



MEDEC

CANADA'S MEDICAL DEVICE TECHNOLOGY COMPANIES

LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIE DES
DISPOSITIFS MÉDICAUX

MEDEC Policy Summit on Cleaning & Sterilization of Reusable (Multiple-use) Medical Devices

*The MEDEC Policy Summit on Cleaning and Sterilization
for Patient Safety was sponsored by the MEDEC
Orthopaedic Committee on October 31, 2006*

MEDEC is the national association created by and for the medical device industry in Canada, and is the primary source for advocacy, information and education on the medical device industry for members, the greater healthcare community, industry partners and the general public. Its goals are to advance health outcomes for patients in Canada and the growth and vibrancy of the industry in Canada. The organization focuses on ensuring access to proven, safe technology and new, innovative medical technology developed by member companies. www.medec.org

MEDEC supported this policy summit in order to continue and foster dialogue with the various stakeholders involved in cleaning and sterilization and to find solutions to the issues involved in the reuse of medical devices.

Summary

The Summit involved senior representatives from government, the clinical setting and industry who reviewed issues of sterilization of reusable medical devices. Each participant was well known in his or her respective field of specialization, with many years experience in areas of operations, device manufacturing, training, safety and the development of standards in device sterilization.

Throughout the Summit, it was noted that new risks are continually evolving (e.g.: Creutzfeldt-Jakob Disease, HIV and exotic viruses) which require constant and informed vigilance.

Specialty reusable devices are entering the market place in rapid succession, allowing for less-invasive procedures, better patient quality of life and swifter recovery times. However, the presence of these reusable devices represents a great economic and logistical challenge to the healthcare system in order to ensure their safe use.

Clearly, there is agreement that patient safety, the quality of patient care and concern for value are of paramount importance to all. Also, waste disposal and the introduction of each new medical centre constitutes a new set of concerns.

Each manufacturer must innovate and compete to provide unique therapeutic features. All the while, they must develop devices for both European and North America markets, yet meet differing sterilization standards and procedures.

Above all, everyone agreed that there will be no quick fixes to the problems relating to sterilization of reusable devices. Collaborative, on-going forums on device safety through sterilization must continue between government, hospitals, and industry to ensure patient safety.

Welcome and Opening Remarks

Stephen Dibert
President & CEO
MEDEC

Stephen Dibert welcomed the participants and provided an overview of MEDEC and MEDEC's Orthopaedic Committee. Dibert outlined that the purpose of the one-day summit was to review the state of cleaning and sterilization of reusable or multiple-use medical devices in Canada from the perspective of health facilities, government-regulatory bodies and industry, with the view to reviewing the evidence-based safety and efficacy of the procedures employed in institutions, the training and standards applied, and the legal implications and liabilities.

Dibert noted that the reprocessing of single-use devices would not be covered in this day-long summit, because of the additional complexity surrounding that issue, noting the topic was being addressed by MEDEC through other venues.

The MEDEC Policy Summit follows Health Canada's creation of the Scientific Advisory Panel on the Reprocessing of Medical Devices (SAP-RMD) which had two mandates: one on single-use devices, the other on multiple-use devices. MEDEC attended several sessions of the Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD) and organized industry participation at the October 12-13, 2006 meeting conducted by Health Canada to present the industry's policy perspective.

Dibert shared with the participants that MEDEC's intent in creating this forum was to contribute to the development of recommendations for further study and improvements to enhance patient and healthcare worker safety.

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The Cleaning & Sterilization of Reusable Medical Devices – Update on the Scientific Advisory Panel Meeting

David Ames

*Johnson & Johnson Medical Products
and MEDEC Orthopaedic Committee Member*

Ames set the stage for the day's discussion and started by reviewing, from an industry perspective, the presentations made at the October 12-13, 2006 meeting of the Scientific Advisory Panel on Cleaning and Sterilization sponsored by Health Canada. The results were positive overall, he concluded. He also suggested that the MEDEC Summit provided an opportunity to start conversations on ethical and practical concerns, as well as to come together to find solutions to common problems, in a venue where trust is encouraged. He noted that industry has its own concerns to be addressed, but that for everyone patient safety is the key.

