

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0031]

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Certifier C. CLAWSON

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Global Harmonization Task Force, Study Groups 1, 2, and 4; New Proposed and Final Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of proposed and final documents that have been prepared by Study Groups 1, 2, and 4 of the Global Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

DATES: Submit written or electronic comments on any of the proposed documents by *[insert date 90 days after date of publication in the Federal Register]*. After *[insert date 90 days after date of publication in the Federal Register]*, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Small Manufacturers, International, and Consumer Assistance

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(HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label 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 guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For Study Group 1: Ginette Y. Michaud, Chairperson, GHTF, Study Group 1, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

For Study Group 2: Mary Brady, GHTF, Study Group 2, Office of Surveillance and Biometrics, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3458.

For Study Group 4: Jacqueline Welch, GHTF, Study Group 4, Office of Compliance, Center for Devices and Radiological Health (HFZ–320), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as the GHTF to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using its own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by three of the Study Groups (1, 2, and 4).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked

to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of its efforts, this group has developed proposed document SG1(PD)N044:2006. SG1(PD)N044:2006 (proposed document), entitled “Role of Standards,” provides guidance on the use of standards by a manufacturer when designing a medical device and, subsequently, when demonstrating the device conforms to relevant essential safety and performance criteria. FDA seeks comment on the document and particularly “Section 5.2 Revision or Replacement of Recognised Standards.” This section addresses the use of a recognized standard during the transitional period when it is being replaced by a revised version.

Study Group 4 was initially tasked with the responsibility of developing guidance documents on quality systems auditing practices. As a result of its efforts, this group has developed document SG4(PD)N33R13:2006. SG4(PD)N33R13:2006 (proposed document), entitled “Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 3: Regulatory Audit Reports,” suggests a structure for audit reports used in multiple jurisdictions, promoting consistency and uniformity and should assist the auditor in preparing a report for use by multiple regulators and/or auditing organizations. Having reports that are consistent in content should facilitate the review and exchange of audit reports. Acceptance of audit reports by multiple regulators should eventually reduce the number of audits for manufacturers.

Study Group 2 was initially tasked with the responsibility of developing guidance documents that will be used for the exchange of adverse event reports. As a result of its efforts, this group developed SG2N54R8:2006.

SG2N54R8:2006 (final document), entitled “Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices,” provides guidance on the type of adverse events associated with medical devices that should be reported by manufacturers to a National Competent Authority. It elaborates on the regulatory requirements existing in the participating member countries.

II. Significance of Guidance

These documents represent recommendations from the GHTF study groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

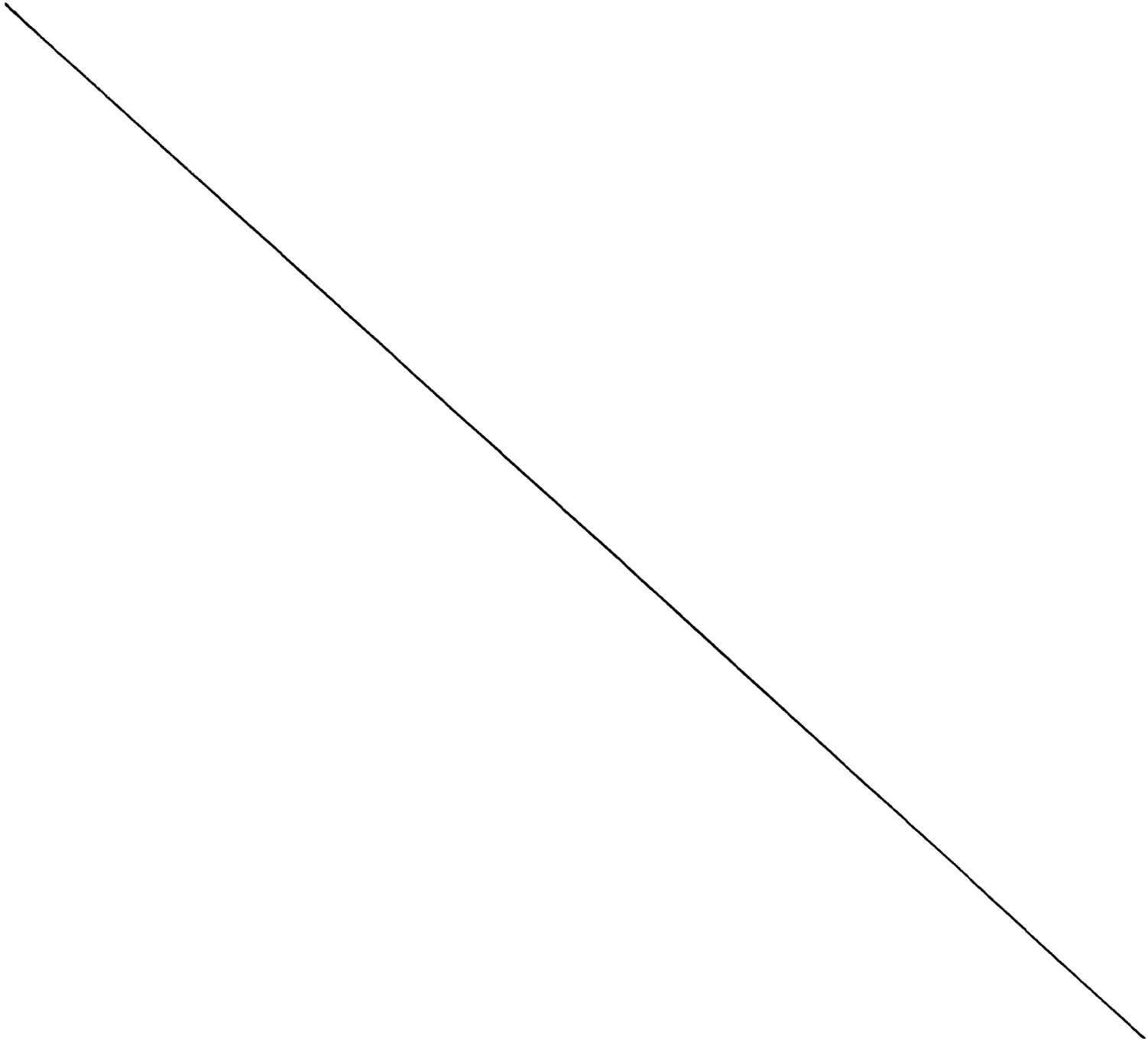
III. Electronic Access

Persons interested in obtaining a copy of the documents may also do so by using the Internet. The Center for Devices and Radiological Health (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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturer’s assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at <http://www.ghrf.org>. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. Submit a single copy of electronic comments or two paper copies of any mailed

comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 1/30/07
January 30, 2007.

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Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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