



VOLUME1/2007

MICRO NEWS

PCD PREPARATION

A SIGNIFICANT PART OF STERILIZATION TESTING



lent, or greater, resistance to ethylene oxide than the product being sterilized. The PCDs act as a surrogate for the actual product thus allowing the user to reduce the number of actual products needed for testing purposes. Using a PCD instead of directly inoculating the product is a cost-effective, timesaver for medical device manufacturers. Once the correct PCD is chosen and prepared, it can be used by manufacturers for different sterilization methods such as ethylene oxide, steam, and VHP.

Like an imperative piece in an intricate puzzle, PCDs are an important element of validation and routine sterilization testing for medical devices. Our company offers information in the various areas concerning PCDs and their association with sterilization testing. Nelson Laboratories is a valuable resource to manufacturers desiring accurate PCD selection for their product, a faster turn-around-time for results, cost-effective testing techniques, a quality guarantee during testing, and one-stop shopping for their sterilization testing needs.

While developing the appropriate PCD can seem like a daunting task, our lab staff, client service representatives and sales department are available to help our customers determine the correct PCD type for their product.

(cont. page 2)

In the medical device industry it is essential that manufacturers have dependable facilities to assist them with sterilization testing. Nelson Laboratories, Inc. (NLI) provides many of the sterilization tests required by ISO, AAMI and USP. One of the most vital and cost-effective portions of ethylene oxide and VHP sterilization is the preparation of process challenge devices, or PCDs.

PCDs contain a biological indicator, or BI, and when properly validated, demonstrate equiva-

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*Manufacturers
with
expensive
products
or products
that are
difficult to
inoculate
will benefit
from
testing
with
PCDs.*

The correct PCD is first determined by comparative resistance testing. This involves a direct comparison of the customer's actual product to several proposed PCD types in fractional sterilization cycles. After the most appropriate PCD is chosen, validation of the PCD in the production vessel follows. After validation, customers can order the number of PCDs necessary and Nelson Laboratories can prepare that amount to send to the device manufacturer or directly to the contract sterilizer. Once the sterilization process is complete the results will enable you to efficiently and effectively sterilize your product.

An advantage of testing with Nelson Laboratories is that we are capable of handling all of the PCD and cycle development testing at our facility. From comparative resistance testing to delivering the carefully made PCDs to the contract sterilizer, Nelson Laboratories alleviates the hassle of transferring products and information from one laboratory to another and this all-in-one arrangement expedites the process for our customers.

Ordering PCDs through Nelson Laboratories benefits the manufacturer because after our company has performed the comparative resistance testing we have the necessary procedure and supplies ready for accurately preparing your PCDs. This not only ensures a faster turn-around-time but it provides extra insurance that our customers have the right PCD containing the correct materials.

Nelson Laboratories has created and validated many different PCD types that have been effectively used with a variety of medical devices with varying resistance to sterilization. This assortment gives our customers a breadth of options to choose from. In addition, our company has just added two new validated PCD types to our procedure (NLI-PCD-010 and NLI-PCD-011). These new PCDs will aid our lab staff in choosing the most compatible PCD for your product and will, in turn, save you time and money.

Along with finding the best PCD for the product, Nelson Laboratories can work with PCD batch sizes ranging from small (10-30 PCDs)

to large (several hundred PCDs). The size of the batch influences the turn-around-time but we will work with each customer to ensure their testing is completed in a time frame that fits their needs. Small batches can be prepared and sent to the contract sterilizer within one or two days while larger batches can be grouped and released together or sent out in smaller batches to speed up the entire process.

Manufacturers with expensive products or products that are difficult to inoculate will benefit from testing with PCDs. For instance, products with a balloon lumen are difficult to fit a biological indicator inside so it becomes necessary to flush inoculum through the lumen. Flushing a device can produce inconsistent results as it's hard to tell how well the organisms have distributed along the length of the lumen. Aside from the inconsistencies of direct inoculation, using PCDs usually has a shorter turn-around-time and ends up saving money in terms of less product waste.

By contracting with Nelson Laboratories for PCD preparation, our company provides a number of ways to assure quality in testing to give our customers accurate results in sterilization testing. Using only the specific components designated by our test method provides consistency in our PCD assembly and enables our customers to get reliable results over time. With the BI being the critical component in a PCD, our company has set up specific standards to determine if the BI to be used in the PCD is suitable. Before the PCD is made, Nelson Laboratories verifies that the BI is within expiry, the population verification is over 1.0×10^6 , and the information on the BI certificate of analysis is current and correct. After preparation the PCD is quarantined until a secondary review is performed to confirm that the correct PCD was prepared and that the accurate components were used in its construction.

Establishing quality into our PCD preparation produces reliable, consistent results for our customer but that is just the first step to accurate PCD assembly. Our company also hires skilled lab technicians who are trained to become specialists in preparing the various



PCD types in our catalog. In addition to quality-minded training for new employees, our sterilization team undergoes an annual validation of their PCD assembly techniques. It is critical that each technician assembles each PCD accurately and consistently. This re-validation of our company's PCD preparation by each sterilization team member will ensure that the PCDs made at our facility will perform consistently and reliably over your products sterilization lifespan.