A theme later repeated by other speakers was that one process will not fit all needs—yesterday's standards are not today's standards—and some cleaning issues are beyond the scope of the manufacturer's control (for example endotoxins). In the search for efficiencies, many hospitals batch the device sterilization instructions for simplicity and efficiency purposes but no one manufacturer's instructions will fit all type of devices. For example the thermodynamic requirements for cleaning and sterilization differ greatly across devices. He pointed out that "loaner" equipment is a large issue, and that it can be dangerous and expensive to pass equipment back and forth between institutions. To underscore his point, Ames suggested that incoming mail in large U.S. companies is often better screened, but at enormous cost, than bio-hazardous materials entering some healthcare facilities.

Common criteria for screening, cleaning and sterilization are needed for North America, while being mindful that industry is geared toward a market that includes Europe's parametric-release standards. More and more, industry has to ask the end users to provide feedback on device designs, something that has been lacking.

The transportation of biohazards is also becoming a growing issue for Transport Canada and Custom officials. Clearly, also we need to develop separate stakeholder criteria for such areas as orthopaedics and gastroenterology. Perhaps a venue such as the Canadian Standards Association (CSA) national meeting would be an appropriate platform, was the suggestion.

In closing, Ames stated that MEDEC members are looking forward to the final recommendations from Health Canada and to ongoing dialogue between the stakeholders.

Perspectives on the State of Cleaning & Sterilization of Reusable Medical Devices in Canada State of Cleaning and Sterilization in Health Facilities in Canada

Colleen Landers

*Registered Nurse Consultant,
Independent Health Care and Member Scientific
Advisory Panel on Reprocessing of Medical Devices*

Landers took participants through a detailed review of what healthcare facilities need when reprocessing a licensed reusable medical device. Although the presentation represented her views, the ideas presented were supported by members of the Scientific Advisory Panel.

Her presentation focused on the importance of Canadian Standards for cleaning, sterilization and disinfection. She stressed throughout her presentation that safety for each and every patient was of paramount concern, from the first scheduled patient to the last. 'Do no harm' to patients and the protection of staff was an apparent theme throughout her presentation.

Healthcare facilities require written manufacturers' device-specific written instructions for cleaning, wrapping and reprocessing. The standards must be written for Canada and designed for Canadian hospitals, by a panel of independent users and manufacturers to provide guidelines to perform the best reprocessing possible for patients, and to allow healthcare providers to identify the crucial elements of medical device reprocessing to achieve infection control.

While the introduction of minimally invasive surgeries has reduced hospital stay times, it has resulted in much more complex medical devices and challenges in their reprocessing, with which healthcare facilities have not necessarily kept pace.

It is, therefore, important to understand the challenges in order to make sound decisions on reprocessing practices, level of medical device in use and the level of sterilization required, in order to protect patients.

Careful selection and training of high-calibre capable staff, and an understanding of micropathogens, regular process and performance audits to correct errors, is required. Staff must possess knowledge of burden of biohazardous waste, risks, quality products, routine practices, reprocessing equipment and procedures, and Workplace Hazardous Materials Information System (WHMIS) and Occupational Health and Safety (OH&S).

Landers stressed that reprocessing committees must be established and must apply the Canadian Standards and Ontario Provincial Infectious Diseases Advisory Committee (PIDAC) guidelines on sterilization, as well as ISO 17664 (CSA Z17664), Association for the Advancement of Medical Instrumentation's (AAMI) ST 81 (U.S. Safety Guidance Documents), which were deemed to be the "Best Practice" documents.

In closing, Landers noted that Health Canada's licensing of medical device classifications needs to be reviewed and changed. This recommendation should be forthcoming in the guidance document from the Scientific Advisory Panel that will inform manufacturers and healthcare facilities.

