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Draft – Not for Implementation

Recognition and Withdrawal of Voluntary Consensus Standards

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance is being distributed for comment purposes only.

Document issued on September 14, 2018.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Office of the Center Director (301) 796-5600 or Scott Colburn at 301-796-6287 or by e-mail at scott.colburn@fda.hhs.gov or CDRHStandards@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

When final, this document will supersede "CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition," issued on September 17, 2007.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 616 to identify the guidance you are requesting.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20903, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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Recognition and Withdrawal of Voluntary Consensus Standards

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) developed this document to provide guidance to industry and FDA staff about the procedures the Center for Devices and Radiological Health (CDRH) follows when we receive a request for recognition of a voluntary consensus standard.[1] The guidance outlines principles for recognizing a standard wholly, partly, or not at all, as well as reasons and rationales for withdrawing a standard.

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 guidance means that something is suggested or recommended, but not required.

II. Background

Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. No. 105-115) and the 21st Century Cures Act in 2016 (Pub. L. 114-255). These acts amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by amending section 514(c), 21 U.S.C. 360d(c), regarding the recognition of standards.

[1] All requests for recognition of a voluntary consensus standard are managed by CDRH, including any requests for recognition of a standard that would apply primarily or solely to a device regulated by CBER.

The term "recognize" in section 514(c) of the FD&C Act refers to FDA's identification of standards as appropriate for manufacturers of products to declare conformance to meet relevant requirements under the FD&C Act, including premarket submission requirements.

FDA's standards recognition program furthers the aim of international harmonization because the same standards (or international equivalents) are relied upon by sponsors to meet other countries' regulatory requirements when appropriate. For example, adherence to such standards is an optional method of meeting "essential requirements" within the European Union's regulatory scheme.

III. Scope

This draft guidance describes the procedures that FDA follows and the actions FDA may take during its review and evaluation of requests for standards recognition or the withdrawal of recognition. This draft guidance provides further clarity and explanation about the regulatory framework, policies, and practices when evaluating requests for recognition.

IV. FDA Recognition of Standards

The Agency recognizes consensus standards to help facilitate meeting requirements under the statute or regulations. The use of recognized consensus standards can increase predictability, streamline premarket review, provide clearer regulatory expectations, facilitate market entry for safe and effective medical products, and promote international harmonization. FDA considers for recognition voluntary consensus standards, i.e., standards developed by voluntary consensus standards bodies. These bodies are defined as any organization that plans, develops, establishes, or coordinates voluntary consensus standards using a voluntary consensus standards development process that includes the attributes or elements outlined in the OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.[2] We believe these attributes or elements help ensure that recognized standards are fair and relevant, which in turn encourages their use by manufacturers or product developers, as well as harmonization. Specifically, these attributes or elements are:

1. *Openness*. The procedures or processes used are open to interested parties. Such parties are provided meaningful opportunities to participate in standards development on a non-discriminatory basis. The procedures or processes for participating in standards development and for developing the standard are transparent.
2. *Balance*. The standards development process should be balanced. Specifically, there should be meaningful involvement from a broad range of parties, with no single interest dominating the decision-making.
3. *Due Process*. Due process shall include documented and publicly-available policies and procedures, adequate notice of meetings and standards development, sufficient time to

[2] https://www.nist.gov/sites/default/files/revised_circular_a-119_as_of_01-22-2016.pdf

review drafts and prepare views and objections, access to views and objections of other participants, and a fair and impartial process for resolving conflicting views.

4. *Appeals Process.* An appeals process shall be available for the impartial handling of procedural appeals.
5. *Consensus.* Consensus is defined as general agreement, but not necessarily unanimity. During the development of consensus, comments and objections are considered using fair, impartial, open, and transparent processes.

In addition, consistent with OMB Circular A-119, a standard that incorporates patented technology must be subject to certain intellectual property rights policies to qualify as a voluntary consensus standard. Specifically, these policies must ensure that the owners of the intellectual property make it available to implementers of the standard on non-discriminatory and royalty-free (or reasonable royalty) terms. The policies must also bind subsequent owners of standards-essential patents to the same terms.

These elements apply to activities related to the development of voluntary consensus standards nationally or internationally. For example, the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) usually develop standards that meet these criteria, as do standards developed under the American National Standards Institute (ANSI). Each organization has a process for development similar to that of ANSI, explained in Essential Requirements: Due process requirements for American National Standards.[3] FDA also has the flexibility to recognize standards developed in the private sector by compendial organizations, such as those developed by the United States Pharmacopeial Convention, Inc. (USP), that meet the criteria discussed in OMB Circular A-119.

