devices exported and the countries to which they were exported.''

In the **Federal Register** of April 2, 1999 (64 FR 15944), FDA published a proposed rule that would establish the notification and recordkeeping requirements for persons exporting human drugs, biologics, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States. Because reactions to the proposed rule thus far have raised numerous issues, the agency wants to ensure that interested persons have an adequate opportunity to examine the rule and to submit comments. Therefore, FDA is extending the comment period until July 16, 1999.

Interested persons may, on or before July 16, 1999, submit to the Dockets Management Branch (address above) written comments on the proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the proposed rule and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. The proposed rule may also be obtained through FDA's web site at ''www.FDA.gov''.

Dated: June 10, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–15395 Filed 6–15–99; 10:04 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 99N–1502]

Quality Mammography Standards; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing mammography. The purpose of the amendments is to incorporate changes required by the Mammography Quality Standards Reauthorization Act (MQSRA). This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Comments on this proposal must be received by August 31, 1999. If FDA receives no significant adverse comment on the provisions of these regulations within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective November 1, 1999.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Roger L. Burkhart, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20857, 301–594–3332.

SUPPLEMENTARY INFORMATION: This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule is identical to the direct final rule. This proposed rule will provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and the direct final rule is withdrawn. FDA is publishing the direct final rule because the rule contains direct incorporations of statutory mandates, and FDA anticipates that it will receive no significant adverse comments. If no significant comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect no later than 135 days after publication. Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives significant adverse comments regarding this rule, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to the comments under this rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. It should be remembered, however, that the requirements themselves were established by the MQSRA. FDA must implement these new statutory provisions.

In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a note-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered a significant adverse comment under this procedure. For example, a comment recommending a rule change in addition to the rule will not be considered a significant adverse comment, unless the comment shows how the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

I. Background

The Mammography Quality Standards Act (the MQSA) (Pub. L. 102–539) was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that, to lawfully provide mammography services after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, shall be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). To become accredited and certified, a facility had to meet national quality standards to be established by the Secretary. The authority to establish these standards, to approve accreditation bodies, and to certify facilities was delegated by the Secretary to FDA.

Facilities were initially accredited and certified if they met the standards contained within the interim rules issued by FDA in the **Federal Register** of December 21, 1993 (58 FR 67558 and 58 FR 67565), and amended by another interim rule published in the **Federal Register** of September 30, 1994 (59 FR 49808). More comprehensive standards were proposed by FDA in the **Federal Register** of April 3, 1996 (61 FR 14856,

61 FR 14870, 61 FR 14884, 61 FR 14898, and 61 FR 14908). After some revision in response to the approximately 8,000 comments received on the proposed rule, a final rule was published in the **Federal Register** of October 28, 1997 (62 FR 55852) (hereinafter referred to as the October 1997 final rule). The effective date of most of the new standards contained within the October 1997 final rule is April 28, 1999, but a few will not become effective until October 28, 2002.

On October 9, 1998, the MQSRA (Pub. L. 105–248) became law. The basic purpose of the MQSRA was to extend the authorities established by the MQSA until September 30, 2002. However, the MQSRA also contained a requirement that was significantly different from the corresponding requirement in the October 1997 final rule. Although this MQSRA requirement will become effective on April 28, 1999, with or without the amendment of the final rule, FDA is proposing to amend the final rule to incorporate the change. The purpose of this proposed amendment is to provide to the mammography facilities the convenience of being able to find all of the quality standards within a single document instead of having to consult both the October 1997 final rule and the MQSRA and to avoid confusion as to the applicable reporting requirement.

Other provisions of the MQSRA clarify the basis for some of the requirements contained within the October 1997 final rule. FDA is also amending the October 1997 final rule to conform its wording of those requirements to that of the statute.

