This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Questions and Answers for the FDA Reviewer Guidance: Labeling Reuseable Medical Devices For Reprocessing In Health Care Facilities

These answers have been prepared by Infection Control Devices Branch to assist with questions that may arise from implementation of this guidance. Please notify Dr. Chiu Lin of the Infection Control Devices Branch if there are additional questions about this guidance.

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REUSE OF MEDICAL DEVICES : QUESTIONS / ANSWERS

CONSUMER OR HEALTHCARE FACILITY

1.Q: Does this Reuse Guidance apply directly to the end user of a reusable medical device?

A: No, not directly. The guidance document is primarily intended as a guide to FDA reviewers and manufacturers. It describes criteria for product evaluation and guidance to the manufacturer of a reusable device on how to validate labeling instructions for reprocessing a reusable device. The guidance includes information that will be of interest to end users. Therefore, we would encourage end users to obtain a copy of the guidance.

2.Q: Does this Guidance Document apply to (1) reuse of single use devices, or (2) when a single use device package is inadvertently opened?

A: No, the Reusable Medical Devices Guidance only applies to medical devices labeled for reuse and to the initial processing of single-use only devices that are supplied non-sterile. FDA guidance is being developed on reuse of single use devices.

3.Q: Can a different method of reprocessing be substituted for the method recommended by the manufacturer?

A: FDA recommends that the manufacturer's labeling instructions be followed. If the end user wishes to use a method of reprocessing different from that recommended by the manufacturer, there is no assurance that the process will be satisfactory. The end user assumes responsibility for validating a method different from that recommended by the manufacturer.

In some cases the labeling for a reusable device that was marketed prior to the FDA initiative on reuse labeling may not be up-to-date in terms of reprocessing information. In that case, the user may find it necessary to supplement the given instructions with additional steps that are consistent with current infection control practices. FDA encourages manufacturers of older devices to upgrade labeling that is not current.

4. **Q:** Can an end user utilize a protective barrier device to eliminate reprocessing steps by reducing the level of gross contamination during use?

A: FDA recommends that the end user follow the manufacturer's instructions for both the barrier and the reusable device. Reusable device labeling may include recommendations on the use of barrier products to minimize the reprocessing steps that otherwise would be needed. While barriers may minimize contamination, their use may not eliminate all opportunities for the reusable device to become contaminated. For this reason even if a barrier product is used with a device there should still be a recommended method of cleaning and disinfection, albeit modified to reflect the use of a barrier. As noted in question #1, if the end user employs an alternative method from that recommended by the manufacturer, they must validate the alternative method. If a barrier device is used, the instructions for utilizing the barrier and reprocessing the device must be carefully followed.

5. **Q:** Can a reusable device be used past its recommended reuse life?

A: The manufacturer's recommended reuse life, if one is stated, should be followed. If the end user uses the device past the recommended reuse life, the end user assumes responsibility for such continued use of the device.

6. **Q:** If the reuse instructions recommended by the manufacturer differ from recommended practices set by professional societies or the healthcare facility, what should one do?

A: If the labeling for the device is current in terms of FDA's initiative on reusable devices then it should be followed. As noted above, older devices may not have current labeling and so professional practices and facility policy may be an important adjunct. When there are significant conflicts between labeling and recommended practices or institutional policy, the end user must reconcile these differences with the device manufacturer.

7. **Q:** If there are questions concerning reprocessing procedures to whom do I go for help?

A: The manufacturer of the reusable device is the appropriate contact for further questions.

ODE Reviewer

1.Q: Are there criteria for evaluating the validity of a reuse protocol the manufacturer has used?

A: Currently there are no specific criteria or standards for evaluating the validation of reprocessing instructions for the reuse protocol. The guidance on labeling of reusable devices includes a general scheme for validation studies and references to information on validation of procedures. The Infection Control Devices Branch is working with standard setting organizations like AAMI to develop specific criteria.

2.Q: Can I ask the manufacturer for validation data in my 510(k) review? What about PMA reviews or IDEs?

A: Requests for in depth evaluation of qualification tests conducted as part of the validation for 510(k) submissions are not necessarily part of the review unless: 1) recommended in a device specific guidance, 2) directed by management on a case by case basis, or 3) when requested by the Office of Compliance.

