FDA Update

AAMI Sterilization Standards Week
Spring 2017

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Standards Recognition Highlights

- 6 FR Notice Publications FY 2016
- N=1209 Currently Recognized Standards
- N=137 Recognized Sterility Standards
- FR Notice List #42 – Symbols
- FR Notice List #44 – Biocompatibility
  - Changes to Extent of Recognition: Complete Recognitions
  - New Recognitions for ISO 10993 Parts 4, 17, 18, 20 and TIR Part 33
FY2016 FR Notice List#s 41-46

![Bar chart showing the numbers of Revised/Reaffirmed Standards, New Standards, and Withdrawn Standards for each list from 41 to 46.](image)
Sterilization Standards FY 2016
Revisions, Reaffirmations, Withdrawals, New Recognitions

• Extent of Recognition Changes List #041:
  – Clauses that call out ISO 13485 no longer excluded
• Sterility standards FY2016: 56
• USP <151> Rabbit Test - transferred to Biocompatibility STG

Find Our FRNs at:
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm
The Symbols Rule...

Symbols established in a standard developed by a standards development organization (SDO) may be used in medical device labeling without adjacent explanatory text.

Find the Symbols Webinar & Rule at: https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm510120.htm
Use of Symbols in Labeling – Recognition List # 042

- **ISO & ANSI/AAMI/ISO 27185** Symbols to be used with cardiac rhythm management device labels
- **ISO & ANSI/AAMI/ISO 15223-1** Medical devices—Symbols to be used with medical devices labels - General requirements
- **ASTM F2503-13** Standard Practice For Marking Medical Devices And Other Items For Safety In The Magnetic Resonance Environment
- **IEC 60417:2002 DB** Graphical symbols for use on equipment
- **ISO 7000: Fifth edition 2014/01/15** Graphical symbols for use on equipment - Registered symbols
- **IEC/TR 60878 Ed. 3.0 b:2015** Graphical symbols for electrical equipment in medical practice
Sterilization Guidances


Deciding When to Submit a 510(k) for a Change to an Existing Device, DRAFT

(Incorporates Submission and Review of Sterility Information in Premarket Notification [510(k)] Submissions for Devices Labeled Sterile)

Medical Device Ban

Banned Devices; Powdered Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon’s Glove

– Issued 12/19/2016
– Effective 01/18/2017

Find the Rule at:
MDUFA IV

Accreditation Scheme for Conformity Assessment (ASCA)
Medical Device User Fee Amendments

• Authorizes FDA to collect fees for review of medical device applications
• Current authority expires October 1, 2017
• MDUFA IV reauthorization 2018-2022
• MDUFA IV Performance Goals & Procedures

Find it: https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm454039.htm
Goals of ASCA Pilot Program

Improve medical device premarket review in areas where conformity assessment activities are met with inconsistent testing practices, conformance declarations and regulatory review by:

– Establishing a FDA-defined third party conformity assessment model to recognize accredited testing laboratories to selected recognized consensus standards and FDA guidance; and

– Using standardized test reports from accredited testing laboratories as evidence of conformity by manufacturers to foster improved review consistency and predictability.
ASCA Next Steps

• Conduct a public workshop by FY2018
• Hold educational sessions with stakeholders
• Develop and initiate a pilot
• Establish a process for accreditation
• Establish a publicly accessible website
• Identify recognized standards
• Compile a report by FY2022
**ASCA Conformity Assessment Model**

**List of FDA ‘Recognized’ Testing Labs**
- Maintains list of recognized test labs

**FDA CDRH Standards Program ASCA “Scheme Owner”**
- Defines, implements, and manages ASCA program
- Sets requirements, rules, and procedures
- Recognizes accredited testing labs & selects accreditation body per defined requirements

**Accreditation Body**
- To be selected by FDA
- Accredits

**Accredited Testing Laboratories**
- Perform testing against defined test criteria in recognized pilot standards

**Manufacturer**
- Contracts with FDA recognized testing lab to conduct product testing
- Enters into contract with FDA test lab
- Selects FDA test lab from list per testing needs

**Contracts with FDA recognized testing lab to conduct product testing**

**Manufacturer receives test report**

**FDA CDRH**
- ISO/IEC 17050 for standardized DOC

**FDA Device Decision**

- FDA CDRH Standards Program
  - ASCA “Scheme Owner”
  - Accreditation Body
  - Accredited Testing Laboratories

- FDA Device Decision
Standards Selection Criteria

(Draft: Not for Implementation)

1. High degree of confidence
   - High frequency of use across a wide variety of medical devices
   - Consistent and repeatable test method/procedures/criteria

2. Standards where testing is conducted by third party as a primary means to demonstrate conformity.
   - Can apply to several types of devices (horizontal): ES, EMC, Material Safety, Biocompatibility, Software, **Sterilization**, QS, UDI, HF/Usability, RM, etc....

