(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:

I. Introduction
II. Pertinent Legal Authority
III. Summary and Explanation of the Regulations
A. Paragraph (a)—*General policy.*
B. Paragraph (b)—*Scope and application.*
C. Paragraph (c)—*Responsible persons.*
D. Paragraph (d)—*Written access orders.*
E. Paragraph (e)—*Presentation of written access order and notice to employees.*
F. Paragraph (f)—*Objections concerning a written access order.*
G. Paragraph (g)—*Removal of direct personal identifiers.*
H. Paragraph (h)—*Internal agency use of personally identifiable medical information.*
I. Paragraph (i)—*Security procedures.*
J. Paragraph (j)—*Retention and destruction of records.*
K. Paragraph (k)—*Results of an agency analysis using personally identifiable employee medical information.*
L. Paragraph (l)—*Annual report.*
M. Paragraph (m)—*Inter-agency transfer and public disclosure.*
N. Paragraph (n)—*Effective date.*
IV. Authority, Signature, and the Regulations

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

widespread interest evidenced by these comments, OSHA announced on October 6, 1978 (43 FR 46322) a schedule for public hearings on this proposal.

Hearings were held in Washington, DC from December 5–8, 1978 and from January 3–5, 1979; in Chicago, Illinois from December 12–13, 1978 and from January 9–10, 1979; and in San Francisco, California on December 15, 1978. A total of 85 individuals and organizations gave oral presentations, and the hearing transcript numbers 2542 pages.

OSHA has in the past exercised its authority to seek access to employee exposure and medical records as part of its regulatory and enforcement powers. For example, specific occupational safety and health standards have always provided for OSHA access to the records required by these standards. Nevertheless, inclusion of a general OSHA access provision in both the interim final rule and the proposed rule raised for public comment the question of the agency's policies and procedures governing access to, and use of, employee medical records. Numerous participants noted OSHA's lack of written procedures and policies concerning access to, and handling of, often highly sensitive medical information, and indicated that appropriate mechanisms protecting the confidentiality of accessed records should be developed (Cal. Dept. of Industrial Relations, Ex. 2(132), p. 3; National Commission on the Confidentiality of Health Records (NCCHR), Ex. 2(151), p. 2; Outboard Marine Corp., Ex. 2(183), pp. 6–8).

OSHA agreed with these concerns, and accordingly developed and made available for public comment draft administrative guidelines governing OSHA access to employee medical records. A copy of these draft guidelines was placed in the public rulemaking record (Docket No. H–112) of the proposed rule on November 24, 1978. OSHA official Grover Wrenn, in his opening statement at the December 5, 1978 hearings, announced the public availability of the guidelines (Tr. 15–16). On January 19, 1979, an additional public notice of the availability of the draft guidelines was published in the **Federal Register** (44 FR 3994). In that notice, OSHA gave the public until March 1, 1979, to comment on the draft guidelines. In addition, OSHA announced its intention to issue the final guidelines as regulations and to limit their scope to confidential medical information, and not apply them to trade secret information. On February 27, 1979 (44 FR 11096) the comment period was extended to March 30, 1979. A total of 43 comments were received into a separate docket created to receive these comments (Docket No. H–112A). The regulations below are based on the total record in Dockets No. H–112 and H–112A and on the agency's experience and expertise.

II. Pertinent Legal Authority

The legal authority for these procedural regulations is found in sections 8(c)(1) and 8(g)(2) of the Occupational Safety and Health Act ("The Act"), 29 U.S.C. 657; in section (e) of the Privacy Act, 5 U.S.C. 552a(e); and in 5 U.S.C. 301.

Section 8(c)(1) of the Act provides that:

> [E]ach employer shall make, keep, preserve, and make available to the Secretary [of Labor] or the Secretary of Health, Education, and Welfare, 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.

Employee medical records are included within the type of records addressed by this provision.

Section 8(g)(2) is the general rulemaking authority of the Act and states that:

> [T]he Secretary and the Secretary of Health, Education, and Welfare, shall each prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under the Act, including rules and regulations dealing with the inspection of an employee's establishment.

These procedural regulations are deemed necessary to enable beneficial use of employee medical records consistent with the employee's right of privacy.

The Privacy Act, 5 U.S.C. 552a, imposes specific obligations on agencies to protect personally identifiable records within their possession. In particular, paragraphs (9) and (10) of section (e) of the Privacy Act require each agency that maintains a system of covered records to:

> (9) establish rules of conduct for persons involved in the design, development, operation and maintenance of any system of records, or in maintaining any record, and instruct each such person with respect to such rules and the requirements of this section, including any other rules and procedures adopted pursuant to this section and the penalties for noncompliance; (and)
>
> (10) establish appropriate administrative, technical, and physical safeguards to insure the security and confidentiality of records and to protect against any anticipated threats or hazards to their security or integrity which could result in substantial harm, embarrassment, invonvenience, or unfairness to any individual on whom information is maintained . . .

Part 70a of 29 CFR constitutes the Department of Labor's implementation of the Privacy Act. The regulations set forth below provide additional procedures with respect to personally identifiable employee medical information which OSHA seeks to examine or obtain.

Section 301 of 5 U.S.C. is the government's general "housekeeping" statute, and authorizes the promulgation of regulations of this nature. It provides:

> The head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public.

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

III. Summary and Explanation of the Regulations

The administrative rules of practice and procedure set forth below maintain the same structure and approach as the draft guidelines, but have been significantly refined in light of the record and the agency's evaluation of it. The provisions have been tailored to the way in which OSHA is structured, managed, and staffed, and would not necessarily be pertinent to any other Federal agency. In forming these procedures, the agency considered both the importance of protecting the right to personal privacy and the equally important interest in facilitating the beneficial use of medical record information. The resulting regulations represent, in OSHA's view, an appropriate balance between the two interests. It is appropriate to stress that OSHA has historically made only limited use of employee medical records, and this policy will not be changed by these regulations. These procedural regulations will govern those situations, primarily concerning employee exposure to toxic substances, where medical record information is highly relevant to, and sometimes crucial to, the agency's performance of

its statutory functions. As a result, these regulations will improve the agency's protection of personally identifiable information, but will not by themselves serve to expand agency attempts to seek use of this information.

A. Paragraph (a)—*General policy*

The final rule expands the "General Policy" section of the draft guidelines into two paragraphs, "General policy" and "Scope and application." Paragraph (a), General policy, notes the importance of both personal privacy and the value of medical records to OSHA's performance of statutory functions. The central constraints on OSHA access to personally identifiable medical information which are created by the regulations are then highlighted. These policies are implemented by the specific provisions which follow.

The final rule omits a waiver provision. The waiver clause of the draft guidelines was criticized by numerous participants as unjustified and as demonstrating a half-hearted agency commitment to personal privacy (USWA, Ex. 160, p.18; Belair (NCCHR), Tr. 1874; SOCMA, Ex. 167(9–36); ORC, Ex. 159, p. 2; National Steel Co., Ex. 157, p. 2; Borg-Warner Chemicals, Ex.167(9–22)). The agency orginally included a waiver clause due to a concern that unforeseen emergency situations could arise where the literal application of the guidelines would frustrate accomplishment of statutory responsibilities. Having reconsidered the issue in view of these comments the agency deleted the provision. The agency is convinced that the final regulations can accommodate all access situations, even emergency situations where the quickest possible action is essential.

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

Paragraph (b) defines the circumstances under which the procedural regulations will apply. Except as provided in paragraphs (b)(3)–(b)(6), the regulations apply to "all requests by OSHA personnel to obtain access to records in order to examine or copy personally identifiable employee medical information, whether or not pursuant to the access provisions of 29 CFR 1910.20(e)." The regulations thus establish the framework under which all agency efforts to examine records containing employee medical information are to be conducted.

The applicability of the regulations turns on the definition of what constitutes personally identifiable information. Subparagraph (b)(2) states as follows:

> For the purposes of this section, "personally identifiable employee medical information" shall mean employee medical information accompanied by either direct identifiers (name, address, social security number, payroll number, etc.) or by information which could reasonably be used in the particular circumstances indirectly to identify specific employees (e. g., exact age, height, weight, race, sex, date of initial employment, job title, etc.).

This definition follows the recommendation of the American Medical Records Association (AMRA) (Ex. 82, pp. 1–2; *See also*, Birdbord (NIOSH), Ex. 22, p. 5), and eplicitly acknowledges the fact that a wide variety of data can in certain situations be used indirectly to identify specific employees (Bierbaum (NIOSH), Tr. 506). These regulations establish procedures to limit access to only that data necessary to accomplish a statutory purpose. OSHA will on occasion need to consider the factors of age, sex, race, height, weight, duration of employment, place of birth, etc., to properly evaluate specific medical tests (Dr. Whorton, Ex. 11, p. 21, Tr. 299). Where this kind of information is reported in a fashion which could reasonably be used under the circumstances to identify specific employees, the information is treated no differently than when direct identifiers are attached. Conversely, where information cannot reasonably be used under the circumstances to identify specific employees, these regulations do not apply.

