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

Guidance for Industry and FDA Staff

CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition

Document issued on: September 17, 2007

This document supersedes CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition; Final Guidance for Industry, June 20, 2001

For questions regarding this document contact Carol Herman 240-276-0556.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Standards Management Staff
Office of Science and Engineering Laboratories

Preface

Public Comment

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

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/osel/guidance/616.pdf . You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 616 to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff

CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

The purpose of this document is to establish internal Center for Devices and Radiological Health (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 Food and Drug Administration Modernization Act (FDAMA) added section 514(c) to the Federal Food, Drug, and Cosmetic Act. This new provision 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.

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

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

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 those outlined in the following subsections.

2.1 Standards Task Group

Each Standards Task Group (STG) is typically comprised of at least one representative from the Offices of Device Evaluation, Science and Engineering Laboratories (OSEL), Surveillance and Biometrics, Communication, Education and Radiation Programs (OCER)and Compliance. (Membership on some STGs by staff from other Center offices or from other FDA components, e.g., Center for Biologics Evaluation and Research (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 Standards Management Staff (SMS) in OSEL, are responsible for coordinating all CDRH consensus standards activities within their assigned technical area. This responsibility includes interacting with the independent Standards Development Organizations (SDO) related to their assigned device area and communicating the status of

standards activities to their respective office managers. The STGs are also responsible for the following:

- identifying existing and needed standards within their technical area and 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
- recommending to Center management recognition of a standard through publication in the *Federal Register*. You can access a current list of STGs at http://www.fda.gov/cdrh/stdsprog.html The STGs report to the Standards Management Staff Director.

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 the following:

- 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
- completing 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 include the CDRH liaison representative to the standards committee of the SDO responsible for the specific standard being assessed, if one exists. The Project Team reports to the STG.

2.3 Standards Management Staff (SMS)

This group is a component of OSEL and consists of the Director and supporting staff. You will find a list of SMS members at **http://www.fda.gov/cdrh/standards/staff.html**. Among other things, they are responsible for the following:

- coordinating 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

- creating and tracking standards recognition packages and standards publications. The SMS Director reports to the OSEL Director.

2.4 CDRH Offices

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 office 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 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 will 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., premarket applications, inspection reports or guidance development.

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 Engineering Laboratories

The SMS Director and/or the OSEL Director 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 SMS Director. 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 SMS, 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 STG or Project Team documents its assessment, including the rationale for its recommendations. The project team recommends one of the following:

- recognition of the whole standard
- recognition of the standard in part, identifying the specific parts of the standard that are appropriate
- deferral of the standard for future assessment
- non-recognition of the whole standard.

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 STG or 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

When a Project Team is used, 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. If the STG endorses the project team recommendation, it forwards the recommendation to the SMS along with draft supplementary information sheets for each recommended standard. Supplementary Information Sheets (SIS) for each recognized standard are data sheets that specify the address(es) where the standard can be obtained, the extent of recognition of the standard, a list of devices or device categories affected by the recognition, and other information pertinent to the use of this standard by industry and in the premarket review and postmarket processes.

3.4 CDRH Review

The SMS compiles recommendations for recognized standards from the various STGs and coordinates the review of candidate standards by each affected Office. Typically, 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, SMS will modify the list and the supplementary information sheets, if necessary, and prepare a *Federal Register* notice announcing and listing the following:

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

At least annually, SMS will create and process for clearance such a *Federal Register* notice. However, CDRH may recognize, at any time, individual standards that are high priority for recognition.

3.6 Clearance

The SMS will coordinate with the CDRH Regulations Staff the clearance of the *Federal Register* notice. The SMS 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 SMS will notify each affected Center component when changes are made to the list of recognized standards. The CDRH branches implementing the recognition of standards will 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. CDRH maintains the list of standards and guidance on their use in product review 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 staff through the Standards Database on the CenterNet.

4. Proposals by Outside Persons for FDA Recognition of Standards

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 FDA simply by submitting the following information:

- the title of the standard

- any reference number and date
- the name and address of the nationally or internationally recognized standards development organization
- a proposed list of device types 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. Such recommendations will be sent to the SMS Director for processing.

4.2 Deadlines for Proposals

Outside bodies may submit recommendations for recognition by CDRH at any time. Recommendations will be reviewed and considered for publication in the next *Federal Register* publication.

4.3 STG Review

The SMS Director 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 SMS Director. If the STG endorses the outside recommendation for recognition, they will also include in their report to the SMS Director 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 will document its rationale for this.

4.4 CDRH Clearance

CDRH should include the STG endorsed proposal in the next *Federal Register* publication. It follows the same clearance process outlined in subsection 3.6 of this guidance. The SMS Director 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.

