this section, exposure records relevant to the employee consist of:

(A) records of the employee's past or present exposure to toxic substances or harmful physical agents,

(B) exposure records of other employees with past or present job duties or working conditions related to or similar to those of the employee,

(C) records containing exposure information concerning the employee's workplace or working conditions, and

(D) exposure records pertaining to workplaces or working conditions to which the employee is being assigned or transferred.

(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) below.

(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) Nothing in this section precludes a physician, nurse, or other responsible health care personnel maintaining employee medical records from deleting 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 employer 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, assure the immediate 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 an employee or designated representative any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in a mixture, as long as the 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 employee to identify where and when exposure occurred.

(2) Notwithstanding any trade secret claims, whenever access to records is requested, the employer shall provide

access to chemical or physical agent identities including chemical names, levels of exposure, and employee health status data contained in the requested records.

(3) Whenever trade secret information is provided to an employee or designated representative, the employer may require, as a condition of access, that the employee or designated representative agree in writing not to use the trade secret information for the purpose of commercial gain and not to permit misuse of the trade secret information by a competitor or potential competitor of the employer.

(g) *Employee information.* (1) 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 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 make readily available to employees a copy of this standard and its appendices, and shall distribute to employees any informational materials concerning this standard 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 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 the appendices 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.

(j) *Effective date.* This section shall become effective on August 21, 1980. All obligations of this section commence on the effective date except that the employer shall provide the information required under paragraph (g)(1) of this section to all current employees within sixty (60) days after the effective date.

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

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) [1]

The final standard, 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)(11) to encompass chemical substances, biological agents, and physical stresses for which there is evidence of harmful health effects. The standard 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 standard 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 standard 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 standard. 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 1978 edition is the most recent printed edition as of May 1, 1980. Its Foreward and Introduction describes the RTECS as follows:

"The annual publication of a list of known toxic substances is a NIOSH mandate under the Occupational Safety and Health Act of 1970. It is intended to provide basic information on the known toxic and biological effects of chemical substances for the use of employers, employees, physicians, industrial hygienists, toxicologists, researchers, and, in general, anyone concerned with the proper and safe handling of chemicals. In turn, this information may contribute to a better understanding of potential occupational hazards by everyone involved and ultimately may help to bring about a more healthful workplace environment. (p. iii)

"This Registry contains 124,247 listings of chemical substances: 33,929 are names of different chemicals with their associated toxicity data and 90,318 are synonyms. This edition includes approximately 7,500 new chemical compounds that did not appear in the 1977 Registry. (p. xiii)

"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

[1] On April 24, 1980, the Director of the Federal Register approved for incorporation by reference into 29 CFR 1910, the 1978 edition of the National Institute for Occupational Safety and Health Registry of Toxic Effects of Chemical Substances (the Registry). (See 29 CFR 1910.20 (c)(11)(ii)).

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 alternate processes which may be less hazardous. (p. xiii)

"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. Data may be used for the evaluation of chemical hazards in the environment, whether they be in the workplace, recreation area, or living quarters. (p. xiii)

"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. (p. xiv)"

The RTECS 1978 printed edition may be purchased for $13.00 from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, D.C. 20402 (202-783-3238) (Order GPO Stock No. 017-033-00346-7). The 1979 printed edition is anticipated to be issued in the summer of 1980. Some employers may also 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 for $14.00 (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, N.W., Washington, D.C. 20210 (202-523-9700), or at any OSHA Regional or Area Office (*See*, major city telephone directories under United States Government-Labor Department).

Subpart T—Commercial Diving Operations

2. Section 1910.440 is amended by revising paragraphs (b)(2) and (b)(4) to read as follows:

s1910.440 Recordkeeping requirements.

* * * * *

(b) * * *

(2) Records and documents required by this standard shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)-(e) and (g)-(i). Safe practices manuals (s1910.420), depth-time profiles (s1910.422), recordings of dives (s1910.423), decompression procedure assessment evaluations (s1910.423), and records of hospitalizations (s1910.440) shall be provided in the same manner as employee exposure records or analyses using exposure or medical records. Equipment inspections and testing records which pertain to employees (s1910.430) shall also be provided upon request to employees and their designated representatives.