Subparagraph (b)(3), for the sake of clarity, excludes from the scope of the rule several forms of information which do not constitute "personally identifiable employee medical information." First, aggregate employee medical information and medical records on individual employees which are not in a personally identifiable form are excluded. Protection of the personal privacy of employees requires only that *personally identifiable* medical information be protected. Many employers periodically analyze the contents of employee medical records as a part of their occupational medical programs, and this practice is a sound one. Research studies, statistical analyses of raw medical data, and listings of biological monitoring results (stripped of identifiers) can be valuable tools in detecting, controlling, and preventing occupational disease. These devices do not impinge on the personal privacy expectations of any specific employee, and could not be used adversely against specific employees. They should be readily available upon request to public health agencies like OSHA.

Subparagraph (b)(3) also excludes the OSHA injury and illness log (29 CFR Part 1904), death certificates, and employee exposure records from coverage by these regulations. Biological monitoring test results treated by 29 CFR 1910.20(c)(5) or by specific occupational safety and health standards as exposure records are also excluded. These kinds of personal records may on occasion be of such significance that they should be treated with discretion and care (*See*, HRG, Tr. 2039–40, Ex. 2(161), p. 3, Ex. 167(9–40), pp. 1–2), and several participants recommended that at least exposure records should be covered by the administrative regulations (*Id.;* Phillips Petroelum Co., Ex. 167(9–23), p. 2; SOHIO, Ex. 167(9–29), p. 2). The agency, however, has not done so because (1) these documents may be already widely known within the workplace; (2) the privacy interests involved in these records are not of comparable magnitude to those involved in identifiable medical records; (3) these records are of such occupational health and safety importance and they will be so frequently used by various agency personnel that rigid approval and security procedures are both impractical and inappropriate; and (4) agency discretion and care can adequately protect whatever privacy interests apply to these records without having to impose these regulations.

By excluding employee exposure records, the language of subparagraph (b)(3) also serves to exclude trade secret information from coverage by these regulations. Although several participants urged that these administrative regulations apply to trade secrets (MCA, Ex. 167(9–38); DuPont, Ex. 167(41), p. 3), and the draft guidelines so provided (Ex. 167(2)), the agency believes that existing regulations and agency procedures are sufficient to protect trade secret information (*See*, 18 U.S.C. 1905; Section 15 of the Act, 29 U.S.C. 664; 29 CFR 1903.9; OSHA Field Operations Manual, Ex. 113). Attention has not been drawn by any participant to deficiencies of current agency procedures concerning trade secrets, and the agency sees no need to expand the scope of these administrative regulations beyond the privacy interests involved in personally identifiable medical records (*See*, HRG, Ex. 167(9–10), pp. 1–2; AFL–CIO, Ex. 152, pp. 60–61; USWA, Ex. 160, p. 17).

Subparagraphs (b)(4)–(b)(6) exclude three situations where agency access to personally identifiable employee medical information need not be regulated by all requirements of these

regulations. Subparagraph (b)(4) excludes situations where OSHA compliance personnel seeks to examine medical records for the sole purpose of verifying employer compliance with mandated recordkeeping requirements. All comprehensive OSHA health standards contain detailed medical surveillance programs with associated recordkeeping provisions (*See*, 29 CFR 1910.1001–1046). Access to medical records is necessary and appropriate to verify compliance with these requirements, as well as the requirements of 29 CFR 1910.20. No analysis is made of the medical content of the file; rather, the compliance officer checks to see that required data is present in the file. Since no personally identifiable medical information is either substantively reviewed or obtained, and no special qualifications are necessary to carry out this task, it is inappropriate to require the prior approval of the Assistant Secretary and the OSHA Medical Records Officer for these routine inquiries. The final regulations provide that these inquiries "shall be conducted on-site and, if requested, under the observation of the recordholder, and the OSHA compliance personnel shall not record and take off-site any information from medical records other than documentation of the fact of compliance or non-compliance."

Subparagraph (b)(5) excludes "agency access to, or the use of, personally identifiable employee medical information obtained in the course of litigation." These litigation situations, including post-citation discovery requests, will generally be controlled by attorneys in the Office of the Solicitor of Labor or the Department of Justice, and not by the Assistant Secretary. Traditional protective orders and other devices may in specific cases be needed to protect personal privacy, but this is a matter which is best handled through the rules of civil and criminal procedure, and may be the subject of further directives from the Solicitor of Labor.

Subparagraph (b)(6) excludes from these procedural regulations situations "where a written directive by the Assistant Secretary authorizes appropriately qualified personnel to conduct limited reviews of specific medical information mandated by an occupational safety and health standard, or of specific biological monitoring test results." OSHA envisions situations where appropriately trained field personnel should be authorized in general to conduct limited reviews of specific kinds of medical information. Some of this medical information could be part of a medical surveillance program mandated by a specific occupational safety and health standard. Examples include hemoglobin and kidney function tests required under the OSHA lead standard (*See*, 29 CFR 1910.1025(j)(3)(ii)), as well as written medical opinions which under the lead standard can serve to initiate special health protection for employees (*See*, 29 CFR 1910.1025 (j)(3)(v), (k)(1)(ii)). In other cases, agency access to specific biological monitoring tests may be extremely important to adequately investigate potential occupational health problems even though the biological monitoring tests were not mandated by existing standards. Possible examples include cholinesterase activity in the blood of pesticides workers, or pulmonary function testing of workers exposed to silica. OSHA may provide its professional personnel with the necessary training either to substantively evaluate these limited test results, or to initially screen them to identify possible problem areas for physicians or other more qualified personnel to review. The agency desires to maintain the flexibility generally to authorize these kinds of limited reviews of medical information, and this is best regulated by written directive by the Assistant Secretary. Where no written directive has been issued, however, these regulations apply.

Finally, subparagraph (b)(7) notes that, "Even if not covered by the terms of this section, all medically related information reported in a personally identifiable form shall be handled with appropriate discretion and care befitting all information concerning specific employees." Due to the personal privacy interests involved, attention is drawn to Freedom of Information Act and Privacy Act regulations (29 CFR 70.26 and 70a.3) which could enable the agency to preclude further disclosure of this information to the public once in the agency's possession. This language in subparagraph (b)(7) will build upon the care which OSHA has historically given to information from and concerning specific employees. Agency personnel protect this information not only due to the inherent privacy interests involved, but also due to other adverse consequences such as possible employment discrimination which could result from an employer's learning the identity of employee sources of information.

C. Paragraph (c)—*Responsible persons*

Paragraph (c), Responsible persons, highlights the special responsibilities of key OSHA personnel to the effectuation of these administrative regulations. Paragraph (c) is largely a summary of duties established by other paragraphs, but is included to focus attention on the accountability of specific personnel. In this regard, the final regulations have been significantly modified from the draft guidelines. All references to the Director of Field Operations Coordination and a Document Control Officer have been deleted due to the judgment that these provisions added nothing meaningful to current internal agency management structures and responsibilities. OSHA expects that internal agency directives will be issued to add greater specificity to, and implementing mechanisms for, the requirements of these regulations. There is no need to include discussion of this in the body of the regulations, since internal directives already govern the manner in which the agency implements new policy (*See*, Ex. 190). Detailed provisions in the 'authorized employee' portion of the draft guidelines concerning who may have access to records, security of records, and agency contractors have also been deleted from the "Responsible persons" paragraph, and relocated elsewhere in the regulations.

Paragraph (c) of the final regulations emphasizes the responsibilities of the Assistant Secretary and the OSHA Medical Records Officer. Paragraph (a) indicates that these procedural regulations are based on two central principles. First, there should be a thorough review of all efforts to examine or copy personally identifiable employee medical information before the information is obtained; and second, personally identifiable information must be carefully protected once obtained. The Assistant Secretary is responsible for the overall administration and implementation of these principles. Several participants urged that the Assistant Secretary be personally involved in decisions to seek access to personally identifiable medical information (Weiner, Ex. 9A, p. 44; Stulberg (HRG), Tr. 2040; Seminario (AFL–CIO), Tr. 644; Nat. Steel Corp., Ex. 157, pp. 2–3; USWA, Ex. 160, p. 18; Continental Oil Co., Ex. 167(9–10), p. 2). Since the agency agrees that this involvement would be beneficial, the final regulations provide that the Assistant Secretary is the ultimate decisionmaker concerning requests for OSHA access to employee medical information subject to this section. As provided in the draft guidelines, the Assistant Secretary also makes final OSHA determinations concerning requests for inter-agency transfers or public disclosures of personally

identifiable employee medical information subject to this section.

The OSHA Medical Records Officer (MRO) has been given several key responsibilities in the final regulations. This official is to be designated by the Assistant Secretary and is to report directly to the Assistant Secretary on records access matters. The MRO must make recommendations to the Assistant Secretary on whether to approve or deny written access orders, and will serve as the central reviewer of the sufficiency of these documents and their supporting justifications (paragraph (d)). The MRO is also made responsible for responding to employee, collective bargaining agent, and employer objections to written access orders (paragraph (f)), regulating the use of direct personal identifiers (paragraph (g)), regulating the internal use and security of personally identifiable medical information (paragraphs (h)–(k)), assuring that the results of investigations are communicated to employees (paragraph (k)), preparing an annual report of OSHA's experience under this section (paragraph (1)), and assuring that advance notice is given of intended inter-agency transfers or public disclosures (paragraph (m)).