FDA may consider national standards of other countries when no international or U.S. national equivalent standard is available. Note that, in other cases, an international standard that another country adopts may be identical to standards recognized by FDA, e.g., ISO or IEC standards adopted as European Standards (EN/ISO), German standards (DIN/EN/ISO, DIN/ISO[4]), or British standards (BS/ISO); however, we will not ordinarily recognize the identical international standard separately. A sponsor should discuss with FDA its plans to use a national standard of another country, along with any other standards issues.

FDA does not ordinarily consider normative references, i.e., standards referenced in an FDA-recognized standard, for separate recognition. This is because normative references do not typically refer to an entire standard; rather, normative references typically refer to a specific clause or clauses. The citation of the normative reference within the FDA-recognized standard will provide information about the extent to which the normative reference is limited or applies.

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[3] https://share.ansi.org/shared%20documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/2016_ANSI_Essential_Requirements.pdf

[4] Deutsches Institut für Normung e.V. (German Institute for Standardization)

You will likely need knowledge of the normative references or referenced documents to appropriately apply that standard.

A. Recognition

FDA recognizes standards by publication of a recognition list in the *Federal Register*. FDA will publish the recognition list at least annually.

After FDA has decided to recognize a standard, we will update our online database for Recognized Consensus Standards to reflect this decision. The database will include a recognition number and a Supplemental Information Sheet for each decision.[5]

B. Requesting Recognition

Any interested party may request recognition of a standard. A recommendation for recognition of a standard should, at a minimum, contain the following information:

- name and electronic or mailing address of the requestor
- title of the standard
- any reference number and date
- proposed list of devices for which a declaration of conformity should routinely apply
- basis for recognition, e.g., including the scientific, technical, regulatory, or other basis for such request
- a brief identification of the testing or performance or other characteristics of the device(s) or process(es), that would be addressed by a declaration of conformity.

Additional advice on procedures for requesting standards for recognition may be found at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123739.htm. Requests may be submitted by mail in writing to the CDRH Standards program at the address below or electronically through CDRHStandardsStaff@fda.hhs.gov.

CDRH Standards Program
Office of the Center Director
Center for Devices and Radiological Health
10903 New Hampshire Avenue
WO66-5514
Silver Spring, MD 20993-0002

[5] A sponsor may rely on an unrecognized standard. For more information, refer to the FDA guidance document, "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077295.pdf (September 14, 2018)

In general, FDA will not automatically request copies of the standard submitted for recognition. However, there may be standards which the Agency does not have access to, such as country specific standards or standards created by professional societies. Therefore, we recommend contacting the CDRH Standards Program prior to submitting a standards recognition request to determine whether the Agency has access to the standard.

When the Agency receives a request for recognition of a standard, we will mail or email an Acknowledgment Letter to the contact person identified in the request. The Acknowledgment Letter will identify the date of receipt (this is the date that FDA received the request), the title of the standard, and a contact person at FDA who is assigned to oversee the recognition request.

C. Extent of Recognition: Complete or Partial Recognition

When a standard is approved for recognition, all or part of that standard is recognized. The extent of recognition (EOR) is FDA's determination regarding which parts of a standard are appropriate for recognition. Within this context, "recognize" is a specific term derived from section 514(c) of the FD&C Act, referring to the process for FDA identification of standards that manufacturers of medical devices may cite to meet relevant requirements of the FD&C Act and implementing regulations. The EOR section of the Supplementary Information Sheet (SIS) specifies the extent to which a standard is recognized. See section V for more information about the supplementary information.

The Standards Program is responsible for reviewing and recommending the supplementary information that accompanies each standard that is recognized. FDA staff may request that the CDRH Standards Program staff contact the submitter for additional clarification regarding their request for recognition.

Complete Recognition

For a standard that can be recognized wholly and in its entirety, the EOR will state "Complete Standard."

Partial Recognition

For a standard that can be recognized in part, the EOR will state "Complete Standard with the following exceptions." The exceptions, those parts of the standard that are not recognized, will be listed by Section or Clause sequentially as they appear in the standard. The titles accompanying the section or clause numbers will also be included.

D. Non-Recognition

Non-recognition or no recognition of a standard means that the standard generally does not satisfy or would not be helpful in satisfying a portion of the statute or regulations. FDA's rationale for this decision will be communicated to the submitter of the request, and the decision will be posted on the Standards web page. FDA will explain the technical, scientific, regulatory,

or other basis for the decision.[6] If the standard contains specifications or methods that are not scientifically acceptable, not technically feasible, or are in conflict with existing recognized standards, existing published policies, regulation, or the statute, FDA generally would not recognize the standard. FDA may also decide not to recognize a standard that creates a barrier to domestic or international trade or that impedes innovation or technical progress. If we decide not to recognize a standard, it would not receive a recognition number.

E. Notification of Decision

FDA's goal is to make a decision on recognition (complete or partial) or non-recognition no later than 60 calendar days from the date the request was received. When such a decision is made, the Agency will issue the decision letter to the submitter by mail using the mailing address provided or electronically using the email address provided. We will announce the decision to recognize the standard (completely or partially) with a subsequent notice in the *Federal Register*.