* * * * *

(4) After the expiration of the retention period of any record required to be kept for five (5) years, the employer shall forward such records to the National Institute for Occupational Safety and Health, Department of Health and Human Services. The employer shall also comply with any additional requirements set forth at 29 CFR 1910.20(h).

* * * * *

Subpart Z—Toxic and Hazardous Substances

3. Section 1910.1001 is amended by revising paragraphs (i)(2) and (j)(6)(ii) to read as follows:

s1910.1001 Asbestos.

* * * * *

(i) * * *

(2) *Access.* Employee exposure records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)-(e) and (g)-(l).

* * * * *

(j) * * *

(6) * * *

(ii) *Access.* Records of the medical examinations required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)-(e) and (g)-(i). These records shall also be provided upon the request to the Director of NIOSH. Any physician who conducts a medical examination required by this paragraph shall furnish to the employer of the examined employee all the information specifically required by this paragraph, and any other medical information related to occupational exposure to asbestos fibers.

4. Section 1910.1003 is amended by revising paragraph (g)(2)(ii) to read as follows:

s1910.1003 4-Nitrobiphenyl.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)-(e) and (g)-(i). These records shall also be provided upon request to the Director.

* * * * *

5. Section 1910.1004 is amended by revising paragraph (g)(2)(ii) to read as follows:

s1910.1004 alpha-Naphthylamine.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)-(e) and (g)-(i). These records shall also be provided upon request to the Director.

* * * * *

6. Section 1910.1006 is amended by revising paragraph (g)(2)(ii) to read as follows:

s1910.1006 Methyl chloromethyl ether.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)-(e) and (g)-(i). These records shall also be provided upon request to the Director.

* * * * *

7. Section 1910.1007 is amended by revising paragraph (g)(2)(ii) to read as follows:

s1910.1007 3-3'-Dichlorobenzidine (and its salts).

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)-(e) and (g)-(i). These records shall also be provided upon request to the Director.

* * * * *

8. Section 1910.1008 is amended by revising paragraph (g)(2)(ii) to read as follows:

s1910.1008 bis-Chloromethyl ether.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

9. Section 1910.1009 is amended by revising paragraph (g)(2)(ii) to read as follows:

s 1910.1009 beta-Naphthylamine.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

10. Section 1910.1010 is amended by revising paragraph (g)(2)(ii) to read as follows:

s 1910.1010 Benzidene.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

11. Section 1910.1011 is amended by revising paragraph (g)(2)(ii) to read as follows:

s 1910.1011 4-Aminodiphenyl.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

12. Section 1910.1012 is amended by revising paragraph (g)(2)(ii) to read as follows:

s 1910.1012 Ethyleneimine.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

13. Section 1910.1013 is amended by revising paragraph (g)(2)(ii) to read as follows:

s 1910.1013 beta-Propiolactone.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

14. Section 1910.1014 is amended by revising paragraph (g)(2)(ii) to read as follows:

s 1910.1014 2-Acetylaminofluorene.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

15. Section 1910.1015 is amended by revising paragraph (g)(2)(ii) to read as follows:

s 1910.1015 4-Dimethylaminoazobenzene.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

16. Section 1910.1016 is amended by revising paragraph (g)(2)(ii) to read as follows:

s 1910.1016 N-Nitrosodimethylamine.

* * * * *

(g) * * *

(2) * * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall also be provided upon request to the Director.

* * * * *

17. Section 1910.1017 is amended by revising the introductory text of paragraph (m)(2) and paragraph (m)(3) and removing paragraphs (m)(4), (m)(5) and (m)(6) to read as follows:

§ 1910.1017 Vinyl chloride.

* * * * *

(m) * * *

(2) Records of required monitoring and measuring and medical records shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i). These records shall be provided upon request to the Director. Authorized personnel rosters shall also be provided upon request to the Assistant Secretary and the Director.

(i) * * *

(ii) * * *

(iii) * * *

(3) In the event that the employer ceases to do business and there is no successor to receive and retain his records for the prescribed period, these records shall be transmitted by registered mail to the Director, and each employee individually notified in writing of this transfer. The employer shall also comply with any additional requirements set forth in 29 CFR 1910.20(h).

