

guidance on the "Overview" section of financial reports.

- **Recognition Of Contingent Liabilities Arising From Litigation: An Amendment of SFFAS 5, Accounting For Liabilities Of The Federal Government.** Written comments to the Board are requested by November 30, 1998. This Exposure Draft contains proposed standards that address accounting for loss contingencies involving specific cases of pending or potential litigation.

Interested parties are encouraged to comment on any issues related to these three documents. The text of the documents can be viewed through the electronic Financenet on the FASAB Home Page www.financenet.gov/fasab.htm. Hard copies may be obtained from FASAB, 441 G St., NW, Suite 3B18, Washington, DC 20548. Telephone: 202-512-7350.

FOR FURTHER INFORMATION CONTACT:

Wendy Comes, Executive Director, 441 G St., NW., Room 3B18, Washington, DC 20548, or call (202) 512-7350.

Authority: Federal Advisory Committee Act, Pub. L. 92-463, sec. 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101-6.1015 (1990).

Dated: November 4, 1998.

Wendy M. Comes,
Executive Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ryan White Care Act Requirement—Secretary's Determination on HIV Testing of Newborns

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice and request for comments.

SUMMARY: Section 2626 of P.L. 104-146 (42 U.S.C. 300ff-34), the "Ryan White CARE Act Amendments of 1996", includes a requirement for the Secretary of HHS to make a determination whether a set of activities prescribed in section 2627 of the Public Health Service (PHS) Act (42 U.S.C. 300ff-35), have become routine practice in the United States. In making this determination, the Secretary is required to consult with the States and other public or private entities that have

knowledge or expertise relevant to the determination.

The purpose of this notice is to request comments from States and such other public or private entities with knowledge or expertise relevant to the practice of activities (1) through (4) in section 2627 of the PHS Act (42 U.S.C. 300ff-35). After consideration of comments submitted, the CDC will provide a summary of comments received to the Secretary as part of the process leading to the Secretary's determination required by Section 2626 of the PHS Act (42 U.S.C. 300ff-34).

DATES: The public is invited to submit comments on the practice of activities (1) through (4) in Section 2627 of the PHS Act by November 23, 1998.

ADDRESSES: Comments should be submitted to: Technical Information and Communication Branch, Division of HIV/AIDS Prevention—Intervention, Research, and Support, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-49, Atlanta, GA 30333.

FOR FURTHER INFORMATION CONTACT:

Technical Information and Communication Branch, Division of HIV/AIDS Prevention—Intervention, Research, and Support, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention (CDC), telephone (404) 639-2072.

SUPPLEMENTARY INFORMATION: Section 2626(d) of the Public Health Service Act (42 U.S.C. 300ff-34), directs the Secretary to publish in the **Federal Register** "a determination of whether it has become a routine practice in the provision of health care in the United States to carry out each of the activities described in paragraphs (1) through (5) of section 2627. In making the determination, the Secretary shall consult with the States and with other public or private entities that have knowledge or experience relevant to the determination." The activities described in section 2627 are as follows: "(1) In the case of newborn infants who are born in the State and whose biological mothers have not undergone prenatal testing for HIV disease, that each such infant undergo testing for such disease. (2) That the results of such testing of a newborn infant be promptly disclosed in accordance with the following, as applicable to the infant involved: (A) To the biological mother of the infant (without regard to whether she is the legal guardian of the infant). (B) If the State is the legal guardian of the infant: (i) To the appropriate official of the State agency with responsibility for the

care of the infant. (ii) to the appropriate official of each authorized agency providing assistance in the placement of the infant. (iii) if the authorized agency is giving significant consideration to approving an individual as a foster parent of the infant, to the prospective adoptive parent. (iv) if the authorized agency is giving significant consideration to approving an individual as an adoptive parent of the infant to the prospective adoptive parent. (C) If neither the biological mother nor the State is the legal guardian of the infant, to another legal guardian of the infant. (D) To the child's health care provider. (3) That, in the case of prenatal testing for HIV disease that is conducted in the State, the results of such testing be promptly disclosed to the pregnant woman involved. (4) That, in disclosing the test results to an individual under paragraph (2) or (3), appropriate counseling on the human immunodeficiency virus be made available to the individual (except in the case of a disclosure to an official of a State or an authorized agency)." The requirement of Section 2627 (5) was deleted for the purposes of Section 2626 through a subsequent technical amendment enacted into law.