The validation of reprocessing instructions for a PMA device will be reviewed in the same manner as other manufacturing and control data. Refer to the Blue Book policy for the specifics. For PMAs the manufacturer will need to submit data documenting the safety and efficacy of the proposed reprocessing instructions. The review of an IDE can include evaluation of a summary of the validation study.

3.Q: Do manufacturers have to submit data from their validation study or is a certification of the study acceptable?

A: For a 510(k), the manufacturers can submit a certification of the validation study unless a device specific guidance requires actual validation data. PMA reviews will continue to require the actual validation data.

4.Q: Are draft standards from a standard setting organization for cleaning and disinfection acceptable as a means for validation?

A: Since draft standards are still in process they may have limited utility or scientific merit. Until tests in draft standards are validated through round robin testing, and the standards are finalized, they should not be relied upon solely as a basis for product validation.

5.Q: What are the acceptable infection control outcomes that an end user is attempting to achieve when reprocessing a reusable device?

A: The goal when reprocessing a reusable device generally depends on the device's intended use. A critical device is a medical device that is intended to enter a normally sterile environment. It must be thoroughly cleaned and sterilized between patient use. A semicritical device is a medical device that is intended to come in contact with mucous membranes and does not ordinarily penetrate body surfaces. It must be thoroughly cleaned and subjected to a germicidal process with a broad spectrum of activity. Sterilization of a semicritical device is desirable, but high level disinfection is acceptable when sterilization is not feasible. A noncritical device is a medical device that comes into contact with intact skin. The device must be thoroughly cleaned. If there is a concern regarding transmission of pathogens, then an intermediate or low-level disinfectant should be used. In some cases thorough cleaning alone, is acceptable.

6.Q: Are the manufacturers aware of this guidance?

A: Yes, it was formally announced and made available for comment in FR Vol 60 No.115 (June 15, 1995) and has been made final as of April 1996. The content of the document was presented at a national conference of the Association for the Advancement of Medical Instrumentation..

7.Q: Can a 510(k) be placed on hold, or found NSE for lack of reprocessing instructions and/or a statement of validation?

A: Yes.

8.Q: If 510(k) reviews don't require the submission of the validation data, how can a reviewer know that the testing of the reprocessing instructions is adequate?

A: Evaluation of preproduction design validation activities is primarily the responsibility of the Office of Compliance and the field staff under the good manufacturing practices regulations. Except as specified in the guidance, the applicant must supply documentation in the 510(k) that the validation has occurred or will occur. Data from labeling validation must be available for inspection by the field staff, if requested.

9.Q: Does the manufacturer have to validate reprocessing instructions that are based upon recommended guidance developed by a related professional practice group?

A: Yes. The manufacturer is required to validate any reprocessing methods they recommend in their labeling or promotional materials.

Manufacturer

1.Q: I have a device which is cleared for single use. If I want to market it as reusable what is required? If I want to market a reusable device as single use what do I do?

A: In order to market a single use device as reusable, a new 510(k) is required since there is a potential impact on the safety and effectiveness of the device. The 510(k) must include the appropriate validation studies that demonstrate that it is compatible for reuse. On the other hand a 510(k) may not be needed when changing a reusable device to single use only. The applicant must assess the impact of the change on its safety and effectiveness.

2.Q: If my device has been cleared for marketing as a reusable device, do I have to file a new 510(k) to conform with the Reuse Guidance?

A: No, the only requirement would be to have validation data on file.

3.Q: Don't Hospitals have their own reprocessing standards? Why is it necessary to recommend a processing procedure?

A: The general reprocessing standards in a healthcare facility may not be appropriate for all devices. Since a device manufacturer has the best knowledge of its device, it is important for the manufacturer to recommend a properly validated procedure for the user to follow.

4.Q: Do I need to validate each step of the validation process?

A: The cleaning and disinfection or sterilization steps must be validated separately since the expected outcomes differ. Cleaning is removal of visible contamination, while disinfection or sterilization is the killing of microorganisms. For specific details consult the references in Appendix 8 of the Reuse Guidance.

5.**Q:** What kind of endpoint can I use to validate cleaning, disinfection and/or sterilization steps?

A: The definition of cleaning is the removal of visible contamination. The manufacturer should design the test to demonstrate that a soiled device can be rendered free from contamination to the degree that the device is visibly free of soil. The accepted endpoints for disinfection depend on the degree of disinfection that is recommended. There are standards on validating sterilization processes which discuss how to verify the required sterility assurance level. Please refer to the following guidance documents for further information: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Healthcare Facilities or Guidance on the Content and Format of Premarket Notification [510(k)] for Liquid Chemical Germicides.

