	Title of standard	Reference number and date	Name of standards development organization
23	Measurement of the Maximum Symmetrical Radiation Field from a Rotating Anode X-Ray Tube Used for Medical Diagnosis.	NEMA XR10–1986 (R1992)	NEMA.
24	Test Standard for Determination of the Limiting Spatial Resolution of X-Ray Image Intensifier Systems.	NEM XR11–1993	NEMA.
25	Test Standard for the Determination of the Visible Entrance Field Size of an X-Ray Image Intensifier System.	NEMA XR15–1991	NEMA.
26	Test Standard for the Determination of the System Contrast Ratio and the System Veiling Glare Index of an X-Ray Image Intensifier System.	NEMA XR16–1991	NEMA.
27	Test Standard for the Measurement for the Image Signal Uniformity of an X-Ray Image Intensifier System.	NEMA XR17–1993	NEMA.
28	Test Standard for the Determination of the Radial Image Distortion of an X-Ray Image Intensifier System.	NEMA XR18–1993	NEMA.
29	Electrical Thermal and Loading Characteristics of X-Ray Tubes Used for Medical Diagnosis.	NEMA XR19–1993	NEMA.
30	Standard for Safety: Photographic Equipment	UL–122	Underwriters Laboratory (UL).
31	Standard for Safety: X-Ray Equipment	UL–187	UL.
32	Standard for Safety: Medical and Dental Equipment—Third Edition.	UL–544	UL.

[1] The recognition of this standard for all devices was proposed for comment January 13, 1998 (63 FR 1974), and is not yet final. *This listing applies only to radiological imaging devices.*

Dated: February 13, 1998.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–4843 Filed 2–20–98; 3:59 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Guidance for Industry on Medical Device Appeals and Complaints: A Guidance on Dispute Resolution; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Medical Device Appeals and Complaints: A Guidance on Dispute Resolution.'' FDA currently has a myriad of dispute resolution and regulatory appeal processes that manufacturers of medical devices and radiological products can avail themselves of in situations where they disagree with a regulatory decision or action initiated by the agency. The agency's Center for Devices and Radiological Health (CDRH) is making this guidance document available in an effort to clarify these various processes and assist the industry in determining which process or processes are appropriate in a given circumstance.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments concerning this guidance document to the contact person listed below. Submit written requests for single copies of the guidance document entitled ''Medical Device Appeals and Complaints: A Guidance on Dispute Resolution'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), 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 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–7491.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document represents an effort by the agency to catalogue the various types of processes for seeking and achieving resolution of disputes that arise between manufacturers of medical devices and radiological products and components of FDA that are involved in clinical, scientific, and regulatory decisionmaking that affects these industries. Although this guidance document does not advocate one process over another, it intends to: (1) Explain the dispute resolution processes that exist by virtue of Federal law, agency regulations, and administrative practices; and (2) provide general guidance on which processes are most suited for particular situations. In addition, the guidance document offers practical, easy-to-use information on how and where to file requests for reconsideration of agency actions and decisions, as well as requests for dispute resolution, and gives useful information that sets forth the variety of FDA and Department of Health and Human Services components that are responsible for reviewing, investigating, and resolving disputes and external complaints. Because dispute resolution processes for medical devices and radiological products and the agency components charged to administer them will likely undergo change over time, this guidance document is subject to periodic revision. For example, the recently enacted Food and Drug Administration Modernization Act of 1997 mandates the agency to establish discrete processes for the resolution of disputes related to the regulation of medical devices. The guidance document lays the groundwork for new agency procedures which, in the coming months, will be articulated in more detail and incorporated into the document.

This is a level 2 guidance document under FDA's Good Guidance Practices policy. This guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

II. Electronic Access

In order to receive the ''Medical Device Appeals and Complaints: A Guidance On Dispute Resolution'' guidance document via your fax machine, call the CDRH Facts-on-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (396) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so by using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. The CDRH home page is updated on a regular basis and includes the ''Medical Device Appeals and Complaints: A Guidance On Dispute Resolution'' guidance document, 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. ''Medical Device Appeals and Complaints: A Guidance On Dispute Resolution'' is also available on the medical device reporting page at http://www.fda.gov/cdrh/modact/modern.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there, follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there, select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Request for Comments

Interested persons, may at any time, submit to the contact person listed above written comments regarding this guidance document. Comments will be considered in determining whether to revise or revoke the guidance.

Dated: February 11, 1998.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–4842 Filed 2–20–98; 4:00 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98D–0078, 98D–0079, 98D–0080, 98D–0081, 98D–0082, and 98D–0083]

FDA Modernization Act of 1997; Guidance Documents for the Medical Device Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of six guidance documents that represent the Center for Devices and Radiological Health's (CDRH) initial approach to implementation of revelant sections of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115). Many of the procedural changes for CDRH that are required by the FDAMA are being implemented initially through these six guidance documents. Due to the timing of the required implementation, the use of guidance documents is the most expeditious way to initially implement the FDAMA. The agency requests comments on these six guidance documents.

DATES: Submit written comments by May 26, 1998. After the close of the comment period, written comments may be submitted at any time to Ron Jans (address below)

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number for the appropriate guidance document found in the SUPPLEMENTARY INFORMATION section. Submit written requests for an IBM PC compatible diskette containing the documents to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), 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 301–443–8818. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

For information on this document contact: Ronald P. Parr, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–7491, ext. 128.

To submit comments after the close of the comment period contact: Ron Jans, Center for Devices and Radiological Health (HFZ–205), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3744.

SUPPLEMENTARY INFORMATION:

I. Background

The FDAMA was signed by the President on November 21, 1997. Several of the provisions of FDAMA go into effect 90 days after enactment. CDRH has issued a guidance document outlining the general approaches FDA intends to take to implement the highest priority provisions of the new law. FDA published a notice of availability of this general guidance (referred to as the ''Day 1 guidance'') in the **Federal Register** of February 6, 1998 (63 FR 6193).

The agency is announcing the availability of the following six guidance documents (each with a separate docket number) that represent CDRH's initial approach to implementation of the various relevant sections of the FDAMA:

(1) ''Early Collaboration Meetings Under the FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff, Final Document'' (Docket Number 98D–0078) (FOD # 310),

(2) ''Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—for Use by CDRH and Industry'' (Docket Number 98D–0079) (FOD # 322),

(3) ''30-Day Notices and 135-day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH'' (Docket Number 98D–0080) (FOD # 795),

(4) ''Determination of Intended Use for 510(k) Devices; Final Document'' (Docket Number 98D–0081) (FOD # 857),

(5) ''New section 513(f)(2)—Evaluation of Automatic Class III Designation; Guidance for Industry and