In association with assuring a high level of quality in preparing PCDs for our customers, Nelson Laboratories ensures that all of the sterilization testing performed at our facility is compliant with our customer's needs as well as applicable regulations. Nelson Laboratories provides a variety of sterilization tests that allow our customers to receive the highest level of service. We commonly perform a range of industrial sterilization tests on medical devices using ethylene oxide, VHP, and steam. Batch release testing offered at Nelson Laboratories enables our customers to sterilize and release small batches of product for clinical or animal

trials without going through a comprehensive full-scale validation. Our company offers a full range of BI testing including D-value, survival/kill time verifications, BI incubation reduction validations, and population verification. Nelson Laboratories also provides experienced microbiologists to perform onsite validations of EO, VHP and steam sterilizers. We have performed our on-site sterilization validations for customers both domestically and abroad who perform their own in-house sterilization.

PCDs are one step in the sterilization process but our company wants to make it easier for you by providing knowledgeable staff members to help with PCD selection, a faster turn-around-time and cost-effective, quality testing including a wide range of sterilization tests

For more information regarding PCDs, Comparative Resistance, or other Sterilization tests please contact us at sales@nelsonlabs.com. Our lab staff, customer service department and sales department are ready to help guide you in choosing the correct testing to compliment your product.

REFERENCES

AAMI TIR 16-2000 Process Development and Performance Qualification for Ethylene Oxide Sterilization- Microbiological Aspects. Association for Advancement of Medical Instrumentation. Arlington, VA.

AAMI TIR 28:2001. Product Adoption and Process Equivalency for Ethylene Oxide Sterilization. Association for Advancement of Medical Instrumentation. Arlington, VA.

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ANSI/AAMI/ISO 14161:2000. Sterilization of Health Care Products- Biological Indicators- Guidance for the Selection, Use, and Interpretation of Results. Arlington, VA.

EN550:1994. Sterilization of Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization. British Standards Institution, London, England.

United States Pharmacopeia 30 and National Formulary 25. 2007. <71>, <55>, and <1035>. United States Pharmacopeia Convention, Inc. Rockville, MD.

SUBMITTING SAMPLES

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LABORATORIES

For all samples shipped to Nelson Laboratories for analysis or preliminary evaluation, please include a completed copy of the Sample Submission Form. The sample submission form is available in **PDF** and **Word** formats. Follow the instructions below for submitting samples to Nelson Laboratories.

When sending samples to the lab for analysis:

1. Download & complete Sample Submission Form (Please include submission form in or on the box of samples)

Including your submission form in the box with your samples ensures quick and efficient processing.

2. Please fill out packing slip (use your own or the NLI packing slip- **WORD** format, **PDF** format)
3. Ship samples and submission form to:

Nelson Laboratories, Inc.
Attn: Log-In
6280 S. Redwood Rd.
SLC, UT 84123-6600 USA
Ph: 801-963-2600

When submitting samples for multiple tests please do the following:

NELSON testfinder

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Keyword Search
KEYWORDS:
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Additional Information

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- Nelson Certifications
- Nelson packing slip (PDF)
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- NLI Submission form
- WORD additional sample subform
- WORD format Sample Subform

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Nelson Laboratories is continually looking for ways to improve the service we provide to our clients. Nelson Laboratories has found that when the necessary sample testing information has been provided with the samples the actual testing process can be completed more quickly and efficiently. In order to understand what items can help to facilitate this process a step by step instruction page has been placed on our web site.

www.nelsonlabs.com/subforms.jsp

Please help us serve you better by following these instructions. Using this process will help ensure a quicker and more efficient processing of your samples. If you have any questions, please contact Client Services at **801-290-7500**.



PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES

ANSI/AAMI/ISO 11607:2006

By
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Section Leader, BS,
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With the newly released revision of ANSI/AAMI/ISO 11607:2006, Packaging for terminally sterilized medical devices, you may find yourself wondering how the document has changed and what it means to the industry.

part one, provides an extensive centralized list of recommended test methods to evaluate these attributes.

The second part of the standard, which is a completely new addition, is geared towards process development and validation. It addresses items such as test methods, installation, operational, and performance qualification methods. This is a critical issue that ensures the integrity of the packaged device is attained and will remain so until opened by the user.

A major hurdle in creating this global standard was agreeing on terminology. Four new definitions were generated to assist in making the document more clear and consistent:

Sterile Barrier System (SBS) – “Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use”

Preformed Sterile Barrier System – “Sterile barrier system that is supplied partially assembled for filling and final closure”

Protective Packaging – “Configuration of materials designed to prevent damage to the sterile barrier system and its contents from their time of assembly to the point of use”

Packaging System – “Combination of the sterile barrier system and protective packaging”

In addition to the release of this standard, TIR22:2007 has recently undergone revision with the objective of providing guidance on the applications of the new 11607 document.