Similar to the draft guidelines, the final regulations state that the MRO shall be an "OSHA employee with experience or training in the evaluation, use, and privacy protection of medical records." Several participants urged that the position of MRO be limited to physicians, or that the necessary qualifications of the MRO be better defined (UAW, Ex. 165, p. 2; AMA, Ex. 167(9–12), pp. 2–3; Phillips Petroleum Co., Ex. 167(9–23), pp. 2–3; Shell Oil Co., Ex. 167(9–28), p. 3; Dow Chemical Co., Ex. 167(9–41), p. 5). The agency agrees that a senior official with a specialized background should occupy this sensitive position. The agency is not convinced, however, that only physicians could perform the duties of a MRO; thus the regulations are deliberately flexible.

The other person with key responsibilities in each instance of OSHA access to personally identifiable medical information is the person to be designated as the 'Principal OSHA Investigator'. The draft guidelines discussed the duties of an 'authorized employee,' but various participants pointed out that uncertainty existed as to who and how many individuals were responsible for using medical records and preserving their security (ORC, Ex. 159, p. 2; SOHIO, Ex. 167(9–29), p. 2; NIOSH, Ex. 167(9–37), p. 2; HRG, Ex. 167(9–40), pp. 2–3; Dow Corning Co., Ex. 167(9–41), p. 4). To clarify OSHA's intent, the final regulations fix primary responsibility on the person designated as the Principal OSHA Investigator to assure that the examination and use of personally identifiable medical information is performed in the manner prescribed by these procedural regulations. Other paragraphs establish who else can have access to this medical information, and how the information is to be protected. No significance is attached by the final regulations on who initiated a request to review records. The Principal OSHA Investigator, however, must be professionally trained in medicine, public health or allied fields (epidemiology, toxicology, industrial hygiene, biostatistics, environmental health, etc.) when access is pursuant to a written access order. Several participants urged that this person's qualifications be better defined (Shell Oil Co., Ex. 167(9–28), p. 3; Mid-Atlantic Legal Foundation, Ex. 167(9–32), p. 2). Rather than attempt this in advance, the final regulations opt for a case-by-case assessment of each Principal OSHA Investigator's qualifications as part of the approval criteria for a written access order (*infra*).

D. Paragraph (d)—*Written access orders*

Paragraph (d), Written access orders, establishes the most formal administrative procedure by which OSHA will seek access to personally identifiable employee medical information. With the exception of two circumstances discussed at the end of the paragraph, "each request by an OSHA representative to examine or copy personally identifiable employee medical information contained in a record held by an employer or other recordholder shall be made pursuant to a written access order. * * *" Subparagraph (d)(2) sets criteria to guide the exercise of the agency's discretion to seek access to identifiable medical information, and subparagraph (d)(3) sets forth the content of the written access order. To be valid, a written access order must be approved by the Assistant Secretary upon the recommendation of the OSHA Medical Records Officer. The approval process for a written access order is meant to assure management control over the exercise of OSHA's discretion, and has been structured in a fashion comparable to the approval process for an administrative subpoena. In practice, a written access order may constitute, or be accompanied by, an administrative subpoena.

Subparagraph (d)(2) establishes the substantive criteria which are to guide the Assistant Secretary's discretion in approving written access orders. First, the Assistant Secretary and the MRO must consider whether the medical information to be examined or copied is "relevant to a statutory purpose and there is a need to gain access to this personally identifiable information." This is at face value less strict than the 'substantial need' requirement of the draft guidelines, and the recommendations of several participants that something more than mere relevance or need should be required (NCCHR, Ex. 2(151), p. 4, Belair (NCCHR), Tr. 1861, 1883; HRG, Ex. 2(161), p. 4; Shell Oil Co., Ex. 167(9–28), p. 4; SOHIO, Ex. 167(9–29), p. 1; SOCMA, Ex. 167(9–36), p. 8; MCA, Ex. 167(9–38), p. 30; Weiner, Ex. 9A, p. 44). Rather than establish rigid or more specific criteria, the final regulations permit case-by-case determinations by the Assistant Secretary and the MRO to assure that access is sought only where there is a genuine need to do so. OSHA believes that a finding of relevance and need by the agency's highest official is a sufficient safeguard against excessive use of the agency's authority to obtain access to personally identifiable employee medical information (*See*, NCCHR, Ex. 2(151), pp. 6–7; Dr. Wegman, Tr. 235; Dr. Whorton, Ex. 11, p. 18; Annas, Tr. 1752–54, 1757–58; Stulberg (HRG), Tr. 2040; USWA, Ex. 160, p. 18; SOCMA, Ex. 167(9–36), p. 8).

Subparagraph (d)(2) next states that consideration must be given to whether the personally identifiable medical information subject to the access order is "limited to only that information needed to accomplish the purpose for access." This will preclude governmental access to the kind of extraneous medical information which the agency can identify in advance as unnecessary to the purpose for access. This requirement follows suggestions that the agency define what medical information is sought, and limit the information sought to just that needed to accomplish the purpose for access (Privacy Commission, Ex. 101, p. 313 (Recommendation No. 11); AMA, Ex. 167(9–12), pp. 2–3; NCCHR, Ex. 2(151), pp. 4–6).

Subparagraph (d)(2) lastly states that the approval process will consider who will substantively review requested records and what their professional qualifications are. The agency's policy is that the personnel authorized to review and analyze the personally identifiable medical information will be "limited to those who have a need for access and have appropriate professional qualifications." As provided by subparagraph (d)(3), the written access

order must list those persons who are expected, at the time the order is written, to review substantively the requested medical information. Other persons, however, may be authorized to review the records at a later time if the need exists (*See infra*). The draft guidelines limited access to physicians or persons under the direct supervision of a physician and trained to evaluate information in medical records (Ex. 167(2), pp. 4, 5). Several participants endorsed these or similar limitations (Ass. Gen. Contractors of Iowa, Ex. 2(3); Cyanamid Co., Ex. 2(102); Dr. Whorton, Ex. 11, p. 18; Samuels (AFL–CIO IUD), Tr. 965–67; Biscuit & Cracker Mfgr. Assn., Ex. 167(9–17), p. 2; Borg-Warner Corp., Ex. 167(9–22), p. 2). Having carefully considered the matter, the agency relaxed the language in the final regulations to permit a case-by-case evaluation of the qualifications of authorized reviewers. Without question, access should be limited on a need-to-know basis, and the regulations so provide (*See*, Weiner, Ex. 9A, pp. 45–6). But, the agency does not believe that every conceivable situation of OSHA access requires the direct personal supervision of a physician. Limited medical information like some biological monitoring tests can be easily reviewed and evaluated by a wide range of trained professionals such as epidemiologists, toxicologists, and industrial hygienists (Dr. Wegman, Tr. 245–48). It is to be anticipated that agency review of medical information will often be performed in consultation with agency staff or contract physicians; however, direct personal supervision by the physician will often be unncessary. As a result, the final regulations permit a case-by-case determination of the qualifications of authorized reviewers.

Paragraph (d)(3) specifies the content of a written access order. The written access order will be presented to the employer and any collective bargaining agent when access is sought, and made available to employees by posting. The written access order is the prime vehicle for informing the employer and employees of the agency's actions and decisionmaking. As a result, the regulations require that the written access order state with reasonable particularly what is being requested and why (*See*, AMA, Ex. 167(9–12), p. 3); whether examination of this information will be conducted on-site and what will be removed off-site; who is authorized to review and analyze the information obtained; who is the OSHA Medical Records Officer; and how long will personally identifiable information likely be retained by the agency. These matters need only be addressed with reasonable particularity, since absolute precision will often be impossible.

Paragraph (d)(4) establishes two special situations where a written access order need not be obtained for OSHA personnel to gain access to personally identifiable medical information. The first situation where a written access order is unnecessary concerns cases where the specific written consent of an employee is given for OSHA access to his or her medical record. This will occur in such situations as Section 11(c) investigations where the complainant's medical records must be reviewed, or where employees in the couse of a complaint inspection desire to have an OSHA official review their medical records. Section 1910.20(e)(2)(ii) of 29 CFR provides the mechanism whereby an employee can release medical records to a designated representative through a specific written consent authorization. If the agency or an OSHA official is listed as a designated representative, then a written access order need not be obtained. Where personally identifiable medical information is received and taken off-site, however, a person must be promptly named to serve as a Principal OSHA Investigator to assure protection of the information, and the MRO notified of this person's identity. Thereafter, the personally identifiable medical information is subject to the use and security requirements of the remainder of the procedural regulations.

