CDRH Learn: Standards Overview
with Colleen Lee

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Hi, I am Colleen Lee, a senior standards advisor in the standards management staff in the Center for Devices and Radiological Health or CDRH. In this CDRH Learn module I will discuss how standards became integral to the mission of CDRH and how they are used.
Standards give the agency flexibility and discretion to use standards other than those that we develop ourselves. This frees the Agency to pursue other priorities. Standards also build in a culture of collaboration that fosters consensus, consistency and predictability. At the FDA, standards have become integrated as part of the execution of the agency's mission.

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At the end of this module you will understand what is a standard, what it is not and what is a voluntary consensus standard. I will provide you an overview of the key pieces of legislation that form the basis of the U.S. national standards strategy. I will discuss the evolution of standards used by the FDA as well as explain the different types of standards. Lastly, you will learn how standards are used in CDRH on a daily basis.

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The word standard calls to mind many definitions, but this module will focus on how FDA views standards in light of our regulatory authority. Specifically, the term standard or technical standard is found in the Food Drug & Cosmetic Act or FD&C Act. This definition includes common and repeated use of rules, conditions, guidelines or characteristics. Standards are used for products, production methods and related management systems practices.

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Standards include many aspects such as a definition, a classification system, a series of procedures, a specification for size or dimension, a material, a performance feature, a design or how something operates. Standards can describe a process, a system, a service, a practice, or a specific product. Standards may be written to outline a specific test method, a sampling plan, or a way to measure size or strength.

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Throughout this module, we'll refer to "voluntary consensus standards" which is a standard developed or adopted by voluntary consensus standards bodies, both domestic and international. Key attributes to the development of standards are due process, balance of interests, openness of committee proceedings, an appeals process and consensus.

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In 1995, Congress passed the National Technology Transfer and Advancement Act, or NTTAA. This Act was signed into law in 1996 and grew out of the Department of Defense experience with regards to military specifications.

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The Act specifically encouraged government agencies like the FDA to use standards developed by voluntary consensus bodies instead of creating proprietary, non-consensus standards. The Law also encouraged Agencies to participate and collaborate with interested parties in the standards development process.

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Here are the links to the NTTAA legislation and the National Institutes of Standards and Technology (NIST) websites. The first link discusses how the Act is interpreted and administered, and the second is a central location for standards activity in the U.S.

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A formal foundation to our work in standards is laid out in the government document OMB Circular A-119.

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OMB stands for the Office of Management and Budget which is housed in the Executive Branch of the White House. In February of 1998, OMB published Circular A-119 which established policies for Federal agencies to follow in the development of voluntary consensus standards. It provided the original framework on conformity assessment activities, and provided definitions of commonly used terms such as "standards", and "voluntary consensus standards."

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The circular set forth requirements for Agency participation on standards committees and working groups, which includes a reporting requirement to Congress on an annual basis. The circular also sets forth requirements for incorporation of standards into Agency regulations. When standards are used at FDA, their use is voluntary. The only exception is when a standard is incorporated by reference into a regulation. When that occurs, and this is very rare, the standard becomes mandatory.

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The goals in the circular include the elimination or reduction of government costs that would be incurred if Agencies were to write their own standards. This provides an incentive for Agencies to write standards that serve the national interests, to encourage long-term economic growth for the US, and to promote competition in the marketplace.

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As mentioned earlier, the NTTAA directs Federal agencies to adopt or recognize standards that were created in the private sector instead of creating government-unique standards. NIST coordinates the Federal, State, and local governments' reliance on voluntary standards and decrease dependency on internally-developed standards.

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Here are links to OMB Circular A 119 and to the NIST websites. These sites give further background on the implementation the US National Standards Strategy.

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How FDA approaches the use of standards is outlined in three key documents listed here - the Code of Federal Regulations or CFR, FDA Policy documents, and the FDA Staff Manual Guide. FDA published its position with regards to standards work and international harmonization for the first time in the Federal Register on October 11, 1995.

