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

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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

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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

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)

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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