The second situation where a written access order need not be obtained concerns physician consultations. As OSHA has acquired staff and contract physicians, situations have arisen where an agency physician was sent to review and discuss a potential problem with an employer's plant physician or corporate medical director. This may be done at the request of the employer. These informal contacts will likely expand in the future. As part of such a professional interaction, employee medical records may be reviewed and discussed with a view towards determining whether a problem actually exists, and if so, what should be done about it. These informal physician contacts can avoid unnecessary full-fledged investigations and focus employer energies on early corrective action where problems are discovered. Until medical information is reviewed and discussed, neither OSHA nor the employer may be aware of the nature or extent of an occupational health problem. OSHA believes that these physician-to-physician contacts should be encouraged, and thus has exempted them from the requirement for a written access order. The final regulations provide that "No employee medical records, however, shall be taken off-site in the absence of a written access order, and no notes of personally identifiable employee medical information made by the OSHA physician shall leave his or her control without the permission of the OSHA Medical Records Officer."

E. Paragraph (e)—*Presentation of written access order and notice to employees*

Paragraph (e) governs the mechanics of presenting a written access order to the employer and notifying employees of its existence. In practice, the written access order may constitute, or may be accompanied by, an administrative subpoena. As suggested, the final regulations provide that a copy of the written access order shall be provided to the employer (SOCMA, Ex. 167(9–36), p. 9; DuPont, Ex. 150, p. 18). An accompanying cover letter must also be provided which summarizes the requirements of this section and indicates that questions or objections concerning the written access order may be directed to the Principal OSHA Investigator or to the OSHA Medical Records Officer. Two copies of these documents must be provided so that one copy of each may be prominently posted as required by 29 CFR 1910.20(e)(3)(ii). The copy to be posted shall not identify specific employees by direct personal identifier (name, etc.). Posting at the workplace will serve to notify employees of what OSHA is doing with their medical records and why, and will let them know that they can lodge objections if they so desire. In addition, the regulations provide that a copy of these two documents shall be promptly provided "to each collective bargaining agent representing employees whose medical records are subject to the written access order." Union officials can be expected to communicate the nature of OSHA's actions to their members, and lodge objections or inquiries if any arise.

The draft guidelines provided for individual notice to employees by certified mail on each occasion that access was sought (Ex. 167(2), pp. 5–6). The final regulations delete this requirement due to the agency's judgment that individual notice would often be unnecessary and overly burdensome. As pointed out by several participants, the administrative and technical costs involved in individual notice are similar to those involved in seeking employee consent (HRG, Ex. 167(9–40), p. 4; NIOSH, Ex. 167(9–37), p. 2). Also, in most cases, posting and

notice to both the employer and union representatives will be fully adequate to inform all employees of OSHA's actions. One significant purpose for notifying employees is to assure that governmental actions are conducted openly to enable interested employees to scrutinize OSHA's actions and complain if they feel the agency is acting improperly. Individual notice to each and every employee will often not be necessary to accomplish this objective. The regulations do, however, contemplate that individual notice may be appropriate in some circumstances. To address this possibility, the regulations provide:

> The Principal OSHA Investigator shall discuss with any collective bargaining agent and with the employer the appropriateness of individual notice to employees affected by the written access order. Where it is agreed that individual notice is appropriate, the Principal OSHA Investigator shall promptly provide to the employer an adequate number of copies of the written access order (which does not identify specific employees by direct personal identifier) and its accompanying cover letter to enable the employer either to individually notify each employee or to place a copy in each employee's medical file.

Employers have ready means available to distribute the written access order, such as with the next employee paycheck or at the beginning or end of a work shift. The regulations opt to use these vehicles to notify employees individually where there is mutual agreement of a need to do so.

F. Paragraph (f)—*Objections concerning a written access order*

Although OSHA does not believe that agency access to employee medical information should depend upon employee consent, OSHA recognizes that it is important that employee objections concerning OSHA access be carefully considered. Paragraph (f) provides that all written employee, collective bargaining agent, and employer objections shall be transmitted to the OSHA Medical Records Officer. Paragraph (l) provides that these objections be discussed in the MRO's annual report. The making of an objection by an employee, collective bargaining agent, or employer does not operate to postpone operation of the written access order. Unless the agency decides otherwise, access to the records shall proceed without delay notwithstanding the objection. Paragraph (f) mandates, however, that the MRO respond in writing to each employee's and collective bargaining agent's written objection concerning OSHA access. Because of an employer's different legal status and relationship to the medical information, a written response to an employer objection is discretionary. A formal written response to the objection will enable a complete reconsideration of the written access order. OSHA recognizes that there may be situations where the agency made a mistake or proceeded on the basis of incomplete information such that the written access order should be revoked. The MRO is the appropriate person to make this decision. The final regulations therefore provide:

> Where appropriate, the OSHA Medical Records Officer may revoke a written access order and direct that any medical information obtained by it be returned or destroyed. The Principal OSHA Investigator shall assure that the instructions of the OSHA Medical Records Officer are promptly implemented.

The draft guidelines also include (1) a waiting period after an access order was presented before OSHA would seek to examine requested records, (2) an automatic reconsideration procedure if an employer or employee objected to OSHA access, and (3) a commitment to treat employer refusals of access as a denial of the right of entry under *Marshall v. Barlow's, Inc.*, 436 U.S. 307 (1978) (Ex. 167(2), p. 6). With the exception of the required review by the OSHA Medical Records Officer of written objections by employees and collective bargaining agents, the final regulations do not mandate that these steps be followed in each case. The presumption of the regulations is that the agency will proceed without delay notwithstanding an objection, although OSHA retains the discretion not to proceed immediately. In the absence of a significant initial union, employee or employer objection, there would be little justification for a substantial waiting period. On the other hand, significant initial objections could cause OSHA to redefine, reaffirm, or withdraw its request for access before records are examined. The possible situations are so numerous and varied that OSHA does not believe it is advisable to limit in advance what the agency responses could be, or to create an explicit or implied obligation on the agency's part to automatically delay execution of a written access order. In light of *Marshall v. Barlow's, Inc., supra,* OSHA also recognizes that its right of access to records may often not be directly enforceable absent a warrant or administrative supoena. This is a rapidly evolving area of the law; thus it is not possible to state in advance precisely what legal recourse OSHA will seek if faced with a refusal to permit access.

G. Paragraph (g)—*Removal of direct personal identifiers*

Subparagraph (h)(5) of the regulations, *infra,* will serve to prevent the agency from unnecessarily obtaining and taking off-site medical information having direct personal identifiers. Where it is necessary to take direct personal identifiers off-site, there will likely be situations where the direct personal identifiers are not continuously needed to permit use of the medical information. For example, direct identifiers may only be needed to permit follow-up at the conclusion of evaluation of medical information. The draft guidelines gave no special protection to direct personal identifiers, but several participants recommended a system of stripping direct personal identifiers, coding the medical information and the direct personal identifiers with a unique code, and maintaining the list of coded personal identifiers apart from the coded medical information (AMRA, Ex. 82, pp. 4, 7, Tr. 2466–67; NCCHR, Ex. 2(151), p. 4, Tr. 1864, 1875–78; Dr. Givens (Cal. Med. Assn.), Tr. 1713–18; Sterling Drug Co., Ex. 167(9–18), p. 2). OSHA believes this to be a sound mechanism to maximize the protection of employee privacy and to minimize possible misuse of personally identifiable medical information. Paragraph (g) of the final regulations incorporates this approach.

Except as authorized by the MRO, direct personal identifiers (name, address, social security number, payroll number, etc.) must be promptly separated from medical information whenever direct identifiers are obtained and taken off-site pursuant to a written access order. The Principal OSHA Investigator is directed to code the medical information and the list of direct personal identifiers with a unique identifying number for each employee, and then hand deliver or mail the list of coded-identifiers to the MRO. The MRO thereafter controls use and distribution of the list of coded identifiers to those with a need to know its contents. In addition, the numerically coded medical information is to be used and kept secured as though still in a directly identifiable form.

H. Paragraph (h)—*Internal agency use of personally identifiable employee medical information*

Paragraph (h) establishes who can have access to personally identifiable employee medical information once it is brought into the agency. Numerous participants favored limiting internal access to the smallest number of individuals possible (*See,* UAW, Ex. 165, p. 2; SOCMA, Ex. 167(9–36), p. 10; ORC,

Ex. 159, p. 2; Dow Chemical Co., Ex. 167(9–41), p. 4; Continental Oil Co., Ex. 167(9–10), p. 2; USWA, Ex. 160, pp. 18–19), although there was recognition that such personnel as supervised abstracters and clericals may have a need for access (NIOSH, Ex. 167(9–37), pp. 1–2; Weiner, Ex. 9A, p. 45; Dr. Whorton, Ex. 11, p. 19, Tr. 305; USWA, Ex. 160, pp. 18–19). The final regulations limit access to those with a need to know and appropriate qualifications, and fix responsibility on key officials to regulate all internal access.

Subparagraph (h)(1) provides that "The Principal OSHA Investigator shall in each instance of access be primarily responsible for assuring that personally identifiable employee medical information is used and kept secured in accordance with this section." Clear accountability is thus primarily fixed on one person in each instance of access for assuring that, in practice, medical information is properly used and kept secured (*See*, Ex. 167(2), p. 4).