6.**Q:** Are draft standards from standard setting organizations for cleaning and disinfection acceptable as a means of validation?

A: Because draft standards have not been validated and are subject to change before finalization, the manufacturer must be sensitive to the fact that the draft procedures may not be scientifically sound and therefore are not acceptable as a reference. However, if you have validated the process referred to for your device, you may describe the method in your labeling.

STATEMENT 2, OPTION 2, VALIDATION NOT COMPLETED:

"This device is virtually identical from an infection control perspective to the [name of predicate device(s)] for which we have previously validated the reprocessing instructions. The validation has been subject to GMP inspection."

The statements submitted do not have to be verbatim, i.e., there may be minor variations.

ODE reviewers will NOT request or review the qualification tests conducted as part of the validation for 510(k) submissions unless requested by the Office of Compliance, as directed by management on a case by case basis, or as recommended in device specific guidance. Evaluation of the validation process is primarily the responsibility of OC and the field staff.

ODE reviewers have latitude to evaluate what is submitted, e.g., to determine whether the basis for the validation is relevant, or whether the summary raises serious concerns. There is a contraint to the evaluation of the summaries. There is a paucity of published specific methods or standards on validation of reprocessing instructions. FDA recommends that the AAMI TIR and FDA guidance on process validation be used as a set of principles regarding methodology from which specific protocols may be developed (see Appendix 3). Until specific methods or standards are published, reviewers are advised to use flexibility in evaluating the summaries, e.g., evaluate the fundamental methodology and principles of the tests described rather than the specifics.

Despite general notices ragarding the availability of this guidance, many applicants will not be aware of FDA's initiative in regard to labeling of reusable devices, so there will be deficiencies. Early communication over the phone with the applicant will resolve most deficiencies. Lack of a statement of status of the validation is a deficiency that can be included in an "unable to determine SE" letter. Lack of a statement on validation can also be a basis for a not substantially equivalent (NSE) determination, i.e., acceptable equivalent performance has not been demonstrated.

2. A PMA must include a complete report of the qualification of the reproaessing instructions in the manufacturing and control section.

The reprocessing validation will be reviewed in the same manner as the other manufacturing and control data according to Blue Book policy.

3. An IDE should include a summary of the qualification of the reprocessing instructions, when completed, or the protoaol for qualification.

   The reviewer should use judgement when considering the extent of the data needed to document the safety of the device. Consider conditions of approval to resolve deficiencies as the default decision unless there are critical safety concerns related to infection control.

F. Person To Contaat With Questions Regarding This Guidance

Any general questions regarding this guidance should be directed, in writing, to Chief, Infection Control Devices Branch, Division of Dental, Infection Control, and General Hospital Use Devices, Office of Device Evaluation, HFZ-480, 9200 Corporate Blvd., Rockville, MD 20850, or by calling (301) 443-8897.

G. Reviewer Checklist for Reproaessing Instructions

The checklist is a summary of Section C of the guidance.

#	QUESTION	Y/N
1.	Ia the device **(1) reusable,** (2) **supplied nonsterile, or** (3) **supplied sterile? Does the** labeling **commonly include reprocessing instructions?** If YES to any, continue review of **instructions.** If NO to all, **processing** instructions **are** not needed.	
2.	**Does** labeling include **(re)processing instructions?** If YES, continue review of **instructions.** **If NO, is there adequate justification for omission?** If NO, STOP review of reuse **instructions. Labeling is** deficient.	
3.	Ie there an instruction for cleaning (see **page a)?**	
4.	Is correct **microbicidal** process **indicated** (see page 5 and Appendices 1 and **2)?**	
5.	**Is** the **process** validated **(see** statement **and** information. **part E)?**	
6.	Is the **process** feasible **(see** page **5)?**	
7.	**Is** the **process understandable** (see page 6)?	
8.	**Is** the **process comprehensive** (see **pages** 6-9)? • **special accessories** • special **pre-processing** handling • **disassembly/reassembly** • cleaning **methods** • **cleaning/lubricating agents** • rinsing • method of **disinfection** or sterilization • special **post-process handling** • reuse life • special **warnings/precautions** • lay uee • **reference** to guidance documents or accessory **labeling** • telephone number • **user** qualification of deviations	
9.	**Are the recommended accessories** legally **marketed?**	

Appendix 1
Reprocessing Triage

Critical Device[1]: a medical device that is intended to enter a normally sterile environment, sterile tissue or the vasculature. A critical device poses a high risk of infection if it is contaminated with any microorganisms. A critical device must be thoroughly cleaned and sterilized before reuse. Examples of reusable critical devices include surgical instruments, rigid endoscopes, and needles.

