CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition; Final Guidance for Industry

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

Office of Science and Technology and
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Carol Herman at (301) 594-4766, Ext. 101, or by electronic mail at czh@cdrh.fda.gov.

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Purpose

The purpose of this document is to establish internal CDRH procedures for the identification and evaluation of consensus standards for recognition through publication of a notice in the Federal Register. This document may be amended in the future to include modified or additional procedures.

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/resolvingdisputes/ombudsman.html.

1. Introduction

The Food and Drug Administration Modernization Act (FDAMA) added section 514(c) to the Federal Food, Drug, and Cosmetic Act. This new paragraph states in part that FDA "shall, by publication in the *Federal Register*, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this Act to which a standard is applicable."

The new provisions of the Act do not prescribe any process for identifying candidate standards

for recognition. These Standard Operating Procedures (SOPs) describe the processes that are used by CDRH. The SOPs also describe a process for systematic integration of a recognized standard into the relevant CDRH program areas. The SOPs are intended to complement existing processes and procedures.

2. CDRH Standards Organization and Staff Responsibilities

A number of organizational components in CDRH share duties and responsibilities in the identification of candidate voluntary consensus standards for recognition and in ensuring their effective use in Center programs. These organizational components include:

2.1 Standards Task Group. Standards Task Groups (STGs) were originally created as a part of CDRH Reengineering activities to help manage the CDRH consensus standards program and are now being used in the recognition of standards under FDAMA. Each STG is comprised of at least one representative from the Offices of Device Evaluation, Science and Technology, Surveillance and Biometrics, and Compliance. (Membership on some STGs by staff from other Center offices or from other FDA components, e.g., CBER, may also be appropriate when those components bear regulatory responsibility for devices addressed by standards under the purview of the STG.) The STGs, under the general direction of the Standards Program Coordination Staff in OST, are responsible for coordinating all CDRH consensus standards activities within their assigned technical area. This responsibility includes interacting with the standards development organizations related to their assigned device area and communicating the status of standards activities to their respective office managers. The STGs are also responsible for:

- Identifying existing and needed standards within their technical area and for prioritizing current and potential standards development activities in terms of their utility to CDRH programs using common criteria;
- Coordinating the assessment of whether a standard can be used to meet a particular premarket or other statutory requirement; and
- Recommending to Center management recognition of a standard through publication in the Federal Register. Attachment 1 is a list of the current STGs. The STGs report to the Director, Standards Program Coordination Staff.

2.2 Project Team. A Project Team may be established by an STG. The Project Team is an ad hoc group of FDA staff, which has knowledge, experience, training, or skills related to the scope of a particular consensus standard. The Project Team is responsible for:

- Conducting the assessment of a standard;
- Championing the initiation and development or revision of a standard;
- Assessing the need for laboratory development of test methods; and
- Other standards-related duties as assigned by the STG.

In some cases, the STG may identify only a lead individual in CDRH who may, in turn, assemble other staff who volunteer to contribute their knowledge, experience, training, and skills to the

task assigned by the STG. The Project Team will normally include the CDRH liaison representative to the standards committee responsible for the specific standard being assessed, if one exists. The Project Team reports to the STG.

2.3 Standards Program Coordination Staff (SPCS). This group is a component of the Office of Science and Technology and consists of the Director and supporting staff. Attachment 2 lists the persons currently in the SPCS. They are responsible, among other things, for helping to coordinate STG and Project Team meetings, providing resource material requested by the STG or Project Team, compiling and creating cross-cutting information for use by STGs and Project Teams, reporting to Center management, and for creating and tracking standards recognition packages and standards publications. The Director, SPCS, reports to the Director, Office of Science and Technology.

2.4 CDRH Branches. The scope of recognized consensus standards varies. Standards may address design, manufacturing, professional practice, nomenclature, testing, performance, etc. Therefore, a recognized standard could impact more than one program or device area in the Center. Staff in each affected branch in the Center should determine the impact of a recognized standard on their work prior to the publication of the recognition in the Federal Register, and should take needed action to prepare for receipt of declarations of conformity to the standard. Actions taken by the branch may include training staff, clarifying existing guidance documents to be consistent with the recognized standard, or supplementing existing guidance to facilitate the effective and efficient use of the recognized standard.

2.5 CDRH Managers and Supervisors. Managers and supervisors in CDRH are responsible for supporting and encouraging individuals assigned to the STGs and Project Teams so that the process of identifying candidate standards for recognition may proceed as expeditiously as possible. STG and Project Team members must coordinate their standards activities with first line supervisors to ensure that other priority work will not be adversely affected. First and second line supervisors should assign a priority to the standards recognition activities commensurate with other high priority assignments, e.g., guidance development, premarket applications, or inspection reports.

Managers and supervisors should consult with their Office's STG members to assure that the standards recognition priorities established by the relevant STGs adequately reflect program needs.

2.6 Office of Science and Technology. The Director, Office of Science and Technology will coordinate with the other affected Center Offices the development, implementation, and monitoring of the policies and procedures on or regarding the use of standards in the Center.

2.7 Program Operations Staff. The Program Operations Staff or its equivalent in each Office is responsible for helping to ensure the orderly integration of recognized standards into current office practices and to develop methods to track the impact of recognizing standards on their programs.