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In this first FR Notice, FDA included a number of goals relating to standards work. The first goal is to ensure that consumer protection standards and requirements are met. The second goal is to facilitate the availability of safe and effective products to the market place. The third goal is to develop and use product standards.

The final goal is to minimize or eliminate inconsistent international standards as standards developers work toward harmonization - where participating countries agree on the key components in the standard and adopt them in their home countries. For us here in the US, it is termed the US adoption of an international standard.

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The third of these documents, the Staff Manual Guide, outlines policies and procedures to assure a unified approach to standards within the FDA. It details employees' responsibilities as participants in standards development nationally and internationally. It also describes the establishment of an agency-wide Standards Management Program.

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FDA will preferentially use international, harmonized standards. Also, whenever FDA releases draft or final guidance documents, FDA may cite standards where needed. In turn, submitters of medical device applications may cite standards in their submissions. Finally, the staff manual guide states that FDA can incorporate consensus standards within its processes or regulation when appropriate.

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Here are the links to the FR Notice on International Harmonization of Standards and FDA Staff Manual Guide 9100.1 outlining what we have just discussed.

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Thus far, we defined a standard, a voluntary consensus standard and shared an overview of the legislation that formed the US Standards Strategy. After our brief review of the evolution of standards-setting activity at the FDA, we can begin our discussion of how standards are used at FDA through the passage of various laws.

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Let's first talk about the FDA Modernization Act of 1997. This Act significantly changed Section 514(c) of the Food Drug and Cosmetic Act in that it allowed for the formal recognition of a standard and added a procedure for accepting a declaration of conformity. These were major revisions and we will define recognition of a standard first.

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The term "recognize" or "recognition" refers to FDA's identification of standards as appropriate to use in a medical device submission to satisfy a requirement. When FDA recognizes a new standard or a new version of an existing standard, the notice is made available through publication in the Federal Register and through the FDA Recognized Consensus Standards Database on the FDA website.

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In December 2016, Congress passed the 21st Century Cures Act, which among other milestones, modified section 514(c) of the FD&C Act. The Cures Act added a timeframe for FDA action on a request for recognition of an appropriate standard. The Law also required FDA to state the basis for its decision.

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The Act required all FDA employees who review premarket submissions to receive training on standards, and for FDA to develop a guidance document about the standards recognition process. These requirements enhance the current processes as well as increase transparency on FDA's decision to recognize standards.

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Section 514(c) states that we will "by publication in the Federal Register, recognize all or part of an appropriate standard that has been established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity."

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Further, if a person elects to use a standard, that person shall provide a declaration of conformity to the standard. Along with the declaration, a person may use data, or information other than data, to meet the requirement. This allows the submitter and FDA to assess the extent of conformity with the standard.

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FDA will confirm receipt of a recognition request by issuing an acknowledgement letter to the person or entity who made the request. Once a decision has been reached, FDA will send a written response to the requestor that includes the basis of the decision. The basis will generally be scientific, technical, or regulatory in nature.

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As mentioned earlier, standards recognitions are publically available via the Federal Register and the Recognized Consensus Standards database. As a result of the 21st Century Cures Act, FDA will make any non-recognition decisions available through the Federal Register in the same manner, except that non-recognitions will be posted to their own web page.
FDA may withdraw recognition of out-of-date or older standards that are no longer published, or standards that no longer meet a requirement.

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Earlier, we discussed the FDA Modernization Act of 1997 which allowed for the formal recognition of a standard and instituted a procedure for accepting a declaration of conformity. A Declaration of Conformity to an FDA-recognized consensus standard is used when a submitter of a medical device application states that its device conforms to all of the requirements of that standard without deviation. The purpose is to certify - so to speak - that the device met certain premarket requirements and thereby reduces the amount of supporting data and information that is submitted to FDA.

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FDA will accept a declaration of conformity to a standard after it is recognized. This recognition occurs when FDA publishes a notice in the Federal Register. FDA will accept a declaration of conformity unless the data or information don't demonstrate that the device conforms with the standard; or if the identified standard is not applicable.

