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Reprocessing Medical Devices in Health Care Settings: Validation Methods & Labeling FDA Final Guidance

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Background

- Final guidance – published March 2015
- Draft – published in 2011
 - 487 public comments
 - From various stakeholders including device manufacturers, testing laboratories, trade / professional organizations, users
 - Common theme: additional information / clarification
 - e.g., scope of the document, steps in the validation of cleaning, the six criteria for reprocessing instructions, resources for developing reprocessing instructions, device design considerations

Webinar Outline

2015 Final Guidance

- Purpose & scope
 - How it differs from the 1996 guidance
- Overview of reprocessing, reusable devices & recent trends
- Formulation of reprocessing instructions
 - Six criteria for reprocessing instructions
- Validation of cleaning process
- Summary – key messages

Purpose of this Guidance

Proper reprocessing of reusable medical devices is important to reduce the risk of patient infections during reuse

- Provides recommendations to medical device manufacturers for developing reprocessing instructions that can be easily understood and followed by users
- Outlines current Agency expectations for manufacturers to conduct scientifically sound testing to validate their reprocessing instructions prior to marketing

Purpose of this Guidance

- Also describes new measures the Agency is taking to enhance its oversight of reprocessing procedures
 - e.g. [Appendix E](#)
- Replaces FDA's 1996 "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities"

What's New in this 2015 Final Guidance (vs the 1996 Guidance)

- Expanded to include information pertaining to validation of reprocessing methods and instructions
 - Specific emphasis on importance of proper cleaning & cleaning validation, importance of worst-case testing, importance of device designs that are less challenging to reprocess
 - Human factors considerations when validating reprocessing methods and instructions

What's New in this 2015 Final Guidance (vs the 1996 Guidance)

- Provides greater clarity on documentation to be provided in the different premarket submissions
 - 510(k), PMA, de novo, HDE, IDE

Scope of the Guidance

Recommendations in this guidance are applicable to:

- Reusable devices initially supplied sterile to user & requiring user to reprocess after each patient use
- Reusable devices initially supplied non-sterile to user & requiring user to process prior to initial use, as well as after each use
- Reusable devices intended for reuse by a single patient and reprocessed between each use
- Single-use devices initially supplied non-sterile & requiring user to process prior to its use



Reprocessing: Overview

Use



Reprocessing: Overview

- Cleaning, disinfection, sterilization:
 - Are distinctly different processes
 - Should be validated separately and independently
- **Point of use processing:** Initial cleaning steps to prevent drying of soil on device surface prior cleaning
- **Cleaning:** Physical removal of soil
- **Disinfection and sterilization:** Intended to kill microorganisms

Reusable Devices: Recent Trends

- Devices with complex designs that are more difficult to reprocess
- Significant advances in knowledge and technology involved in reprocessing reusable medical devices
 - Recommendations in this guidance reflect the scientific advances in these areas

Formulation of Reprocessing Instructions: Device Design Considerations

- Starts in early stages of device design and engineering
 - Challenging designs: shaft-within-lumen configurations, fine channels, seals and mated articulating surfaces
 - Less challenging alternatives: single-use parts; flush ports; dedicated cleaning accessories
- Use designs that facilitate cleaning, disinfection and sterilization methods that can be easily & effectively implemented by the users

Formulation of Reprocessing Instructions: Ensuring Safety

- Device labeling should:
 - Provide instruction on how to prepare the device for the next patient use
 - Identify materials and equipment that will be needed and are readily available to users

Formulation of Reprocessing Instructions: Human Factors

- Use consistent format for all devices of a type
 - Use consistent terminology and the same document layout for all devices of a type
 - Improve user comprehension & adherence
- Address any known post-market human factors issues
 - e.g., Actions requiring substantial dexterity, strength, good visual acuity or familiarity with uncommon practices
- Validate instructions to ensure that users will thoroughly understand and follow them

FDA's Six Criteria for Reprocessing Instructions

1. Should reflect the intended use of the device
2. Should advise users to thoroughly clean the device
3. Should indicate the appropriate microbicidal process for the device
4. Should be technically feasible and include only devices and accessories that are legally marketed
5. Should be comprehensive
6. Should be understandable