V. Supplementary Information

The recognition of a standard includes a Supplemental Information Sheet (SIS) for each standard recognized. This document, developed by FDA, is intended to assist manufacturers and product developers should they elect to use standards in their product development, manufacturing, or for other purposes. The SIS also includes the standard's scope and other helpful information. The SIS for most vertical standards, e.g., device-specific standards, includes a list of relevant regulations and product codes for which the standard may be applicable. Although the Agency makes every effort to keep the list in the SIS current, note that new product codes are continually being created, and as such the list may not always be up to date. The list of product codes is intended to provide examples of products for which the standard may be applicable. Product codes and regulations are typically not provided for horizontal standards, e.g., biocompatibility or sterility standards, because maintaining a representative list would be impractical given the number of products impacted.

A. Essential Information Provided

The SIS includes essential information such as the record or recognition number, which allows for sorting the standard based on Specialty Task Group (STG). Other information includes the standard's designation number, date of publication, and title. The SIS also includes the date of the *Federal Register* notice announcing the standard's recognition. The contents of a SIS are as follows:

- Recognition category
- Recognition list
- *Federal Register* publication date

[6] See section 514(c)(1)(C)(ii) of the FD&C Act.

- Recognition number
- Standard designation number
- Title of the standard
- Identical U.S. adoption[7]
- Extent of recognition (e.g., wholly or in part)
- Rationale, including basis, for recognition[8] (technical, scientific, regulatory, or other basis)
- Transition period (if any)[9]
- Relevant FDA guidance
- FDA technical contact or contacts
- FDA Specialty Task Groups
- Standards Development Organization (SDO)
- History of recognition

B. Scope

FDA will include the standard's scope in the SIS to assist manufacturers of devices in determining whether or not the standard may be useful to them. Where a standard's scope is extensive, the main body of the scope will be included with reference to the website where the entire scope can be located.

C. FDA Decision Making Rationale/Justification

There are several reasons for the Agency to recognize a standard. Recognition of a voluntary consensus standard, either in whole or in part, can help facilitate meeting a requirement under the statute or implementing regulations. Although reasons for recognition of a standard are many, generally a recognized standard may meet or satisfy requirements under any one or more of the following categories:

- Performance Specification
- Material Characterization
- Biocompatibility
- Cleaning, Disinfection, Reprocessing, or Sterilization
- Sterile Barrier, Packaging
- Device-Specific Performance Characterization
- Electrical Safety, Immunity

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[7] "Identical" or "parallel" U.S. adoption is when the United States, through ANSI, adopts ("in parallel") a standard published by an international SDO, such as ISO or IEC. FDA will update the SIS of the international standard on our website when either ANSI or a U.S. SDO publishes the parallel adoption. Since such standards are identical, we will not ordinarily assign a separate recognition number or separately announce recognition in the *Federal Register*.

[8] See section 514(c)(1)(C)(ii) of the FD&C Act.

[9] For further information regarding transition periods of recognized standards, please refer to the FDA guidance, "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

- Software
- Statistical Treatment of Data
- Clinical Issue
- Labeling
- Symbol Use
- Device Identifier
- Pre-Market Submission
- Post-Market Activity
- Radiological Health
- Public Health Concern or Hazard
- Informed Consent, Study Subject Protection
- Manufacturing
- Quality Systems Regulation
- Risk Management, Assessment
- Human Factors
- Good Laboratory Practices

FDA will provide its rationale/justification for recognition of the standard in the SIS, including the scientific, technical, regulatory, or other basis, as applicable.

VI. Withdrawal of Recognition

FDA may withdraw recognition of a previously-recognized standard if the Agency determines that the standard is no longer appropriate for meeting a requirement regarding devices under the FD&C Act (see section 514(c)(2)). There are two primary situations where FDA may make this determination. The first situation occurs when an SDO issues a new edition, e.g., a reaffirmation, reapproval, or revision, of a standard previously recognized by FDA. If FDA decides to recognize the new edition, we will announce the change, i.e., recognition of the new edition and (usually) withdrawal of the older edition, in a notice published in the *Federal Register.* We will add the new edition to the Recognized Consensus Standards database upon publication of the notice, and we will usually remove the older edition from the database. If we remove the old edition, a Declaration of Conformity to it will no longer be acceptable for future submissions. However, FDA may provide a transition period during which both the old and new editions of a standard are recognized. The transition period, if any, will be included in the SIS.

The second situation for withdrawal occurs when FDA determines that the recognized standard is "no longer appropriate for meeting a requirement regarding devices" for other reasons (section 514(c)(2) of the FD&C Act). In such an instance, a notice would be published in the *Federal Register* withdrawing FDA recognition.