Healthcare Reprocessing FAQ Sheet

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Reusable Device Cleaning/Disinfection Validation

Devices intended to be reprocessed in a clinical setting must have cleaning/disinfection instructions provided with the product. These instructions for use (IFUs) will detail the correct way to reprocess the device prior to use to ensure patient safety. These instructions must be validated. At Nelson Labs we offer all testing needed to meet this validation requirement, along with the technical expertise to circumvent any problems.

Nelson Labs Offering

Nelson Laboratories offers a full range of medical device cleaning/disinfection validation services to validate manufacturers' reprocessing instructions for reusable devices. These services include contamination, cleaning, and post-reprocessing effectiveness evaluations. Nelson Labs' simulated-use testing practices are employed to simulate actual clinical procedures rather than the direct inoculation methods utilized by other labs. Options are available to use validated or customized test soils to create clinically relevant conditions. The following test markers are available and should be chosen based on the products' clinical use:

TEST MARKERS:

Protein	Total Organic Carbon
Hemoglobin	Carbohydrate Residual
Cytotoxicity	Detergent Residual
Bacterial Endotoxin	Bioload Reduction

Sample Types, Required Sample Size

MEDICAL DEVICE — **5 Devices are required for the validation** (3 test articles, 1 positive, 1 negative or a neutralization device)

Quotes

CLEANING/DISINFECTION PROTOCOL	RVC105, RHL105	Average 10 days- dependent on project scope
CLEANING VALIDATION	RVC110, RVC120	Average 28 days- dependent on project scope
DISINFECTION VALIDATION	RHL110, RHL120, RHL130	Average 35 days- dependent on project scope

Expert Advisor Contacts:

AdvisoryServices@NelsonLabs.com **OR** call +1-801-290-7500

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SUPPLEMENTAL INFORMATION

What is a cleaning validation?
A cleaning validation assesses the efficacy of a process designed to affect the physical removal of contamination from all surfaces (inner and outer) of a reusable device. This is usually performed as a precursor to a prescribed terminal disinfection or sterilization process.

Do I need to perform both a manual and an automated cleaning validation?
If the device can be processed in an automated washer without incurring damage, and the healthcare facility is likely to possess automated washing capabilities, only the automated validation is required. If the device cannot be run through an automated wash cycle without incurring damage, a manual cleaning validation alone is appropriate. If the target market is unlikely to possess automated wash capabilities, it is our recommendation that both automated and manual cleaning validations be performed. Please be aware of the expectation that all procedures outlined in your instructions for use be validated.

What is a disinfection validation?
A disinfection validation demonstrates the efficacy of a process designed to reduce microbial contamination present on the exposed surfaces of a reusable device through chemical or thermal methods.

What level of disinfection validation is appropriate for my product?
Nelson Laboratories can help you determine what level of disinfection is appropriate for your device based on its use and where it fits in the Spaulding classification (i.e. Noncritical, Semi-critical or Critical).

Do I need to have my cleaning or disinfection validations performed according to Good Laboratory Practices (GLP)?
Given the scrutiny surrounding cleaning and disinfection validations, it is Nelson Laboratories' recommendation that reprocessing validations conducted with the intent of submittal to a regulatory body (e.g. FDA) be performed according to GLP standards. A GLP study will recruit the services of our quality assurance department (QA), subjecting all data generated to an even more extensive review and incorporating audits during active phases of the testing.

Am I required to perform cleaning and disinfection separately?
Yes. AAMI TIR12:2010 and ISO 17664 provide guidance for cleaning and disinfection validations being performed separately. They are conducted separately because the focus of a cleaning validation is the physical removal of contamination, and the focus of a disinfection validation is the killing/inactivation of microorganisms through chemical or thermal processes.

How many samples do I need to submit? Can they be shared between studies? Do I need to submit all of my samples at once?
For a cleaning or a high level disinfection validation, 5 samples are requested for maximum efficiency in turnaround time. For a low or intermediate level disinfection, 10 samples are requested to evaluate the increased number of organisms associated with these studies. If fewer than the requested number of samples are available, testing can be performed with fewer samples but the standard turnaround time may be increased. Please note that if a minimum of 4 samples cannot be provided, both the turnaround time and cost of testing may increase. Samples can be shared between two or three studies with only a small impact to the turnaround time given that only a relatively small portion of the quoted turnaround time is consumed with active testing on the samples themselves. It is best if all samples are submitted at once as testing and associated turnaround time commitments do not commence until all samples have been received.

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What are the references for the sample size rationale for my cleaning or disinfection validation?
AAMI TIR12:2010 states that "at least three test replicates and one concurrent control should be used in the validation testing." AAMI TIR30:2011 specifies "a minimum of 3 replicates and one concurrent positive control." There is additional guidance regarding appropriate negatives and controls in both TIR30:2011 and the FDA guidance Reprocessing Medical Devices in Health Care Settings: 2015.

What is the turnaround time (TAT) for these tests?
The TAT is dependent on the scope of the study. Please consult your sales representative for current turnaround times for your requested testing.

Note: The current state of development of your project may have an impact on the testing timeline. The quoted TAT for your testing begins with the approval of your Customer Specification Sheet (CSS), and receipt of all test samples with a purchase order.