1. Intended use of the device

- Appropriate reprocessing instructions depend on:
 - Physical design of device
 - Intended use of the device
 - Direct or indirect contact with patient
 - Soiling and contamination exposure during clinical use
 - Use of toxic chemicals on the device
 - Any specific or unique risks to patient or user

2. Thoroughly clean the device

- Cleaning is the first step in reprocessing
- Adequate sterilization or disinfection depends on the thoroughness of cleaning
- Details of the cleaning procedure will vary depending on the complexity of the device
 - Disassembly
 - Use of protective covers to reduce soiling
 - Flushing

3. Appropriate Microbicidal Process

- **Spaulding Classification Scheme**
 - **Critical devices**
 - **Semi-critical devices**
 - **Non-critical devices**

3. Appropriate Microbicidal Process: Spaulding Classification Scheme

Critical devices: Introduced directly into the bloodstream or contact a normally sterile tissue or body-space during use

- e.g., Surgical instruments, irrigation systems for sterile instruments in sterile tissues, endoscopes used in sterile body cavities (laparoscopes, arthroscopes and intravascular endoscopes), all endoscope biopsy accessories
- Likelihood of microbial transmission and risk of infection if the device is not sterile
- Disassemble (if applicable), thoroughly clean, and **sterilize** after each use

3. Appropriate Microbicidal Process: Spaulding Classification Scheme

Semi-critical devices: Contact intact mucous membranes or non-intact skin; do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body

- e.g., Endotracheal tubes, bronchoscopes, laryngoscope blades and other respiratory equipment, esophageal manometry probes, diaphragm fitting rings, and gastrointestinal endoscopes, such as duodenoscopes
- Intact mucosal surfaces are relatively resistant to small numbers of spores
- Thoroughly clean and then reprocess by **sterilization or**, if sterilization is not feasible, by **high level disinfection**

3. Appropriate Microbicidal Process: Spaulding Classification Scheme

Non-critical devices:

- Contact only intact skin and do not penetrate it
 - e.g., Blood pressure cuffs, stethoscopes, skin electrodes
- Devices that have no direct patient contact but may become contaminated with microorganisms and organic soil (blood, body fluids) during patient care
 - e.g., Infusion pumps, ventilators
- May not be visibly contaminated
- Thoroughly clean, then **intermediate or low level disinfection** depending on the nature and extent of contamination.

4. Feasible to implement & include only legally marketed devices and accessories

- Intended use location
 - Health care setting or home use
- Equipment and accessories needed to implement the instructions should be readily available to users
 - e.g., Type of brushes and detergents for cleaning
 - Type of sterilizer, manufacturer-validated sterilization cycle parameters and sterilization accessories
- Sterilization methods and parameters should be technically feasible for the user to implement

4. Feasible to implement & include only legally marketed devices and accessories

- **Extended cycles**

- Specifications that deviate from those found on commonly used, FDA-cleared sterilizers
- Limited or no FDA-cleared sterilization accessories
- Typically include longer exposure times and/or higher or intermediate temperatures
- Pose serious technical challenges in health care settings

5. Instructions should be comprehensive

- A. Special accessories and any special protection during reprocessing
 - Valves, plugs or stoppers to prevent ingress of harsh chemicals or water; special tools, sizes and types of brushes; flush port connectors and connector size specifications
- B. Point-of-Use Processing
- C. Disassembly and Reassembly – step-by-step instructions with visual aids; reassembly before or after sterilization
- D. Method of Cleaning - Detailed validated method of cleaning; list of parameters, including duration of each processing step, temperatures, water quality

5. Instructions should be comprehensive

- E. Cleaning Agents – agents or class of agent used in validation testing; preparation and use
- F. Rinsing – to remove processing chemical residues; type and quality of water, duration, temperature
- G. Lubricating Agents – validate reprocessing methods using the lubricating agent
- H. Visual Inspection – if not visually clean, then repeat cleaning or dispose of device
- I. Method of Disinfection or Sterilization

5. Instructions should be comprehensive

- J. Reduction of Sterilant Residues – eg. rinsing or aeration
- K. Drying – Devices should be thoroughly dried after processing and before storage
- L. Reuse Life – How many times the device can be reused or method to ascertain if exceeded use life
- M. Additional Labeling Recommendations
- N. Patient or Lay Use
- O. Reference to Guidelines or Accessory Labeling
- P. Manufacturer’s Contact Information

6. Instructions should be understandable

- Clear and legible
- Sequential order from the initial processing step through the terminal processing step
- Simple language
- Sufficiently detailed to explain the correct procedures for all steps
- Charts, diagrams, pictures that can be posted in work stations

Cleaning Methods Validation

- Worst-case conditions
- Clinically relevant soil
- Pre-determined test endpoints

Validation of Cleaning Process: Worst-case Testing

- Artificial Soil
 - Represent materials that the device would likely be exposed to during actual clinical use, and would create the greatest challenge to cleaning
 - e.g., During visualization of the larynx, a laryngoscope would likely be exposed to both blood and mucus
 - The artificial test soil should be a multi-component soil that includes substances that simulate both blood and mucus

Validation of Cleaning Process: Worst-case Testing

- Inoculation Sites
 - Application of test soil should mimic worst-case clinical use conditions
 - Inoculate the device in all locations likely to contact patient materials, especially all locations that are difficult to clean (e.g., mated surfaces, lumen, hinges)

Validation of Cleaning Process: Worst-case Testing

- Simulated Use Conditions
 - Incorporate multiple full use cycles
 - Assess the accumulation of soil over time
 - Account for real-world use conditions to mimic worst-case clinical use
 - e.g., Conduct all functional procedures, such as repeated articulations, flexures, manipulations, in order to soil the device sufficiently; powered hand-pieces and electrosurgical instruments need to be powered-on to simulate use conditions

Validation of Cleaning Process: Worst-Case Testing

- Validation Protocols
 - Shortest times, lowest temperatures, weakest dilutions, etc., for each step of the cleaning instructions
 - e.g., If instructions recommend 10-20 min pre-soak, the validation protocol should specify 10 min
 - Side-by-side comparison of label cleaning instructions and cleaning process used in validation protocol

Validation of Cleaning Process: Choice of Test Types

- At least two quantitative test methods
 - Measure clinically meaningful levels of test soil
 - Predetermined cleaning endpoints for residual soil
- Validate the quantitative test methods chosen to measure residual soil
 - Analytical sensitivity and specificity

Validation of Cleaning Process: Extraction Method

- Extraction methods:
 - Exhaustive extraction
 - Extraction using a known quantity of soil
- Recovery efficiency determined as part of its validation
- Sample all surfaces, including internal surfaces (e. g., lumens) and mated surfaces
- Use appropriate extraction volume to remove test soil from the device

Validation of Cleaning Process: Methods Validation

- Appropriate controls
 - Negative device control – unsoiled and cleaned
 - Positive device control – soiled
 - Negative sample control – used as a blank
 - Positive sample control – extraction with no device.
This control addresses interference of the extraction fluid and extraction method with soil detection

Validation of Microbicidal Process

- Disinfection
 - e.g., Demonstrate that device can be disinfected to the appropriate endpoint(s) using contact conditions that are consistent with those specified in labeling for legally marketed disinfectant and under worst case conditions
- Sterilization
 - Validate cycle specifications that are consistent with the conventional parameters (Appendix C)

Pre-market Review

- FDA will review the reprocessing instructions included in the labeling when we review premarket submissions for reusable medical devices
- All cleaning, disinfection, and sterilization procedures should be validated, and validations should be **completed prior to submission of your pre-market application**

Pre-market Review

- PMA, HDE and de novo: Protocols and complete test reports of validation of reprocessing instructions
- 510(k): FDA expects manufacturers of a subset of devices (Appendix E) to include data in 510(k) submissions to validate their reprocessing instructions
 - Validation data *may* also be requested ‘as needed’ for substantial equivalence
- IDE: Summary of the validation of reprocessing instructions

Key Messages

- Manufacturers should provide adequate labeling that includes instructions for reprocessing and reusing devices and device accessories safely
- All cleaning, disinfection, and sterilization procedures provided in the labeling should be validated

Key Messages

- The labeling should provide sufficient instructions on how to prepare the device for the next patient use
 - Manufacturers should identify the materials and equipment that the users will need to reprocess the devices
 - These materials and equipment should be readily available to users

Questions?

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