

Frequently Asked Questions on the Recognition of Consensus Standards; Guidance for Industry and for FDA Staff

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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

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 Dr. Mel Altman at 301-594-4766, ext. 106 or E-mail: <mailto:mra@cdrh.fda.gov>.

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Frequently Asked Questions on the Recognition of Consensus Standards; Guidance for Industry and for FDA Staff

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.

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.

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/> .

DECLARATION OF CONFORMITY

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

The seven 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 noted 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 were 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; and
- If a test laboratory or certification body was employed, 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.

2. 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. Generally, the process to be followed within the Office of Device Evaluation when a declaration of this type is submitted is that the assigned reviewer proposes a course of action through his/her supervisor which then goes to the decision-making official in the Office of Device Evaluation to determine if the declaration of conformity is appropriate for a previously unidentified device. For 510(k)s, the decision-making official is the Division Director and for PMAs, it is the Office Director. Additionally, when a person considers declaring conformity to a standard, he/she should examine the supplemental information sheets posted on the FDA web site, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. Among other things, those sheets identify which parts of the standard have been recognized and how the part(s) will be applied by the agency in medical device reviews, as well as a list of devices for which declarations of conformity with a recognized standard will be routinely accepted by agency reviewers.

3. Can I submit a declaration of conformity for a device even when the device falls outside the stated scope of that standard?

Yes, however, in order to allow proper evaluation, the manufacturer should justify why that standard is appropriate for the device in question. The manufacturer's declaration will be evaluated by the FDA Office of Device Evaluation to determine if it is appropriate to apply the standard to the device.

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

The answer to this is addressed in two places in the guidance document, "[Recognition and Use of Consensus Standards](#)" under the heading, "Procedures for the Use of Consensus Standards." Reviewers and managers in the Office of Device Evaluation can exercise discretion as to whether such data should be provided.

First, under the sub-heading, "Review of a declaration," the guidance document states:

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.

Second, under the sub-heading, "Requesting additional information," the guidance document states:

... 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. ... 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 that person concurs, the reviewer should request, in accordance with applicable regulations and established procedures, 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, they should assure the reliability of certifications periodically which could include 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.

- 6. Experience in the past has shown that stating conformity to a test method standard, e.g., 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 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.

CHANGES

- 7. 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 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/ost/guidance/616.html> so that applicants can examine the procedures that are used by the agency to identify standards for recognition.

- 8. 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.

- 9. 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?**

At a minimum, the manufacturer needs to document whether the declaration of conformity still applies to the product. This would not necessarily require a change to the declaration of conformity. If the manufacturer documents 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>, then 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.

10. If you've declared conformance to a standard and now you want to modify your device and the standard has been revised and recognized, must you 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 during inspections as stated in [#9](#) 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. 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.

FAILURE TO MEET STANDARD/FALSE DECLARATION

11. Assuming that a product is cleared or approved using a declaration of conformity to a standard, what are the consequences of unintentionally delivering a product that does not meet the standard?

A product which does not meet the standard in the declaration of conformity which was submitted to FDA is adulterated under the Federal Food, Drug, and Cosmetic Act (the Act). Section 301(a) of the Act (21 U.S.C. 331(a)) prohibits the introduction of adulterated devices into interstate commerce. If a firm unintentionally delivers a product that does not meet the standard, FDA would evaluate the potential public health risk and the history of violations of this sort to determine what action, if any, is appropriate. If the violative product is not removed from distribution or continues to be distributed, a range of civil money actions from product seizure to injunction and civil penalties could be taken.

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 declaration 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 is 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. How will conformance to and applicability of standards be addressed in pre-submission meetings (IDE, PDP, PMA)?

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 typically the subject of IDEs and PMAs but for which specific standards have not yet been developed?

Yes. See also #14 above.

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

No, only standards that have completed the standards development organization's written procedures for approval/issuance can be recognized.

17. How can I get information on new standards that have been recognized prior to the next "official" publication in the Federal Register?

Standards are recognized by publication in the Federal Register. However, newly recognized standards will be listed on the CDRH web site as soon as the Federal Register notice goes on display (usually two days prior to publication) and may be used by manufacturers at that time.

18. Will FDA issue any guidance on the information required in a recommendation submitted by the public for recognition of a standard?

