section of the applicable PW4000 series Engine Manuals.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Engine Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector (PMI), who may add comments and then send it to the Engine Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The records of the mandatory inspections required as a result of revising the Time Limits section of the PW4000 series Engine Manuals and the air carrier's continuous airworthiness maintenance program as provided by paragraph (a) of this AD shall be maintained by FAA-certificated air carriers which have an approved continuous airworthiness maintenance program in accordance with the record keeping system currently specified in their manual required by sections 121.369 of the Federal Aviation Regulations (14 CFR 121.369); or, in lieu of the record showing the current status of each mandatory inspection required by sections 121.380(a)(2)(vi) of the Federal Aviation Regulations (14 CFR 121.380(a)(2)(vi)), certificated air carriers may establish an approved alternate system of record retention that provides a method for preservation and retrieval of the maintenance records that include the inspections resulting from this AD, and include the policy and procedures for implementing this alternate method in the air carrier's maintenance manual required by sections 121.369 (c) of the Federal Aviation Regulations (14 CFR 121.369 (c)); however, the alternate system must be accepted by the appropriate PMI and require the maintenance records be maintained either indefinitely or until the work is repeated.

Note 3: These record keeping requirements apply only to the records used to document the mandatory inspections required as a result of revising the Time Limits section of the PW4000 series Engine Manuals as provided in paragraph (a) of this AD, and do not alter or amend the record keeping requirements for any other AD or regulatory requirement.

Issued in Burlington, Massachusetts, on October 30, 1998.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 98–29603 Filed 11–4–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 314, and 600

[Docket No. 98N–0750]

RIN 0910–AB42

Electronic Reporting of Postmarketing Adverse Drug Reactions; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is considering preparing a proposed rule that would require applicants, manufacturers, packers, and distributors of marketed human drugs and licensed biological products to submit postmarketing expedited individual case safety reports and individual case safety reports contained in periodic safety reports to the agency electronically using standardized medical terminology, data elements, and electronic transmission standards recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The proposed rule would help harmonize reporting of postmarketing safety information worldwide and expedite detection of safety problems for marketed drugs, thus enhancing FDA's ability to protect and promote public health. FDA is soliciting comments from interested persons to assist with the development of the proposed rule. The agency is specifically seeking comments on whether exemptions from any electronic safety reporting requirements should be granted to any entity and, if so, the basis on which they should be granted, the cost benefits or burdens of such requirements, and timeframes for implementing the requirements.

DATES: Written information and comments by February 3, 1999.

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

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), 5600 Fishers Lane, Rockville, MD 20857, 301–594–5621 (Internet electronic mail: kuchenbergt@cder.fda.gov) or Marcel Salive, Center for Biologics Evaluation and Research (HFM–220), 1401 Rockville Pike, Rockville, MD 20852, 301–827–3974 (Internet electronic mail: salive@cber.fda.gov).

SUPPLEMENTARY INFORMATION:

I. Background

A. International Harmonization

For several years, FDA has cooperated with industry associations and the regulatory authorities of certain other nations to promote international harmonization of regulatory requirements. Much of this effort has been coordinated through ICH, which is facilitating the harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are: the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research at FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization (WHO), the Canadian Therapeutic Products Directorate, and the European Free Trade Area.

One ICH initiative is to harmonize certain safety reporting requirements of the three regions. Through the ICH process, recommendations have been developed regarding the content, format, and reporting frequency for expedited individual case safety reports and periodic safety reports for human drugs and biological products. In the **Federal Register** of March 1, 1995 (60 FR 11284), FDA published an ICH final guidance entitled ''Clinical Safety Data Management: Definitions and Standards for Expedited Reporting'' (the ICH E2A guidance). In the **Federal Register** of May 19, 1997 (62 FR 27470), FDA published an ICH final guidance entitled ''Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' (the ICH E2C guidance). Under the auspices of ICH, standards for electronic submission of safety information have been developed, as described in the Appendices, including a standard

medical terminology for regulatory purposes, ICH M1 (see Appendix A in section VII.A of this document); electronic standards for the transfer of regulatory information, ICH M2 (see Appendix B in section VII.B of this document); and standardized data elements for transmission of individual case safety reports, ICH E2B format (see Appendix C in section VII.C of this document). FDA believes the changes recommended by ICH will result in more effective and efficient safety reporting to regulatory authorities worldwide.

