The 21st Century Cures Act (Cures), signed into law on December 13, 2016, amended several sections of the Federal Food, Drug, and Cosmetic Act. This guidance was developed and issued prior to the enactment of Cures, and certain sections of this guidance may no longer be current as a result. FDA is assessing how to revise this guidance to represent our current thinking on this topic. For more information please contact CDRH-Cures@fda.hhs.gov.

Guidance for Industry and FDA Staff

Frequently Asked Questions on Recognition of Consensus Standards

Document issued on: September 17, 2007

This document supersedes the "Frequently Asked Questions on Recognition of Consensus Standards; Guidance for Industry and for FDA Staff" document issued on July 22, 2002.

For questions regarding this document contact Carol Herman at carol.herman@fda.hhs.gov or 240-276-0556.

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/109.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 109 to identify the guidance you are requesting.

Table of Contents

Introduction 1
The Least Burdensome Approach 1
Frequently Asked Questions 2
- **Declaration of Conformity** 2
- **Changes** 4
- **Failure to Meet Standard/False Declaration** 5
- **Inspections/Audits** 6
- **Standards Recognition Process** 6
- **Product Submissions/Approvals** 10
- **Third-party Certification** 11

Guidance for Industry and FDA Staff

Frequently Asked Questions on Recognition 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

This guidance document was developed to answer frequently asked questions concerning FDA's implementation of section 514(c) of the Food, Drug, and Cosmetic Act (the Act), which addresses FDA recognition of consensus standards to satisfy certain regulatory requirements. The guidance will periodically be updated as new questions are asked of the Agency and as the recognition of standards by FDA increases and the use of standards by the industry grows.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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/.

Frequently Asked Questions

Declaration of Conformity

1. **What specific information should be contained in the "declaration of conformity?"**

   The elements that should be in a declaration are included in the guidance document, "Recognition and Use of Consensus Standards" under the heading, "Procedures for the Use of Consensus Standards." If you submit a declaration of conformity, it should:

   - 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.

2. **How can I find out if FDA believes a standard can apply to my device?**

   When a person considers declaring conformity to a standard, he/she should examine the Supplemental Information Sheet (SIS) posted on the FDA web site, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. Each

recognized standard is accompanied by a SIS, which is a data sheet that specifies the following:

- address(es) where the standard can be obtained
- the extent of recognition of the standard
- a list of devices or device categories affected by the recognition
- other information pertinent to the use of the standard by industry and in the premarket review and postmarket process

3. **If my device is not listed in the supplemental information sheets for a particular standard, but I believe the standard still applies, can I still submit a declaration of conformity?**

   Yes. The guidance document, "Recognition and Use of Consensus Standards" recognizes that a manufacturer may do this and states that the Office of Device Evaluation will determine whether conformity with that standard satisfies the particular regulatory requirement for that device. To allow proper evaluation, the manufacturer should justify why that standard is appropriate for the device in question.

4. **Under what conditions will FDA request the submission of data underlying the declaration of conformity?**

   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.

5. **Can I base my declaration of conformity, partially or totally, on data or information supplied to me by a component manufacturer? What would I have to submit? What would I have to retain in my files?**

   FDA places the responsibility for supporting the declaration of conformity on the person submitting an application to FDA. The declaration of conformity may be based on data or information provided by the component manufacturer(s), but it is the responsibility of the submitter to assure the accuracy of the information. The Quality System (QS) regulation specifies certain controls that a manufacturer

must have in place, including those for purchasing, vendor audits, and component quality. The finished device manufacturer may rely on certifications from suppliers including component vendors without, in some cases, performing incoming tests; however, the finished device manufacturer should assure the reliability of certifications periodically, e.g. through audits, testing, etc. Further, the QS regulation requires that the finished device meet all final release specifications and that appropriate records of component acceptance and testing are maintained (21 CFR 820.80).

6. **Experience in the past has shown that stating conformity to a test method standard, e.g., International Organization for Standardization (ISO) 10993-1, has not always been sufficient and FDA has asked for a summary of conformity. Will this continue to be the case?**

   Yes. In situations where the standards conformed to are test methods, test data often will still be required. For the specific case of ISO 10933-1, manufacturers need to specify the particular series of tests chosen from the standard and will likely need to provide summaries of the results of actual testing, since these standards do not include pass/fail criteria.

