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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 98 N-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. Burkhart, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332.

**SUPPLEMENTARY INFORMATION:**

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## **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**

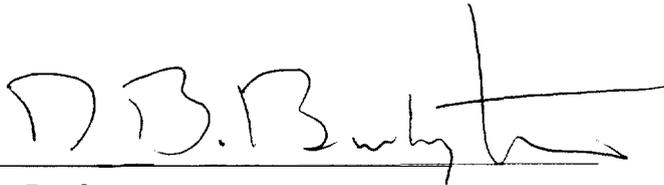
In order to receive a copy of the "Approval of an Alternative Requirement of the Mammography Quality Standards Act" to § 900.12(e)(5)(vii)(A) via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from the touch-tone telephone. At the first voice prompt press 1 to 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: 10-28-98  
October 28, 1998



D.B. Burlington  
Director  
Center for Devices and Radiological Health

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