There is now international agreement on the major components for standardizing electronic transmission of certain safety reports, and worldwide implementation of this initiative has begun.

B. Postmarketing Safety Reports

Under existing regulations, manufacturers, packers, distributors, applicants of approved new and abbreviated marketing applications for drugs, and licensed manufacturers of biological products must submit expedited individual case safety reports of postmarketing adverse drug experiences under §§ 310.305, 314.80, 314.98, and 600.80 (21 CFR 310.305, 314.80, 314.98, and 600.80). Applicants and licensed manufacturers must also submit periodic reports of postmarketing adverse drug experiences under §§ 314.80, 314.98, and 600.80.

Expedited individual case safety reports are required to be submitted for each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible, but in no case later than 15 calendar days of initial receipt of the information (§§ 310.305(c)(1), 314.80(c)(1)(i), and 600.80(c)(1)(i)). Followup reports to these expedited reports are required to be submitted within 15 calendar days of receipt of new information or as requested by FDA (§§ 310.305(c)(2), 314.80(c)(1)(ii), and 600.80(c)(1)(ii)).

Presently, periodic reports are required to be submitted at quarterly intervals for 3 years from the date of approval of the application and annually thereafter (§§ 314.80(c)(2)(i) and 600.80(c)(2)(i)). The periodic report is required to contain: (1) A narrative summary and analysis of the information in the report and an analysis of the expedited individual case safety reports submitted during the reporting interval, (2) individual case safety reports for each adverse drug experience not previously reported, and (3) a history of actions taken since the last periodic report (§§ 314.80(c)(2)(ii) and 600.80(c)(2)(ii)).

Each adverse drug experience is required to be submitted to the agency on an FDA Form 3500A (§§ 310.305(d), 314.80(f), and 600.80(f)). Foreign events may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS (Council for International Organizations of Medical Sciences) I form.

FDA is in the process of revising these regulations to be consistent with safety reporting recommendations developed by ICH. In the **Federal Register** of October 27, 1994 (59 FR 54046), FDA published a proposed rule to amend its postmarketing expedited and periodic safety reporting requirements, as well as others, to implement international standards and to facilitate the reporting of adverse drug experiences. In the **Federal Register** of October 7, 1997 (62 FR 52237), FDA published a final rule amending its premarketing and postmarketing expedited safety reporting regulations to implement certain recommendations in the ICH E2A guidance on definitions and standards for expedited reporting. At this time, the agency is considering other recommendations in the ICH E2A guidance and plans to propose additional amendments to its postmarketing expedited safety reporting regulations. With regard to the amendments to the postmarketing periodic adverse drug experience reporting requirements proposed on October 27, 1994, FDA has decided to repropose these amendments based on recommendations in the ICH E2C guidance on postmarketing periodic safety update reports. In developing the reproposal, FDA will consider comments submitted in response to the proposed rule of October 27, 1994, regarding postmarketing periodic adverse experience reports.

