

CDRH Standards Recognition Process

with Scott Colburn

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Hello, I am Scott Colburn, the Director of the Standards Management Staff in the Center for Devices and Radiological Health or CDRH. In this CDRH Learn Module, I will discuss how CDRH evaluates candidate standards for recognition and how you may request recognition of a standard.

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Let's review the learning objectives of this module. You'll understand how CDRH assesses and recognizes standards. You'll be able to identify the different types of recognition and find Federal Register notices that list the recognized standards. You'll understand how the different standards organizations maintain standards, and you'll learn how to request the recognition of a standard.

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To begin this module, I would like to state our mission. The CDRH Standards Program was established as a result of the Food and Drug Administration Modernization Act (FDAMA) of 1997. The program contributes to the Center's mission of protecting and promoting public health through the development and recognition of voluntary consensus standards that serve to establish safe and effective medical devices, radiation-emitting products and emerging technologies.

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Our vision is that CDRH stakeholders have access to high-quality, safe, and effective medical devices of public health importance first in the world through timely development and recognition of voluntary consensus standards. The CDRH Standards Program is the world's leader in standards implementation and utilization for medical device innovation and manufacturing, and radiation-emitting product safety. Medical Device manufacturers, consumers, patients, and providers have access to voluntary consensus standards for medical devices and use this information to protect and promote the public health.

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The Standards Management Staff, or SMS, is located within the Office of the Center Director in CDRH and has a number of functions and responsibilities.

We guide the standards recognition process, set priorities for standards participation, manage standards travel and travel budget priorities, oversee the Center consensus process with regards to review of committee drafts and ballots, administer and maintain FDA liaison representatives to Standards Development Organizations, or SDOs, and committees and working groups. We maintain membership to SDOs, maintain agreements for access to published standards, and manage Federal Register publications.

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CDRH manages the standards consensus process through the establishment of specialty task groups. This slide lists the CDRH specialty task groups. The specialties are very similar to the CDRH Advisory Committees or panels; however, they also include cross-cutting specialties such as biocompatibility, quality systems, risk management, electrical safety, materials, software and informatics, and sterility to name a few.

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Each Specialty Task Group or STG is comprised of at least one representative from the different Offices within CDRH. In addition, STGs may include staff from other FDA organizations where appropriate, such as the Center for Biologics Evaluation and Research, or CBER, if these other organizations bear regulatory responsibility for devices addressed by standards under the purview of the STG. The STGs, under the general direction of the SMS, are responsible for coordinating all CDRH consensus standards activities within their assigned technical area. This responsibility includes interacting with the independent Standards Development Organizations, or SDOs, related to their assigned device area and communicating the status of standards activities to their respective office managers.

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The STG has a number of duties. The STG identifies existing and needed standards within its technical area and prioritizes current and potential standards development activities using an objective criteria that evaluates its utility to CDRH programs. The STGs coordinates the assessment of whether a standard can be used to meet a particular premarket or other statutory requirement.

It recommends the recognition of standards through publication in the Federal Register. The STG recommends liaisons, alternates, and technical experts and develops the Supplemental Information Sheet, or SIS, for a recognized standard. You can access a current list of STGs at the CDRH Standards Program page. The STGs report to the Standards Management Staff Director.

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CDRH recognizes standards. The term "recognize" or "recognition" is defined in Section 514(c) of the Food, Drug, and Cosmetic Act, and refers to FDA's identification of standards as appropriate for manufacturers of medical devices to declare conformance or to use the standard in a submission or other aspect to satisfy a requirement.

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The SMS is responsible for coordinating the Center's efforts to recognize standards. It does this by collecting information on newly published standards, searching the internet and standards developer's publications, and compiling this into a list of candidate standards for recognition.

The SMS looks specifically for title changes, newly published amendments and corrigenda, and new editions of standards that have been published. In addition, the

SMS searches for standards that are no longer in publication that would be candidates for withdrawal.

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After the SMS completes the tasks described in the prior slide, the list of candidate standards is moved to the STG. If a standard requires a particular expertise that is not available within the STG, then a Project Team is formed.

The STG or Project will then recommend one of the following decisions:

1. recognition of the complete standard,
2. recognition of the standard in part, identifying the specific parts of the standard that are not appropriate; or
3. non-recognition of the complete standard. The standard may also be deferred for future assessment.

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.

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After the STG has made a decision, the SMS will compile this information into a Federal Register notice and announce the list of recognitions as outlined in Section 514 (c) of the regulations on standards. This is done twice a year. The Federal Register announcement is directly in effect for immediate availability for industry, stakeholders, and regulators to use in their submissions or processes.

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The SMS places links to each published Federal Register on the FDA website as noted on this screenshot. The link to this website is also included on this slide.

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The SMS updates the FDA Recognized Standards Database that is available on the FDA website. This slide shows a screenshot of the standards database search wizard as well as the link to the website. For every recognized standard, we also generate the Supplemental Information Sheet that describes the Agency's thinking on each standard. You can get more information about this process by viewing the companion CDRH Learn module titled Standards Resources and Premarket Use.

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Standards are maintained by the standards developing organization on a fairly predictable schedule. Typically, a newly published standard will come up for renewal or revision 3 years after its first publication. After that, standards are reviewed for either

revision or reaffirmation, which is renewal without any changes, every 5 years. Within the US, each ANSI accredited standards developing organization has written policies and procedures for how often they maintain the standards they produce.

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As noted on this slide, the Center has a guidance and process for requests for recognition.

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Any stakeholder may propose a standard be recognized. To make a request, one should include this information: the title of the standard, any reference number and date for that standard, the name and address of the SDO, a proposed list of devices or device types, and a brief discussion of the testing or performance or other characteristics that would be addressed by the standard.

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If you are interested in submitting a request, follow the link to this slide for the contact information to reach us.

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This slide gives a visual of the process or pathway of the steps that the Center takes when considering a candidate standard for recognition. I'll touch upon some of the key milestones in the process. When a request is received, the SMS Director will transmit any outside recommendations for recognition to the appropriate STGs 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.

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Let's review what we discussed in this module. First, we learned how CDRH assesses and recognizes standards. We identified the different types of standards. We learned where FDA posts the Federal Register notices of lists of recognized standards. We learned how different standards organizations maintain standards. And we learned how to request the recognition of a standard. Thank you.

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