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Recognition and Withdrawal of Voluntary Consensus Standards

Guidance for Industry and Food and Drug Administration Staff

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This document supersedes "CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standard for Recognition," issued on September 17, 2007.

For questions about this document, contact the Office of Strategic Partnerships and Technology Innovation (OST) at (301) 796-5600 or the Standards and Conformity Assessment Program by e-mail at CDRHStandardsStaff@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.

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

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2018-D-2936. Comments may not be acted upon by the Agency until the document is next revised or updated.

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 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), 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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

Table of Contents

I. Introduction....1
II. Background....1
III. Scope....2
IV. FDA Recognition of Standards....2
A. Recognition....4
B. Requesting Recognition....5
C. Extent of Recognition: Complete or Partial Recognition....6
D. Non-Recognition....6
E. Notification of Determination....7
V. Supplementary Information....7
A. Essential Information Provided....7
B. Scope....8
C. FDA Decision Making Rationale....8
VI. Withdrawal of Recognition....8
A. FDA-Recognized Consensus Standard Replaced by New Version....8
B. FDA-Recognized Consensus Standard "no longer appropriate for meeting a requirement"....9
VII. Paperwork Reduction Act of 1995....9

Recognition and Withdrawal of Voluntary Consensus Standards

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 for medical products.[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.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2]

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. 105-115) and the 21st Century Cures Act of 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 for medical devices are managed by CDRH, including any requests for recognition of a standard that would apply to a device regulated by CBER. In this guidance, "product" refers to medical devices including those that are licensed as biological products under section 351 of the Public Health Service (PHS) Act.

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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. This guidance refers to voluntary consensus standards recognized by FDA in the *Federal Register* in accordance with section 514(c) of the FD&C Act as "FDA-recognized consensus standards."

CDRH's Standards and Conformity Assessment Program (S-CAP) 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 the General Safety and Performance Requirements ("GSPR") under the European Medical Device Regulation ("EU MDR").

III. Scope

This 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 guidance provides further clarity and explanation about the regulatory framework, policies, and practices regarding FDA's recognition and withdrawal of recognition of voluntary consensus standards.

IV. FDA Recognition of Standards

The Agency recognizes voluntary consensus standards to help facilitate meeting requirements under the statute or regulations. The use of FDA-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 that are developed by voluntary consensus standards bodies. These bodies are defined as any organization that plans, develops, establishes, or coordinates 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.[3] We believe these attributes or elements help ensure that standards recognized by FDA are fair and relevant and useful for regulatory purposes. This in turn encourages their use by manufacturers and advances opportunities for national and international 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.

[3] https://www.nist.gov/system/files/revised_circular_a-119_as_of_01-22-2016.pdf

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 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.

These elements apply to activities related to the development of voluntary consensus standards nationally or internationally. For example, the International Electrotechnical Commission (IEC), International Organization for Standardization (ISO), Institute of Electrical and Electronics Engineers (IEEE) and ASTM International, usually develop standards that meet these criteria, as do standards developed in adherence with the American National Standards Institute (ANSI) Essential Requirements.[4] FDA may also recognize standards developed in the private sector, for example, by professional societies, industry associations and other organizations such as The United States Pharmacopeia Convention (USP), that meet the criteria discussed in OMB Circular A-119.

FDA prioritizes international and U.S. voluntary consensus standards for recognition; however, 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 or region 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[5]), or British standards (BS/ISO); however, we will not ordinarily recognize the identical international standard separately. These standards may be used as described in the FDA guidance document, "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[6] 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 within an FDA-recognized consensus 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 consensus standard will provide information about the extent to which the normative reference applies.

[4] https://www.ansi.org/essentialrequirements

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

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

In limited circumstances, FDA-recognized consensus standards are referenced within other standards recognized by FDA. In these circumstances, manufacturers and others might wish to refer to more recent versions of the normative reference that have been recognized by FDA. More recent versions of the normative reference may address emerging issues of safety or technology before the currently-recognized standard is updated to incorporate more-recent normative references.

For example, the 60601 family of standards includes multiple collaterals[7] describing general testing for basic safety and essential performance and many particulars[8] describing specific test methods by product type and application. A particular typically includes reference to a collateral, and a collateral is typically updated prior to the particulars that reference it. In the circumstance in which a manufacturer is using a particular that references a collateral and both standards are recognized by FDA, a manufacturer may wish to refer to the most recent version of the collateral that has been recognized by FDA.