Semicritical Device: a medical device that is intended to come in contact with mucous membranes or minor skin breaches. Mucous membranes are generally resistant to infection by moderate levels of most bacteria but may be susceptible to certain pathogens. Compromised skin presents an opportunity for infection but a sterile device is not absolutely required for a minor breach. If a semicritical device poses a high risk, or is known to be contaminated by high grade, fomite transmissible pathogens, additional processing is necessary, A semicritical device must Be thoroughly cleaned and subjected to a germicidal process with a broad spectrum of activity. Sterilization is desirable, but high level disinfection is acceptable if sterilization is not practicable. Examples of semicritical reusable devices include gastrointestinal (GI) endoscopes (trans-oral and trans-rectal), and urological (GU) endoscopes (trans-urethral).

Noncritical Patient Contact Device: a medical device that comes in contact with intact skin. The risk of infection is low. The device must be thoroughly cleaned. If there is a concern regarding cross-transmission of pathogens then an intermediate level disinfectant should be used, otherwise treatment with a low level disinfectant, or in some cases thorough cleaning alone, is acceptable. Examples of these reusable devices include blood pressure cuffs, stethoscopes, and skin electrodes.

Medical Equipment: a device, or a component of a device, that does not typically come in direct contact with the patient. It may serve as a vector for cross-contamination. The same level of care is exercised as for the noncritical devices. Examples include lights, stands, and examination tables.

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[1] The term 'Critical Device' is also defined under 21 Code of Federal Regulations, Part 820, Good Manufacturing Practices for Medical Devices. The definition and its usage under GMPs is not the same as that presented above. Recognizing the potential for confusion, this document still maintains use of the term 'critical device' in order to be consistent with terminology in infection control guidance produced by the Centers for Disease Control and publications by infection control practitioners and associations.

Appendix 2
correlation of Triage to Microbicidal Process

Category	process
Critical	Sterilization
Semicritical	Sterilization desirable High Level Disinfection is acceptable in most cases
Noncritical	From Intermediate Level Disinfection to Cleaning depending upon patient contact, type and amount of contamination
Equipment	Same as noncritical

Note: Some allowance is stated between the type of process that is desirable and that which is minimally acceptable for semicritical and noncritical devices, This margin of tolerance is consistent with direction from CDC and infection control practitioners,[1]

All critical reusable devices must be sterilized without exception. Reusable semicritical devices should likewise be sterilized but in some cases this will not be practicable. For example, the device materials may not withstand sterilization processes, or clinical circumstances may dictate the method of choice.

Appendix 3
summary of Validation of Reprocessing Instructions

1. Introduation

It is likely that revised GMPs will require that the manufacturer validate the design of their reusable device and the reprocessing procedures to make certain the device can be adequately reprocessed over its use life. *An* industry standard for validating design and processing instructions is not available. The AAMI Technical Information Report on Reprocessing of Reusable Devices provides guidance on this matter.

There is ample additional information on sterilization validation that can be directly applied to reprocessing validation. The manufacturer may refer to the FDA Sterile Medical Devices Workshop Manual, USP XXIII, other AAMI sterilization validation standards, and the literature for assistance in developing their protocols. Available FDA guidance also discusses reconditioning (cleaning and resterilizing) of returned devices.

2. Definition of Reprocessing Instructions validation

A documented program which provides a high degree of assurance that a specific reprocessing procedure will consistently produce a device that meets predetermined specifications.