What information is needed for protocol development?
Once you have received your quotes and have decided to move forward with testing, the next steps would be:

1. Provide Nelson Labs with a purchase order that covers the cost of the intended testing.
2. Ship the requested number of samples along with any specialty detergents or disinfectants (include the material safety data sheet) to Nelson Laboratories. A link to the sample submission form can be found in the same email in which you received your quotes--as well as on the Nelson Labs website.
3. Provide a copy of your instructions for use (IFU). Nelson Labs' Consulting services are available if IFU development is needed.

Note: For all cleaning validations and disinfection validations that include cytotoxicity testing, a copy of the surface area calculations for your device (or identified testing sites) is also required.

What is the minimum surface area required for testing?
In most cases a minimum of 15 cm2 of surface area is required for the performance of a cleaning or disinfection validation. Certain combinations of test markers may necessitate a slightly larger surface area. Consultation is available for more specific details regarding surface area requirements.

Do I need to validate both sterilization and disinfection?
Per ISO 17664:2017, certain markets (mainly in Europe) are increasingly recommending the validation of both disinfection and sterilization as the terminal processes for reusable medical devices. Many small healthcare facilities/clinics or emerging markets do not have access to an autoclave and would require an alternative terminal process i.e. disinfection. Both the material make up of your device and the constraints of the processor should be evaluated during the risk assessment.

When validating a surgical kit or tray, do I need to send in the whole tray?
Per AAMI TIR12:2010, a worst case, or "master product" device can be chosen as a representative for the performance of your cleaning validation. Only the identified worst case device is required for the validation of a manual cleaning procedure. If an automated cleaning is to be performed, it is recommended that the entire tray be sent so that the complete tray can be loaded into the washer for the processing of the target samples. This method will most closely simulate the conditions experienced in a clinical environment. Our Nelson Labs' Consulting Department can determine worst case or master product if needed.

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How many markers do I need to test for my cleaning validation?
The FDA guidance published in 2015 requires testing two quantitative organic cleaning markers for a cleaning validation. Nelson Laboratories recommends correspondence with all applicable regulatory bodies prior to completing any test protocol to identify any variables specific to your set of circumstances. Additionally, if the device comes into direct contact with the patient during clinical use, it is recommended that cytotoxicity be evaluated in conjunction with the cleaning and disinfection validation. This is done to verify that if there is any detergent/disinfectant residue, it is not present in toxic concentrations post reprocessing. Reference: ISO 10993-5:2009. Nelson Labs offers the following quantitative markers: Protein, TOC, Hemoglobin, Carbohydrates, and Bacterial Endotoxins.

What standards do you reference in your testing?
A partial list is included below for your review. The standards that pertain to your particular device and testing will be listed on your Nelson Laboratories Standard Test Protocol.

AAMI TIR12:2010
AAMI TIR30:2011
ANSI/AAMI ST81:2004
ANSI/AAMI ST79:2010
ANSI/AAMI ST35:2003
ASTM E 1837-96. (R2014)
FDA. 2000
FDA. 2002
WHTM 01-01 Part B. 2013
BS/EN/ISO 17664:2017
ASTM E 2314-03. (R2014)
FDA. 2015
ANSI/AAMI ST58:2013
ASTM E 1766-15. 2015
BS/EN/ISO 10993-5:2009
ASTM F 3208-17

What are the acceptance criteria and where are they found?
Most of the acceptance criteria for reprocessing studies can be found in AAMI TIR30:2011 for cleanings, AAMI TIR12:2010 and Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff for disinfections. A list of established acceptance criteria has been included here for your review:

- AAMI TIR30:2011 Section 7.5 states "protein, < 6.4 µg/cm2; carbohydrate, < 1.8 µg/cm2; hemoglobin, < 2.2 µg/cm2; and endotoxin, < 2.2 EU/cm2.
- An AAMI webinar presented by FDA personnel on December 5, 2006 lists the acceptance criteria for total organic carbon as < 12 µg/cm2.
- AAMI TIR12:2010 Section 5.4 part C states "Acceptance criteria for a **low-level disinfection** is a 6 log reduction of a mixed suspension of typical vegetative organisms, such as Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, and representatives of the Klebsiella-Enterobacter group. Acceptance criteria for **intermediate-level disinfection** is a 6 log reduction of a mixed suspension of typical vegetative organisms, such as Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, and representatives of the Klebsiella-Enterobacter group, and a 3 log reduction of an appropriate Mycobacterium species. Acceptance criteria for **high-level disinfection** is a 6 log reduction of an appropriate Mycobacterium species."

References:

ANSI/AAMI ST81:2004 Section 3.5 states, "A validated method of manual cleaning shall be specified. At least one validated automated cleaning/washing method shall also be specified unless the medical device cannot withstand any such process, in which case a warning should be issued."

ISO 17664 Section 4.1 states, "The medical device manufacturer shall validate each process that is identified in the information supplied with the medical device. Validation shall demonstrate that each process is suitable for processing of the medical device."

ISO 17664 Section 6.6.1 states "At least one validated automated cleaning method (which may include a validated manual cleaning method as part of the automated cleaning validation) shall be specified unless the medical device cannot withstand any such process, in which case a statement shall be provided which alerts the user to this issue.