The term routine practice provided in section 2626 (d) was not defined within the statute of Public Law 104-146 (42 U.S.C. 300ff-34). The joint explanatory statement of the committee on conference included the following legislative history on page 46 of the Conference Report 104-545 regarding the Secretary's determination: "(2) Within 2 years following the implementation of such a system, the Secretary will make a determination whether mandatory HIV testing of all infants born in the U.S. whose mothers have not undergone prenatal HIV testing has become a routine practice. This determination will be made in consultation with States and experts."

Section 2628 of the Public Health Service Act (42 U.S.C. 300ff-36) directs the Secretary to request that the Institute of Medicine (IOM) of the National Academy of Sciences evaluate the extent to which State efforts have been effective in reducing the perinatal transmission of HIV and an analysis of the existing barriers to the further reduction in such transmission. The IOM assembled a 14-member expert committee with combined expertise in obstetrics and gynecology, pediatrics, preventive medicine, and other relevant specialties, social and behavioral sciences, public health practice, epidemiology, program evaluation, health services research, bioethics, and public health law. The IOM committee

reviewed a wide variety of quantitative and qualitative information pertaining to the prevention of perinatal HIV transmission. To augment the committee's two public workshops and a series of site visits through which the committee consulted a wide array of state and local public health officials and other policy makers, health care providers, consumers, ethicists, advocacy groups for women and children with HIV and others affected and concerned with these policy issues.

This notice will build upon the testimony and material already provided to the IOM as part of its statutorily required evaluation by seeking any additional public comment beyond that already provided to the IOM as part of its consultative process. The purpose of this notice is not to duplicate the testimony, data or other information and background material already provided to the IOM committee through its workshops, site visits, and other information gathering and consultative activities.

Dated: November 3, 1998.

Jeffrey P. Koplan,

Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-29903 Filed 11-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0633]

Approval of an Alternative Requirement of the Mammography Quality Standards Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Approval of an Alternative Requirement of the Mammography Quality Standards Act" (the MQSA). The MQSA final regulations require that the collimation of the mammography unit permit the x-ray field to extend to or beyond the edges of the image receptor. FDA has approved a request from General Electric (GE) Medical Systems for an alternative to the MQSA requirement to apply to GE Senographe mammographic systems.

ADDRESSES: Submit written requests for single copies of the "Approval of an Alternative Requirement of the Mammography Quality Standards Act" document to the Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-594-3306. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the alternative requirement.

FOR FURTHER INFORMATION CONTACT:

Roger L. Burkhardt, 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 MQSA final regulations in 21 CFR part 900 will become effective on April 28, 1999. Under § 900.12(e)(5)(vii)(A) (21 CFR 900.12(e)(5)(vii)(A)), the regulations will require that the collimation of a mammography unit permit the x-ray field to extend to or beyond the edges of the image receptor. This provision was made because some facilities stressed the importance of blackening the x-ray film to the edges. These facilities stated that this would help eliminate the effect of view box light passing through the unexposed edges of the film on accuracy of interpretation. However, the current Electronic Product Radiation Control (EPRC) performance standards require that mammography units be manufactured to ensure that the x-ray field does not extend beyond the nonchest wall edges of the image receptor.

Although it is possible for a mammography unit to meet both of these sets of standards, it has come to the agency's attention that certain GE models were designed to prevent the x-ray field from reaching the nonchest wall edges of the image receptor. These models, which make up a large proportion of the mammography units currently in use in facilities, were designed to meet the EPRC standard. GE requested that an alternative requirement be approved that would allow, but not require, the x-ray field to extend to or beyond the edge of the image receptor, permitting continued

use of the presently installed units without modification.

Under the provisions of 21 CFR 900.18, the agency granted the request for an alternative requirement. The alternative requirement applies to all GE Senographe mammographic systems including models 500T, 600T, 700T, 800T, and DMR.

II. Electronic Access

In order to receive a copy of the "Approval of an Alternative Requirement of the Mammography Quality Standards Act" to § 900.12(e)(5)(vii)(A) via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from the touch-tone telephone. At the first voice prompt press 1 to access the Division of Small Manufacturers Assistance Facts, at second voice prompt press 2, and then enter the document number 2249 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the alternative requirement may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text graphic, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the "Approval of an Alternative Requirement of the Mammography Quality Standards Act" to § 900.12(e)(5)(vii)(A), device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at "<http://www.fda.gov/cdrh>". "Approval of an Alternative Requirement of the Mammography Quality Standards Act" to § 900.12(e)(5)(vii)(A) will be available at "<http://www.fda.gov/cdrh/dmgrp.html>".

Dated: October 28, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health

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