7. **If a person declares conformity of a device to a recognized standard, what data and information must be submitted regarding the declared standard?**

   If a manufacturer submits a declaration of conformity to a recognized standard, the declaration itself needs to provide identifying information on the standard to which the person is declaring conformity. The declaration will be acceptable in lieu of any information and/or data addressed by the standard. For example, if a recognized standard is a test standard and a person declares conformity to the standard, then the test protocol itself need not be submitted. However, FDA may require that the test results be submitted for evaluation. If there is FDA guidance relevant to the device, then it may indicate in detail the test data that should be submitted.

Changes

8. **Once a standard is recognized, will its revisions automatically be recognized?**

   Not automatically. Standards Task Groups (STGs) in the Center for Devices and Radiological Health (CDRH) will actively assess the impact of new standards and revisions of existing standards on the premarket review process and, as appropriate, recommend them for recognition. As new or revised standards are recognized by FDA, they will be published in the *Federal Register* and listed on the CDRH web site. Superseded standards that FDA has withdrawn from the list of recognized standards cannot subsequently be used in declarations of

conformity. Additionally, FDA has published the document, "CDRH Standard Operating Procedures for the Identification of Candidate Consensus Standards for Recognition" on the web site http://www.fda.gov/cdrh/osel/guidance/321.html to explain the procedures that are used by the agency to identify standards for recognition.

9. **Will changes in a recognized standard affect my previously cleared or approved product?**

   No. Changes in a recognized standard do not retroactively affect a product's clearance or approval status.

10. **What happens if I make changes to my product that would not require a new submission, but now my declaration of conformity is no longer completely accurate? What should I do?**

    Assuming that the standard is still applicable, the manufacturer should document that the change(s) would not affect device safety and effectiveness and that they are consistent with existing guidance documents regarding premarket submissions for changes, e.g., "Deciding When To Submit A 510(k) For A Change To An Existing Device," http://www.fda.gov/cdrh/ode/510kmod.html. The manufacturer should maintain records regarding the changes and the rationale for not needing a premarket submission for them and provide such records to FDA investigators for review upon request.

11. **I've previously declared conformance to a standard and now want to modify my device. However, in the meantime, the standard has been revised and the revision recognized by FDA. Must I comply with all parts of the revised standards?**

    This depends on the effect that the modification has on the device's safety and effectiveness. If the device modification doesn't significantly affect safety and effectiveness, then the manufacturer should maintain records of the modifications and testing, in accordance with the Quality System regulation, and make them available to FDA investigators upon request during inspections as stated in #10 above. If the modifications significantly affect safety and effectiveness, then a new premarket submission is usually needed, as well as a new declaration of conformity, if the manufacturer decides to submit one. The new declaration of conformity would be for the revision recognized by FDA. As with the original declaration of conformity, it may not be necessary to comply with all parts of the revised standard(s), but the declaration of conformity should specify what parts of the revised standard(s) the device does not meet and explain any deviations.

Failure to Meet Standard/False Declaration

12. **What are the consequences associated with intentionally submitting a false declaration of conformity? Or unintentionally submitting a false declaration of conformity?**

    The intentional submission of a false declaration is a prohibited act under Section 301(x) (21 U.S.C. 331(x)) of the Act) and is a violation of Section 1001 of Title 18 of the U.S. Code (18 U.S.C. 1001), and would subject a person to possible criminal sanctions. Also, the intentional or unintentional submission of a false report, including a declaration of conformity that is used to obtain device clearance or approval, is a prohibited act under Section 301(q) of the Act (21 U.S.C. 331(q)), and subjects a person to injunction, civil money penalty, and possible criminal sanctions. FDA will evaluate evidence of intent as well as other factors in determining whether criminal sanctions are appropriate.

Inspections/Audits

13. **During inspections, will FDA make it routine now to audit the data/information that support the declaration of conformity?**

    FDA continues evaluating how to most effectively assure the reliability of declarations of conformity. A data and information audit during an inspection is one way to accomplish this.

Standards Recognition Process

14. **Should conformance to and applicability of standards be addressed in pre-submission meetings?**

    Yes. A sponsor should discuss its plans to use standards and the specific issues regarding the standards related to its product at any pre-submission meeting with FDA.

15. **Will there be some latitude for a manufacturer or sponsor to declare conformity to parts of recognized standards for new devices or technologies that are not included in the Supplementary Information Sheet?**

    Yes. See also #14 above.