3. The Basics of Reprocessing Validation

There are several steps to a complete validation as follows:

a. Pre-qualification

Defining product Specifications:
- Design
- Materials
- Operating Requirements

Defining Processing Specifications:
- Cleaning and Germicidal Agents
- Precleaning and Rinsing
- Packaging
- Processing Equipment
- Microbicidal Process
- Post-processing

b. Qualification of specified processing Equipment to be Recommended in Labeling

c. Performance Qualifications of (1) the Cleaning/Rinsing Steps, and (2) the Sterilization or Disinfection and Final Rinsing Steps
    - Processing Equipment Evaluation
    - Microbiological Challenge
    - Product Functionality Evaluation (repeated studies for reuse)
    - Residue Evaluation

d. Documentation
    - Documentation
    - QC Review and Approval

e. Re-qualification

4. Simulated and Actual Use Studies

The performance qualifications require, at a minimum, simulated testing of reprocessing of the device. The rationale for use of only simulations should be documented by the applicant and held for inspection. The simulated use test conditions should mimic the worst-case actual use conditions (e.g., extremes of contamination and reprocessing conditions over the reuse life of the product). If the applicant cannot adequately simulate actual use conditions, then the applicant should subject the device to actual use, i.e., clinical, tests to confirm the validity of the procedures.

Appendix 4
Definition of Terms

The following are common microbiological terms that a reviewer may encounter in evaluating reprocessing instructions in device labeling culled from referenced literature.[2,3,4,5] The list is not exhaustive. The terms marked with an asterisk are used in this document. Additional definitions of terms can be found in the referenced literature.

1. Antiseptic: A substance that prevents or arrests the growth or action of microorganisms on living tissue either by inhibiting their activity or destroying them. Antiseptics are regulated as drugs.

2. Bioburden: The number and types of viable microorganisms which contaminate an article; also known as "bioload" or "microbial load". When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.

3. Bioburden Based Sterilization: A sterilization process based on known levels of microbial contamination on all surfaces to be sterilized.

4.* Biological Indicator (BI): A sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to have high resistance to the mode of sterilization being monitored.

5. Chemical Indicator: A sterilization monitoring device designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber.

6.* Cleaning: The removal of adherent visible soil (e.g., blood, protein substances, and other debris) from medical devices by a manual or mechanical process, as part of a decontamination process.

7. Death Rate Curve (or Survivor Curve): A graphic representation of the microbial death rate kinetics of a specific microbicidal agent on a defined microbial population.

8.* Decontamination: According to the United Stated Occupational Safety and Health Administration (OSHA), "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting

infectious particles and the surface or item is rendered safe for handling, use, or disposal" [29CFR1910.1030]

Note - In common usage, "decontamination" generally refers to all pathogens (microorganisms aapable of producing disease or infection), not just those transmitted by human blood.

9.* **Disinfectant:** An agent that disinfects.

10.* **Disinfection:** A process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection *processes* do not ensure the same margin of safety associated with sterilization processes. The lethality of the disinfection prooess may vary, depending on the nature of the disinfectant, which leads to the following subcategories:

a. High Level Disinfection: A lethal process utilizing a sterilant under leas than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

b. Intermediate Level Disinfection: A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores.

c. Low Level Disinfection: A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi, and lipid viruses.

11.* Fomite: An inanimate object or material on which disease producing agents may be conveyed.

12.* Germicide: An agent that destroys microorganisms, particularly pathogenic organisms. Other terms with the suffix -cide (e.g., virucide, fungicide, bactericide, sporicide, tuberculocide) destroy the microorganism identified by the prefix.

13. Microbicidal Kinetics: The mathematical relationship between a condition of exposure of a known microbicidal agent to the number of specified microorganism killed.

14. Organic and Inorganic Load: Ambient or applied inorganic (e.g. metal salts) or organic (e.g., proteins) contaminants on the surface of a medical device prior to reprocessing. *The* naturally occurring organic load is also known as bioburden.

15. Overkill Sterilization: A sterilization process that is

based on an arbitrarily established higher initial concentration and resistance of bioburden than that actually expected on the medical devices to be sterilized. Overkill processes typically are based upon a 10^4-10^6 colony forming unit (CFU) population of bacterial spores known to be resistant to the sterilization process.

16.* Performance Qualification: An element of the sterilization validation program consisting of selected engineering and microbiological demonstrations performed according to a predefined protocol to show process reproducibility and product acceptability.

17.* Process Residue:. The substance remaining on the surface of a medical device after exposure to a decontamination or terminal process.

18. Qualification: The documented procedure of a test protocol to show compliance to an established standard or specification.

19.* Reusable Medical Device: A device intended for repeated use either on the same or different patients, with appropriate decontamination and other reprocessing between uses.

