PROGRAM DIRECTIVE

Program Directive: <u>A-220</u> Issued: <u>March 23, 1998</u> Revised: <u>May 3, 2007</u>

SUBJECT: 1,3-Butadiene

AFFECTED STANDARDS/

DIRECTIVES:	This compliance instruction is applicable to:
	1910.1051, 1,3-Butadiene;
	Division 2, General Industry Standards;
	Division 3, Construction; and
	Division 5, Maritime Activities.

- **PURPOSE:** This instruction establishes policies and provides clarification to ensure uniform enforcement of the Occupational Exposure to 1,3-Butadiene Standard, 1910.1051 and authorizes appropriately qualified OR-OSHA personnel to conduct reviews of the medical records specified in C. of this instruction where there is a need to gain access for enforcement purposes.
- **SCOPE:** This instruction applies OR-OSHA wide
- **REFERENCES:** OSHA Instruction CPL2-2.66, 1,3-Butadiene

BACKGROUND: In May 1997, OR-OSHA adopted by reference federal OSHA's Occupational Exposure to 1,3-Butadiene standard. This program directive provides agreement with existing federal OSHA policy regarding enforcement of this standard.

ACTION: OR-OSHA Health Compliance Officers (HCOs), Safety Compliance Officers (SCOs) and Health Consultants, Safety Consultants and their respective Field Managers must use the guidelines in this instruction to ensure uniform application of this standard.

Field office safety and health managers must assure that this authorization to review specific medical information is administered and implemented according to $B_{-} - F_{-}$ of this instruction.

A. Background

- 1. For compliance purposes, and solely in order to verify employer compliance with recordkeeping requirements, OR-OSHA compliance personnel are permitted access to employee medical information which is part of a medical surveillance program mandated by specific occupational health standards; i.e., in order to determine that the medical information exists. (See Division 2/Z 1910.1020(e)(3) and 29 CFR 1913.10. In doing so:
 - a. OR-OSHA compliance personnel should verify employer compliance with medical recordkeeping requirements by interviewing employer and employee representatives, employees, and, where appropriate, physicians.
 - b. In addition, compliance officers may want to verify compliance by determining what appropriate medical records exist as required. Where medical records are used to verify compliance:
 - i. Documentation of non-compliance will comprise only the employee's name and the violation, and not the specific medical information.
 - ii. Documentation of compliance will consist of a statement attesting to a check of some of the records and compliance with the specific recordkeeping requirements.
 - iii. No analysis is to be made of the medical content of the file. If copying or review of the content of the records is necessary, the Field Manager must follow the procedures set forth in 29 CFR 1913.10(c)(3)(e.g., appoint a Principal OSHA Investigator).
- 2. OR-OSHA compliance personnel also are permitted access (for compliance purpose) to biological monitoring results which directly assess the absorption of a substance or agent by body systems(e.g., blood lead levels). These results are treated as Division 2/Z 1910.1020(c)(5) as exposure records.
- 3. Procedures for access to medical opinions mandated by existing standards are described in OSHA Instruction CPL 2-2.30.

- 4. There may, however, be compliance needs for reviewing the content of and if appropriate, copying employee medical records that pertain to diagnostic tests which measure or reflect the adverse effects of exposure to toxic substances or harmful physical agents. Division 2/Z 1910.1020(c)(6) treats these as medical records.
- B. Application and Statutory Purpose
 - 1. 29 CFR 1913.10(b)(6) excluded from the rules of agency practice and procedure 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."
 - 2. Thus, this instruction authorizes appropriately qualified field personnel to conduct reviews of the tests named in C. of this instruction where the Field Manager determines that there is a need to gain access for enforcement purposes.
 - a. This authorization applies where the tests are part of medical surveillance programs mandated by standards; or where a laboratory test is not mandated by a standard but is:
 - i. A recognized indicator of a worker's past and/or potential exposure to a toxic substance or harmful physical agent which is known to be present or is likely to be present (e.g., hippuric acid found in the urine due to exposure to toluene); or
 - ii. A recognized indicator of an adverse health effect of that substance or agent (e.g., pulmonary function testing of workers exposed to silica).
 - b. For the purposes of this instruction, "employee medical record" means any record concerning a current or former employee's health as it pertains to the laboratory tests specified in C. of this instruction, and which is made or maintained by a physician, nurse, technician, or other health care personnel. This includes:

- i. The results of the laboratory test; and
- ii. Control, certification, and standardization data used for the laboratory determinations and findings.
- 3. Statutory Purpose. The purpose of obtaining access to this medical information is to assure safe and healthful working conditions for working men and women by providing an effective enforcement program for OR-OSHA standards and the Oregon Safe Employment Act.

C. Specific Medical Information

This instruction authorizes the examination of the content of and, if appropriate, the copying of employee medical records pertaining to the following:

- 1. Pulmonary function tests.
- 2. Audiograms.
- 3. Blood Urea Nitrogen (BUN)
- 4. Serum creatinine
- 5. Complete blood count with differential and description of peripheral smear.
- 6. Serum electrolytes.
- 7. Serum calcium.
- 8. Serum phosphorus.
- 9. Lactic dehydrogenase (LDH).
- 10. Creatine phosphokinase (CPK).
- 11. Serum glutamic-oxaloacetic transaminase (SGOT).
- 12. Serum glutamic-pyruvic transaminase (SGPT).
- 13. Urinalysis, including test for hematuria, glucosuria, proteinuria, ketonuria, and microscopic examination of urine.
- 14. Zinc protoporphyrin test.
- 15. Erythrocyte and plasma cholinesterase assays.
- 16. Metabolites found in urine when a specific exposure is identified or postulated.
- 17. Radiologists' interpretations of employee X-rays.
- 18. Erythrocyte sedimentation rate.
- 19. Platelet count.
- 20. Serum bilirubin.
- 21. Urine and sputum cytology reports.
- 22. Serum triglycerides.
- 23. Serum cholesterol.