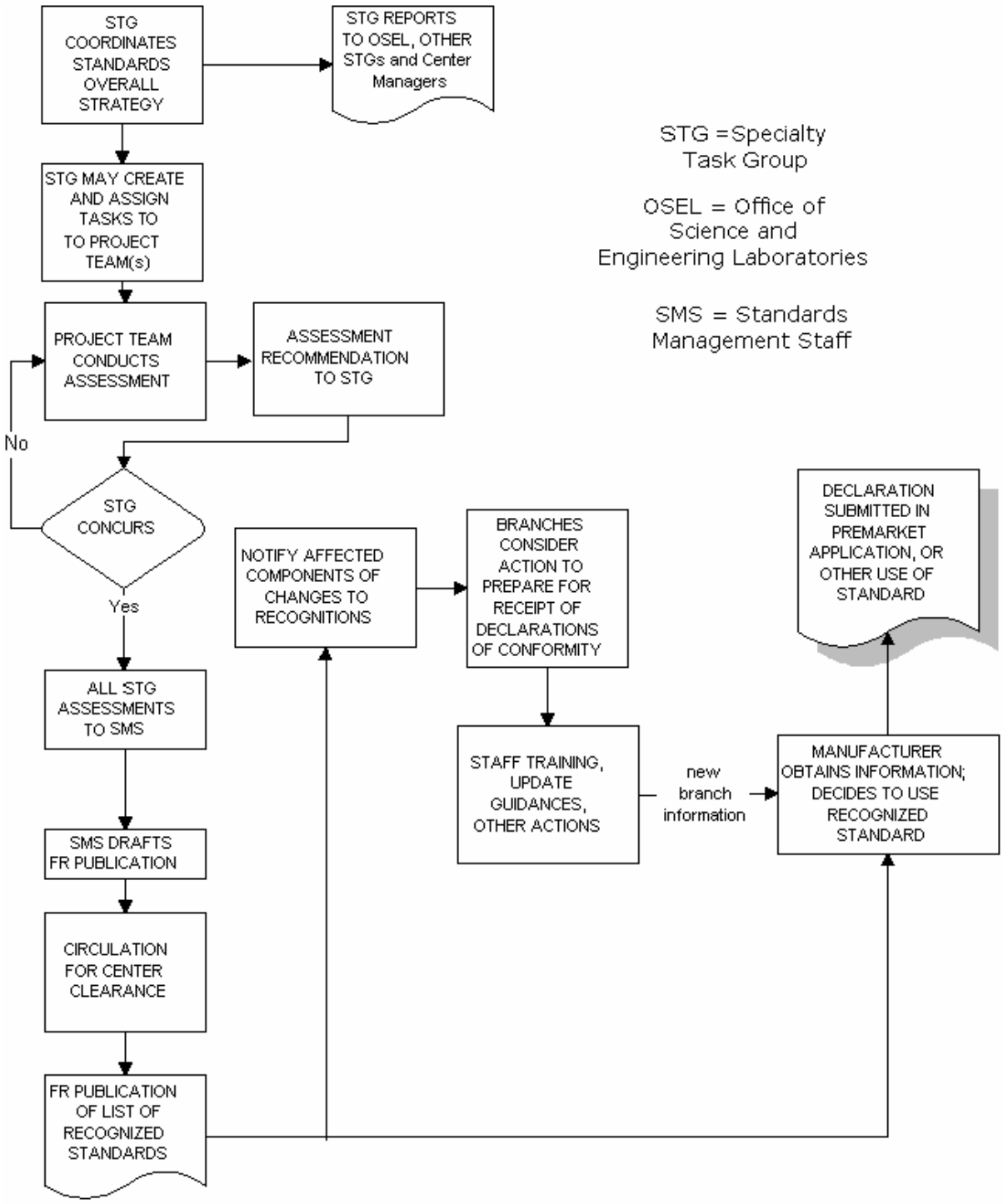
5. Attachment

Attachment 1: CDRH Recognition Process Flow Chart

A flow diagram of the CDRH process for identifying voluntary consensus standards that may be candidates for recognition.

Attachment 1:

CDRH Recognition Process Flow Chart


STG COORDINATES STANDARDS OVERALL STRATEGY
STG REPORTS TO OSEL, OTHER STGs and Center Managers
STG =Specialty Task Group
OSEL = Office of Science and Engineering Laboratories
SMS = Standards Management Staff
STG MAY CREATE AND ASSIGN TASKS TO TO PROJECT TEAM(s)
PROJECT TEAM CONDUCTS ASSESSMENT
ASSESSMENT RECOMMENDATION TO STG
No
STG CONCURS
Yes
ALL STG ASSESSMENTS TO SMS
SMS DRAFTS FR PUBLICATION
CIRCULATION FOR CENTER CLEARANCE
FR PUBLICATION OF LIST OF RECOGNIZED STANDARDS
NOTIFY AFFECTED COMPONENTS OF CHANGES TO RECOGNITIONS
BRANCHES CONSIDER ACTION TO PREPARE FOR RECEIPT OF DECLARATIONS OF CONFORMITY
STAFF TRAINING, UPDATE GUIDANCES, OTHER ACTIONS
new branch information
MANUFACTURER OBTAINS INFORMATION; DECIDES TO USE RECOGNIZED STANDARD
DECLARATION SUBMITTED IN PREMARKET APPLICATION, OR OTHER USE OF STANDARD