

submitted for clinical image review, the accreditation body shall ensure that this information is provided to the facility and that the clinical images are returned to the facility. Both shall occur no later than 10-business days after identification of the suspected abnormality.

* * * * *
4. Section 900.12 is amended by revising paragraphs (c)(2) and (f)(3) and the first sentence of paragraph (j)(2) to read as follows:

§ 900.12 Quality standards.

* * * * *
(c) * * *
(2) *Communication of mammography results to the patients.* Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(i) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.

(ii) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

* * * * *
(f) * * *
(3) *Audit interpreting physician.* Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the audit interpreting physician shall also be responsible for documenting the nature of the followup.

* * * * *
(j) * * *
(2) If FDA determines that the quality of mammography performed by a facility, whether or not certified under § 900.11, was so inconsistent with the quality standards established in this section as to present a significant risk to individual or public health, FDA may require such facility to notify patients who received mammograms at such

facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as FDA may require. * * *

Dated: June 9, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99-15293 Filed 6-16-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-371]

RIN 1218-AB46

Occupational Exposure to Tuberculosis

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Notice of limited reopening of rulemaking record.

SUMMARY: On October 17, 1997, OSHA published its proposed standard to regulate occupational exposure to tuberculosis (TB). Public hearings on the proposal were held in Washington, DC, Los Angeles, CA, New York City, NY, and Chicago, IL between April 7 and June 4, 1998. The post-hearing comment period closed on October 5, 1998. OSHA is now reopening the rulemaking record for 45 days to submit two reports to the docket: OSHA's report on TB control practices in homeless shelter settings (Ex. 179-1); and the National Institute for Occupational Safety and Health's (NIOSH) Health Hazard Evaluation (HHE) of a medical waste treatment facility (Ex. 179-2). OSHA invites public comment on the findings of these reports and the underlying issues of the coverage of homeless shelters and medical waste treatment facilities within the scope of a final TB standard. OSHA also seeks comment on including TB and AIDS clinics and probation and parole officers within the scope of the standard as well as expanding the coverage of the standard to include all social service workers.

In addition, OSHA is submitting to the docket four other documents, previously unavailable, that relate to issues addressed during the public hearings. These documents are: The American College of Occupational and Environmental Medicine's (ACOEM)

"Guidelines for Protecting Health Care Workers Against Tuberculosis" (Ex. 179-3); "Laboratory Performance Evaluation of N95 Filtering Facepiece Respirators, 1996" (Morbidity and Mortality Weekly Report, December 11, 1998) (Ex. 179-4); "The Costs of Healthcare Worker Respiratory Protection and Fit-Testing Programs" by Scott E. Kellerman et al. (September 1998, Journal of Infection Control and Epidemiology) (Ex. 179-5); and "The Relative Efficacy of Respirators and Room Ventilation in Preventing Occupational Tuberculosis" by Kevin Fennelly and Edward Nardell (October 1998, Journal of Infection Control and Epidemiology)(Ex. 179-6). Public comment on these documents is also invited. Comments should be limited to the issues raised in these documents, and participants do not need to resubmit evidence or comments that are already in the record.

DATES: Comments must be postmarked no later than August 2, 1999.

ADDRESSES: Send two copies of your comments to: Docket Office, Docket H-371, Room N2625, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210. Comments limited to 10 pages or fewer may also be transmitted by FAX to: 202-693-1648, provided that the original and one copy of the comment are sent to the Docket Office immediately thereafter.

Comments may also be submitted electronically through OSHA's Internet site at URL, <http://www.osha-slc.gov/e-comments/e-comments-tb.html>. Information such as studies and journal articles cannot be attached to electronic submissions and must be submitted in duplicate to the above address. Such attachments must clearly identify the respondent's electronic submission by name, date, and subject, so that they can be attached to the correct submission.

The entire record for the TB rulemaking, including the new reports being submitted, is available for inspection and copying in the Docket Office, Docket H-371, telephone 202-693-2350.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210, Telephone (202) 693-1999, FAX (202) 693-1634.

SUPPLEMENTARY INFORMATION:

Background

On August 25, 1993, the Labor Coalition to Fight TB in the Workplace petitioned OSHA to initiate rulemaking for a permanent standard issued under Section 6(b) of the Occupational Safety and Health (OSH) Act to protect workers from occupational exposure to TB. Citing the recent resurgence of TB and the emergence of new cases of multidrug-resistant TB (MDR-TB), the petitioners stressed the need for a substance-specific standard to address the particular hazards associated with occupational exposures to TB. The petitioners contended that the non-mandatory TB Guidelines published by the Centers for Disease Control and Prevention (CDC) do not provide adequate protection because they are not fully or rigorously implemented in most workplaces.