3. Can apply to a [high] number of manufacturers in a device area (vertical)
   - Use the FDA’s Registration/Listing database.


Standards Selection Criteria – cont’d

(Draft: Not for Implementation)

4 Standards are performance based
   – Measurable (i.e. test method(s) defined) and have at least some pass/fail criteria or means to establish the criteria by (i.e. not a process standard).
     • Test Method should be easily reached if not already accounted into the standard.
       – Concept of a TMP (test method package)
         » # of docs (0-N) that can be complements to an existing standard to complete the standards methodology.
         » Notion of a TMP gives FDA the freedom to get back to the SDOs to improve standards.
   – If not fully quantified with endpoints, have added criteria (technical guidance).

5 Standards meeting the above criteria that required the most Additional Information (AI) on historical testing (high resource expenditure from CDRH)
   – When AI was asked, additional testing was required.
   – When AI asked, increased time for a regulatory decision.
21st Century Cures Overview

“Expedite the discovery, development, and delivery of new treatments and cures and maintain America’s global status as the leader in biomedical innovation.”

→ First proposed May, 2014 by Members of the House Energy and Commerce Committee

→ Legislative hearing April, 2015

→ Passed by the House, July, 2015

→ The Senate passed their version of the bill in 2016

→ FDA was given the opportunity to provide feedback throughout the process

→ Bill signed into law on December 13, 2016
21st Century Cures

Updates to Sec 514(c) of the FD&C Act focus on:

- Transparency of regulatory decisions related to standards recognition
- Improve the number of standards recognized form outside stakeholder requests
- Ensure training to all employees involved with premarket review
- Update guidance demonstrating principles for recognizing and withdrawing standards
- Moving outward focus on how Agency action supports harmonization among regulatory authorities in the regulation of devices.
Subtitle F – Medical Device Innovations

- Sec. 3053 Recognition of Standards 514(c) amendments
  - Recognition: Any person may request recognition
  - FDA shall make a determination to recognize, all, part or none
  - Not later than 60 days
  - FDA shall issue a response in writing including the basis for the determination
  - Basis shall be:
    - Scientific, technical, regulatory or other
  - FDA’s response shall be made public:
    - All or part, found in the FR Notice & Recognition Database
    - None, developing an online vehicle to house FDA responses to requestors.
  
**Stay Tuned!**
21st Century Cures

- Subtitle F – Medical Device Innovations
  - Sec. 3053 Recognition of Standards (cont’d)
    - All FDA employees who review premarket submissions for devices shall receive periodic training on standards
    - Training on premarket submission requirements
    - Training on other applicable requirements
    - Includes training on standards relevant to an employee’s area of review
    - Issue guidance

Find it:

(Check back with GPO/OFR for the official publication of the slip law P.L 114-255:2016)
21st Century Cures

Want to Recommend a Standard for Recognition?

» Name & email/mailing address
» Standard’s title
» Reference number/Date
» Proposed list of devices affected
» Basis for recognition
» Brief identification of the testing, performance, or other characteristic the standard addresses.

Submit Electronically:
www.CDRHStandardsStaff@fda.hhs.gov
Changes to Supplementary Information

(Draft: Not for Implementation)

• Additions
  – Scope
  – Rationale for Recognition, all or part
  – Transition (if requested or needed)

• Deletions
  – Devices affected
  – Processes affected

Find Supplementary Information for each standard at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

www.fda.gov
Stay Tuned...