16. **Will a standard be recognized before its final approval?**

    Ordinarily, only standards that have completed the standards development organization's written procedures for approval/issuance will be recognized. With product specific standards CDRH will recognize a Final Draft International Standard (FDIS) document and then re-recognize the final standard in a subsequent recognition.

17. **How can I get information on new standards that have been recognized <u>prior</u> to the next publication in the *Federal Register*?**

    Standards are recognized by publication in the *Federal Register*. FDA's decision to recognize a standard will be reflected on the CDRH web site as soon as the *Federal Register* notice goes on display (usually two days prior to publication).

18. **What organizations can develop consensus standards for FDA recognition?**

    FDA will recognize standards developed by organizations that follows a process where the standard development is transparent (i.e., open to public scrutiny), where the participation is balanced, where an appeals process is included, where the standard is not in conflict with any statute, regulation, or policy under which FDA operates, and where the standard is national or international in scope. For example, International Electrotechnical Commission (IEC) and ISO standards usually meet these criteria, as do standards developed by an American National Standards Institute (ANSI)-accredited standards development organization.

19. **Are compendial standards, e.g., United States Pharmacopeial Convention, Inc. (USP), considered consensus standards?**

    Standards such as those developed by USP meet the criteria discussed in #18 above and, therefore, may be recognized.

20. **Is there a difference between a "consensus standard" and a "recognized consensus standard"?**

    A "recognized consensus standard" is a consensus standard that FDA has evaluated and recognized for use in satisfying a regulatory requirement and for which FDA has published a notice in the *Federal Register*. A "consensus standard" is a standard developed by a private sector standards body using consensus process.

21. **Is the scope of recognition of national and international consensus standards limited to U.S.-developed standards and ISO/IEC or would national standards of other countries also be considered?**

    National standards of other countries would be considered, where appropriate. A sponsor should discuss its plans to use the national standard of another country, along with any other standards issues, at any pre-submission meeting with FDA.

22. **What is the relationship between the FDA's recognized standard program and the use of standards in other parts of the world?**

    The FDA use of consensus standards is voluntary; i.e., it is an alternative procedure to addressing some of the issues of safety and effectiveness (or

substantial equivalence in the case of 510(k)s) in device submissions. It is thus similar to the use of consensus standards in the European Union's regulatory scheme, where adherence to standards is an optional method for meeting "essential requirements." FDA's standards recognition program furthers the aims of harmonization because mutual recognition often relies on different countries basing their product approvals on the same international standards where appropriate.

23. **Are normative references in a standard automatically recognized?**

No. A normative standard is one that is referenced in the recognized standard. There referenced (normative) standards are recognized by FDA only to the extent that they are used within the FDA recognized standard. Such standards will not automatically be recognized as independent entities.

Information about the normative references should be used to apply a recognized standard. Normative references do not typically reference an entire standard; rather normative references are typically limited to a specific clause or clauses. The cite to the normative reference should provide information on the extent the reference is limited or applies.

24. **Can a manufacturer still rely on standards that may be in an FDA guidance document but not yet recognized officially through the *Federal Register* by FDA? When a standard is recognized and is not mentioned in a guidance document, which applies?**

When standards are referenced in an FDA guidance document, it represents FDA's current thinking about the applicability of the standard (whether recognized or not) to the issue being addressed. Following these recommendations is one way for the submitter to address the identified issue. However, the applicant is free to use an alternative approach, including other standards (whether recognized or not), to address the issues. Therefore, a manufacturer can rely on standards that may be in an FDA guidance document but not recognized through a *Federal Register* publication. A submitter may also rely on a recognized standard that is not mentioned in a guidance document if the submitter concludes that the recognized standard is an appropriate way to address the issue the agency has identified.

25. **Under what circumstances would FDA withdraw recognition of a standard?**

There are two primary situations where FDA may withdraw recognition of a standard. The first situation occurs when a new edition of a standard, previously recognized by FDA, is issued by a standards development organization. If FDA decides to recognize the new edition, the old edition will usually be removed from the list of officially recognized standards on the CDRH web site, the new edition will be added, and the change will be recorded in a notice published in the

Federal Register. If the old edition is removed, a declaration of conformity to the old edition will no longer be acceptable. However, on a case by case basis, FDA may provide a transition period during which both the old and new editions of the standard will be recognized. The transition period will be included in the supplemental information sheet.