3. The CDRH Process for Identifying Candidate Standards for Recognition

3.1 STG assessment. The STG will coordinate the assessment of consensus standards and

recommend candidate standards for recognition to the Director, SPCS. As part of the assessment activity, the STG may assemble information on relevant existing consensus standards and periodically identify new or revised standards to be assessed. The SPCS, and other Center personnel as needed, will assist in the information gathering.

3.2 Project Team responsibility. The STG may designate a Project Team when a standard requires particular expertise that is not available within the STG. The Project Team documents its assessment, including the rationale for its recommendations. The project team recommends either (1) recognition of the standard in whole, (2) recognition of the standard in part, identifying the specific parts of the standard that are appropriate, (3) deferral of the standard for future assessment, or (4) non-recognition of the standard in whole. If the Project Team recommends all or part of a standard for recognition, it must identify examples of devices to which the standard would ordinarily apply. The Project Team will also identify whether there are any applicable guidances and any areas of agreement or disagreement between the standard and such guidances.

3.3 STG review. The Project Team provides its recommendation to the STG, which coordinates all recommendations from Project Teams under its purview. The STG evaluates recommendations to ensure that they are comprehensive and consistent with the assigned task. The STG may send the recommendation back to the Project Team for reevaluation. If the STG endorses the project team recommendation, it forwards the recommendation to the SPCS along with draft supplementary information sheets for each recommended standard.

3.4 CDRH Review. The SPCS compiles recommendations for recognized standards from the various STGs and coordinates the review of candidate standards by each affected Office. The evaluation of proposed recognized standards will proceed as determined by the Director, Office of Science and Technology, but, generally, the list of standards proposed for recognition by the STGs will be circulated along with the supplementary information sheets to CDRH management for review and comment.

3.5 Federal Register Notice. Once the review is complete, the SPCS will modify the list and supplementary information sheets, if necessary, and prepare a Federal Register notice announcing and providing a list of:

- all newly recognized standards;
- any modification to the recognition of a recognized standard; and
- any previously recognized standards that will no longer be recognized.

At least annually, the SPCS will create and process for clearance such a Federal Register notice, however, standards that are high priority for recognition may be recognized individually at any time.

3.6 Clearance. SPCS will circulate the Federal Register notice for clearance by the affected CDRH offices. The SPCS will also coordinate placement of the revised list of recognized standards and the supplementary information sheets on the CDRH web site with the publication of the notice in the Federal Register.

3.7 Dissemination to staff. The SPCS will notify each affected Center component when changes

are made to the list of recognized standards. The CDRH branches implementing the recognition of standards must prepare for the receipt of declarations of conformity to the standards as noted in Section 2 above. Branch staff should be familiar with the resources available to help them in this task. The list of standards and guidance on their use in product review is maintained on the CDRH Internet website. In addition, supplementary information sheets providing useful information on the recognized standards are accessible from the list of standards on the CDRH Internet web site. A document containing frequently asked questions (and answers) is also maintained there and updated as necessary. Copies of the recognized standards are available to state through the Standards Database on the CenterNet.

4. Proposals for Recognition of Standards by Outside Persons

4.1 Requested information. As noted in the Federal Register notice of February 25, 1998, (63 FR 9561) which announced the standards recognition program and associated guidance, outside groups may propose standards for recognition by the agency simply by submitting the following information:

1. Title of the standard;
2. Any reference number and date;
3. Name and address of the nationally or internationally recognized standards development organization;
4. A proposed list of device types for which a declaration of conformity should routinely apply; and
5. A brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity. Such recommendations will be sent to the Director, SPCS, for processing.

4.2 Deadlines for proposals. The Director, SPCS, will establish a date for submission by outside bodies of recommendations for recognition such that recommendations received prior to that date can be reviewed and assessed for recognition prior to the next anticipated publication of changes to the list of recognized standards in the Federal Register. He/she will publicize this date using the internet or any other reasonable means so that the public will be aware of the deadline. Recommendations received after that date will also be reviewed, but the work may not be completed until the subsequent Federal Register publication.

4.3 STG review. The Director, SPCS, will transmit any outside recommendations for recognition to the appropriate STG(s) for assessment, along with a reasonable timeframe for the STG response. The report of the assessment of the STG will be referred back to the Director, SPCS. If the STG endorses the outside recommendation for recognition, they will also include in their report to the Director, SPCS, one or more completed supplementary information sheets for the standard proposed for recognition. If the STG does not endorse or does not fully endorse the outside recommendation for recognition, it shall document its rationale for this.

4.4 CDRH review and approval. The Director, SPCS, will then circulate the standards recommended for recognition by outside groups to CDRH management for review and approval

along with any internally generated recommendations for recognition.

5. Process Flow Diagram for Identifying Candidate Standards for Recognition

A flow diagram of the CDRH process for identifying voluntary consensus standards that may be candidates for recognition is provided in Attachment 3.

6. Attachments

Attachment 1: Standards Task Groups
Attachment 2: Office of Science and Technology, Standards Program Coordination Branch
Attachment 3: CDRH Recognition Process Flow Chart