• Database upgrades are ongoing
• Expect to see new SIS FY 2017 Fall list
FDA Liaisons/Appointments

• AAMI/ST/ WG 01, Industrial EO sterilization  
  – Steve Turtill, Primary  
  – Steve Elliott, Alternate

• AAMI/ST/ WG 02, Radiation sterilization  
  – Pat Weixel, Primary  
  – Dupeh Palmer, Alternate

• AAMI/ST/ WG 03, Industrial moist heat sterilization  
  – Ramesh Panguluri, Primary  
  – Daniel Fedorko, Alternate

• AAMI/ST/ WG 04, Biological indicators  
  – Cesar Perez, Primary  
  – Ramesh Panguluri, Alternate

• AAMI/ST/ WG 05, Sterilization Terminology  
  – Victoria Rodriguez, Primary  
  – Aprajita Garg, Alternate

• AAMI/ST/ WG 06, Chemical Indicators  
  – Clarence Murray, Primary  
  – Elizabeth Claverie-Williams, Alternate

• AAMI/ST/ WG 07, Packaging  
  – Steve Turtill, Primary  
  – Hung Lee, Alternate

• AAMI/ST/ WG 08, Microbiological Methods  
  – Elizabeth Gonzalez, Primary  
  – Angel Soler-Garcia, Alternate
FDA Liaisons/Appointments

- AAMI/ST/WG 09, Aseptic processing
  - Myra Smith, Primary
  - Elaine Mayhall, Alternate
- AAMI/ST/WG 10, Liquid Chemical Sterilization
  - Elaine Mayhall, Primary
  - Christopher Dugard, Alternate
- AAMI/ST/WG 11, General criteria for sterilization processes
  - Allison Rodriguez, Primary
  - Steve Turtil, Alternate
- AAMI/ST/WG 12, Instructions for reusable device reprocessing
  - Steve Turtil, Primary
  - Shani Haugen, Alternate
- AAMI/ST/WG 13, Washer-disinfectors
  - Elaine Mayhall, Primary
  - Steve Elliott, Alternate
- AAMI/ST/WG 15 (WG90), Assurance of Sterility
  - Myra Smith, Primary
  - Victoria Rodriguez, Alternate
- AAMI/ST/WG 40, Steam sterilization hospital practices
  - Clarence Murray, Primary
  - Ramesh Panguluri, Alternate
- AAMI/ST/WG 42, Dry heat sterilization
  - Elaine Mayhall, Primary
  - Cesar Perez, Alternate
FDA Liaisons/Appointments

- AAMI/ST/WG 43, Hospital steam sterilizer
  - Ramesh Panguluri, Primary
  - Myra Smith, Alternate
- AAMI/ST/WG 60, EO Sterilization hospital practices
  - Steve Turtil, Primary
- AAMI/ST/WG 61, Chemical sterilants hospital practices
  - Elaine Mayhall, Primary
  - Christopher Dugard, Alternate
- AAMI/ST/WG 62, Hospital EO sterilizer
  - Steve Turtil, Primary
- AAMI/ST/WG 63, Sterilization residuals
  - Anne Lucas, Primary
  - Ramesh Panguluri, Alternate
- AAMI/ST/WG 83, Reusable surgical textiles processing
  - Steve Elliott, Primary
  - Bifeng Qian, Alternate
- AAMI/ST/WG 84, Endoscope reprocessing WG
  - Shani Haugen, Primary
  - Elaine Mayhall, Alternate
- AAMI/ST/WG 85, Human factors for device reprocessing WG
  - Hanniebey Wiyor, Primary
  - Keith Marin, Alternate
FDA Liaisons/Appointments

- **AAMI/ST/WG 86, Quality systems for device reprocessing WG**
  - Cesar Perez, Primary
  - Peter Cheung, Alternate
- **AAMI/ST/WG 91, Resistometer**
  - Cristina Ortega, Primary
  - Elaine Mayhall, Alternate
- **AAMI/ST/WG 92, Process challenge devices**
  - Clarence Murray Primary
  - Ramesh Panguluri, Alternate
- **AAMI/ST/WG 93, Cleaning of reusable medical devices**
  - Steve Turtil, Primary
  - Sunny Park
- **AAMI/ST/WG 94, Rigid sterilization container systems**
  - Steve Elliott, Primary
  - Christopher Dugarg, Alternate
- **AAMI/ST/WG 95, Water quality for reprocessing medical devices**
  - Steve Turtil, Primary
  - Mary Wen, Alternate
- **AAMI/ST/WG 96, Compatibility of materials subject to sterilization**
  - Anne Lucas, Primary
  - Peter Cheung, Alternate
Visit our webpages & recognition database:

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm
Welcome to Baltimore’s Inner Harbor
Send requests, comments, suggestions, good vibrations to:

www.CDRHStandardsStaff