18. Section 1910.1018 is amended by revising paragraphs (q)(3)(ii) and Appendix A Section VIII, by removing paragraph (q)(3)(iii) and by adding paragraph (q)(4)(iv) to read as follows:

s1910.1018 Inorganic arsenic.

* * * * *

(q) * * *

(3)* * *

(ii) Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i).

(4)* * *

(iv) The employer shall also comply with any additional requirements involving the transfer of records set in 29 CFR 1910.20(h).

* * * * *

Appendix A—Inorganic Arsenic Substance Information Sheet

* * * * *

VIII. Access to Records

You or your representative are entitled to records of your exposure to inorganic arsenic and your medical examination records if you request your employer to provide them.

* * * * *

19. Section 1910.1025 is amended by revising paragraphs (n)(4)(ii), removing paragraph (n)(4)(iii) and by adding paragraph (n)(5)(iv) to read as follows:

§1910.1025 Lead.

* * * * *

(n)* * *

(4)* * *

(ii) Environmental monitoring, medical removal, and medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (2)–(i). Medical removal records shall be provided in the same manner as environmental monitoring records.

(5)* * *

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

* * * * *

20. Section 1910.1028 is amended by revising paragraphs (l)(3)(ii) and Appendix A Section VII, by removing paragraphs (l)(3)(iii) and (l)(3)(iv) and by adding paragraph (l)(4)(iv) to read as follows:

§1910.1028 Benzene.

* * * * *

(1)* * *

(3)* * *

(ii) Employee exposure measurement records and employee medical records required by this section shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

(4) * * *

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

* * * * *

Appendix A—Substance Safety Data Sheet, Benzene

* * * * *

VII. Access to Records.

You or your representative are entitled to see the records of your exposure to benzene and your medical examination records if you request your employer to provide them.

* * * * *

21. Section 1910.1029 is amended by revising paragraphs (m)(3)(ii), removing paragraphs (m)(3)(iii) and (m)(3)(iv), and by adding paragraph (m)(4)(iv) to read as follows:

§1910.1029 Coke oven emissions.

* * * * *

(m) * * *

(3) * * *

(ii) Employee exposure measurement records and employee medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

(4) * * *

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

* * * * *

22. Section 1910.1043 is amened by revising paragraphs (k)(3)(ii) by removing paragraphs (k)(3)(iii) and (k)(3)(iv) and by adding paragraph (k)(4)(iv) to read as follows:

§1910.1043 Cotton dust.

* * * * *

(k) * * *

(3) * * *

(ii) Employee exposure measurement records and employee medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i).

(4) * * *

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

* * * * *

23. Section 1910.1044 is amended by revising paragraphs (p)(3)(ii) by removing paragraphs (p)(3)(iii) and (p)(3)(iv) and by adding paragraph (p)(4)(iv) to read as follows:

§1910.1044 1,2-Dibromo-3-chloropropane.

* * * * *

(p) * * *

(3) * * *

(ii) Employee exposure monitoring records and employee medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

(4) * * *

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

* * * * *

24. Section 1910.1045 is amended by revising paragraphs (q)(4)(ii) and Appendix A section VI, D by removing paragraph (q)(4)(iii) and by adding paragraph (q)(5)(iv) to read as follows:

§1910.1045 Acrylonitrile.

* * * * *

(q) * * *

(4) * * *

(ii) Records required by paragraphs (q)(1)–(q)(3) of this section shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (q)–(i). Records required by paragraph (q)(1) shall be provided in the same manner as exposure monitoring records.

(5) * * *

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

* * * * *

Appendix A—Substance Safety Data Sheet for Acrylonitrile

* * * * *

VI. Access to Information

* * * * *

D. Your employer is required to release your exposure and medical records to you or your representative upon your request.

* * * * *

25. Section 1910.1046 is amended by revising paragraph (h)(2)(ii) and by adding paragraph (h)(3)(iv) to read as follows:

§1910.1046 Exposure to cotton dust in cotton gins.

* * * * *

(h) * * *

(2) * * *

(ii) Employee medical records shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

(3) * * *

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

* * * * *

26. Section 1990.151 is amended by revising paragraphs (q)(3)(ii) by removing paragraph (q)(3)(iii) and by adding paragraph (q)(4)(iv) to read as follows:

§1910.151 Model Standard pursuant to section 6(b) of the Act.