II. Changes in the Regulations

A. Reporting Requirements

Section 900.12(c)(2) (21 CFR 900.12(c)(2)) of the October 1997 final rule describes the requirements for communicating mammography results to the patients. As published in the October 1997 final rule, these requirements mandated that each mammography facility have a system to ensure that the results of each examination are communicated to the patient in a timely manner. Patients without a referring health care provider were to be sent the report of the examination (as described in § 900.12(c)(1)) directly by the mammography facility, along with a written notification or summary of the results in lay terms. It was further required by the October 1997 final rule that such self-referred patients should be referred to a health care provider when clinically indicated.

In the case of patients with a referring health care provider, § 900.12(c)(3) required that the health care provider receive the report of the examination. The facility's system for ensuring that results reached the patient could utilize the services of that health care provider to achieve that goal. There was no specific requirement that a summary in lay terms be provided to the patient with a referring health care provider.

The MQSRA amended the MQSA to specifically require that all patients, not just self-referred patients, receive directly from the mammography facility, a summary of the written report in terms easily understood by a lay person. As previously noted, this MQSRA requirement will go into effect on April 28, 1999. FDA is proposing to amend § 900.12(c)(2) to incorporate this new requirement.

B. Clarifications

The MQSRA at several points clarified the provisions of the MQSA upon which certain requirements of the interim and final rules were based. In contrast to the change in the patient reporting requirements, these clarifications became effective on October 9, 1998, the date on which the MQSRA became law. FDA is proposing to amend the regulations to similarly clarify the wording of the October 1997 final rule on these points.

1. Review Physicians

The most important function of the accreditation bodies approved by FDA is to conduct a quality review of clinical images submitted by facilities seeking accreditation. This review is the key factor in determining if the facility should be accredited and then certified. It has been recognized from the start of the MQSA program that the physicians used by the accreditation bodies to review the clinical images submitted by the facilities should meet qualifications beyond those needed to serve as interpreting physicians in mammography facilities. All accreditation bodies applying to FDA for approval must demonstrate that their reviewing physicians have the high qualifications necessary to perform such reviews before approval is given.

In section 4, the MQSRA emphasized these points by defining the physicians reviewing clinical images for the accreditation bodies as ''review physicians.'' In the MQSRA definition, it is further recognized that the accreditation bodies can establish, with FDA approval, additional qualifications for these review physicians beyond the qualifications applicable to interpreting physicians in mammography facilities.

FDA is proposing to add § 900.2(yy) to incorporate the MQSRA definition of ''review physician'' into the final rule. FDA is further proposing to amend § 900.4 in order to use the term review physician at the appropriate points. In addition, since this term could be confused with the term ''reviewing interpreting physician,'' presently used in connection with the requirements for the mammography audit, FDA is proposing to change the term, ''reviewing interpreting physician'' to ''audit interpreting physician'' in § 900.12(f).

2. Patient Notification

The October 1997 final rule at § 900.12(j) states that if FDA determines that any activity related to the provision of mammography at a facility presents a sufficiently serious risk to human health, the agency may require the facility to notify the patients, their physicians, and/or the public of actions that may be taken to minimize this risk. This provision was established to aid FDA in fulfilling its general responsibility under the MQSA to inform the public about facilities against which the agency has been required to take action for failure to meet the quality standards. In section 10(a), the MQSRA provided a specific statement of the agency's authority to require patient notification. FDA is proposing to amend the wording of § 900.12(j) to bring it into conformance with the wording of the MQSRA on this point.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of these proposed amendments under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze the impact of a rule on small entities. The Unfunded

Mandates Reform Act requires (in section 201) that agencies prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million (adjusted annually for inflation).

As previously noted, the proposed amendments explained under section II.B of this document merely clarify provisions already contained within the October 1997 final rule. The impacts of the provisions of that final rule were discussed in the preamble of the final rule (62 FR 55852 at 55961), and are unchanged by the clarifications. Any economic impact of the proposed amendments is related solely to the change in the patient reporting requirement mandated by the MQSRA. Given the statutory basis for extending this requirement to all mammography facilities effective April 28, 1999, FDA did not consider alternatives to implementing the requirements.

