Guidance for Industry and FDA Staff

Recognition and Use of Consensus Standards

Document issued on: September 17, 2007

This document supersedes the "Recognition and Use of Consensus Standards; Guidance for Industry and for FDA Staff" document issued on June 20, 2001.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Standards Management Staff
Office of Science and Engineering Laboratories

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/osel/guidance/321.pdf . You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 321 to identify the guidance you are requesting.

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Recognition and Use of Consensus Standards

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

The purpose of this guidance document is to provide guidance to Center for Devices and Radiological Health (CDRH) reviewers and industry on the recognition and use of national and international consensus standards, including declarations of conformity to these standards, during the evaluation of premarket submissions for medical devices.

Many domestic and international consensus standards address aspects of safety and/or effectiveness relevant to medical devices. Many of these standards have been developed with the participation of Center for Devices and Radiological Health (CDRH) staff. This guidance describes how CDRH should recognize and use consensus standards pursuant to the Food and Drug Administration Modernization Act of 1997 (P.L. 105-115), which amends section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)). A list of currently recognized standards appears on CDRH's Internet page at http://www.fda.gov/cdrh/stdsprog.html.

A person required to submit a premarket application (i.e., Premarket Notification (510(k)), Investigational Device Exemptions application (IDE), Premarket Approval application (PMA), Humanitarian Device Exemption application (HDE), or Product Development Protocol (PDP)) must provide information as required by the statute and regulations to allow CDRH to make an appropriate decision regarding the clearance or approval of the submission. This guidance describes how CDRH should use information on conformance with recognized consensus standards to satisfy premarket review requirements. It does not affect CDRH's ability to obtain any information authorized by the statute or regulations. (21 U.S.C. 360d)

CDRH believes that conformance with recognized consensus standards can support a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices. Therefore, information submitted on conformance with such standards should have a direct bearing on safety and effectiveness determinations made during the review of IDEs, HDEs, PMAs, and PDPs. In 510(k)s, information on conformance with recognized consensus standards may help establish the substantial equivalence of a new device to a legally marketed predicate device. This information may be used to show that the new device is as safe and effective as the predicate in the areas covered by the standards. Moreover, if any premarket submission contains a declaration of conformity to the recognized consensus standards, as discussed below, this declaration should, in many cases, eliminate the need to review the actual test data for those aspects of the device addressed by the standards[1].

Conformance with recognized consensus standards may not always be a sufficient basis for regulatory decisions. For example, a specific device may raise a safety or effectiveness issue not addressed by any recognized consensus standard, or a specific FDA regulation may require additional information beyond what conformity to the recognized consensus standards provides. Under such circumstances, conformity with recognized standards will not satisfy all requirements for marketing, or investigating, the product in the United States. Below, we discuss procedures for the use of recognized consensus standards as well as limitations on their use for purposes of premarket review.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

Recognition and Use of Consensus Standards

Procedures for the Use of Consensus Standards

- General Use in the Premarket Application Review Process
- Voluntary Conformance
- Declaration Review

[1] If a recognized standard describes a test method, but does not specify a performance limit or pass/fail criteria, the manufacturer should submit the test results.

- "Declaration of Conformity" Content
- Consistency with ISO/IEC Guide 22
- Additional Information Requests
- Review Documentation
- Supervisory Review

General Use in the Premarket Applications Review Process
To simplify and streamline the premarket review process, applicants may utilize FDA recognized standards in premarket submissions. Consensus standards are often very useful when an FDA-recognized consensus standard exists that serves as a complete performance standard for a specific medical device. In these cases, the standard may include specific acceptance criteria that describe the relevant performance characteristics of that specific medical device. Conformity to the recognized standard should, in these cases, minimize the amount of data and documentation needed in the 510(k) submission to demonstrate substantial equivalence. However, such comprehensive consensus standards are rare.

If applied appropriately, conformance to other more general vertical standards (i.e., device specific standards that may not encompass all aspects of device performance) can also serve as a means to streamline the premarket review process. Conformance and declarations of conformance to any recognized consensus standard that clearly spells out acceptance criteria is a very effective use of standards in the premarket process. Used this way, conformity to FDA recognized consensus standards will reduce the amount of documentation that you need to submit and may allow FDA to reduce review time.