Health Canada and the Scientific Advisory Panel

Philip Neufeld, Ph.D
Device Surveillance Division
Medical Devices Bureau
Health Canada, Ottawa

The major recommendations arising from the Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD) final meeting October 12 -13, 2006, centred on improvements in reprocessing instructions for reusables; compiled an extensive table of reusables that are difficult to clean or have inadequate cleaning instructions; and, recommended that residual soil on reprocessed devices is unacceptable, even if sterile.

The issue of cleaning reusable devices arose at an Ontario Hospital Association (OHA) meeting in April 2004 at which time it became clear that there were many problems which had been previously neglected. Most notably, Neufeld noted that many reusable devices are not free of visible soil after being cleaned, according to manufacturers' instructions. There have been several very public cases of devices which had had excellent instructions for disassembly and cleaning, but the instructions did not make it to the people who did the reprocessing. Other devices cannot be disassembled for adequate cleaning, and often the instructions are inadequate or impractical for users to follow. Another serious issue is that manufacturers often do not provide users with validation data for their reprocessing procedures.

In response to these concerns, Health Canada established the SAP on Reprocessing of Medical Devices (SAP-RMD), to advise on the reprocessing of both single-use and reusable devices. The SAP issued its recommendations on the reuse of single-use devices in February 2005. Since then, most meetings have been concerned with the reprocessing of reusable devices.

The Panel held its final meeting and its recommendations will be published on the Health Canada website.

One of the tasks of the Panel was to develop a table of reusable devices that are difficult to clean or have inadequate instructions. This resulted in a generic list of devices hospitals have difficulty cleaning properly.

In cases where manufacturers have shown that residual soil is sterile, the Panel has nonetheless rejected the notion of any foreign matter remaining on a device, whether it is sterile or not, believing it can cause serious consequences in certain types of surgery (e.g.: in eye surgery leading to blindness, and hip and knee which can cause loosening of the joints).

Neufeld reviewed the primary findings of the Panel:

- Manufacturers' instructions are vague
- Recommended cleaning does not remove all biomaterial
- Instruction for disassembly and reassembly are vague or absent
- Recommended sterilization times and temperatures are not the same as those validated by the manufacturer of sterilizers and not the same as those commonly used in North America.

In the immediate future, Health Canada will publish a guidance document on reprocessing information to be supplied by manufacturers with the device when it is sold to the user. This will be accomplished by recognizing ISO 17664, which was adopted as a National Standard of Canada under CAN/CSA-Z17664-06. The US FDA recognizes AAMI/ANSI ST 81, which is almost identical to ISO 17664. Many manufacturers already comply with these Standards.

Health Canada has a list of recognized standards which manufacturers may refer to when submitting a licence application for a medical device. The manufacturer can submit a declaration of conformity to a recognized standard. However, standards are not mandated in the regulations—they are still voluntary. The manufacturer has the option of declaring conformity with a different standard, in which case they have to prove their standard is as good as or better than the Health Canada standard. A third option is for the manufacturer not to declare conformity to any standards, but to submit alternative evidence that the device meets the safety and efficacy requirements of the regulations.

A great number of instruments are Class I and are not subject to licensing or review; a few are Class II devices; even fewer are Class III or IV. Neufeld stated that in order to make progress with respect to instructions, the focus needs to be on Class I and II devices.

Health Canada will post the Draft Guidance On Reprocessing for public comment for 60 days, planned for the end of November, 2006. Implementation of the Guidance will require a suitable phase-in period for manufacturers. The final issue covered by the Panel is to be on reprocessing devices containing sterile residue, which in many cases will require a major redesign of devices or reclassification as a single-use device. This may be acceptable alternative in theory, but would be prohibitively costly if such devices became single-use devices.