Subparagraph (h)(2) regulates who has the authority to permit the examination and use of personally identifiable employee medical information. The Principal OSHA Investigator, the OSHA Medical Records Officer, the Assistant Secretary, and any other authorized person listed on a written access order are the only individuals who can permit the examination of the information. They are responsible for assuring that, in addition to those listed on the written access order, no one is permitted to examine or use this information other than agency employees and contractors who have a need for access and appropriate qualifications for the purpose for which they are using the information. No OSHA employee or contractor is authorized to examine or otherwise use this information unless so permitted. This need-to-know criterion is necessarily flexible so that supervised clerical and other similar uses are not categorically forbidden, but at the same time the criteria is meant to preclude unauthorized and unsupervised access. The draft guidelines contained a similar need-to-know requirement (Ex. 167(2), p. 7).

As was the case with the draft guidelines (Ex 167(2), p. 4), the final regulations permit access by attorneys in the Office of the Solicitor of Labor and by independent agency contractors on a need-to-know basis. In most instances, the only contractors having a need for access to personally identifiable medical information would be contract physicians, who already would be under legal and ethical obligations to protect confidential medical information. Where other contractors are permitted to use this information, they must contractually agree to abide by the requirements of this section and any implementing agency directives and instructions (*See*, Dr. Wegman, Tr. 236–37; Bridbord (NIOSH), Ex. 22, p. 6; NIOSH, Ex. 107D).

Subparagraph (h)(4) provides that "OSHA employees and contractors are only authorized to use personally identifiable employee medical information for the purposes for which it was obtained, unless the specific written consent of an employee is obtained as to a secondary purpose, or the procedures of paragraphs (d)–(g) of this section are repeated with respect to the secondary purpose." This provision serves to preclude secondary agency uses of personally identifiable employee medical information (*See*, NCCHR, Ex. 58, p. 46; Ex. 167(2), p. 7), unless a new written access order is obtained, or employees consent to a new use.

Finally, subparagraph (h)(5) provides that "Whenever practicable, the examination of personally identifiable employee medical information shall be performed on-site with a minimum of personally identifiable medical information to be taken off-site." No similar requirement was in the draft guidelines, but the agency felt it was beneficial to add this provision. Unlike the case with NIOSH or other research agencies, OSHA anticipates that it will not normally be necessary for OSHA to microfilm or otherwise copy entire medical records and then later abstract relevant information. The requirement that a minimum of personally identifiable medical information be taken off-site also recognizes that OSHA access to identifiable records may sometimes be for the sole purpose of stripping identifiers so that all medical information obtained is not in a directly identifiable form. Where this can reasonably be performed on-site, OSHA will do so.

I. Paragraph (i)—*Security procedures*

Paragraph (i) of the final regulations establishes security procedures to govern internal agency use of personally identifiable employee medical information. As was the case with the draft guidelines (Ex. 167(2), p. 7), the final regulations provide for segregation of agency files containing this information, and require that these agency files be kept secured in a locked cabinet or vault when not in active use (*See*, Dow Chemical Co., Ex. 167(9–14), p. 6). The OSHA Medical Records Officer and the Principal OSHA Investigator are each required to maintain a log of uses and transfers of this medical information and lists of coded direct personal identifiers, except as to necessary uses by staff under their direct personal supervision (*See*, Ex. 167(2), p. 7; Dow Chemical Co., Ex. 167(9–41), p. 6; NIOSH, Ex. 167(9–37), p. 3). As was the case with the draft guidelines (Ex. 167(2), p. 8), the final regulations permit photocopying of covered records, but all forms of duplication "shall be kept to the minimum necessary to accomplish the purposes for which the information was obtained." The final regulations also recognize that agency personnel may create worksheets or other similar documents which contain personally identifiable employee medical information. In light of this, subparagraph (i)(4) provides that all protective measures established by this section apply to these worksheets, as well as duplicate copies or other agency documents containing personally identifiable employee medical information.

Finally, subparagraph (i)(5), as was the case in the draft guidelines, stipulates that intra-agency transfers of personally identifiable employee medical information must be by hand delivery, United States mail, or equally protective means, and not by inter-office mailing channels (Ex. 167(2), p. 7).

The final regulations omit provisions concerning computerized records or supplemental security procedures (Ex. 167(2), p. 8) since (1) OSHA does not currently contemplate situations where OSHA would computerize personally identifiable medical information, and (2) supplemental security procedures do not depend on any authorizing language in these regulations. Additional directives on the security of personally identifiable employee medical information will be issued as needed.

J. Paragraph (j)—*Retention and destruction of records*

The draft guidelines provided for early destruction of personally identifiable information when the original purposes for access had been accomplished (Ex. 167(2), p. 8). Several participants urged that this information not be retained any longer than necessary (Mobay Chemical Corp., Ex. 2(97), p. 5; HRG, Ex. 2(161), p. 4; Stulberg (HRG), Tr. 2041; DuPont, Ex. 150, pp. 19–20; Dow Chemical Co., Ex. 167(9–41), p. 6). OSHA agrees that personally identifiable information (including lists of coded direct personal identifiers) should be destroyed or returned to the original recordholder when no longer needed for the purposes for which it was obtained. The final regulations so

provide in subparagraph (k)(1), subject to applicable agency records disposition programs. OSHA, as are other Federal agencies, is subject to several statutes and implementing regulations governing the disposal of records received in connection with the transaction of public business (*See*, 44 U.S.C. 2901–3324; 41 CFR 101–11.4). The agency has a formal records disposition program which may need to be modified to facilitate early destruction of personally identifiable medical information, and the agency intends to pursue this during the implementation of the procedural regulations.

OSHA can contemplate situations where personally identifiable medical information, after its initial utility, need not be used again until some time in the future. For example, medical information upon which a citation is based may be used during the hearing stage of an enforcement case. The medical information may not be utilized while the case is on appeal, but there may be a need for the information if the case is remanded for further proceedings. Similarly, an investigation of an apparently new health hazard may produce uncertain results. Before completely closing out this investigation, it may be appropriate to await the outcome of an ongoing research study or parallel investigation elsewhere in the country. In these cases, the regulations provide that the medical information is to be transferred to the OSHA Medical Records Officer. And, as suggested by one participant (Nat. Steel Corp., Ex. 165, p. 3), the MRO is directed to "conduct an annual review of all centrally-held information for the purpose of determining which information is no longer needed for the purposes for which it was obtained."

K. Paragraph (k)—*Results of an agency analysis using personally identifiable employee medical information*

The draft guidelines were silent on the issue of individual notification to employees of the results of OSHA analyses using personally identifiable employee medical information. Several participants urged that individual notice to each employee should be incorporated in the procedural regulations (DuPont Co., Ex. 150, p. 22; Dr. Whorton, Ex. 11, pp. 18–19; NIOSH, Ex. 167 (9–37), p. 2). In many cases, employees will learn the results of an OSHA investigation through a closing conference or informal post-inspection conference with union representatives, through the posting of a citation, or by calling the relevant OSHA Area Office. In other kinds of investigations similar to a NIOSH Health Hazard Evaluation or Field Study where disease is diagnosed in specific employees, individual notification might be essential (*See*, 41 CFR 85.11, 85a.8; Ex. 20, 21). OSHA believes that it is best to permit a case-by-case consideration of the need for individual notification. Accordingly, the final regulations provide that "The OSHA Medical Records Officer shall, as appropriate, assure that the results of an agency analysis using personally identifiable employee medical information are communicated to the employees whose personal medical information was used as part of the analysis."

L. Paragraph (1)—*Annual report*

The draft guidelines provided for a semi-annual report by the OSHA Medical Records Officer to the Assistant Secretary concerning OSHA's medical records access experience (Ex. 167 (2), p. 3). The final regulations continue this requirement in paragraph (1), but changes it to an annual report. The report must be made available to the public, and must discuss the number of written access orders and their purposes, the nature and disposition of employee, collective bargaining agent, and employer written objections, and the nature and disposition of requests for inter-agency transfer or public disclosure of personally identifiable employee medical information. This annual report will serve to focus the attention of the Assistant Secretary and interested members of the public on OSHA's use of personally identifiable employee medical information.

M. Paragraph (m)—*Inter-agency transfer and public disclosure*

The draft guidelines contained limitations on inter-agency sharing and public disclosure of employee medical records (Ex. 167 (2), pp. 8–11). Several participants argued that personally identifiable employee medical information should practically never be shared or disclosed without employee consent, even for public health purposes (HRG, Ex. 2 (161), p. 4, Tr. 2041, Ex. 167 (9–40), pp. 3–4; NCCHR, Ex. 2 (151), p. 8; Continental Oil Co. Ex. 167 (9–10), p. 2; Caterpillar Tractor Co., Ex. 167 (9–21), p. 3; SOHIO, Ex. 167 (9–29), p. 2). Other participants could accept strictly controlled inter-agency sharing for public health purposes (Weiner, Ex. 9A, p. 45; USWA, Ex. 160, p. 18; AMA, Ex. 167 (9–12), pp. 4–5). All participants, however, were concerned that personally identifiable medical information not be shared or disclosed in a manner which could adversely affect subject employees (Becker (USWA), Tr. 2390; Belair (NCCHR), Tr. 1862–63, NCCHR, Ex. 2 (151), pp. 2, 8).