In the October 1997 final rule, FDA estimated that there were 9,800 mammography facilities that would be considered small. Moreover, FDA previously estimated the impact of a requirement for sending a lay summary of results to all patients during the development of its proposed rule of April 3, 1996 (61 FR 14856), although that requirement was removed from the October 1997 final rule in response to public comments (Ref. 1). FDA believes that these estimates remain accurate.

The earlier estimate concerning the impact of required lay summaries was based upon the assumption that an adequate lay summary of results could be provided in the great majority of cases in a brief, standardized format. Using this assumption, it was estimated that the compliance cost per examination would be $0.94, including the labor of the office worker and the cost of postage.

To convert this per examination cost to a national total, it was necessary to make several other assumptions. Using the best data and expert opinion available at the time, it was estimated that approximately 25 million mammography examinations were conducted annually in this country. Of this, it was estimated that 7.7 percent or 1,925,000 were examinations of self-referred patients. Because facilities were already required by the MQSA (and by the interim rule) to provide a lay summary of results to self-referred patients, that portion of the cost of sending lay summaries had already been included in the impact estimates made in association with the development of the interim rule of October 27, 1993.

There remained then approximately 23,075,000 patients for which this was potentially a new requirement. However, it was further estimated that 40 percent of the patients were already receiving a lay summary in some form from the facility at which they received their examinations. Thus, the new requirement would lead to additional lay summaries in only 60 percent of the referred examinations or approximately 13,845,000. At $0.94 a lay summary, the added cost would be slightly over $13 million a year.

Two major changes have occurred since the information upon which these estimates were based was collected in late 1995. Most significantly, through FDA's activities and those of other private and government groups, public awareness of the need for regular mammography examinations and public confidence that a high quality examination will be received have both increased. As a result, the number of examinations given per year has increased to an estimated 40 million. This requires increasing the costs estimated previously by 60 percent. Postage rates have also gone up $0.01 per letter thus the cost per lay summary would increase from $0.94 to $0.95. The combined impact of these two changes is to increase the estimate of the annual incremental costs to meet this proposed new requirement to approximately $21 million.

For the great majority of cases, the assumption that the lay summaries can be provided in brief, standardized format is valid. However, in approximately 10 percent of the cases, the overall assessment of the findings is expected to be ''suspicious'' or ''highly suggestive of malignancy.'' In such cases, the facility is required to ''make reasonable attempts to ensure that the results are communicated to the patients as soon as possible.''

Facilities that accept self-referred patients are already required by the final rule to make such attempts for cases with an overall assessment of ''suspicious'' or ''highly suggestive of malignancy.'' Based upon the assumption that the attempt would involve a 5 minute telephone conversation of the interpreting physician with the patient, a cost of $8.93 per examination was estimated. This cost would be in addition to the $0.95 estimated cost for the written lay summary which would still need to be sent. Assuming that this would be a new cost for 10 percent of the 60 percent of the referred patients among the 40 million receiving examinations annually, the incremental cost for these contacts is approximately $21.4 million.

The total annual incremental cost due to this proposed new requirement, therefore, would be approximately $42.4 million. Previously, the annual cost for compliance with the interim and final MQSA rules was estimated at $61.5 million (Ref. 2). Adding the cost of compliance with this proposed new requirement brings the total annual cost of compliance with the final rule as amended to approximately $103.9 million.

Compliance with the proposed new requirement would also be expected to increase the benefits from mammography. Mammography is the most effective technique presently available for the early detection of breast cancer. Early detection of breast cancer followed by prompt treatment can avert mortalities that can result if treatment is delayed until the cancer reaches a more advanced stage. In addition, the cost and severity of the treatment methods will in general be less when the cancer is treated at an early stage. Even in cases where the assessment is negative, there will be an expected benefit arising from relieving the anxiety of the patient about the possible results of the examination through prompt reporting of results to her. But for these benefits to be gained, the patient must be informed of the results of her examination so that necessary followup actions can be promptly taken. Unfortunately, although it is not possible to make a quantitative estimate of the number of such cases, there have been frequent complaints about patients receiving the results of their examinations after an undue delay or not at all. Studies have also shown that direct communication of results to the patient by the mammography facility (as compared to traditional communication procedures where the facility communicates only with the referring provider), produces an improvement in compliance with followup recommendations (Ref. 3). The new requirement should thus add to the benefits expected from interim and final rules, which were previously estimated to range from $284 to $408 million (61 FR 55986), primarily due to a gain in averted mortalities (Ref. 2).