Applicants referencing a national or international standard should include a completed Standards Data Form for 510(k)s (FDA Form #3654, Form Approved OMB #0910-0120) as part of their 510(k).

Voluntary Conformance
Conformance with recognized consensus standards is strictly voluntary for a medical device manufacturer. A manufacturer may choose to conform to applicable recognized standards or may choose to address relevant issues in another manner.

Declaration Review
If a manufacturer elects to conform with one or more recognized consensus standards in satisfying part of a premarket review requirement, the manufacturer must submit a "declaration of conformity" to the standards (21 U.S.C. 360d(c)(2)(B)). A manufacturer must maintain all records relating to its compliance and/or declaration of conformity with the standards after clearance or approval of the device for a period of two years or for the expected design life of the device, whichever is longer (21 U.S.C. 360d(c)(3)(C)). Those records are subject to inspection (21 CFR 820.180).

If a recognized standard describes a test method, but does not specify a performance limit or pass/fail criteria, the manufacturer should submit the test results.

If a submission includes a declaration of conformity to one or more recognized consensus standards from the party submitting the regulatory application, and these standards include performance limits or acceptance criteria, a reviewer should not ordinarily request the data relating to the aspects of safety and/or effectiveness covered by the standards in the premarket submission. A declaration of conformity to the standard(s) should suffice both to document conformance to the standards, and to provide evidence of device safety and/or effectiveness with respect to those aspects covered by these standards. Where a recognized standard describes a test method, but does not specify a performance limit or acceptance criteria, the manufacturer should submit the test results, unless the manufacturer consults with the review Division and the review Division decides otherwise. If a manufacturer declares conformance to a recognized standard, but data or other information in the submission raise questions about the extent of conformity, then the reviewer, in consultation with his or her branch chief or other supervisors, may request additional data to assess the performance of the device relative to the standard.

A manufacturer may base declarations of conformity on the manufacturer's own testing and analysis or on that of a third party, such as a testing laboratory or certification body. Falsifying a declaration of conformity is a prohibited act under 21 U.S.C. 331(x). Any device for which a declaration of conformity has been falsified is adulterated under 21 U.S.C. 351(e)(2).

All records relating to a manufacturer's declaration of conformity, whether based upon third party or in-house testing and review, should be maintained by the manufacturer as noted above and may be reviewed in inspections to assess conformance to the Quality Systems Regulation (21 CFR 820.180).

"Declaration of Conformity" Content

To help streamline the review process for those consensus standards where there are no clear acceptance criteria and there are broad horizontal standards, applicants' submissions should include clear documentation of the extent of conformance. FDA recommends that submissions include a matrix that identifies all sections of the consensus standard with an indication of "yes," "no," or "not applicable" to indicate conformance. A submission should further specify acceptance criteria that are relevant to the specific medical device and should identify any deviations to the consensus standard. With adequate justification for the acceptance criteria and for any deviations from the standard, FDA can usually accept a declaration of conformance without the need to review test protocols and analyze the raw data.

A declaration of conformity to a recognized consensus standard should do the following:

- identify the applicable recognized consensus standards that were met

- specify, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations as described below
- identify, for each consensus standard, any way(s) in which the standard may have been adapted for application to the device under review, e.g., identify which of an alternative series of tests were performed
- identify, for each consensus standard, any requirements that were not applicable to the device
- specify any deviations from each applicable standard that was applied (e.g., deviations from international standards that are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70)
- specify what differences exist, if any, between the tested device and the device to be marketed and justify the use of test results in these areas of difference
- provide the name and address of each laboratory or certification body that was involved in determining the conformance of the device with the applicable consensus standards and a reference to any accreditations of those organizations, if a test laboratory or certification body was employed

Premarket Notification applications should refer to the Standards Data Form for 510(k)s (FDA Form #3654, Form Approved OMB #0910-0120) to address these elements.