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.

A list of consensus standards that FDA has recognized or decided to recognize is available on the FDA Recognized Consensus Standards Database Web site.[9] Such standards are those that FDA has recognized by notice published in the *Federal Register* or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the *Federal Register*). The database will provide the most up-to-date list of suitable standards because, after FDA has decided to recognize a standard, we will update our online database to reflect the decision even before recognition of the standard. The database will include a recognition number and a supplemental information sheet (SIS) for each decision, including for cases for which recognition is pending.[10]

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[7] An IEC collateral standard is defined as a standard that addresses additional basic safety and essential performance requirements that are common to a subgroup of medical electrical equipment; or a standard that addresses additional basic safety and essential performance requirements that deal with characteristics of medical electrical equipment or medical electrical systems that are not fully covered by the general standard. See ANSI/AAMI ES60601-1:2005/(R) 2012 and A1 2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text): *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance* (IEC 60601-1:2005, MOD).

[8] An IEC particular standard is defined as a standard that addresses additional basic safety and essential performance requirements that deal with characteristics of particular medical electrical equipment that are not covered by the general standard.

[9] FDA Recognized Consensus Standards Database for Medical Devices: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

[10] A sponsor may rely on an unrecognized standard. For more information, see the FDA guidance document, "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

B. Requesting Recognition

Any interested party may request recognition of a standard. A request 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 product types for which a Declaration of Conformity (DOC) should routinely apply
- basis for recognition, e.g., including the scientific, technical, regulatory, or other basis for the request
- a brief identification of the testing or performance or other characteristics of the product(s) or process(es), that would be addressed by a DOC.

Additional advice on procedures for requesting standards for recognition may be found at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/recognition-standard. Requests may be submitted by mail in writing to the Standards and Conformity Assessment Program (S-CAP) at the address below or electronically through CDRHStandardsStaff@fda.hhs.gov.

Standards and Conformity Assessment Program
Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health
10903 New Hampshire Avenue
WO66
Silver Spring, MD 20993-0002

In general, FDA will not automatically request copies of the standard submitted for recognition. However, there may be certain standards to which the Agency does not have access, such as country specific standards. Therefore; we recommend contacting S-CAP at CDRHStandardsStaff@fda.hhs.gov 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 intend to 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

FDA may recognize or decide to recognize all or part of a standard.[11] The extent of recognition (EOR) is FDA's determination regarding which parts of a standard are appropriate for

[11] See the FDA guidance document "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

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, which demonstrate scientific and technical merit, that manufacturers of medical products 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.

S-CAP is responsible for reviewing and recommending the supplementary information that accompanies each standard that is recognized. S-CAP staff may contact the submitter for additional clarification regarding the request for recognition.

Complete Recognition

For a standard that can be recognized in its entirety the EOR will state "Complete Standard" followed by the basis for that determination. FDA may have more than one reason for its determination.[12]

Partial Recognition

For a standard that can be recognized in part, the EOR will state "Partial Recognition" followed with text that lists the part(s) of the standard that is/are not recognized. The titles and numbers of non-recognized sections or clauses of the standard will be listed sequentially as they appear in the standard stating that they are not recognized. FDA will provide its rationale (basis for that determination) for the part(s) of the standard that are and are not recognized.

D. Non-Recognition

Non-recognition of a standard, while it does not preclude the appropriate use of a standard under general use,[13] 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 listed on the Non-Recognized Standards database.[14] FDA will explain the technical, scientific, regulatory, or other basis for the decision.[15] If the standard contains specifications or methods that are not scientifically acceptable, not technically feasible, or conflict with existing FDA-recognized consensus 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 FDA decides not to recognize a standard, it would not receive a recognition number.

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[12] The Supplementary Information Sheet (SIS) (discussed in Section V. of this guidance) includes a section titled "Rationale for Recognition," which is considered the "basis for such determination" discussed 514(c)(1)(C)(ii)(II).
[13] See the FDA guidance document "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."
[14] See Non-Recognized Standards database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/nr_results.cfm
[15] See section 514(c)(1)(C)(ii) and (D) of the FD&C Act.