II. Proposed Policy

FDA is considering preparing a proposed rule that would require that applicants, manufacturers, packers and distributors of marketed human drugs and licensed biological products submit postmarketing expedited individual case safety reports and individual case safety reports contained in periodic safety reports to the agency electronically rather than on paper. The proposed rule would require that the electronic submission of postmarketing expedited and periodic individual case safety reports be precoded in the standardized M1 international medical terminology, use the E2B format, and be transmitted using M2 specifications. FDA may also propose requiring that textual materials contained within periodic safety reports (e.g., narrative summary and analyses, history of actions taken) be submitted electronically.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a final rule in part 11 (21 CFR part 11) providing the conditions under which the agency will accept electronic signatures, electronic records, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed to paper records. Part 11 applies to any required records submissions under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or Title 21 of the Code of Federal Regulations. Part 11 provides that for records required to be maintained but not submitted to the agency, electronic records and accompanying signatures may be used in lieu of traditional records and signatures provided certain requirements are met. Electronic records and accompanying signatures that are submitted to the agency must meet the requirements of part 11 and must also be identified in public docket number 92S–0251 as the type of submission the agency is prepared to accept electronically. It is important to note that the use of electronic records, as well as their submission to FDA under part 11, is voluntary.

However, for a number of reasons, FDA believes that it is essential to mandate the electronic submission of postmarketing expedited and periodic individual case safety reports as well as the use of international standards for electronic safety reporting.

The rapid identification and dissemination of information about emerging problems with individual drugs or harmful drug interactions is central to the agency's mission to protect and promote public health and safety. First, receipt of safety information electronically will vastly increase FDA's ability to quickly analyze data and identify emerging safety problems. Second, the agency believes that use of international standards for electronic safety reporting will eliminate the costs to industry associated with maintaining multiple systems designed to meet the needs of different terminologies, data elements, and electronic transmission standards of different regulatory authorities, and would thereby greatly enhance the utility of the system. Third, electronic submissions will improve the speed and efficiency of industry and agency operations and enhance the quality of the safety data.

III. Solicitation of Comments

All interested persons are invited to submit to FDA their comments on any aspect of this advance notice of proposed rulemaking (ANPRM). In particular, FDA is seeking public comment on the following subjects:

1. Exemptions

The agency believes that the electronic reporting of postmarketing individual case safety reports will be welcomed by most of industry. The agency is aware, however, that some entities may have difficulty adapting existing systems to the requirements of a mandatory standardized electronic reporting system. The agency seeks guidance on whether exemptions should be granted and, if so, what considerations should be used to determine whether requesting entities may continue submitting postmarketing individual case safety reports in a paper format and whether any such exemptions should continue indefinitely or be terminated after a certain period of time.

In the **Federal Register** of October 30, 1997 (62 FR 58647), the Securities and Exchange Commission (SEC) published a final rule stating that it would no longer accept paper copies of filings and required filers to submit information electronically unless certain requirements for a temporary or continuing hardship were met. Filers may claim or request, as appropriate, hardship exemptions based on certain criteria, including: Technical difficulties in filing and undue burden and expense of conversion to electronic format. A temporary hardship exemption, generally for unanticipated technical difficulties, is available automatically, but submission of a paper copy of the filing must be followed, within 6 business days, by a confirming electronic copy. A continuing hardship exemption is also available but must be granted by the SEC. It may be granted for a specific period (after which a confirming electronic copy of the paper copy must be filed) or for an indefinite period.

FDA is seeking specific comments on whether a similar exemption provision would be appropriate for electronic reporting for postmarketing individual case safety reports.

2. Cost Benefits and Burdens

The agency is interested in comments on the impact of a mandatory standardized electronic reporting requirement on different segments of regulated industry. For example, how will such a requirement affect manufacturers of different type and size over the short term during implementation and over the long term once systems are established? FDA is also interested in information on the benefits that industry could derive from a mandatory standardized electronic reporting requirement (e.g., reduced paperwork burden, reduced errors, increased convenience and more timely receipt of information).

3. Timeframes for Implementation

The SEC model, described in section III.1 of this document, phased companies into its electronic filing system over a 4-year period, with small business filers being the last to be required to file electronically. The agency is seeking comments on whether a similar implementation plan, based on the size of a firm, would be appropriate for electronic reporting of postmarketing individual case safety reports and, if not, how it should be modified, and what criteria should be used to define an implementation plan.