Neufeld referenced the following Health Canada contact information and postings on their website: http://www.hc-sc.gc.ca/dhp-mps/md-im/index_e.html

Cleaning and Sterilization of Medical Devices: An Association's Viewpoint

Sudha Kutty
Director, Patient Safety and Clinical Best Practice
Ontario Hospital Association (OHA)

OHA is a hospital association dedicated to the continuing improvement of health services in Ontario, through leadership, advocacy, education, communication and service. Membership includes all hospital and some 200 affiliate members ranging from community care access centres and some for-profit healthcare providers. It does not regulate its members or mandate that they take certain actions. Rather they provide tools, make recommendations and advocate on their behalf.

In November 2003, the Ontario Ministry of Health and Long-Term Care (MOHLTC) asked all hospitals to conduct a hospital-wide Patient Safety and Infection Prevention and Control Audit. The OHA acted as the communications coordinator between the Ministry of Health and hospitals, and also assisted with the development of a template for the audit.

Kutty proposed a process pertaining to communications flow when there is an issue around cleaning and sterilization. It is a complex environment with many players and many steps are required. The key points are that one must establish the most salient sources of information, determine key contacts in advance, list possible stakeholder activities (e.g.: who alerts whom, who conducts the environmental scan) and elaborate on a risk assessment process.

Past incidents set into place a process of rapid-fire communication between the MOHLTC, Public Health and the OHA as well as other stakeholders such as Healthcare Insurance Reciprocal of Canada (HIROC). In October 2004, the OHA decided to set up a committee to address issues in a pro-active manner.

The Medical Devices Committee is jointly co-chaired by OHA and MOHLTC, and membership includes representatives from:

- Health Canada
- HIROC – Healthcare Insurance Reciprocal, (a leading provider of healthcare liability insurance)
- Public Health
- Experts in the field
- Central Service Association of Ontario
- Legal Counsel
- Ontario Medical Association
- MEDEC

The Committee has the ability to provide timely advice and information to hospitals when medical device issues arise. As an example, it has issued a Bulletin on the Reprocessing of Flexible Endoscopes. It provides hospitals with resource materials and information of interest, brings to light unresolved medical devices issues, and participates in initiatives such as the creation of Health Canada's Scientific Advisory Panel.

The OHA's involvement in medical devices is part of a broader initiative focused on patient safety. In 2004, with seed funding from the MOHLTC, the OHA created the Patient Safety Support Service (PSSS). The goal of the PSSS is to implement innovative programs to improve patient safety and raise awareness of patient safety issues across the province of Ontario.

In terms of education, the OHA wishes to explore ways to work with the Central Service Association of Ontario (CSAO) to develop core competencies and education programs for Central Reprocessing Staff with MOHLTC to educate hospitals on the Provincial Infectious Diseases Advisory Committee (PIDAC) documentation on Cleaning and Sterilization and work with MEDEC and manufacturers to explore a potential partnership around education in cleaning and sterilization of specific devices.

In closing, Kutty noted that she was pleased with the findings of the SAP and that the OHA is willing to work with MEDEC to facilitate dialogue between users and manufacturers.

Device Manufacturer's Perspective in Canada

Rodney D. Parker, Ph. D.
Senior Manager, Regulatory Sciences
Stryker – Instruments Division,
MEDEC Orthopaedic Committee Member

Parker put forward that the current situation in Canada is not so different from anywhere else in the world. For example, instructions are required to be provided by the manufacturer and must be followed. Personnel performing these instructions must be properly trained. Many of the themes raised by other presenters, for example that a one-size standard will not fit all situations, are no different in Canada than elsewhere.

The players are the same everywhere and, as everywhere, the clinical users, usually surgeons and nurses, are often forgotten in the 'process' at the expense of the real benefactor of the device, the "patient."