The Federal Register Notice dated February 25, 1998, (63 FR 9531) contains a section, "Recommendation of Standards for Recognition by FDA" which outlines the type of information to be included in a recommendation. There is no prescribed format for submitting the information.

19. What organizations can legitimately develop consensus standards for FDA recognition?

FDA will recognize standards developed by any organization that follows a process where the standard development was transparent (i.e., open to public scrutiny), 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, regardless of the organization that developed it. For example, IEC and ISO standards usually meet these criteria, as do any standards developed by an ANSI-accredited standards development organization.

20. Are compendial standards, e.g., USP, considered consensus standards? If not, how (or will) such standards be recognized by FDA in the regulatory process?

Standards such as those developed by USP meet the criteria discussed in [#19](#) above and, therefore, may be recognized.

21. 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 that FDA has published in a notice in the Federal Register. A "consensus standard" is a standard developed by a private sector standards body using an open and transparent consensus process.

22. Is the scope of acceptability 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.

23. How does the U.S. use of standards relate to the use of standards by other major regions or countries of the world, e.g., Europe, Japan, Australia, etc.? Will the recognition of standards further harmonization or are we creating technical barriers to trade?

The FDA use of consensus standards is voluntary; i.e., it is an alternative procedure to demonstrate 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." Because FDA's standards recognition program is voluntary and, in any case, relies heavily on international standards, it should not create technical barriers to trade. The program should further the aims of harmonization because mutual recognition often relies on different countries basing their product approvals on the same international standards where appropriate.

24. Are normative references in a standard automatically recognized?

No, standards referenced in an FDA recognized standard (normative references) 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.

25. 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?

Reliance on a standard, whether it is in an FDA guidance document or officially recognized through the Federal Register, is strictly voluntary. A manufacturer may, but is not required to, comply with a standard identified in an FDA guidance document. Likewise, such manufacturer may, but is not required to, comply with a recognized standard unless he/she declares conformity to it. However, the procedures outlined in "Recognition and Use of Consensus Standards" refer to the recognition and use of consensus standards recognized by FDA.

26. 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 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.

27. 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 unless and until the marketed device is found to be adulterated or misbranded, or otherwise in violation of the Act. 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 standard.

28. How often does FDA expect to be publishing a current list of recognized standards?

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

29. How can a person (i.e., manufacturer, the public, trade association, etc.) 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 Program Coordination Staff (HFZ-84)
Office of Science and Technology
Center for Devices and Radiological Health
2094 Gaither Rd
Rockville, MD 20850

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

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

31. 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.

32. Does FDA anticipate partial recognition of any standards? Would the policy allow that?

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

33. 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, staff assigned, etc.). However, when standards are used in the review process, FDA expects that review times will decrease below the current review times.

34. Will the FDA demand 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.

35. Will FDA continue to request information on compliance with standards that are not yet recognized, e.g., NCCLS EP-5?

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

36. How will I know when a standard can be used for submission for a particular device?

As FDA recognizes a new standard or modification of an existing standard, this information will be published in one of the supplemental information sheets on CDRH's web site. Once on the web site, a declaration of conformity to that standard can be provided with the premarket submission and will be accepted by FDA. Manufacturers should note that recognition of a standard officially occurs when FDA publishes a notice in the Federal Register, and listing on the web site will occur approximately two days prior to that.

37. 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

38. 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 a submitter of a premarket application. 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.

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

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

40. 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.

41. 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 declaration. 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.

Miscellaneous

42. Given the current budget constraints, will FDA continue to participate in standards-setting activities with national and international organizations?

FDA is committed to the use of consensus standards, where applicable, in all of its regulatory programs. This commitment includes continued participation by the agency in the development of standards with national and international standards development organizations. Where budget resources permit, FDA will participate directly in the standards development process.

43. Will manufacturers be able to declare conformity to FDA mandatory standards, e.g., laser emissions?

FDA will accept declarations of conformity to mandatory electronic product radiation control standards ([21 CFR 1010 - 1050](#)), but manufacturers are reminded to meet other existing reporting requirements, such as those found in Part 1002 of the agency's regulations ([21 CFR Part 1002](#)) regarding the documentation of compliance with a standard.