4. OMB Circular A–130

Section 8a(3) of OMB circular A–130 cites a policy to encourage agencies to explore the use of automated techniques for the collection of information and conditions conducive to the use of those techniques. Section 8a(3) reads as follows:

Electronic Information Collection. Agencies shall use electronic collection techniques where such techniques reduce burden on the public, increase efficiency of government programs, reduce costs to the government and the public, and/or provide better service to the public. Conditions favorable to electronic collection include:

(a) The information collection seeks a large volume of data and/or reaches a large proportion of the public;

(b) The information collection recurs frequently;

(c) The structure, format, and/or definition of the information sought by the information collection does not change significantly over several years;

(d) The agency routinely converts the information collected into electronic format;

(e) A substantial number of the affected public are known to have ready access to the necessary information technology and to maintain the information in electronic form;

(f) Conversion to electronic reporting, if mandatory, will not impose substantial costs or other adverse effects on the public, especially State and local governments and small business entities.

FDA is soliciting comments on whether a proposed rule consistent with the objectives discussed in this ANPRM would advance the objectives of the policy stated in the OMB circular.

If FDA develops a proposed rule for electronic reporting of postmarketing individual case safety reports, it will take into consideration comments submitted in response to this ANPRM.

IV. Executive Order 12866 Analysis

In any rulemaking proposed as a result of comments received on this ANPRM, FDA will examine the economic implications of the proposed rule as required by Executive Order 12866, which directs agencies to assess all costs and benefits of available regulatory alternatives. Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. In any rulemaking, the agency will examine the potential costs and potential benefits of the proposed rule. FDA requests information that would aid the agency in responding to the Executive Order.

V. Regulatory Flexibility Analysis

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze options that would minimize the economic impact of that rule on small entities. FDA requests information regarding the impact on small entities of the three subjects identified in section III of this document.

VI. Comments

Interested persons may on or before February 3, 1999, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. Appendices

A. Appendix A: M1 Medical Terminology

Most organizations currently process their regulatory data using an international adverse drug reaction (ADR) terminology in combination with a morbidity terminology. In Europe, many users combine the World Health Organization's Adverse Reaction Terminology with the ninth revision of the International Classification of Diseases (ICD–9). In the United States, Coding Symbols for a Thesaurus of Adverse Reaction Terms with Clinical Modification of ICD–9 (ICD–9–CM) is

very commonly used, and Japan has developed its own version of these ADR terminologies, J–Art and MEDIS.

The established terminologies have been criticized for a number of reasons, including: Lack of specificity, limited data retrieval options, and an inability to effectively handle complex combinations of signs and symptoms (syndromes). In addition, use of different terminologies at different stages in the development and use of products complicates data retrieval and analysis of information and makes it difficult to effectively cross-reference data through the lifetime of a product. Internationally, communication is impaired between regulatory authorities because of the delays and distortions caused by the translation of data from one terminology to another.

Use of different terminologies also has significant consequences for pharmaceutical firms. Companies operating in more than one jurisdiction have had to adjust to subsidiaries or clinical research organizations that use different terminologies because of variations in data submission requirements. The difficulty of analyzing data comprehensively may be compounded by use of incompatible terminologies and could lead to delays in recognizing potential public health problems.

A medical terminology designed for regulatory purposes was recognized as necessary by industry and regulatory authorities to support the computerization and transmission of information related to many aspects of the regulation of medical products. In October 1994, the ICH Steering Committee introduced a multidisciplinary communication initiative to establish an international medical terminology for regulatory purposes (M1).

In November 1994, the ICH Steering Committee released a draft (or alpha) version of the M1 terminology for review and evaluation. The alpha version was made available free of charge to all national regulatory entities participating in the WHO International Drug Monitoring Program and, on request, to pharmaceutical companies and contract research organizations. More than 600 electronic copies were distributed with a testing guide which provided suggestions on how the terminology could be evaluated.