OSHA agrees that inter-agency transfer and public disclosure of medical information should be carefully controlled, and paragraph (m) governs these issues. Inter-agency transfer and public disclosure are not categorically forbidden by the final regulations, however, because (1) the agency may not legally make such a commitment, and (2) situations may arise where transfer or disclosure is appropriate. Situations could conceivably arise where OSHA as a matter of law was compelled to transfer information to another agency or disclose it to a non-governmental individual. An example might be a General Accounting Office investigation, or where there is a compelling public interest in disclosure of medical information to which no significant privacy expectation attaches (e.g., cause of death). The final regulations establish strict criteria as to when inter-agency transfer or public disclosure of personally identifiable employee medical information may occur. Except when required by law, all inter-agency transfer or public disclosure of this information must be approved by the Assistant Secretary in accordance with these criteria. OSHA employees may, however, transfer or disclose aggregate employee medical information or medical information on individual employees which is not in a personally identifiable form.

Subparagraph (m)(2) governs the approval of an inter-agency transfer of personally identifiable employee medical information which has not been consented to by affected employees. First, transfer will only be permitted to a public health agency (such as EPA, CPSC, FDA, etc.) for a substantial public health purpose. Second, the recipient agency must have a demonstrable need for the medical information in a personally identifiable form. Third, the recipient agency may not use the requested information to make individual determinations concerning affected employees which could be to their detriment. Fourth, the recipient agency must have regulations or established written procedures which provide protection to privacy interests substantially equivalent to that of OSHA's procedures. And fifth, the requested transfer must satisfy an exemption to the Privacy Act to the extent that the Privacy Act applies to the requested information.

These five limitations on inter-agency transfer follow several of the suggestions of rulemaking participants. Since OSHA collects medical

information only for a public health purpose, it is appropriate to restrict all subsequent discretionary agency transfers to those with an equally clear public health purpose. The recipient agency's privacy protections must be as protective as OSHA's, but are not required to be identical since agencies vary significantly in their management structures and modes of operation. Unlike the draft guidelines, the final regulations attach no special status to an agency memorandum of understandings (USWA, Ex. 160, pp. 18–19; SOCMA, Ex. 167(9–36), p. 2; HRG, Ex. 167(9–40), pp. 4–5). This form of formal agreement may in specific cases satisfy several of the five criteria for approval of inter-agency sharing, but OSHA believes it to be important to consider each request for inter-agency transfer individually rather than as part of some comprehensive agreement.

The fifth and last limitation on inter-agency transfer concerns the Privacy Act, which would protect personally identifiable medical information which is part of a "system of records" as defined in paragraph (a)(5) of that Act (5 U.S.C. 552a(a)(5); 29 CFR 70a.2). The Privacy Act prohibits inter-agency transfers of covered records unless one of several exemptions is met (5 U.S.C. 552a(b), 29 CFR 70a.3). The two exemptions which could most likely pertain to employee medical information held by OSHA would be exemption (7) governing civil and criminal law enforcement, and exemption (8) governing compelling circumstances affecting the health or safety of an individual (5 U.S.C. 552a(b)(7), (8); 29 CFR 70a.3(e)(vii), (xi)). Thus, unless one of these two narrow exemptions is met, the Privacy Act where applicable serves to further prevent the discretionary inter-agency transfer of personnally identifiable employee medical information. To the extent that the Privacy Act does not apply to a particular record covered by these regulations, the Assistant Secretary could share that information with another Federal agency without regard to the Privacy Act exceptions. The four preceding limitations would apply to the transfer, however.

Subparagraph (m)(3) contains two exceptions to the requirements of subparagraph (m)(2). First, upon the approval of the Assistant Secretary, personally identifiable employee medical information may be shared with NIOSH. NIOSH is a sister public health agency to OSHA and its research activities complement OSHA's regulatory responsibilities. The two agencies are increasingly attempting to coordinate their activities and maintain close prefessional staff contacts. OSHA's ability to analyze employee medical information will often be improved by gaining NIOSH's assistance, and medical information collected by OSHA for one purpose may have major research value to NIOSH. Subparagraph (m)(3) is meant to permit sharing medical information with NIOSH in these circumstances. In the judgment of OSHA, NIOSH has, due to its frequent use of medical records, developed and demonstrated appropriate sensitivity to the privacy interests involved with employee medical records. As a result, identifiable medical information may be transferred to NIOSH upon the approval of the Assistant Secretary, without further inquiry into the sufficiency of their programs for protecting medical records.

Subparagraph (m)(3) also permits, upon the approval of the Assistant Secretary, the inter-agency transfer of personally identifiable employee medical information to the Department of Justice when necessary with respect to a specific action under the Occupational Safety and Health Act. For example, the Justice Department prosecutes criminal violations of the Act (*See*, s17(e)–(h), 29 U.S.C. 666) as well as civil penalty collection actions (*See*, Section 17(1), 29 U.S.C. 666(k)). The Justice Department also represents OSHA in Freedom of Information Act (FOIA) suits. Personally identifiable employee medical information may, on occasion, be relevant to these proceedings, and OSHA must necessarily share this information in these circumstances. While medical information obtained in the course of litigation is already exempt from these regulations, this additional language makes it clear that medical information collected for other purposes, but which becomes necessary for litigation in which the Department of Justice is involved, may be transferred to the Department.

Subparagraphs (m)(4) and (5) govern public disclosure of personally identifiable employee medical information which has not been consented to by affected employees. Exemption (6) of the Freedom of Information Act (FOIA) authorizes OSHA to withhold personally identifiable information where its disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552(b)((6)). The Department of Labor's implementing regulations broadly construes this exemption and treats medical records as presumptively non-disclosable (29 CFR 70.26). It is OSHA's judgment that where identifiable medical records are concerned, disclosure will necessarily impede OSHA's functions. OSHA's access to necessary medical information depends on protecting personal privacy, and OSHA's overall success as a public agency depends on employee and public confidence in the agency's discharge of its functions in a manner sensitive to individual rights. These considerations dictate that identifiable medical information not be disclosed absent compelling circumstances, even though the Department of Labor's FOIA regulations otherwise encourage the release of exempt information where disclosure will not impede the discharge of agency functions (29 CFR 70.11(b)).

Accordingly, subparagraph (m)(4) provides that "The Assistant Secretary shall not approve a request for public disclosure of employee medical information containing direct personal identifiers unless there are compelling circumstances affecting the health or safety of an individual." The "compelling circumstances" exception is meant to be extremely limited in nature, and parallels exemption (8) of the Privacy Act (5 U.S.C. 552a(b)(8); 29 CFR 70a.3(e)(xi)). In addition, subparagraph (m)(5) concerns employee medical information which contains information which could reasonably be used indirectly to identify specific employees, and provides that this shall not be disclosed to the public if to do so would constitute a clearly unwarranted invasion of personal privacy. Together, these subparagraphs express OSHA's intent to deny requests for public disclosure of personally identifiable employee medical information, unless there are compelling countervailing circumstances relating to health and safety.

Subparagraph (m)(6) governs the issue of notice when OSHA intends to transfer personally identifiable employee medical information to another agency or disclose it to a member of the public other than to an affected employee. The draft guidelines provided for written notice to the employer and to affected employees (Ex. 167(2), pp. 9, 10). Several participants stressed the importance of notice (Sterling Drug Co., Ex. 167(9–18), p. 1; Phillips Petroleum Co., Ex. 167(9–23), p. 2; Shell Oil Co., Ex. 167(9–28), p. 4; SOHIO, Ex. 167(9–29), p. 2; MCA, Ex. 167(9–38); p. 31; Dow Chemical Co., Ex. 167(9–41), p. 7. The final regulations delete the rigid time requirements of the draft guidelines, but provide that the OSHA Medical Records Officer shall assure that advance notice is provided

to any collective bargaining agent representing affected employees and to the employer, except with respect to transfers to NIOSH or to the Department of Justice. Where the intended inter-agency transfer or public disclosure contains direct personal identifiers, the OSHA Medical Records Officer must also, when feasible, take reasonable steps to assure that affected employees are notified. In the case of release of information pursuant to exemption (8) of the Privacy Act, the Act itself requires notification of individuals upon the disclosure.

As a final matter, several participants urged that the final regulations explicitly discuss penalties to be assessed against OSHA employees who violate these regulations (AMRA, Ex. 82, pp. 4–5; API, Ex. 158, p. 42; Ohio Bldg. Chpt., Ex. 167(9–3), p. 1; SOCMA, Ex. 167(9–36), p. 5; HRG, Ex. 167(9–40), p. 5; Dow Chemical Co., Ex. 167(9–41), p. 4.) The draft guidelines contained no provisions on this topic, and having considered the matter, the agency declined to explicitly address this topic in the final regulations.