Based on these analyses, FDA has determined that the rule is consistent with the principles set forth in the Executive Order, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act. The wording of the requirement related to sending lay summaries to referred patients directly parallels that of the MQSRA and so, in accordance with the Executive Order, maximizes the net benefits to the extent

allowed by that statute. Similarly, in accordance with the Regulatory Flexibility Act, the impact of the rule on small entities has been analyzed. Finally, as noted previously, the incremental annual expenditures (beyond those already incurred from the previous interim and final rules) required by the rule are estimated at $42.4 million and thus do not exceed $100 million in 1 year so the rule does not come under the requirements of the Unfunded Mandates Reform Act.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate are the times for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Lay Summary of Examination Results to Patients

Description: This proposed rule would merely implement a statutory information collection requirement; there is no additional burden attributable to the regulation. The proposed rule would conform the requirements of this section with the requirement of section 6 of Pub. L. 105–248 that states: ''(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person.'' To produce the required lay summary, the mammography facilities will review the medical report of each patient's examination and collect from it the necessary information.

Respondent Description: Businesses and other for-profit organizations, nonprofit organizations.

For consistency with the direct final rule to which this proposed rule is a companion, FDA is following the PRA comment procedures for direct final rules in this proposed rule. As provided in 5 CFR 1320.5(c)(1), collections of information in a direct final rule are subject to the procedures set forth in 5 CFR 1320.10. Interested persons and organizations may submit comments on the information collection provisions of this proposed rule by August 31, 1999, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. At the close of the 75-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of the direct final rule, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Eastern Research Group, ''Cost and Benefit Analysis of Regulations Under the Mammography Quality Standards Act of 1992–Preliminary Final,'' March 14, 1996.

2. Eastern Research Group, ''Economic Impact Analysis of Regulations Under the Mammography Quality Standards Act of 1992–Final,'' October 7, 1997.

3. Agency for Health Care Policy and Research (AHCPR), ''Quality Determinants of Mammography,'' AHCPR Pub. No. 95–0632, October 1994.

List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 900 be amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

2. Section 900.2 is amended by adding paragraph (yy) to read as follows:

§ 900.2 Definitions.

* * * * *

(yy) *Review physician* means a physician who, by meeting the requirements set out in § 900.4(c)(5), is qualified to review clinical images on behalf of the accreditation body.

3. Section 900.4 is amended by revising the last sentence of paragraph (a)(4); and by revising paragraphs (c)(3)(ii), (c)(5) introductory text, (c)(5)(i), (c)(5)(ii), and (c)(6)(ii) to read as follows:

§ 900.4 Standards for accreditation bodies.

(a) * * *

(4) * * * Such individuals who review clinical or phantom images under the provisions of paragraphs (c) and (d) of this section or who visit facilities under the provisions of paragraph (f) of this section shall not review clinical or phantom images from or visit a facility with which such individuals maintain a relationship, or when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility.

* * * * *

(c) * * *

(3) * * *

(ii) All clinical images submitted by a facility to the accreditation body shall be reviewed independently by two or more review physicians.

* * * * *

(5) Review physicians. Accreditation bodies shall ensure that all of their review physicians:

(i) Meet the interpreting physician requirements specified in § 900.12(a)(1) and meet such additional requirements as have been established by the accreditation body and approved by FDA;

(ii) Are trained and evaluated in the clinical image review process, for the types of clinical images to be evaluated by a review physician, by the accreditation body before designation as review physicians and periodically thereafter; and

* * * * *

(6) * * *

(ii) If a review physician identifies a suspicious abnormality on an image

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: