

(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>.

"Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3 will be available at <http://www.fda.gov/cdrh/mammography/guidance-rev.html>.

#### IV. Comments

Interested persons may submit to the contact person (address above) written comments regarding this guidance at any time. Such comments will be considered when determining whether to amend the current guidance. 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.

Dated: June 29, 2000.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99D-2152]

#### Guidance for Industry and FDA Reviewers on Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management." This guidance describes how to incorporate human factors techniques and theory into risk management during medical device design and development. The guidance is intended to assist reviewers of premarket device submissions, design control documentation, and manufacturers that develop devices. The guidance is necessary to decrease problems with the use of medical devices that impact

safety and effectiveness, and help ensure safer and more effective devices.

**DATES:** Submit written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 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. Submit written comments on "Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management" to the contact person listed below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Ron D. Kaye, Center for Devices and Radiological Health (HFZ-230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-2436.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The guidance is intended to provide a suggested approach for integrating human factors within risk management for medical device design and development. It also contains an introduction to both risk management and human factors and a discussion of how they are linked. The focus is on reducing hazards related specifically to the use of medical devices. Human factors techniques are discussed within the context of applying risk management. The guidance also suggests how human factors-risk management efforts should be documented and included in premarket submissions. This guidance document was published for public comment on August 3, 1999, as a draft guidance entitled "Device Use Safety: Incorporating Human Factors in Risk Management." The document has been modified from the original draft version to address public comments. There were changes made in the document for the purposes of clarity, but there were no major substantive changes.

##### II. Significance of Guidance

This guidance document represents the agency's current thinking on the application of human factors to new medical device design and development to help ensure that intended users can

use a device safely and effectively. It 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.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

##### III. Electronic Access

In order to receive "Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1497) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes "Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management," 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 Use—Safety: Incorporating Human Factors Engineering into Risk Management" is also available at <http://www.fda.gov/cdrh/HumanFactors.html>.

##### IV. Comments

Interested persons may, at any time, submit written comments on the guidance to the contact person (address above). Such comments will be considered when determining whether to amend the current guidance. 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. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2000.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0331]

#### Medical Devices; Draft Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of Availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft revision to the guidance entitled, "Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997." FDA is proposing to amend this guidance to provide procedures for third party review of additional moderate risk (class II) devices under the FDA Modernization Act of 1997 (FDAMA) Accredited Persons Program. As described in this document and in the draft guidance, FDA intends to expand the list of devices eligible for third party review. The revised guidance would assist those who are interested in participating in the expanded program.

**DATES:** Submit written comments on the draft guidance to ensure their adequate consideration in the preparation of the final document by September 1, 2000.

**ADDRESSES:** Submit written requests for single copies on a 3.5 inch diskette of the draft guidance entitled "Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 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 information on electronic access to the draft guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

**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, 301-443-6597.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On August 1, 1996, FDA began a voluntary Third Party Review Pilot Program. The purpose of the pilot program was to: (1) Provide manufacturers of eligible devices an alternative review process that could yield more rapid marketing clearance decisions; and (2) enable FDA to target its scientific review resources at higher risk devices, while maintaining confidence in the review by third parties of low-to-moderate risk devices. Under the program, all class I devices that were not exempt from premarket notification (510(k)) at that time and 30 class II devices were eligible for third party review. During the first 18 months of the pilot program, FDA received 22 510(k)'s that were reviewed by Recognized Third Parties. In contrast, during the same period, FDA received more than 1,300 510(k)'s for third party eligible devices that were not reviewed by third parties.

FDAMA was signed into law by the President on November 21, 1997. Section 210 of FDAMA essentially codified and expanded the Third Party Review Pilot Program by establishing a new section 523 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360m). Section 210 of FDAMA directs FDA to accredit third parties (Accredited Persons) in the private sector to conduct the review of 510(k)'s for low-to-moderate risk devices and make recommendations to FDA regarding the initial classification under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)). FDA established and published criteria in the **Federal Register** on May 22, 1998 (63 FR 28388) to accredit or deny accreditation to persons who request to review 510(k)'s. In addition, FDA issued a list of devices that are eligible for review by Accredited Persons (May 20, 1998) as well as a guidance document entitled

"Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997" (October 30, 1998). Copies of these documents can be found at <http://www.fda.gov/cdrh/thirdparty>. By November 21, 1998, FDA accredited 13 organizations to review 510(k)'s, and the agency was prepared to begin accepting reviews and recommendations from Accredited Persons. Concurrently, FDA terminated the Third Party Review Pilot Program that began on August 1, 1996. In the first 17 months that the FDAMA third party program has been in effect, 28 companies have used third parties to review a total of 54 510(k) submissions. During that same period, nearly 2,000 510(k) submissions from approximately 800 companies were eligible for third party review. This approach has typically yielded rapid marketing clearance decisions. In fiscal year 1999, the average total elapsed time between a third party's receipt of a 510(k) submission and FDA's substantial equivalence determination was 57 days. The portion of this time that occurred between FDA's receipt of the third party's recommendation and FDA's determination averaged just 15 days. In spite of these advantages, industry use of the third party approach has been low.

In an effort to expand the use of the Accredited Persons Program, the agency is proposing to initiate a pilot that will allow third party review of a greatly expanded list of devices (see details below). Accordingly, FDA is issuing a draft revision of the guidance document entitled "Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997" as well as making available an expanded list of additional devices that will be eligible under the pilot. Copies of these documents can be found at <http://www.fda.gov/cdrh/thirdparty>. After FDA reviews comments and finalizes this guidance, it will supersede the October 30, 1998, guidance currently in effect.

The May 20, 1998, list of devices eligible for review by Accredited Persons included 50 class I devices and 104 class II devices. FDA included all class I devices, not exempt from 510(k), because the agency determined that general guidance provided by CDRH is a sufficient basis for third party review of these relatively low risk products. However, FDA's decision to include class II devices was partly dependent on the existence of device specific guidance and/or FDA recognized standards. FDA is currently updating the May 20, 1998, list to reflect changes