On October 17, 1997, OSHA published its proposed standard for occupational exposure to TB (62 FR 54160). Based on a review of the data, OSHA made a preliminary determination that workers in hospitals, nursing homes, hospices, correctional facilities, homeless shelters, and certain other work settings are at significant risk of incurring TB infection while caring for their patients and clients or performing certain procedures. To reduce this occupational risk, OSHA proposed a standard that would require employers to protect TB-exposed workers by means of infection prevention and control measures that have been demonstrated to be highly effective in reducing or eliminating job-related TB infections. These measures include procedures for the early identification of individuals with suspected or confirmed infectious TB, the isolation of such individuals in rooms designed to protect those in the vicinity of the room from contact with microorganisms causing TB, the use of respirators when performing certain high-hazard procedures, employee training, employee skin testing and, where appropriate, medical management and follow-up after an exposure incident or skin test conversion has occurred.

Homeless Shelters

Throughout the development of the proposal, OSHA has been concerned about the feasibility of implementing a TB standard in homeless shelters because of the unique characteristics of the workforce in such shelters, the unique characteristics of the client population, and the non-profit nature of most homeless shelters. Prior to publication of the proposal, OSHA held

stakeholder meetings with homeless shelter representatives and met with the Interagency Council on the Homeless to discuss issues related to the potential impact the standard might have on homeless shelters. In addition, during review under the Small Business Regulatory Enforcement Fairness Act (SBREFA), small business representatives from the homeless shelter sector raised specific concerns about many shelters' ability to implement certain provisions of OSHA's proposed standard. To address issues related to the feasibility of the proposed standard for homeless shelters, OSHA requested information in the proposal and held special sessions at each hearing site to receive testimony from employers, employees, clients and others representing homeless shelters. In addition, OSHA initiated a study to examine these issues further through an on-site survey of a number of homeless shelters. The results of this study (Ex. 179-1) did not become available to OSHA until after the close of the public comment period. This study has now been placed in the docket for this rulemaking and is available for public comment.

Waste Treatment Facilities

During the development of the proposal, OSHA was also concerned about additional types of work settings that might need to be included within the scope of the TB standard because they pose a significant risk of occupational TB exposure to their employees. During the public hearings, testimony was submitted that addressed the potential for significant occupational exposure to TB at medical waste treatment facilities handling medical wastes that had not been decontaminated. Preliminary findings from investigations at a medical waste treatment facility where a TB outbreak had occurred were presented at the hearings and used as supplemental evidence to support the inclusion of medical waste treatment facilities within the scope of the standard. Other commenters suggested that instead of including the waste treatment facilities, laboratories covered under the TB standard should be required to decontaminate their TB wastes prior to sending them offsite for disposal. At the time of the public hearings on the TB rule, NIOSH was in the process of conducting a Health Hazard Evaluation (HHE) to evaluate the potential for occupational exposure to *Mycobacterium tuberculosis* during the processing the medical wastes. The final HHE (Ex. 179-2) was completed after the close of the public comment period,

and has now been entered into the docket for public comment.

Other Work Settings

In addition to homeless shelters and medical waste treatment facilities, other work settings were also recommended by various commenters for possible inclusion in the final standard. Several commenters urged OSHA to cover TB and AIDS clinics based on the fact that these types of clinics are likely to have a high percentage of clients at risk for having infectious TB. OSHA is considering including these ambulatory clinics within the scope of the final standard and seeks additional information on whether such inclusion is warranted. In particular, OSHA solicits information on the number of such clinics, the number of employees typically employed by these clinics, and data on the risk of TB to employees of these facilities.

Commenters also urged the Agency to include parole and probation officers within the scope of the final standard. These commenters testified during the public hearings that parole and probation officers must often interact with the same type of high-risk populations as employees in correctional facilities and therefore, they should be included within the scope of the final standard. Therefore, OSHA also solicits additional information on whether the inclusion of parole and probation officers under the final standard is warranted.

Finally, commenters urged the Agency to expand the standard's coverage of social service workers to include all social service workers and not just social service workers providing services to individuals who are in TB isolation or who are otherwise segregated or isolated due to having infectious TB. OSHA solicits information on whether expanding coverage to all social service workers is warranted. In particular, OSHA is concerned about the feasibility of including such a broad spectrum of workers in the final standard. Thus, the Agency is interested in ways to determine the type(s) of social service workers who may reasonably be anticipated to incur occupational exposure to TB and types of provisions that would be most effective to reduce TB risks of such employees.

Additional Submissions to the Record

In addition, four other documents pertinent to issues raised during the rulemaking became available after the close of the rulemaking record. These documents are: (1) the American College of Occupational and Environmental

Medicine's (ACOEM) "Guidelines for Protecting Health Care Workers Against Tuberculosis" (Ex. 179-3); (2) "Laboratory Performance Evaluation of N95 Filtering Facepiece Respirators, 1996" (Morbidity and Mortality Weekly Report, December 11, 1998) (Ex. 179-4); (3) "The Costs of Healthcare Worker Respiratory Protection and Fit-Testing Programs" by Scott E. Kellerman et al. (September 1998, Journal of Infection Control and Epidemiology) (Ex. 179-5) and (4) "The Relative Efficacy of Respirators and Room Ventilation in Preventing Occupational Tuberculosis" by Kevin Fennelly and Edward Nardell (October 1998, Journal of Infection Control and Epidemiology) (Ex. 179-6).