In March 1995, the M1 ICH working group met to evaluate the results of the alpha test, review proposals submitted by potential users participating in the alpha test, and evaluate suggested changes. Since 1995, the working group has: (1) Refined and documented the definitions of the levels in the structural hierarchy; (2) reviewed and established the scope of the terminology; (3) reviewed terms and codes of the established terminologies, made necessary linkages and deletions, and included the most recent versions of the current terminologies to facilitate the transfer of historical data; (4) reviewed the results of the extensive and systematic Organ Class reviews performed in the United States and Japan; and (5) made necessary changes to facilitate data analysis and presentation.

Over time, it is essential that the M1 medical terminology be maintained and updated in response to medical/scientific advances and regulatory changes. An international maintenance and service organization (MSSO) is being established to provide this function as well as serve as the licensing agent for the distribution of the M1 medical terminology. It is anticipated that the MSSO will begin licensing the M1 medical terminology in the near future.

B. Appendix B: Electronic Transmission Standards

The ICH Steering Committee recognized the need for rapid communication of regulatory information between pharmaceutical manufacturers and regulatory authorities and, in particular, the need for the electronic communication of safety information. The ICH Steering Committee also noted that rapid communication required universal standards and that separate, uncoordinated initiatives launched in various countries could compromise the benefits of electronic communication and jeopardize the harmonization process. As a result, the ICH Multidisciplinary Group 2 (M2) Expert Working Group (EWG) was established in October 1994 to recommend electronic standards and provide solutions to facilitate international electronic communication in the three ICH regions.

The M2 EWG recommended various open international standards that allow for the worldwide transmission of information regardless of the technical infrastructure. The electronic standards for the transfer of regulatory information (ESTRI) gateway is designed to ensure reliable regulatory communications by using certain common electronic elements. The M2 EWG recommended the following:

1. Physical Media

Use of 3.5 inch floppy disk (ISO 8860) (1 and 2) and CD–ROM 640 MB (ISO 9660) as standard media for physical data storage and transferability across heterogenous computer platforms.

2. Network Messaging

Use of the Internet (STP/MIME) and X400 as network messaging standards that will provide for the efficient transport of heterogenous data formats and complex documents among the three ICH regions.

3. Electronic Document Format

Use of the Portable Document Format (PDF) as the interchange format for the transfer of certain types of documents.

4. Secure Electronic Data Interchange (EDI) Over the Internet

Use of Templar, a standards-based solution that facilitates the transmission of secure EDI over the Internet in all three ICH regions.

In addition, the M2 EWG facilitated the implementation of E2B data elements by defining an attribute list and deriving a relational view that allows for transmission of all types of individual case safety reports, regardless of source and destination. The E2B/M2 attribute list will form the basis for defining E2B data elements in various structured formats such as standard generalized markup language (SGML).

C. Appendix C: E2B Data Elements for Transmission of Individual Case Safety Reports

In the **Federal Register** of October 1, 1996 (61 FR 51287), FDA published a draft guidance entitled ''Data Elements for Transmission of Individual Case Safety Reports.'' The notice gave interested parties an opportunity to submit comments by December 30, 1996. After consideration of the comments received and revisions to the guidance, a final draft was submitted to the ICH Steering Committee and endorsed by the three participating regulatory parties on July 17, 1997. The final guidance entitled ''E2B Data Elements for Transmission of Individual Case Safety Reports'' (ICH E2B guidance) was published in the **Federal Register** of January 15, 1998.

The guidance is intended to facilitate the standardization of data elements for transmission of individual case safety reports. The format for individual case safety reports includes provisions for transmitting all the relevant data elements useful to assess an individual ADR or adverse event report. The data elements are sufficiently comprehensive to cover complex reports from most sources, different data sets, and transmission situations or requirements. In many, if not most, instances a

substantial number of the data elements will not be known, but as much information as possible should be provided. The minimum information for the transmission of a safety report should include an identifiable patient, an identifiable reporter, a reaction/event, and a suspect drug or biological product.