Consistency with ISO/IEC Guide 22

These elements of a declaration of conformity are consistent with International Standards Organization/International Electrotechnical Commission (ISO/IEC) Guide 22. Note that where a recognized standard describes a test method, but does not specify a performance limit or pass/fail criteria, the applicant should submit the test results unless the manufacturer consults with the review Division and the review Division decides otherwise**.**

Additional Information Requests

As indicated above, when a regulatory submission includes a declaration of conformity to an FDA-recognized consensus standard, and this declaration of conformity is adequate, a reviewer should consider the documentation for the aspects of the device addressed by the standards to be acceptable. (A reviewer should, however, expect to see the results of testing when the standard merely specifies a test method without associated performance limits and/or acceptance criteria.) There may be rare instances in which a reviewer has specific concerns about the adequacy of a recognized consensus standard to address particular aspects of device performance under review. (See "Limitations of Consensus Standards" below.) In such instances, the reviewer should consult his or her immediate supervisor. If the supervisor concurs, the reviewer should request additional information from the submitter of the premarket application. For example, in a 510(k), a reviewer who has specific concerns about the adequacy of a standard with regard to a particular aspect of the device should consult with his or her Branch Chief on the need for additional information.

A reviewer may also request additional information if a declaration of conformity or other information submitted as evidence of conformance to a consensus standard identifies deviations from the standard that may reduce FDA's ability to rely upon the standard to demonstrate device safety and/or effectiveness. In this case, a reviewer should request any appropriate additional information in accordance with existing procedures.

Review Documentation
After reviewing all information included in a premarket submission, a reviewer should make his or her recommendation in writing according to existing practices and procedures. When relying on a declaration of conformity, a reviewer should indicate in the review memorandum that a declaration was provided and relied on.
Where conformance to consensus standards is insufficient to ensure safety or effectiveness of the device (or, in the case of 510(k)s, substantial equivalence to a legally marketed predicate device), a reviewer should state why the conformance is insufficient to support a regulatory decision. The reviewer should state whether the deficiency is due to an inadequacy of the standards or the existence of issues outside the scope of the standards. For example, a reviewer should identify those aspects of safety and/or effectiveness that are inadequately addressed, or are not addressed, by the standards.

Limitations of Consensus Standards

A specific device may raise issues not addressed by recognized consensus standards. For example, submissions for class III devices may require data from animal testing or clinical trials not addressed in recognized standards. In other instances, a standard established by FDA may impose additional requirements (e.g., FDA standards in 21 CFR Parts 1010 - 1050 for electronic products) that medical devices must meet. When an application contains a manufacturer's declaration of conformity with one or more consensus standards, a reviewer should review the premarket submission to ensure it contains all the other necessary information for FDA to evaluate the safety and effectiveness or, in the case of a 510(k), the substantial equivalence of the device.

Manufacturers may make a declaration of conformity to an FDA-recognized standard even if its device type is not listed in the supplemental information sheet. In these instances, reviewers, with the concurrence of their supervisors, should determine whether the declaration of conformity provides sufficient information to support a regulatory decision for this type of device. When reviewing Divisions accept the applicability of a standard to a device that was previously not identified on the supplemental information sheet, the reviewer should alert the Standards Management Staff (SMS) in the Office of Science and Engineering Laboratories (OSEL) about the need to update the Supplemental Information Sheets.

Recognition of Consensus Standards

To recognize a new standard or a new version of an existing standard, FDA will post this information in one of the Supplemental Information Sheets on CDRH's Internet page. FDA will accept a declaration of conformity to a standard after it is recognized. This recognition occurs when FDA publishes a notice in the *Federal Register*. A simultaneous listing on the CDRH Internet page should also occur.

FDA maintains the current list of recognized standards on the CDRH Internet page. In addition to these documents, the Internet page contains Supplemental Information Sheets which, among other things, identify some or most types of devices to which each standard should ordinarily be expected to apply.

Additional Information

Carol L. Herman, Director, Standards Management Staff, Office of Science and Engineering Laboratories (OSEL), can answer questions on consensus standards and issues related to declarations of conformity. You can reach Ms. Herman at (240) 276-0556.

OSEL maintains a consensus standards database that can be accessed at: http://www.fda.gov/cdrh/stdsprog.html

CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition

Frequently Asked Questions on Recognition of Consensus Standards

Guidance Pertaining to the FDA Modernization Act

http://www.fda.gov/oc/fdama/default.htm

Updated September 17, 2007