D. Qualified Compliance Personnel

Review of the results of any medical tests named in C. of this instruction which are in personally identifiable form must be limited to:

- 1. OR-OSHA field-qualified grade 3 and 4 Industrial Hygienists.
- 2. Professionals with specific training or experience in medical disciplines.
- E. Compliance Procedures
 - Before obtaining access to the medical information described in C. of this instruction, it must be determined by the Field Manager that there is a genuine and supportable need to gain access for OR-OSHA enforcement purposes.
 - a. Review of the medical information named in C. of this instruction could be relevant to the type of enforcement action OR-OSHA may initiate against an employer, or could serve as evidence of the appropriateness of an enforcement action. The following considerations are among those which could indicate the need to gain access to such personally identifiable employee medical information:
 - i. To document employer knowledge by establishing that the records show a pattern of disease.
 - ii. To provide evidence that the employer willfully violated an OR-OSHA standard.
 - iii. To provide supporting evidence that a "general duty clause" violation occurred.
 - iv. To document inadequate management of employees found to have evidence of adverse health effects. For example, to documents that workers were not adequately notified of abnormal laboratory values or that appropriate follow-up protective measures were not taken.
 - v. To verify compliance during follow-up inspections.

- b. A determination must also be made that:
 - An employee is subjected to a toxic substance or harmful physical agent in the course of employment through any route of entry (e.g., inhalation, ingestion, skin contact or absorption, etc.). This determination of the employee's exposure includes both past or potential exposure.
 - The laboratory test is a recognized indicator of this employee's past and/or potential exposure to a toxic substance or harmful physical agent, or recognized indicator of an adverse health effect of such an exposure. This can be derived from a variety of sources, including recognized textbooks in the fields of industrial hygiene, medicine and toxicology; federal or state publications; and technical journals.
- c. This instruction does not authorize the compliance officer to examine records for the purpose of identifying trends of illnesses which are not directly related to the recognized adverse effects of specific substances or agents. This, the compliance officer is not to do investigative research or conduct a wholesale investigation of medical records to identify possible violations.
- 2. Access to medical information named in C. of this instruction must, if practicable, involve on-site review. A minimum of personally identifiable information must be recorded for enforcement purposes and taken off-site.
- 3. Compliance personnel must use, if available, the normal ranges for the laboratory conducting the test, or normal values established in accepted medical texts.

- 4. When an abnormality is identified, the compliance officer must investigate the abnormality through one or more of the following mechanisms:
 - a. Consult with the examining physician or health care personnel in charge of or who has access to employee medical records. If, based on this consultation, the compliance officer determines that no further investigation is necessary, documentation must be made in the files of:
 - i. Whose records and which tests were examined;
 - ii. The rationale for examining those tests;
 - iii. All abnormalities found (without personally identifiable information); and
 - iv. What procedures were followed.

NOTE: Personally identifiable information from all other field notes concerning these test results once a decision has been made that no further action is necessary.

- b. If the procedure described in I.4.a above was not followed, or it was followed but no satisfactory response was given, obtain the services of a medical consultant or contact OR-OSHA's contracted occupational health physician's staff.
- 5. Notifying Employees of Abnormal Results
 - a. When abnormalities have been satisfactorily explained by the employer's physician, the compliance officer must investigate whether the physician notified the employee of the results.
 - b. When the services of a contract have been used, the compliance officer must ensure that they physician notifies the employee of any abnormalities found.

- 6. OR-OSHA compliance officers have the responsibility to maintain the confidentiality of all medical information and records.
 - a. The compliance officer must not discuss any of the information found in the records which is or could be identified with specific individuals, with any employer or employee representatives, except the physician or health care personnel in charge of or who has access to employee medical records. This restriction applies even in situations where such medical information may be known to those (or other) individuals.
 - b. However, the compliance officer is authorized to reveal the following information to an employee whose medical record has been looked at:
 - i. The laboratory test examined;
 - ii. The rationale for examining that test;
 - iii. The normal ranges used and where these ranges were derived; and
 - iv. The numerical test result if known by the compliance officer.

NOTE: Under no circumstances should the compliance officer attempt any further discussion with the employee of the meaning of the results, conclusions, interpretations, diagnoses, etc. These judgments can only be made in view of the total medical record and only by an examining physician. If the employee wants clarification, they must be referred to a physician for any discussion of test results.

NOTE: The compliance officer must not re-examine the medical records solely to inform an employee of their test results.

- 7. Security Procedures. Whenever personally identifiable employee medical information is obtained pursuant to this instruction and taken off-site, the Field Manager must:
 - a. Assure protection of this information.
 - b. Assure that the personally identifiable medical information obtained must thereafter be subject to the use and security requirements of 29 CFR 1913.10(h)-(m).
- 8. Access to this medical information for purposes other than for the limited enforcement needs illustrated in I. of this instruction will require a written access order (29 CFR 1913.10(d)) unless:
 - a. Specific Written Consent of an employee is obtained pursuant to Division 2 1910.1020(e)(2)(ii), and the agency or an agency employee is listed on the authorization as the designated representative to receive the medical information.
 - An OR-OSHA staff or contract physician consults with an employer's physician pursuant to 29 CFR 1913.10(d)(4)(ii).

F. Citations

- 1. If abnormalities have not been detected and the employee has not been notified, the Field Manager should consult with the Health Field Operations Manager before issuing a citation.
- 2. To support a citation (see paragraph E. 1. a. of this instruction) include documentation of personally identifiable information. However, this information will not be disclosed on the citation.

EFFECTIVE This directive is effective immediately and will remain in effect until canceled superseded.