Parker provided a historical perspective to the situation in medical device sterilization, outlining a number of reasons responsible for the current situation. Often, requests for more documentation lead to instructions being lengthy and overwhelming. The result is that manufacturers group similar instructions and, at times, the manufacturers' instructions are shortened or genericized with the intent to help the user. Also, sterilization standards are based on the science of microorganisms with the highest resistance to a given sterilization process. Further adding to the problem, single-use devices are made for simplicity for the user, but no one will throw away a \$20,000 device. Cost considerations have moved manufacturers to return to making reusable devices, but with advances in technology, newer devices are often more complex. In addition, with the emergence of Creutzfeldt-Jacob, SARS, and Avian flu, concerns of mutations and non-viable transmissions, for which sterilization may be an insufficient procedure, need to be addressed.

Today, there is a heightened awareness on cleanliness and other forms of potentially infectious agents. We can validate we are able to kill bacterial spores, but the healthcare institution seemingly has less confidence in the manufacturers' ability to establish an effective cleaning mechanism against the newer agents.

In addition to ISO 17664 and AAMI ST 81, there are also cleaning requirements such as AAMI TIR 12 and TIR 30 which are recommended guidance documents. They are based on log reductions, using countable bacteria load, being able to wash them off and say how much was removed. But what is an "acceptable" log reduction needs to be understood. Cleaning standards need to be written according to the ability of users to understand them.

Parker also suggested that the question being asked about how many times a device can be used is impossible to answer, without a definition of "use" which is not clearly defined.

How can we move forward?

Parker proposed that partnering with all stakeholders to understand the "shared responsibility" is needed to produce an effective system for patients. Training and opportunities for all stakeholders is required to gain knowledge of the needs of reprocessed equipment. Communicating issues in a constructive, reasonable and practical format that can be implemented will result in change and improvements.

Industry Perspective - Safety

Tom Frazar

*DePuy Orthopaedics Inc.,
a Johnson & Johnson Medical Products company
Director, Sterilization and Microbiology
Orthopaedic, Spinal, Sports Medicine and
Neurosurgical Medical Devices*

Safe and effective reprocessing requires a collaborative effort among all stakeholders: device manufacturers, reprocessing equipment and materials suppliers and healthcare facilities, with patient well-being and safety as the primary focus.

Advances in medical technology have resulted in increasingly complex and sophisticated instruments. As a result, more effective surgical treatment options are available that benefit patients, such as minimally invasive procedures, image guided surgery and endoscopic procedures. As a consequence, more complicated designs have added complexity to reprocessing procedures.

In addition, the emergence of new pathogens has put greater awareness on reprocessing and potential transmission of infectious agents, such as prion diseases and Creutzfeldt-Jakob Disease.

In a global economy, manufacturers make products for world wide distribution. Commonly used healthcare facility reprocessing procedures vary from region to region: manual versus automated cleaning; cleaning chemistry; and sterilization process parameters.

Reprocessing instructions should follow the requirements set forth in ISO 17664:2004 etc. The manufacturer must provide validated reprocessing instructions using processes that are available in healthcare facilities to achieve instruments that are clean, sterile and functional. But not enough is defined in terms of validation.

Striking a suitable balance between the benefits of disassembly for ease of cleaning versus the risks of handling and reassembling multiple, small components are a key issue. Operating room ease of use considerations has resulted in instruments that do not require a lot of operating room assembly.

Frazar suggested that design for reprocessing is a topic for future discussion—the balance between ease of reprocessing and cleaning versus the risks incurred by handling or mishandling tiny components. Also, defining what clean means is still left largely undefined.

Frazar then touched on the challenges of a series of other key topics, including Manual Cleaning, Automated Cleaning, Considerations for Manufacturers in Cleaning Validation, Cleaning Validation Goal, Cleanliness Attributes, Disinfection, Sterilization, Approach to Steam Sterilization Validation and Grouping of Precuts for Validation.

Frazar concluded by saying that reprocessing instructions and validation should be applicable to country regulations, reproducible in the healthcare environment, able to withstand normal cycles used in the healthcare environment, and clearly defined for the customer and readily available.