E. Notification of Determination

The statute directs FDA to make a determination on recognition (complete or partial) or non-recognition no later than 60 calendar days from the date the request was received. When such a determination is made, the Agency will issue the determination letter to the submitter by mail using the mailing address provided or electronically using the email address provided. We will officially recognize the standard (completely or partially) by subsequent publication in the *Federal Register*. Note that the determination (and corresponding update to our database) may precede recognition via publication of the standard in the *Federal Register* through updates to the FDA Recognized Consensus Standards Database for Medical Devices.[16]

V. Supplementary Information

The recognition of a standard typically 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 development, manufacturing, or for other purposes. The SIS includes the standard's scope and other helpful information. The SIS for most vertical standards, e.g., product-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 and is not intended to be exhaustive. 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 typically includes essential information such as the recognition number and FDA Specialty Task Group (STG). Other information may include the standard's designation number, date of publication, title, scope, U.S. parallel adoption (if any),[17] extent of recognition (complete or partial), rationale for recognition,[18] date of recognition, and transition periods (if any).[19]

B. Scope

FDA intends to include the standard's scope in the SIS to assist manufacturers and FDA staff in determining whether the standard may be useful to them. Where a standard's scope

[16] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

[17] "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, without modification to its content. 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*.

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

[19] 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."

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

Recognition of a voluntary consensus standard, either in whole or in part, can help facilitate meeting a requirement under the FD&C Act or implementing regulations. Reasons for recognition are many and varied. For example, the standard may satisfy requirements regarding performance specifications, labeling, informed consent, or post market activity. A standard may be relevant for a specific device, group of like devices, or a broad range of devices and medical products. A standard may also satisfy requirements related to Quality Systems Regulations, risk management, or Good Laboratory Practices, as examples.

FDA will provide its rationale for recognition of the standard in the SIS, including the scientific, technical, regulatory, or other basis, as applicable. For the regulatory basis, FDA intends to provide supporting information illustrating the standard's regulatory applicability. For example, how the standard(s) is/are relevant to FDA regulatory processes, guidance and/or supportive publications.

VI. Withdrawal of Recognition

FDA may withdraw recognition of a previously recognized standard if the Agency determines that the standard is no longer appropriate to support a DOC for meeting a requirement regarding devices under the FD&C Act (see section 514(c)(2)). The two primary situations where FDA may make this determination are described below.

A. FDA-Recognized Consensus Standard Replaced by New Version

When an SDO issues a new version or revision that supersedes a standard recognized by FDA, FDA reviews the changes and decides whether to recognize the new version. If the new version is recognized, we will announce the change, i.e., recognition of the new version and (usually) withdrawal of the older version, in a notice published in the *Federal Register*. We will add the new version to the Recognized Consensus Standards database, and we will remove the older version from the database.

FDA may provide a transition period during which both the old and new versions of a standard are recognized. This means that, per 514(c)(1)(A), a DOC may be submitted for either FDA-recognized consensus standard (i.e., the new or the older version). Once we withdraw recognition of the old version, a DOC to the old version of the standard will no longer be acceptable for future submissions. The transition period, if any, will be included in the SIS. Note that a transition period is only applicable to standards whose recognition is being withdrawn.

When determining the timing of a transition period, FDA considers the public health impact of delaying implementation of significant scientific updates and the difficulty manufacturers may face while implementing the specific changes in the new version compared to the older version.

For example, a standard with only minor technical or editorial changes may have a shorter transition period than a standard with changes that may take longer to implement. When a change to the standard impacts an emergent public health issue, FDA may assign a shortened or no transition period to respond to the issue with appropriate timeliness. For additional discussion regarding transition periods, please see the FDA guidance document "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.[20]"

Standards may be revised after marketing authorization is granted. As discussed in section VIII. of the FDA guidance document "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," changes in a recognized consensus standard do not retroactively affect a product's clearance or approval status.

B. FDA-Recognized Consensus Standard "no longer appropriate for meeting a requirement"

FDA may withdraw recognition of a standard if it determines that the standard is "no longer appropriate for meeting a requirement regarding devices" (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. Use of non-recognized standards are discussed in the FDA guidance document "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

VII. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

The time required to complete this information collection is estimated to be 1 hour per request. Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff,
Office of Operations,
Food and Drug Administration,
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-xxxx (expires xx-xx-xxxx).

[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices