

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0265]

Global Harmonization Task Force, Study Groups 1 and 5; New Proposed and Final Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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**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 and 5 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 by [*insert date 90 days after date of publication in the Federal Register*]. After the 90 day 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 of the guidance documents to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health,

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ADM  
Display Date 7-12-07  
Publication Date 7-12-07  
Certifier SKES

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 information regarding 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 information regarding Study Group 5:* Herbert Lerner, GHTF, Study Group 5, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3641.

**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 Global Harmonization Task Force (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 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 two of the Study Groups (1 and 5).

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)/N045R12:2007 and SG1(PD)/N046R3:2007.

SG1(PD)/N045R12:2007 (proposed document) entitled “Principles of In Vitro Diagnostic (IVD) Medical Devices Classification” assists a manufacturer to allocate its IVD Medical Device to an appropriate risk class using a set of harmonized classification principles based on an IVD Medical Device’s intended use. This document applies to IVD Medical Devices.

SG1(PD)/N046R3:2007 (proposed document) entitled “Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices” provides an overview of conformity assessment elements to demonstrate conformity to GHTF final document entitled “Essential Principles of Safety and Performance for Medical Devices.” “Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices” applies to IVD Medical Devices. It 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.

Study Group 5 was initially tasked with the responsibility of developing guidance documents on the content and format for clinical investigation reports and on how to conduct and document a clinical evaluation. As a result of its efforts, this group has developed documents SG5/N1R8:2007 and SG5/N2R8:2007.

SG5/N1R8:2007 (final document) entitled “Clinical Evidence—Key Definitions and Concepts” introduces the concepts of clinical evaluation and clinical evidence, and examines the relationship between clinical investigation, clinical data, clinical evaluation, and clinical evidence. SG5/N2R8:2007 (final document) entitled “Clinical Evaluation” provides guidance

on how to conduct the clinical evaluation of a medical device as part of the conformity assessment procedure prior to placing a medical device on the market, as well as to support its ongoing marketing.

## 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

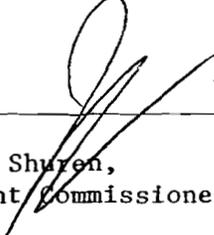
Persons interested in obtaining a copy of the guidance may also do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet 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: 7/5/07  
July 5, 2007.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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