The second situation occurs when FDA determines that the recognized standard is "no longer appropriate for meeting a requirement regarding devices." (Section 514(c)(2) of the Act). This would be a very rare occurrence given FDA's involvement in the development of the recognized standard and the independent review given prior to recognition; however, in such an instance, a notice would be published in the *Federal Register* withdrawing FDA recognition.

26. **If a device is found substantially equivalent and the recognized standard upon which the device was cleared is subsequently withdrawn from the recognized standards list, what is the impact on the clearance?**

    The cleared device remains legally marketed and it remains eligible as a predicate device. Any new device making reference to this predicate in a premarket notification submission will not enjoy the regulatory benefit of declaring conformity to the standard that is no longer on the recognition list. FDA will likely recommend the submission of more supporting data and information than that needed for the prior device that was supported by a declaration of conformity to the previously recognized standard.

27. **How often does FDA update its list of recognized standards?**

    As stated in the February 25, 1998, *Federal Register* notice (63 FR 9531), FDA publishes in the *Federal Register* a modified list of recognized standards at least once per year and more frequently, if necessary.

28. **How can an interested party (manufacturer, the public, or trade association) request recognition of a standard?**

    Any interested party can request recognition of a standard. As specified in the *Federal Register* notice dated February 25, 1998 (63 FR 9531), a recommendation for recognition of a standard should, at a minimum, contain the following information:

    - title of the standard
    - any reference number and date
    - name and address of the nationally or internationally recognized standards development organization
    - proposed list of devices for which a declaration of conformity should routinely apply

- a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

The recommendation should be sent to:

Carol L. Herman
Director, Standards Management Staff (HFZ-84)
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, MD 20850

29. **What process will FDA go through to recognize a standard?**

This process is outlined on the FDA web site in the guidance document entitled, "CDRH Standard Operating Procedures for the Identification of Candidate Consensus Standards for Recognition" http://www.fda.gov/cdrh/osel/guidance/616.html.

30. **Will manufacturers be able to declare conformity with only parts of a standard?**

Yes, but only to parts of an FDA recognized standard and only those parts that are applicable to the device under review.

31. **Does FDA anticipate partially recognizing any standards?**

Yes. The current list of standards contains some partial recognitions. Also, the supplemental information sheets on the FDA web site identify these partial recognitions of a standard.

Product Submissions/Approvals

32. **Will the lack of an FDA-recognized standard delay approvals?**

The lack of a recognized standard that can be applied to a device will not mean a longer review time compared to the current process, everything else being equal (e.g., similar number of incoming submissions, or staff assigned). However, FDA believes that using standards in the review process can allow for a more efficient review.

33. **Will the FDA request copies of standards (or parts thereof) in submissions? If so, would these copies have to be obtained from some official source?**

No. Agency reviewers have access to all recognized standards electronically and no copies of standards will be requested from submitters.

34. **Will FDA continue to request information on compliance with standards that are not yet recognized, e.g., ISO 13485?**

    Yes, if those standards are referenced in the submission to meet regulatory requirements.

35. **Are there any examples where FDA has allowed use of a standard in product clearance or approval and subsequently found the standard to be inappropriate or unreliable? What happens to the product clearance or approval in those circumstances?**

    FDA is unaware of any examples where this has occurred. The cleared or approved product would be evaluated on a case-by-case basis to determine if any action was necessary.

Third-party Certification

36. **Will third-party certification be accepted? If so, must such certification be obtained from an FDA-approved body and must such approval be specific for the device?**

    FDA will accept declarations of conformity only from submitters of premarket notifications or applications. Third-party declarations or certifications of conformity may be provided to the submitter, but the submitter is responsible for declaring conformity to the Agency. The submitter is responsible for evaluating the reliability of the third party certification as part of the verification requirements under the Quality Systems regulation.

37. **What's an appropriate accreditation for a test laboratory or certification body?**

    Although FDA does not require accreditation from any specific test laboratory or certification body, accreditation can be accomplished through an accreditation body using applicable ISO/IEC Guides for conformity assessment.

38. **If FDA recognizes a standard, must my device conform to that standard?**

    No. Use of any consensus standard, whether recognized or not, is voluntary on the part of the applicant submitting its device for evaluation by FDA.

Updated September 17, 2007