It is crucial to assure package integrity for sterile medical devices. The methods developed at NLI conform to the standard covered in ISO 11607 “Packaging for terminally sterilized medical devices”. Some of the NLI validated package tests available to help meet the requirements of ISO 11607 consist of:



Nelson Laboratories, Inc. (NLI) had several members on the ISO Technical Committee Work Group 7 who were involved in the revision of this standard. This publication represents a harmonized version of the former ISO 11607 and EN868-1. This standard has been developed to meet the European Requirements of the European Medical Device Directive and is expected to become an FDA consensus standard sometime this fall. With the acceptance of the FDA consensus standard, manufacturers can use one validation to fulfill both regulatory body requirements.

The first thing that warrants attention is the fact that the document has been split into two parts. Before a package for a terminally sterilized medical device can be designed, it is necessary to evaluate all the characteristics and requirements of the device which could affect the design of the package. The first part of the standard addresses the basic attributes required of materials and preformed systems while considering a wide range of materials, sterilization, medical devices, and packaging system designs. One of the annexes in

Microbial barrier - we offer two options on this area, a whole package microbial aerosol challenge test and the ASTM F1608 Microbial Ranking (Exposure Chamber Method). The whole package test includes the microbial challenge, subsequent sterility testing on the packaged product to determine penetration of the indicator organism used and test controls. The ASTM F1608 is specific to porous materials and employs a low flow rate, extended exposure time, and increased challenge level, which allows testing of materials with high differential pressure values.

Dye migration - The package is examined for evidence of seal failure demonstrated by dye slipping through the seal.

Bubble emission - A probe is inserted into the samples package and the machine started. The package is submerged in an immersion fluid.

Burst/Creep test - The burst test determines package strength by pressurizing a package until it bursts. The creep test determines package strength by pressurizing a package

at 80% of the known burst pressure for a set amount of time.

Seal Peel - The sample segment is inserted into the grips of an instrument with the heat seal centered between the two grips. The results are reported as maximum load.

Accelerated aging - Simulated aging studies can be run with a designated time period ranging from one month to five years (or longer). The time of simulated aging depends on the temperature at which the products are held. Real-time aging is required when establishing an expiration date. Accelerated aging is an option allowing manufacturers the ability to get product to market faster.

NLI has been performing package testing for many years and has a dedicated section to assist with compliance to ISO 11607. To find out more regarding packaging testing, please visit our web site www.nelsonlabs.com/packaging.jsp or contact Wendy Mach at wmach@nelsonlabs.com. Contact the Nelson Sales team for a quote and our complete list of packaging test services at sales@nelsonlabs.com.



With the acceptance of the FDA consensus standard, manufacturers can use one validation to fulfill both regulatory body requirements.

NELSON LABORATORIES ANNOUNCES NEW TELEPHONE NUMBER

Nelson Laboratories is happy to announce that we have successfully implemented a new secure internet protocol (IP) based telephone system. This system provides us with redundant telephone capabilities that will ensure our ongoing business continuity. The system is now active, and a new general telephone number is available for your use:

(801)-290-7500.

We invite you to begin using this number at your convenience. In addition to this general number, we are now providing direct inward dial numbers for many of our specialty departments (accounting, customer service, etc). We hope this change makes it even easier for you access the service and expertise you have come to expect from Nelson Laboratories. You can access a directory of these numbers at the following location:

www.nelsonlabs.com/contacts.jsp

Our existing telephone numbers **(801) 963-2600** and **(801)-963-5299** + extension will remain active during this transition phase but will eventually be discontinued (with additional prior notice). Our toll free number, **(800)-826-2088**, is not affected by this change and will continue to function into the future.

If you have any questions regarding our new telephone system or need assistance with phone numbers, please feel free to contact our client services department.



FUTURE EVENTS BY NELSON LABORATORIES

ETHYLENE OXIDE AND RADIATION STERILIZATION WORKSHOP

Join us for this two day workshop offering an opportunity to understand Radiation and EO Sterilization methods, microbiological basics and how to validate your sterilization and manufacturing process.

TOPICS TO INCLUDE:

Sterilization Basics
Microbiology Basics
Radiation Sterilization
EO Sterilization
Biocompatibility
Packaging
Methods for Monitoring

LOCATION: DoubleTree Park Place Hotel,
Minneapolis, Minnesota

DATE: June 5-6 2007 • 8:00-5:00

PRICE: Before May 15, 2007 \$700.00,
after \$850.00

CONTACT: Mike Pizzi or Jared Forsyth
at Seminars@nelsonlabs.com
800-963-6280, ext. 9203 or 9051

FOR MORE INFO:
www.nelsonlabs.com/seminars.jsp

— Limited Seating —

STEAM FLUSH PRESSURE PULSE STERILIZATION VALIDATION

Nelson Laboratories, Inc. has the capability to perform Steam Flush Pressure Pulse (SFPP) steam sterilization validations at our facility. The SFPP cycle is an efficient, high-volume sterilization process that works well with porous loads. The temperature validated is 270° F (132° C). This cycle utilizes a series of steam flushes and pressure pulses at pressures above atmospheric throughout the conditioning and exposure phases, which prevents air leakage into the chamber during the conditioning phase of the cycle. Please contact Emily Mitzel or Jason Pope for more information. For a price quote contact sales@nelsonlabs.com.



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