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Thus far, we've defined standards, we've outlined the US standards strategy, and we've described the standards-related laws including the 21st Century Cures Act. We're now ready to discuss how standards are used at CDRH on a day-to-day basis.

The use of consensus standards can increase predictability, streamline premarket review, provide clearer regulatory expectations, and facilitate market entry for safe and effective medical products. Consensus standards provide a group approach to certain aspects of device evaluation, such as testing methods, pass or fail performance criteria, and processes to address risk management and usability. For decades, CDRH has supported and relied on the development and use of consensus standards to support the Agency's mission in protecting and promoting the public health.

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There are many types of standards such as vertical and horizontal standards, test methods and material specifications, and national and international standards. Over the next few slides, let me describe these in detail.

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Vertical standards apply to a specific device or device grouping. These standards typically call out specific test methods or performance aspects of a specific grouping of devices. CDRH has recognized several hundred vertical standards. An example of a vertical standard specific to electrocardiographs or EKGs is listed here on the slide.

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In contrast to vertical standards, Horizontal standards may be applied across a wide range of devices and device types. There is built in flexibility that may apply when a condition is not covered by a vertical standard. These types of standards include biocompatibility, sterilization, materials, software and informatics. CDRH has recognized several hundred horizontal standards. An example of a horizontal standard addressing sterilization for medical devices is listed on the slide.

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Standards may be written as a test method with a specific procedure that produces a test result. This result may then be used to assess compliance with a standard specification. CDRH has recognized approximately 100 test methods. An example of a test method specific to determining susceptibility to antimicrobials is listed on the side.

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Material specifications are a set of requirements that may be physical, mechanical or chemical in nature. The specification may be achieved by a design feature, a system, or a service. An example of a test method for burst strength of a surgical sealant is listed on the slide.

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A U.S. national standard can be identified in several ways. It may be published by ANSI with "ANS" or "ANSI" in the title of the standard. ANS stands for the American National Standard, and ANSI is the American National Standards Institute. In addition, a US standards developing organization, or SDO, may also publish a national standard. ANSI accredits SDO's using the ANSI Essential Requirements. In this case, the national standard is identified as ANSI along with the SDO as shown in this example.

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International standards are standards developed by international standards organizations. International standards are available for consideration and use worldwide.

The most common organizations are the International Organization for Standardization (ISO) and the IEC, or International Electrotechnical Commission. Others include ASTM International, IEEE and UL, or Underwriters Laboratories among several others.

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ANSI has procedures for an American standards developer that wishes to adopt an ISO or IEC standard, and this adoption can take the form of an identical national adoption or a modified adoption of the standard.

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Other types of standards products include standard practices, guides, or other practice guidelines. These products typically do not include normative requirements or referenced sections in a standard. Instead they include a set or collection of information or options that may not necessarily recommend a specific course of action as would a standard. A short description of each of these standards products is included here.

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Standards may be used in a variety of processes as described on this slide. Most Standards typically do not satisfy all the required elements of a premarket submission. It's important to understand that FDA recognition of a standard does not supersede other aspects of the FD&C Act and the regulations for marketing or investigating medical devices in the U.S.

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Consensus standards are used in a variety of premarket submission types to facilitate their review. These include 510(k), De Novo, premarket approvals, humanitarian device exemptions, investigational device exemptions, and pre-submissions. Also, standards may be used in applicable submissions regulated by the Center for Biologics Evaluation and Research. Submitters may choose to conform to applicable consensus standards or address issues relevant to approval or clearance in another manner.

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Let's recap what we reviewed in this module.
First, we learned the definition of a standard and its different types. We reviewed the key pieces of legislation that formed the basis of the U.S. National Standards Strategy. We discussed the evolution of standards and how standards are used by FDA and specifically CDRH on a daily basis.

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Thank you for your attention to this CDRH Learn Module on the Overview of the Standards Program. We encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Thanks for watching this program and we'll see you next time.

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