* * * * *

(q) * * *
(3) * * *

(ii) Employee exposure measurement records and employee medical records required by this section shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

(4) * * *

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

* * * * *

27. Section 1990.152 is amended by revising paragraphs (q)(3)(i) and (q)(3)(ii) and removing (q)(3)(iii) to read as follows:

s1990.152 Model Emergency Temporary Standard pursuant to section 6(c).

* * * * *

(q) * * *
(3) * * *

(i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure measurement records and employee medical records required by this section shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1990.20(a)–(e) and (g)–(i).

* * * * *

(Secs. 6(b), 8(c) and 8(g) (84 Stat. 1593, 1599, 1600; 29 U.S.C. 655, 657), the Secretary of Labor's Order 8–76 (41 FR 25059) and 29 CFR Part 1911, Chapter XVII of Title 29)

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29 CFR Part 1913

Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records

AGENCY: The Occupational Safety and Health Administration of the United States Department of Labor (OSHA).

ACTION: Final rule.

SUMMARY: These rules of agency practice and procedure, promulgated today as a new 29 CFR 1913.10, govern OSHA access to personally identifiable employee medical information contained in medical records. The rules are structured to protect the substantial personal privacy interests inherent in identifiable medical records, while also permit OSHA to make beneficial use of these records for proper occupational safety and health purposes. The rules regulate the manner in which OSHA will seek access to employee medical records, and how the medical information will be protected once in the agency's possession.

EFFECTIVE DATE: August 21, 1980.

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:

I. Introduction

The statement of reasons accompanying these regulations (the preamble) is divided into four parts, numbered I through IV. The following is a table of contents for this preamble:

Part III is a provision-by-provision discussion of the regulations in lettered paragraphs corresponding to the lettered paragraphs of the regulations. It provides a brief summary of each provision and the evidence and rationale supporting it. References to the rulemaking record in the text of the preamble are in parentheses, and the following abbreviations have been used:

1. Ex. : Exhibit number to Docket H–112
2. Tr. : Transcript page number

These rules of agency practice and procedure are issued pursuant to sections 8(c)(1) and 8(g) of the Occupational Safety and Health Act of 1970 ("the Act") (84 Stat. 1599, 29 U.S.C. 657), section (e) of the Privacy Act (5 U.S.C. 552a(e)), and the government's general housekeeping statute (5 U.S.C. 301).

A. Background

The Occupational Safety and Health Administration (OSHA) has today published a final standard, 29 CFR 1910.20, governing access to employee exposure and medical records. Subparagraph (e)(3) of section 1910.20 provides for unconsented OSHA access to personally identifiable employee medical records. The need for OSHA access to employee medical records, and the decisionmaking involved in providing for unconsented OSHA access, are explained in the preamble accompanying 29 CFR 1910.20. The final regulations set forth below as § 1913.10 of 29 CFR establish agency procedures governing OSHA access to these records. These rules of agency practice and procedure serve to (1) control the circumstances under which OSHA seeks access to personally identifiable medical records, and (2) protect personally identifiable medical information once it has been obtained by the agency. These procedures are intended to preclude possible misuse of employee medical records, while at the same time enable medical record information to play a constructive role in agency efforts directed to the prevention of occupational injury and disease.

B. History of the regulations

These final regulations, 29 CFR 1913.10, have been developed in concert with the promulgation of 29 CFR 1910.20. 29 CFR 1910.20 was first published on July 19, 1978 (43 FR 31019) as an interim final rule. This rule required the indefinite retention of employee exposure and medical records, and required that these records be made available upon request to OSHA and to NIOSH (the National Institute for Occupational Safety and Health). This interim final rule was followed by a proposed rule published on July 21, 1978 (43 FR 31371) which proposed to expand 29 CFR 1910.20 to include employee and employee representative access to employee exposure and medical records, whether or not these records were subject to specific occupational safety and health standards. The proposed rule also set a definite minimal time period for the retention of these records. OSHA gave interested persons until September 22, 1978 to present written comments, views or arguments on any issue raised by the proposal. A total of 211 initial comments were received. Based on the