OSHA agrees that agency employees must be made aware of these regulations, and that public confidence in OSHA will depend on strict enforcement of these regulations. It is not necessary, however, that penalty procedures be discussed in the regulations. All Department of Labor employees are given an "Employee Handbook" (Ex. 191). Chapter 23 of this handbook, "Standards of Conduct," briefly discusses the Department's longstanding regulations governing employee conduct (Ex. 191, P. 55). These ethics and conduct regulations are given to new employees, and each current employee is reminded of them on an annual basis (29 CFR 0.735–2(b); Ex. 191, p. 81). These regulations provide:

> Failure of an employee to comply with any of the standards of conduct set forth in this part shall be a basis for such disciplinary or other remedial action as may be appropriate to the particular case. (29 CFR 0.735–3(a); Ex. 191, p. 81)
>
> Employees may not, except with specific permission * * * directly or indirectly use or allow the use of official information for private purposes or to further a private interest when such information is not available to the general public; nor may employees disclose official information in violation of any applicable law, Executive order, or regulation. (29 CFR 0.735–8; Ex. 191, p. 83)
>
> The effectiveness of the Department of Labor in serving the public interest depends upon the extent to which the Department and its employees hold the public confidence. Employees are therefore required not only to observe the requirements of Federal laws, policies, orders, and regulations governing official conduct, they must also avoid any apparent conflict with these requirements. (29 CFR 0.735–4(a); Ex. 191, pp. 81–82)

These existing provisions, in conjunction with Office of Personnel Management and Department of Labor procedures for disciplinary actions, are adequate to deal with misuse of employee medical records by OSHA employees. Other forms of punishment, such as criminal penalties beyond the existing criminal provisions of the Privacy Act, are matters for Congress to address (*See*, HRG, Ex. 2(161), pp. 4–5).

IV. Authority, Signature, and the Regulations

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, NW, Washington, DC 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 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (84 Stat. 1599, 1600; 29 US.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), Chapter XVII of Title 29, the Code of Federal Regulations, is hereby amended by adding a new Part 1913.

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

Eula Bingham,

Assistant Secretary of Labor.

A new Part 1913 is added to Title 29 of the Code of Federal Regulations (CFR), consisting of §1913.10, reading as follows:

PART 1913—RULES OF AGENCY PRACTICE AND PROCEDURE CONCERNING OSHA ACCESS TO EMPLOYEE MEDICAL RECORDS

Sec.

1913.10 Rules of agency practice and procedure concerning OSHA access to employee medical records.

Authority: Secs. 8(c) and 8(g) (84 Stat. 1599, 1600; 29 U.S.C. 657), section (e) of the Privacy Act (88 Stat. 1899, 1900; 5 U.S.C. 552a(e)), and 5 U.S.C. 301 (80 Stat. 379).

§ 1913.10 Rules of agency practice and procedure concerning OSHA access to employee medical records.

(a) *General policy.* OSHA access to employee medical records will in certain circumstances be important to the agency's performance of its statutory functions. Medical records, however, contain personal details concerning the lives of employees. Due to the substantial personal privacy interests involved, OSHA authority to gain access to personally identifiable employee medical information will be exercised only after the agency has made a careful determination of its need for this information, and only with appropriate safeguards to protect individual privacy. Once this information is obtained, OSHA examination and use of it will be limited to only that information needed to accomplish the purpose for access. Personally identifiable employee medical information will be retained by OSHA only for so long as needed to accomplish the purpose for access, will be kept secure while being used, and will not be disclosed to other agencies or members of the public except in narrowly defined circumstances. This section establishes procedures to implement these policies.

(b) *Scope and application.* (1) Except as provided in paragraphs (b)(3)–(b)(6) below, this section applies to all requests by OSHA personnel to obtain access to records in order to examine or copy personally identifiable employee medical information, whether or not pursuant to the access provisions of 29 CFR 1910.20(e).

(2) For the purposes of this section, "personally identifiable employee medical information" means employee medical information accompanied by either direct identifiers (name, address, social security number, payroll number, etc.) or by information which could reasonably be used in the particular circumstances indirectly to identify specific employees (e.g., exact age, height, weight, race, sex, date of initial employment, job title, etc.).

(3) This section does not apply to OSHA access to, or the use of, aggregate employee medical information or medical records on individual employees which is not in a personally identifiable form. This section does not apply to records required by 29 CFR Part 1904, to death certificates, or to employee exposure records, including biological monitoring records treated by 29 CFR 1910.20(c)(5) or by specific occupational safety and health standards as exposure records.

(4) This section does not apply where OSHA compliance personnel conduct an examination of employee medical records solely to verify employer compliance with the medical surveillance recordkeeping requirements of an occupational safety and health standard, or with 29 CFR 1910.20. An

examination of this nature shall be conducted on-site and, if requested, shall be conducted under the observation of the recordholder. The OSHA compliance personnel shall not record and take off-site any information from medical records other than documentation of the fact of compliance or non-compliance.

(5) This section does not apply to agency access to, or the use of, personally identifiable employee medical information obtained in the course of litigation.

(6) This section does not apply where a written directive by the Assistant Secretary authorizes appropriately qualified personnel to conduct limited reviews of specific medical information mandated by an occupational safety and health standard, or of specific biological monitoring test results.

(7) Even if not covered by the terms of this section, all medically related information reported in a personally identifiable form shall be handled with appropriate discretion and care befitting all information concerning specific employees. There may, for example, be personal privacy interests involved which militate against disclosure of this kind of information to the public (*See*, 29 CFR 70.26 & 70a.3).

(c) *Responsible persons.* (1) *Assistant Secretary.* The Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) shall be responsible for the overall administration and implementation of the procedures contained in this section, including making final OSHA determinations concerning:

(i) Access to personally identifiable employee medical information (paragraph (d)), and

(ii) Inter-agency transfer or public disclosure of personally identifiable employee medical information (paragraph (m)).

(2) *OSHA Medical Records Officer.* The Assistant Secretary shall designate an OSHA official with experience or training in the evaluation, use, and privacy protection of medical records to be the OSHA Medical Records Officer. The OSHA Medical Records Officer shall report directly to the Assistant Secretary on matters concerning this section and shall be responsible for:

(i) Making recommendations to the Assistant Secretary as to the approval or denial of written access orders (paragraph (d)),

(ii) Assuring that written access orders meet the requirements of paragraphs (d)(2) and (d)(3) of this section,

(iii) Responding to employee, collective bargaining agent, and employer objections concerning written access orders (paragraph (f)),

(iv) Regulating the use of direct personal identifiers (paragraph (g)),

(v) Regulating internal agency use and security of personally identifiable employee medical information (paragraphs (h)–(j)),

(vi) Assuring that the results of agency analyses of personally identifiable medical information are, where appropriate, communicated to employees (paragraph (k)),

(vii) Preparing an annual report of OSHA's experience under this section (paragraph (l)), and

(viii) Assuring that advance notice is given of intended inter-agency transfers or public disclosures (paragraph (m)).

(3) *Principal OSHA Investigator.* The Principal OSHA Investigator shall be the OSHA employee in each instance of access to personally identifiable employee medical information who is made primarily responsible for assuring that the examination and use of this information is performed in the manner prescribed by a written access order and the requirements of this section (paragraphs (d)-(m). When access is pursuant to a written access order, the Principal OSHA Investigator shall be professionally trained in medicine, public health, or allied fields (epidemiology, toxicology, industrial hygiene, biostatistics, environmental health, etc.).

(d) *Written access orders.* (1) *Requirement for written access order.* Except as provided in paragraph (d)(4) below, each request by an OSHA representative to examine or copy personally identifiable employee medical information contained in a record held by an employer or other recordholder shall be made pursuant to a written access order which has been approved by the Assistant Secretary upon the recommendation of the OSHA Medical Records Officer. If deemed appropriate, a written access order may constitute, or be accompanied by, an administrative subpoena.

(2) *Approval criteria for written access order.* Before approving a written access order, the Assistant Secretary and the OSHA Medical Records Officer shall determine that:

(i) The medical information to be examined or copied is relevant to a statutory purpose and there is a need to gain access to this personally identifiable information,

(ii) The personally identifiable medical information to be examined or copied is limited to only that information needed to accomplish the purpose for access, and

(iii) The personnel authorized to review and analyze the personally identifiable medical information are limited to those who have a need for access and have appropriate professional qualifications.

(3) *Content of written access order.* Each written access order shall state with reasonable particularity:

(i) The statutory purposes for which access is sought,

(ii) A general description of the kind of employee medical information that will be examined and why there is a need to examine personally identifiable information,

(iii) Whether medical information will be examined on-site, and what type of information will be copied and removed off-site,

(iv) The name, address, and phone number of the Principal OSHA Investigator and the names of any other authorized persons who are expected to review and analyze the medical information.

(v) The name, address, and phone number of the OSHA Medical Records Officer, and

(vi) The anticipated period of time during which OSHA expects to retain the employee medical information in a personally identifiable form.

(4) *Special situations.* Written access orders need not be obtained to examine or copy personally identifiable employee medical information under the following circumstances:

(i) *Specific written consent.* If the specific written consent of an employee is obtained pursuant to 29 CFR 1910.20(e)(2)(ii), and the agency or an agency employee is listed on the authorization as the designated representative to receive the medical information, then a written access order need not be obtained. Whenever personally identifiable employee medical information is obtained through specific written consent and taken off-site, a Principal OSHA Investigator shall be promptly named to assure protection of the information, and the OSHA Medical Records Officer shall be notified of this person's identity. The personally identifiable medical information obtained shall thereafter be subject to the use and security requirements of paragraphs (h)–(m) of this section.