Sterilization Effectiveness

How to Verify the Effectiveness of One's Sterilizer

Sylvie Dufresne, Ph.D.

*Chief Microbiologist, TSO3
MEDEC Orthopaedic Committee Member*

Dufresne's goal was to explain sterilization effectiveness and what the user can do to verify the effectiveness of their sterilizer. The manufacturers know how their instrument should be sterilized, and the user must also participate in verifying the effectiveness of the process.

Dufresne touched on the use of steam and ethylene oxide as well as other gaseous chemical sterilants. She stated that we disinfect devices to minimize nosocomial infections and ensure patient safety. This is done through the application of regulations and standards that allow for efficient and predictable sterilization processes.

She introduced the notion of Performance Qualification (PQ), and described it as the way to verify that a sterilizer is working well (IQPQOQ in ISO standards). This requires a Quality System which does not exist in most hospitals. This is a process that helps document the evidence that the sterilizer consistently performs in accordance with predetermined criteria and yields products meeting its specification.

Dufresne also touched on physical monitors (not parametric release); biological and chemical indicators which verify adequate kill of a population of microorganisms.

Referring to routine load release and sterilizer efficiency, Dufresne reviewed comparative standards under CSA and AAMI and presented a reference table of recommendations in determining sterilizer load efficacy.

Steam	CSA: daily AAMI: weekly, preferably daily Manufacturer : AAMI
ETO	CSA: every cycle AAMI: every cycle Manufacturer: every cycle
Sterrad	CSA: no recommendation AAMI: daily, preferably every cycle Manufacturer: hospital practices, daily
Ozone 125L	CSA: no recommendation AAMI: daily, preferably every cycle Manufacturer: every cycle

Dufresne closed by providing information on how to select a biological indicator based on its D-value, and survival and kill time or dose.

Importance of Quality Systems for Hospital Reprocessing

Barbara Bolding RN, MBA
Clinical Educator

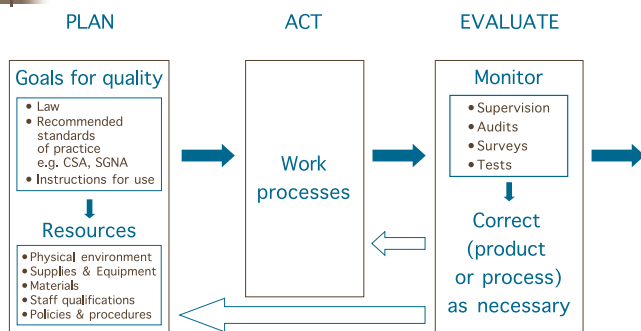
Advanced Sterilization Products, Johnson & Johnson

In her function as an educator Bolding travels to many reprocessing departments in Western Canada, and stated that her remarks would be based on her personal observations.

Bolding covered four key issues: the importance of a quality system for the Sterile Processing Department (SPD); the current state of quality systems in SPDs; some of the priorities that we need to look at; and how to improve reprocessing quality.

There are many models of quality systems. Bolding looks at what features various quality system models have in common and has found that most quality systems have three parts: planning, action and feedback. Planning includes setting goals and identifying the resources required for goal achievement. With a plan in place, work processes that are required to achieve the goals can be implemented. As work processes are completed, they must be monitored i.e. compared to the original goals. If the work outcomes do not meet the goals, adjustments are made in either the work processes themselves, or in resources or the original goals. Feedback creates a continuous loop, which includes establishing goals for quality; defining the work process and then evaluating and correcting the product or process as necessary.

1. What is a quality system?



While various reprocessing standards are used to establish quality goals, it is important to note that they are recommendations and practice guidelines and are not legislated. Nonetheless, organizations such as the Canadian Standards Association (CSA), Canadian O.R. Nurses (ORNAC) and the Society of GI Nurses (SGNA) standards, all set reprocessing that help to set goals.

