

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0011]

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	SDM

Global Harmonization Task Force, Study Groups 1, 2, 3, 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 several proposed and final documents that have been prepared by Study Groups 1, 2, 3, and 4 of the Global Harmonization Task Force (GHTF). These documents are intended to provide information only and 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 the close of the comment period, 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 on a 3.5" diskette of the guidance documents to the Division of Small Manufacturers, International, and

Consumer Assistance (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, 301-443-8913, ext.143.

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, 301-594-2102.

For Study Group 3: Kimberly Trautman, GHTF, Study Group 3, Office of Compliance, Center for Devices and Radiological Health (HFZ-340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240-276-0296.

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. At this time it was decided to form a 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 their own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices in order 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 in order 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 four of the study groups (1, 2, 3, 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 documents SG1/(PD)N015:2005 and SG1(PD)/N040:2005 and final documents SG1/N29R16:2005, SG1/N41R9:2005, and SG1/N43:2005.

SG1(PD)N015:2005 (proposed document) entitled “Principles of Medical Devices Classification” assists a manufacturer to assign its medical device to an appropriate risk class using a set of harmonized principles. This document applies to products that have a medical purpose, as described in GHTF document SG1/N29:2005 entitled “Information Document Concerning the Definition of the Term ‘Medical Device,’” except for those devices used for the in vitro examination of specimens derived from the human body. SG1/(PD)/N040:2005 (proposed document) entitled “Principles of Conformity Assessment for Medical Devices” describes the evidence and procedures that may be used by the manufacturer to demonstrate that a medical device is safe and performs as intended by the manufacturer, and the process by which a Regulatory Authority, or Conformity Assessment Body, may confirm that the procedures are properly applied by the manufacturer. This document applies to all products that fall within the definition of a medical device, as described in GHTF document SG1/N29:2005 entitled “Information Document Concerning the Definition of the Term ‘Medical Device,’” except for those devices used for the in vitro examination of specimens derived from the human body.

SG1/N29R16:2005 (final document) entitled “Information Document Concerning the Definition of the Term ‘Medical Device’” describes a

harmonized definition of a medical device and provides information on products that may be considered to be medical devices in some jurisdictions. This document applies to products that have a medical purpose, including those used for the in vitro examination of specimens derived from the human body.

SG1/N41R9:2005 (final document) entitled “Essential Principles of Safety and Performance of Medical Devices” is a revised version of previously published guidance on the subject and describes the six general requirements of safety and performance that apply to all medical devices and provides a comprehensive list of design and manufacturing requirements of safety and performance, some of which are relevant to each medical device. This document applies to all products that fall within the definition of a medical device that appears within the GHTF document entitled “Information Document Concerning the Definition of the Term ‘Medical Device,’” including those used for the in vitro examination of specimens derived from the human body. The new guidance is intended to supersede the previous version of the guidance. SG1/N43:2005 (final document) entitled “Labelling for Medical Devices” describes harmonized principles for the labelling of medical devices and recommends harmonized content of labeling such as the device identity and intended purpose; how to use, maintain and store a device; residual risks; warnings and contraindications. This document applies to all products that fall within the definition of a medical device that appears within the GHTF document SG1/N29:2005 entitled “Information Document Concerning the Definition of the Term ‘Medical Device,’” including those used for the in vitro examination of specimens derived from the human body. The new guidance is intended to supersede the previous version of the guidance.

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 has developed proposed documents SG2(PD)/N54R6:2005, SG2(PD)/N57R6:2005, and SG2(PD)/N79R5:2005 and final document SG2/N38R14:2005.

SG2/(PD)/N54R6:2005 (proposed document) entitled “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 (NCA). SG2(PD)/N57R6:2005 (proposed document) entitled “Medical Devices: Post Market Surveillance: Content of Field Safety Notices” identifies elements that should be included in safety related notifications issued by the medical device manufacturer. SG2/(PD)/N79R5:2005 (proposed document) entitled “Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form” provides guidance, procedures, and forms for the exchange of reports concerning the safety of medical devices between NCA and other participants of the GHTF National Competent Authority Report (NCAR) exchange program.

SG2/N38R15:2005 (final document) entitled “Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program” describes the prerequisites and commitments required from an organization before it can participate in the NCAR exchange program founded by GHTF SG2.

Study Group 3 was initially tasked with the responsibility of developing guidance documents on quality systems. As a result of its efforts, this group

has developed final document SG3/N15R8:2005. SG3/N15R8:2005 (final document) entitled “Implementation of Risk Management Principles and Activities within a Quality Management System” is intended to assist medical device manufacturers with the integration of a risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples. This document assumes a basic understanding of quality management system requirements and a basic knowledge of quality management system terminology.

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)/N30R16:2005. SG4(PD)/N30R16:2005 (proposed document) entitled “Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 2: Regulatory Auditing Strategy” is intended to assist medical device regulators and auditing organizations conducting quality management system audits of medical device manufacturers based on the process approach to quality management system requirements (e.g., ISO 13485:2003 and 21 CFR Part 820).

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 guidances 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.gh tf.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: 1-17-06

January 17, 2006.

Linda S. Kahan

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

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