(ii) *Physician consultations.* A written access order need not be obtained where an OSHA staff or contract physician consults with an employer's physician concerning an occupational safety or health issue. In a situation of this nature, the OSHA physician may conduct on-site evaluation of employee medical records in consultation with the

employer's physician, and may make necessary personal notes of his or her findings. No employee medical records, however, shall be taken off-site in the absence of a written access order or the specific written consent of an employee, and no notes of personally identifiable employee medical information made by the OSHA physician shall leave his or her control without the permission of the OSHA Medical Records Officer.

(e) *Presentation of written access order and notice to employees.* (1) The Principal OSHA Investigator, or someone under his or her supervision, shall present at least two (2) copies each of the written access order and an accompanying cover letter to the employer prior to examining or obtaining medical information subject to a written access order. At least one copy of the written access order shall not identify specific employees by direct personal identifier. The accompanying cover letter shall summarize the requirements of this section and indicate that questions or objections concerning the written access order may be directed to the Principal OSHA Investigator or to the OSHA Medical Records Officer.

(2) The Principal OSHA Investigator shall promptly present a copy of the written access order (which does not identify specific employees by direct personal identifier) and its accompanying cover letter to each collective bargaining agent representing employees whose medical records are subject to the written access order.

(3) The Principal OSHA Investigator shall indicate that the employer must promptly post a copy of the written access order which does not identify specific employees by direct personal identifier, as well as post its accompanying cover letter (*See,* 29 CFR 1910.20(e)(3)(ii)).

(4) The Principal OSHA Investigator shall discuss with any collective bargaining agent and with the employer the appropriateness of individual notice to employees affected by the written access order. Where it is agreed that individual notice is appropriate, the Principal OSHA Investigator shall promptly provide to the employer an adequate number of copies of the written access order (which does not identify specific employees by direct personal identifier) and its accompanying cover letter to enable the employer either to individually notify each employee or to place a copy in each employee's medical file.

(f) *Objections concerning a written access order.* All employee, collective bargaining agent, and employer written objections concerning access to records pursuant to a written access order shall be transmitted to the OSHA Medical Records Officer. Unless the agency decides otherwise, access to the records shall proceed without delay notwithstanding the lodging of an objection. The OSHA Medical Records Officer shall respond in writing to each employee's and collective bargaining agent's written objection to OSHA access. Where appropriate, the OSHA Medical Records Officer may revoke a written access order and direct that any medical information obtained by it be returned to the original recordholder or destroyed. The Principal OSHA Investigator shall assure that such instructions by the OSHA Medical Records Officer are promptly implemented.

(g) *Removal of direct personal identifiers.* Whenever employee medical information obtained pursuant to a written access order is taken off-site with direct personal identifiers included, the Principal OSHA Investigator shall, unless otherwise authorized by the OSHA Medical Records Officer, promptly separate all direct personal identifiers from the medical information, and code the medical information and the list of direct identifiers with a unique identifying number for each employee. The medical information with its numerical code shall thereafter be used and kept secured as though still in a directly identifiable form. The Principal OSHA Investigator shall also hand deliver or mail the list of direct personal identifiers with their corresponding numerical codes to the OSHA Medical Records Officer. The OSHA Medical Records Officer shall thereafter limit the use and distribution of the list of coded identifiers to those with a need to know its contents.

(h) *Internal agency use of personally identifiable employee medical information.* (1) The Principal OSHA Investigator shall in each instance of access be primarily responsible for assuring that personally identifiable employee medical information is used and kept secured in accordance with this section.

(2) The Principal OSHA Investigator, the OSHA Medical Records Officer, the Assistant Secretary, and any other authorized person listed on a written access order may permit the examination or use of personally identifiable employee medical information by agency employees and contractors who have a need for access, and appropriate qualifications for the purpose for which they are using the information. No OSHA employee or contractor is authorized to examine or otherwise use personally identifiable employee medical information unless so permitted.

(3) Where a need exists, access to personally identifiable employee medical information may be provided to attorneys in the Office of the Solicitor of Labor, and to agency contractors who are physicians or who have contractually agreed to abide by the requirements of this section and implementing agency directives and instructions.

(4) OSHA employees and contractors are only authorized to use personally identifiable employee medical information for the purposes for which it was obtained, unless the specific written consent of an employee is obtained as to a secondary purpose, or the procedures of paragraphs (d)–(g) of this section are repeated with respect to the secondary purpose.

(5) Whenever practicable, the examination of personally identifiable employee medical information shall be performed on-site with a minimum of medical information taken off-site in a personally identifiable form.

(i) *Security procedures.* (1) Agency files containing personally identifiable employee medical information shall be segregated from other agency files. When not in active use, files containing this information shall be kept secured in a locked cabinet or vault.

(2) The OSHA Medical Records Officer and the Principal OSHA Investigator shall each maintain a log of uses and transfers of personally identifiable employee medical information and lists of coded direct personal identifiers, except as to necessary uses by staff under their direct personal supervision.

(3) The photocopying or other duplication of personally identifiable employee medical information shall be kept to the minimum necessary to accomplish the purposes for which the information was obtained.

(4) The protective measures established by this section apply to all worksheets, duplicate copies, or other agency documents containing personally identifiable employee medical information.

(5) Intra-agency transfers of personally identifiable employee medical information shall be by hand delivery, United States mail, or equally protective means. Inter-office mailing channels shall not be used.

(j) *Retention and destruction of records.* (1) Consistent with OSHA records disposition programs, personally identifiable employee medical information and lists of coded direct personal identifiers shall be destroyed

or returned to the original recordholder when no longer needed for the purposes for which they were obtained.

(2) Personally identifiable employee medical information which is currently not being used actively but may be needed for future use shall be transferred to the OSHA Medical Records Officer. The OSHA Medical Records Officer shall conduct an annual review of all centrally-held information to determine which information is no longer needed for the purposes for which it was obtained.

(k) *Results of an agency analysis using personally identifiable employee medical information.* The OSHA Medical Records Officer shall, as appropriate, assure that the results of an agency analysis using personally identifiable employee medical information are communicated to the employees whose personal medical information was used as a part of the analysis.

(l) *Annual report.* The OSHA Medical Records Officer shall on an annual basis review OSHA's experience under this section during the previous year, and prepare a report to the Assistant Secretary which shall be made available to the public. This report shall discuss:

(1) the number of written access orders approved and a summary of the purposes for access;

(2) the nature and disposition of employee, collective bargaining agent, and employer written objections concerning OSHA access to personally identifiable employee medical information, and

(3) the nature and disposition of requests for inter-agency transfer or public disclosure of personally identifiable employee medical information.

(m) *Inter-agency transfer and public disclosure.* (1) Personally identifiable employee medical information shall not be transferred to another agency or office outside of OSHA (other than to the Office of the Solicitor of Labor) or disclosed to the public (other than to the affected employee or the original recordholder) except when required by law or when approved by the Assistant Secretary.

(2) Except as provided in paragraph (m)(3) below, the Assistant Secretary shall not approve a request for an inter-agency transfer of personally identifiable employee medical information, which has not been consented to by the affected employees, unless the request is by a public health agency which:

(i) needs the requested information in a personally identifiable form for a substantial public health purpose,

(ii) will not use the requested information to make individual determinations concerning affected employees which could be to their detriment,

(iii) has regulations or established written procedures providing protection for personally identifiable medical information substantially equivalent to that of this section, and

(iv) satisfies an exemption to the Privacy Act to the extent that the Privacy Act applies to the requested information (*See*, 5 U.S.C. 552a(b); 29 CFR 70a.3).

(3) Upon the approval of the Assistant Secretary, personally identifiable employee medical information may be transferred to:

(i) the National Institute for Occupational Safety and Health (NIOSH) and

(ii) the Department of Justice when necessary with respect to a specific action under the Occupational Safety and Health Act.

(4) The Assistant Secretary shall not approve a request for public disclosure of employee medical information containing direct personal identifiers unless there are compelling circumstances affecting the health or safety of an individual.

(5) The Assistant Secretary shall not approve a request for public disclosure of employee medical information which contains information which could reasonably be used indirectly to identify specific employees when the disclosure would constitute a clearly unwarranted invasion of personal privacy (*See*, 5 U.S.C. 552(b)(6); 29 CFR 70.26).

(6) Except as to inter-agency transfers to NIOSH or the Department of Justice, the OSHA Medical Records Officer shall assure that advance notice is provided to any collective bargaining agent representing affected employees and to the employer on each occasion that OSHA intends to either transfer personally identifiable employee medical information to another agency or disclose it to a member of the public other than to an affected employee. When feasible, the OSHA Medical Records Officer shall take reasonable steps to assure that advance notice is provided to affected employees when the employee medical information to be transferred or disclosed contains direct personal identifiers.

(n) *Effective date.* This section shall become effective on August 21, 1980.

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