20. Sanitizer: An agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements.

21.* Spore: The dormant state of a microorganism, typically a bacterium or fungus, which exhibits a lack of biosynthetic activity and reduced respiratory activity.

22.* Sterilant: Physical or chemical agent(s) which causes sterilization.

23.* Sterile: The absolute state where all forms of life have been eliminated. In a practical sense absolute sterility cannot be proven, therefore, sterility is considered achieved when organisms are eliminated, inactivated, or destroyed such that they are undetectable in standard media in which they have previously been found to proliferate.

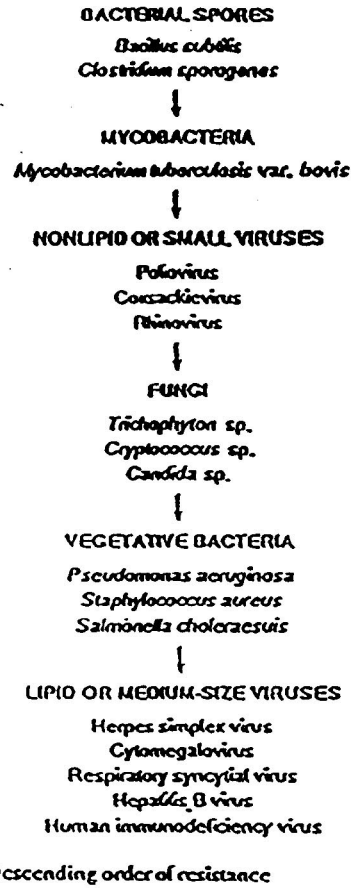
24. Sterility Assurance Level: A value indicating the probability of a microbial survivor after a sterilization process.

25.* sterilization: An act or process which completely eliminates or destroys all forms of life, particularly microorganisms.

26.* **Validation: A documented program which provides a high degree of assurance that a specific process will consistently produce a product that meets its predetermined specifications and quality attributes.**

27. **Vegetative: An active growth phase of a microorganism.**

Appendix 5 (reproduced with permission)
Resistance to Germicidal Chemicals[1]



Disinfectant Activity According to Type of Microorganism[1]

Levels of disinfectant action according to type of microorganism

Disinfectant level	Killing effect[a]					
	Bacteria			Fungi[b]	Virus	
	Spores	Tubercle bacillus	Vegetative cells		Nonlipid and small	Lipid and medium size
High	+[c]	+	+	+	+	+
Intermediate	–[d]	+	+	+	±[e]	+
Low	–	–	+	±	±	+

[a] +, killing effect can be expected; –, little or no killing effect.
[b] Includes asexual spores but not necessarily chlamydospores or sexual spores.
[c] Only with extended exposure times are high-level disinfectants capable of killing high numbers of bacterial spores in laboratory tests; they are, however, capable of sporicidal activity.
[d] Some intermediate-level disinfectants (e.g., hypochlorites) may exhibit some sporicidal activity, whereas others (e.g., alcohols or phenolic compounds) have no demonstrated sporicidal activity.
[e] Some intermediate-level disinfectants, although tuberculocidal, may have limited virucidal activity.

Appendix 6
COMPARISON OF TERMINOLOGY FDA/CDC/EPA

CDC and FDA use similar terminology pertaining to chemical sterilants and disinfectants. EPA defines these products differently. For information purposes the correlation of terms is as follows:

DEVICE RISK CATEGORY	CDC/FDA GERMICIDE TERM	EPA GERMICIDE TERM
Critical Device	Sterilant	
		Sterilant
Semicritical Oevice	High Level Disinfectant	
Noncritical Device	Intermediate Level Disinfectant	Hospital Disinfectant (with TB claim)
	Lou Level Oisinfectant	Hospital Disinfectant
		Sanitizer

Appendix 7
FDA Status of Microbicidal Processes

1. Sterilization

There are many legally marketed sterilizers. Steam, dry heat, ethylene oxide (EtO), and boiling water sterilizers are classified in the Code of Federal Regulations. Ultraviolet light sterilization is classified for water purification. Other types of legally marketed sterilizers have been found substantially equivalent to the above classified devices.

2. Disinfection

Disinfection is typically achieved by the use of liquid chemical germicides. There are a growing number of legally marketed sterilants and high level disinfectants. There are numerous legally marketed intermediate and low level disinfectants.

Appendix 8
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