A quality system is important to an SPD because we all want devices that are infection-free, functioning correctly, and for staff to be safe. The nature of SPD work is such that destructive tests cannot be used to check final product quality. Such tests would jeopardize the sterility of products. Therefore, the process that creates the final product needs to be managed. This requires the standardization that can be provided by a quality system.

The calibre of Quality Systems in SPDs in Western Canada is variable. Sterile Processing Departments in the Fraser Health Authority are probably the first in Canada to be ISO certified. At the same time, there are opportunities for practice improvements almost everywhere.

However, there are many issues that hinder quality improvements in SPD. They include:

- Knowledge and skill of reprocessing managers and the availability of such managers.
- Knowledge and skill of reprocessing staff. Certification and recertification are issues.
- Quality of reprocessing standards.
- Reprocessing environment. The area is often unknown/ignored by facility administrators. Space, equipment and supplies can be less than optimal.
- Monitoring programs are limited. While most departments have some form of supervision, formal audits, surveys and/or testing programs are rare.

Key elements in turning the current situation around include: developing qualified managers and staff, increasing SPD managers' authority and budgets, and developing mechanisms to address common reprocessing issues within regions and across Canada.

In closing, Bolding asked participants to consider whether or not there should be a national coordinator for reprocessing issues.

QUALITY SYSTEMS Healthcare Facility Perspective

Colleen Landers

Registered Nurse Consultant,

Independent Health Care and Member Scientific Advisory Panel on Reprocessing of Medical Devices

Landers defined Quality Systems (QS), and many aspects of a quality system, and looked at whether healthcare facilities have a Quality Systems, and what can be done should they not have QS.

Government officials and CEOs of institutions must be made aware of the patient risks associated with reprocessing practices. Reprocessing managers and device users must learn about the CSA standards on reprocessing. The assembly-line approach must end, and reprocessing committees must review all medical device purchases in a structured manner. More and more, appropriate equipment is needed, with a replacement plan and documented maintenance programs in place - at the time of purchase. The equipment purchased must meet CSA Z17664 standards.

Landers stated that Health Canada should examine medical device classifications, and that hospitals need to start reporting risk issues that occur with reprocessing to Health Canada. As well, device manufacturers need to provide parameters that healthcare facilities can meet in using North American sterilizers. The demand should be the same level for reprocessing of a medical device for all patients that all in the room would want in terms of safety. Landers closed with ten recommendations on what needs to change within healthcare facilities, including such things as the need to educate governments and hospital CEOs about the importance of patient risks associated with reprocessing practices and the education of managers about the CSA standards and reprocessing.

THE LEGAL PERSPECTIVE

Phil Spencer

Partner

Cassels Brock & Blackwell LLP

Spencer provided an overview of how the legal position should be considered in determining what is done with respect to cleaning and sterilization of reusable devices.

In simple terms, Spencer spoke to the main goal as being patient safety.

He specified the duties, breaches of compliance and duties of manufacturers and healthcare facilities, by reviewing a full range of instructions and standards for reprocessing reusable devices.

The healthcare facility assumes legal liability for its cleaning and sterilization of reusable medical devices. The manufacturer satisfies its obligation by providing complete and understandable instructions.

Spencer gave several instances of serious infection for which the healthcare facility assumes risk. For example, healthcare facilities have the obligation to notify patients of the potential for infection and harm; the manufacturer has no such obligation for this or the validation of hospital methods and operations.

Spencer stated that one of the biggest challenges for an investigator is the lack of proper record keeping. He urged everyone cleaning reusable devices to keep detailed and accurate records and tracking of cleaning and sterilization, including the number of times the device has been reprocessed.

His overall theme was that a healthcare facility should keep records indicating they have thought through the eventualities, recognizing the ongoing obligation to ensure risks are assumed, controlled and managed.