Reopening of the Record and Request for Comments

In order to complete the rulemaking record on issues related to the feasibility of the proposed standard for homeless shelters and medical waste treatment facilities, OSHA is now reopening the rulemaking record and placing in the record the final homeless shelter study, "Final Report on Site Visits to Nine Homeless Shelters", (Ex. 179-1) and the NIOSH medical waste facility HHE (Ex. 179-2). OSHA is also submitting four additional documents, listed above, which include three articles related to respiratory protection issues discussed during the hearings and one article by the ACOEM outlining recommendations for controlling the transmission of TB. These exhibits are available in the Docket Office at the address listed above.

OSHA seeks public comment on (1) the homeless shelter report, (2) the NIOSH HHE, and (3) the underlying issues related to the feasibility of the proposed standard for homeless shelters, and whether the standard should cover medical waste treatment facilities, to help OSHA determine whether and, if so, how homeless shelters and medical waste treatment facilities should be regulated under the final TB standard. Comments are also requested on whether OSHA should require laboratories to decontaminate medical wastes containing *Mycobacterium tuberculosis* before these wastes are sent offsite for disposal. In addition, new information on including TB and AIDS clinics as well as social service workers and parole and probation officers within the scope of a final standard is sought.

OSHA also requests comment on four additional documents: the ACOEM TB guidelines and three articles addressing respiratory protection against TB, which are listed above. In particular, the Agency is interested in comments

regarding the adequacy of qualitative fit-testing for N95 respirators for determining a face-seal leakage of no greater than 10 percent.

This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

It is issued under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), Secretary of Labor's Order No. 1-90 (55 FR 9033) and 29 CFR part 1911.

Signed at Washington, DC, this 9th day of June, 1999.

Charles N. Jeffress,

Assistant Secretary of Labor.

[FR Doc. 99-15240 Filed 6-16-99; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

[SPATS No. MO-035-FOR]

Missouri Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of additional information about a previously proposed amendment to the Missouri regulatory program (Missouri program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Missouri submitted supporting documentation for the normal husbandry practices proposed in the previous amendment. The practices include applying pesticides and soil amendments; subsoiling; repairing rills and gullies; burning; overseeding; and planting and pruning trees. Missouri intends to revise its program to be consistent with the corresponding Federal regulations.

DATES: We will accept written comments until 4:00 p.m., c.d.t., July 19, 1999.

ADDRESSES: You should mail or hand deliver written comments to John W. Coleman, Mid-Continent Regional Coordinating Center, at the address listed below.

You may review copies of the Missouri program, the amendment, and

all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Mid-Continent Regional Coordinating Center.

John W. Coleman, Mid-Continent Regional Coordinating Center, Office of Surface Mining, Alton Federal Building, 501 Belle Street, Alton, Illinois 62002, Telephone: (618) 463-6460.

Missouri Department of Natural Resources, Land Reclamation Program, 205 Jefferson Street, P.O. Box 176, Jefferson City, Missouri 65102, Telephone: (573) 751-4041.

FOR FURTHER INFORMATION CONTACT: John W. Coleman, Mid-Continent Regional Coordinating Center. Telephone: (618) 463-6460. Internet:

jcoleman@mcrwgw.osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Missouri Program

On November 21, 1980, the Secretary of the Interior conditionally approved the Missouri program. You can find general background information on the Missouri program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the November 21, 1980, **Federal Register** (45 FR 77017). You can find later actions on the Missouri program at 30 CFR 925.12, 925.15, and 925.16.

II. Discussion of the Proposed Amendment

By letter dated October 10, 1990, Missouri sent us an amendment to its program under SMCRA (Administrative Record No. MO-519). We announced receipt of the amendment in the November 1, 1990, **Federal Register** (55 FR 46076) and invited public comment on its adequacy. The public comment period closed December 3, 1990. In the September 29, 1992, **Federal Register** (57 FR 44660), we approved the amendment with exceptions. The exceptions included revisions to Missouri's regulation at 10 CSR 40-7.021(1)(B)2 concerning normal husbandry practices. We did not approve this regulation because Missouri had not provided evidence to substantiate the use of each proposed practice as a normal husbandry practice. As codified at 30 CFR 925.16(p)(15), we required Missouri to provide such evidence for the administrative record or to delete the regulation at 10 CSR 40-7.021(1)(B)2.

By letter dated June 4, 1999, Missouri submitted agricultural publications and