Dated: October 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29564 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 98N–0728]

Quality Mammography Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing mammography that published in a document entitled ''Quality Mammography Standards.'' The purpose of these amendments is to eliminate a conflict between the mammography regulations, which must be followed by all facilities performing mammography, and FDA's Electronic Product Radiation Control (EPRC) performance standards, which establish radiation safety performance requirements for x-ray units, including mammographic systems.

DATES: Submit written comments on the proposed rule by January 4, 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 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

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

A specific requirement of the MQSA was that quality standards be established for mammographic equipment and practices, including quality assurance and quality control programs. Mammography facilities had to meet these standards to become accredited and certified. The standards were intended to replace the patchwork of Federal, State, and private standards existing in 1992 to ensure that all women nationwide receive uniformly high quality mammography services. Since October 1, 1994, these standards have been provided by interim rules published in the **Federal Register** of December 21, 1993 (58 FR 67558 and 58 FR 67565) and amended in the **Federal Register** of September 30, 1994 (59 FR 49808).

On April 3, 1996, FDA proposed final regulations to replace the interim regulations (61 FR 14856, 14870, 14884, 14898, and 14908). Developed with strong congressional encouragement, these proposed final regulations reflected FDA's belief that more comprehensive quality standards would further optimize facility performance. After analysis of the extensive public comments received on the proposed regulations, revisions were made and a final rule was published on October 28, 1997 (62 FR 55852). The effective date for most of the final rule is April 28, 1999. A few equipment and equipment quality assurance requirements do not become effective until October 28, 2002.

FDA has subsequently discovered that some mammographic x-ray systems will have difficulty meeting certain of the new requirements because of design features that were used by the manufacturers in order to ensure that their units met the agency's EPRC performance standards for diagnostic x-ray systems. The purpose of these amendments is to resolve this conflict.

II. Need for Proposed Amendments

The source of the conflict lies in the requirements for the collimation of the x-ray field and the alignment of that field with the image receptor found in § 900.12(b)(5) and (e)(5)(vii)(A) (21 CFR 900.12(b)(5) and (e)(5)(vii)(A)) of the MQSA final regulations. Two problems exist with these provisions as they appeared in the **Federal Register** of October 28, 1997.

First, both of these provisions permit the x-ray field ''to extend to or beyond the edges of the image receptor.'' This allowance was made in response to the expressed desire of some mammography facilities to have the capacity to ''blacken'' the film to the edges, a capacity that is particularly useful when automated viewing devices are used. Masking clear borders of mammography films is difficult to accomplish with such devices. However, the manufacturers of all diagnostic x-ray systems, including mammography systems, must comply with applicable performance standards established by FDA. These performance standards currently require that mammography systems be manufactured with collimation to ensure that the x-ray field does not extend beyond the nonchest wall edges of the image receptor.

It is possible for a mammography system to meet both of these sets of standards as they are currently written. However, FDA has been informed by one manufacturer that in the past, in order to be sure to meet the EPRC standards, their systems were designed so that the x-ray field does not reach the nonchest wall edges of the image receptor. Such systems would not meet the final MQSA regulations as presently written. Units of other manufacturers may have the same problem.

Without an amendment to the MQSA regulations, in order to be in compliance, some facilities would have to choose among three courses of action. The first would be to apply for and receive approval of an alternative requirement for alignment under 21 CFR 900.18 of the MQSA regulations that would allow the facility to continue using its system unchanged. The second would be to purchase a retrofit of their system under a variance to the performance standards that has already been approved by FDA for one manufacturer. The third would be to purchase a new system that meets both sets of existing requirements.

FDA is proposing to solve this first problem by changing § 900.12(e)(5)(vii)(A) so that the x-ray field will be allowed, but not required as at present, to extend to or beyond the nonchest wall sides of the image receptor. This would permit facilities whose systems are not presently capable of ''blackening'' the films to these edges to continue to use those systems without the need of either applying for an alternative requirement or purchasing an expensive retrofit.

The second problem is that the limit on the extension of the x-ray field