Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA

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U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Science and Technology and
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, 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.

For questions regarding the use or interpretation of this guidance contact Tim Ulatowski at (301) 443-8879 or tau@cdrh.fda.gov.

Additional Copies

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Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency'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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Purpose

The purpose of this guidance document is to provide guidance to ODE 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.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Background

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 CDRH staff. This guidance describes how the Center for Devices and Radiological Health will 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 Food, Drug, and Cosmetic Act (21 U.S.C. 514(c)). A list of currently recognized standards appears in Appendix A.

Overview

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 the Center to make an appropriate decision regarding the clearance or approval of the submission. This guidance describes how the Center will use information on conformance with recognized consensus standards to satisfy premarket review requirements. It does not affect the Center's ability to obtain any information authorized by the statute or regulations.

The Center believes that conformance with recognized consensus standards can provide a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices. Therefore, information submitted on conformance with such standards will have a direct bearing on safety and effectiveness determinations made during the review of IDEs, HDEs, PMAs, and PDPs. In the case of 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 can 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 will, in most cases, eliminate the need to review the actual test data for those aspects of the device addressed by the standards.

Conformance with recognized consensus standards in and of itself, however, 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. Discussed below are procedures for the use of recognized consensus standards as well as limitations on their use for purposes of premarket review.

Procedures for the Use of Consensus Standards

- Conformance is voluntary : Reviewers should recognize that 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.

- Review of a declaration : 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 USC 514(c)(2)(B)). (Guidance on the suggested content of a declaration of conformity is provided below.) All records relating to a manufacturer's compliance and/or declaration of conformity with the standards must be maintained by the manufacturer after approval of the device for a period of two years or for the expected design life of the device, whichever is longer (21 USC 514(c)(3)(C)), and are subject to inspection. Regulatory submissions that include actual test data/information to demonstrate safety and effectiveness will continue to be reviewed under existing procedures.

  If a submission includes a declaration of conformity to recognized consensus standards from the party submitting the regulatory application, **data relating to the aspects of safety and/or effectiveness covered by the standards will not**

ordinarily be required in the premarket submission. A declaration of conformity to the standards will normally suffice both to document conformance to the standards and as 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, the test results would normally be submitted unless the review Division decides otherwise.

Declarations of conformity may be based 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 USC 331(x), and any device for which a declaration of conformity has been falsified is adulterated under 21 USC 351(e)(2). Reviewers should note that all records relating to a manufacturer's declaration of conformity, whether based upon third party or in-house testing and review, are maintained by the manufacturer as noted above and will be reviewed under a compliance program added to inspections to assess conformance to the Quality Systems Regulation (21 CFR 820).

- Content of the "declaration of conformity" : Reviewers should rely on a declaration of conformity to the recognized consensus standards when the declaration:
    - Identifies the applicable recognized consensus standards that were met;
    - Specifies, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below;
    - Identifies for each consensus standard any way(s) in which the standard may have been adapted for application to the device under review, e.g., identifies which of an alternative series of tests were performed;
    - Identifies, for each consensus standard, any requirements that were not applicable to the device;
    - Specifies any deviations from each applicable standard that were applied (e.g. deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70)).
    - Specifies what differences exist, if any, between the tested device and the device to be marketed and justifies the use of test results in these areas of difference; and
    - If a test laboratory or certification body was employed, provides 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.

These elements of a declaration of conformity are consistent with ISO/IEC Guide 22. **Note that where a recognized standard describes a test method, but does not specify a performance limit, the test results would normally be submitted.**

- Requesting additional information : As indicated above, when a regulatory submission includes a declaration of conformity to recognized consensus standards, reviewers should generally consider the device to be safe and/or effective with respect to those aspects of the device addressed by the standards. (Reviewers should, however, expect to see the results of testing, when the standard merely specifies a test method without associated performance limits.) There may be, however, rare instances in which a reviewer has specific concerns about the adequacy of a recognized consensus standard to address safety and effectiveness or substantial equivalence with regard to a particular device under review. (See "Limitations of Consensus Standards" below.) In such instances, the reviewer should consult, through his or her immediate supervisor, with the official under 21 CFR Part 5 who is delegated the authority to make decisions on a particular regulatory submission, e.g., the division director or the director of ODE. If they concur, the reviewer should request, in accordance with applicable regulations and established procedures, additional information from the submitter of the premarket application. For example, in the case of 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 her/his branch chief on the need for additional information, including the underlying test data. If the branch chief concurs, they should seek concurrence at the division level to request the additional information needed to address the concerns. All such requests are to be made on behalf of the person who has authority to take action on the application and are to be documented in the review record as being made by that person.

  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 the assurance of device safety and/or effectiveness. In this case, reviewers should request any appropriate additional information in accordance with existing branch 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, reviewers should clearly indicate in the review memorandum that a declaration was provided and relied on.

  In instances in which conformance to consensus standards is not sufficient to ensure safety of the device (or, in the case of 510(k)s, comparable safety and/or effectiveness) whether this is due to an inadequacy of the standards or the existence of issues outside the scope of the standards, reviewers should clearly state why the conformance is inadequate, i.e., identify those aspects of safety and/or effectiveness that are inadequately addressed, or are not addressed, by the standards.

- Supervisory Review : As in the case of all premarket review decisions, a supervisor with decision-making authority may elect not to accept a reviewer's recommendation with respect to acceptance of a manufacturer's conformance with consensus standards as provided in new Section 514(c)(3), even if the recommendation is made in accordance with these procedures. In this circumstance, the supervisor shall record the basis for not agreeing with a reviewer's determination in the administrative record.

Limitations of Consensus Standards

It must be recognized that 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) which medical devices must meet. Therefore, when relying on a manufacturer's declaration of conformity with consensus standards, reviewers should ensure that the premarket submission also contains all the other information besides that related to consensus standards that is necessary for the agency to evaluate the safety and effectiveness or, in the case of a 510(k), the substantial equivalence of the device.

Devices That May Be Covered By Recognized Consensus Standards

The list of recognized standards is maintained on the CDRH website and is updated at least annually. Documentation of the CDRH internal procedures for adding/removing standards to/from the list is also maintained there. In addition to these documents, the website contains Supplemental Information Sheets which, among other things, identifies some or most types of devices to which each standard would ordinarily be expected to apply. **Reviewers should note that manufacturers have the right to make a declaration of conformity to a listed standard even if its device is not listed in the supplemental information sheet**. Reviewers will be faced in these instances with determining whether the declaration of conformity satisfies the particular review requirement. In such instances, reviewers should recommend an appropriate course of action through their supervisor to the decision making official for the particular review activity, e.g., in the case of a 510(k), the Division Director will decide whether the declaration of conformity is appropriate for the previously unidentified device. When such decisions are made, reviewers should alert the Standards Program Coordination Staff in the Office of Science and Technology (OST) so that changes may be made in future updates to the Supplemental Information Sheets.

Additional Information

Dr. Mel Altman, Associate Director for Standards and Policy, OST, can answer questions on consensus standards and issues related to declarations of conformity. Dr. Altman can be reached at (301) 594-4766, ext. 106. OST maintains a consensus standards database augmented by the CDRH library.

Appendix A: Recognized Consensus Standards (http://www.fda.gov/cdrh/modact/recstand.html)

Guidance Pertaining to the FDA Modernization Act (http://www.fda.gov/cdrh/modact/modguid.html)