What happens if third-party processors take on the responsibility of cleaning reusable devices? In such cases, the healthcare facility must be able to track its devices and ensure that the manufacturer's specifications for cleaning and sterilization are met. Using a third-party reprocessor to clean and sterilize reusable devices does not create liability for the manufacturer.

The medical device manufacturer is neither responsible for the healthcare facilities operation nor staff nor their actions. Nor is it responsible to validate the hospitals cleaning and sterilization process and protocol.

Sterilization Standards A Manufacturer's Perspective CSA Standards

Tim Richardson

3M Canada Company, Technical Manager

MEDEC Orthopaedic Committee Member

Richardson shared with the group names of who are involved in writing the Standards and listed the large number of institutions which make up the CSA Standards Board, including regulators from Health Canada, professional associations, industry representatives, universities/academia, consultants and certain manufacturers. Instrument manufacturing representatives are notably absent.

CSA Sterilization Standards follow a set format and while they are not law they probably are seen as the minimum level of practice in negligence suits.

European standards are written differently. The ISO target audience is usually industry, so they are written for in engineering language for engineers, without much "user" input. CSA tries to involve more users.

CSA Standards are mostly aligned with ISO (International Standards from Europe) or AAMI (U.S.).

The CSA Standards strive to bridge the gap between what manufacturers recommend and the practical realities in institutions as a minimum level of practice to get the desired result (i.e. instruments that are properly processed - a reasonable quality assurance level).

He described parametric release which is not used in North America. In North America, an audit system is used whereby the process and challenges are looked at to detect failures, as they occur. Parametric release is based on the concept that if all of the inputs of processes are controlled, the outcome can be reliably predicted. Industrially this has proven to be a good concept. However, according to parametric release any change to a parameter requires revalidation, something that is difficult in the healthcare environment. It could work in an industrial sterilization process where it is easier to establish control over the inputs and process. But, for example, steam at hospitals cannot be controlled for input as it is often primarily used for other functions.

Load is another area where there are issues in Canada and North America, because it is extremely difficult to achieve a level of control in hospital sterilizers. In North America (as well as many other parts of the world) an audit system to monitor sterilizers is used. This is outlined clearly in the CSA Standards.

Routine, ongoing, in-process testing challenges are used to determine if a machine performs as it is supposed to do.

Richardson listed a number of CSA Standards, including typical sterilization cycles, requirements of manufacturers from whom equipment is purchased which are available, as well as standards pertaining to sterilization which can meet minimum legal standards: a combination of ISO standards, Canadian written standards and some which are morphed into Canadian standards from ISO.

In conclusion, Richardson stated that Canadian Standards provide users with guidelines for a Quality Assurance program, based mainly on manufacturer's directions and commonly available equipment. The recent proliferation of extended cycles is problematic because they cannot be monitored in the usual fashion and they do not fit with existing validated sterilization methods in hospitals.

Closing Remarks

Stephen Dibert
President & CEO
MEDEC

Stephen Dibert thanked all of the participants, as well as the MEDEC Orthopaedic Committee which sponsored the Summit. The meeting was a great opportunity for shared dialogue and information, and a positive way to foster ongoing discussions. A package of the presentations followed. As well, MEDEC will meet with a subgroup of the SAP that is currently working with the Canadian Standards Association's Sterilization Committee.

There were great discussions and many issues raised at this Summit. On an ongoing basis, MEDEC as the national association for medical devices in Canada, would be pleased to play a role in furthering those discussions, and will call on members to actively participate.

MEDEC Orthopaedic Committee Members

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 Johnson & Johnson Medical Products
 Medtronic of Canada Ltd.
 OsTek Orthopaedics Inc.
 TSO3 Inc.
 Tyco Healthcare Group Canada

Web Sources

American National Standards Institute – ANSI
www.ansi.org

Association for the Advancement of
 Medical Instrumentation - AAMI
www.aami.org

Canadian Standards Association - CSA
www.csa.ca

International Standards Organization - ISO
www.iso.org

Speakers

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