

**Therapeutic Products Directorate
Scientific Advisory Panel on Reprocessing of Medical Devices
(SAP-RMD)
October 12-13, 2006**

Record of Proceedings

Panel Members Present: Dianne Trudeau (Chair), Michelle Alfa, Janina Berenyi, Susan Hadfield, Linda Jakeman, Sudha Kutty, Sue Lafferty, Colleen Landers, Diane Pinsonneault, Cheryl Swan, Alice Wong, Timothy Zakutney

Regrets: Michael Gardam, Jean Richmond, Mary Vearncombe

Health Canada (HC) Representatives: Jean-Bernard Bitchoka, Maureen Burton, Monique Châiné, Rolande D'Amour, Andrew Gaffen, Philip Neufeld, Roland Rotter, Hripsime Shahbazian, Dongjiang Song.

Presenters: Jane Northey, Representatives of MEDEC

Day 1 Proceedings

Opening Remarks & Welcome

Members were thanked for their active contribution to this Panel. It was noted that their expertise and experience was invaluable to the success of this Panel. It was acknowledged that members have met and exceeded the expectations set out in the mandate of this Panel.

Review of the Agenda and Conflict of Interest (COI) declaration

The agenda was reviewed and accepted.

A Conflict of Interest declaration was completed and no conflicts were declared at present time.

Review of previous minutes and final approval

Minutes of the previous meeting were reviewed and accepted.

Progress report on the HC Guidance Document

Members were informed that this guidance document was the outcome of the May 15-16th Panel deliberations on the ISO 17664 document. The draft guidance document is entitled "Information to be provided by manufacturers for the reprocessing and sterilization of reusable medical devices".

Members were advised that the document has already gone through interdirectorale discussion process and will be presented to the Directorate Management Committee. After their approval, the document will be posted for public comments. Once the comment period is over, all received feedback will be considered before this document is finalized.

Should the document be accepted, there will likely be a phase-in period to allow Industry to come into compliance with the new Guidance.

Members requested that a notice be sent to them at the time of posting for public comment. The Office of Science has agreed to notify them of the posting.

Due to the voluntary nature of compliance to a guidance document, members wished to know how they could better ensure that Industry will respect this new Guidance. The Panel has requested that HC send a notice to healthcare facilities advising them of the document once it is finalized.

The draft Guidance document was reviewed by members of the Panel and they accepted the Guidance in its entirety with minor changes. These changes will be considered by the HC and revised document will be processed for approval for public consultation.¹

HC Update on the Reprocessing of Single Use Devices

Jane Northey was invited to provide an overview of a legal framework that Health Canada operates in. This introduction was offered to aid members in the understanding of the decisions made by HC with respect to the regulation of reprocessing of Single Use Devices (SUDs).

The scope of the Food and Drugs Act and Regulations that govern Health Canada was provided. It was explained that the definition of “sale” within the Act, does not permit HC to regulate the reprocessing of Single Use Devices. It was noted that the Food and Drugs Act deals with activities of manufacturers, importers and vendors relating to the sale of the product; it does not regulate activities of the purchaser. Changes in regulations would be required in order to allow HC to regulate the reprocessing of Single Use Devices.

Members expressed their concerns regarding the issue related to leased or loaned equipment. It was agreed that this is a different issue that needs to be addressed separately. Members recommended that HC request a legal opinion on this matter.

¹ The draft document has been posted for public comment on December 4, 2006.

In Summary:

The current Act and Regulations do not give HC the authority to regulate reuse. The HC policy direction now is to pursue this through other means than regulatory; i.e., through provincial counterparts.

Members felt that this is a national issue and HC needs to explore alternatives for regulating the reuse of single-use medical devices. Members were informed that HC is planning to work with the Deputy Ministers of Health and based on their recommendation it is possible that this issue may return to the Federal agenda and at that time they will look at the various options, one of which could be a recommendation to amend the regulations in order to allow regulation of the reprocessing of SUDs.

Members stated that the Provinces are waiting for a national directive regarding this issue. They agreed that if there is strong Provincial support through Deputy Ministers of Health this will raise the importance of finding a national solution to this issue.

Members felt that since this issue was identified in the Auditor General's report, the Panel would like to report back on its recommendations regarding this issue. Members agreed that a letter should be sent to DG on behalf of the Panel to ensure that this issue is looked at.

Panel members agreed that there is a need for their active participation to heighten the interest of Provincial authorities in this regard.

Review of Manufacturer Instructions

Linda Jakeman presented a summary of identified issues based on review of sample instructions compiled by the members. The presentation is available upon request.

In general it was noted that manufacturers' instructions are often incomplete, generic or non-existent. Cleaning and maintenance instructions are poor. Some devices require servicing by the manufacturer. However, often this information is not provided to the user.

Another concern is that the manufacturer usually does not provide means to track devices that are designed for a limited number of uses. These devices often fail before the number of recommended uses.

It was stated that the lack of appropriate and adequate cleaning instructions can lead to adverse reactions. (e.g. Patient reactions to cleaning agents residues)

In some cases European instructions for sterilization are provided for the North American market. The number of different sterilization times and temperatures recommended by device manufacturers is growing daily. Often different cycles are required with no

rationale provided by the manufacturer. Users need to be aware that change in parameters must be done in consultation with the manufacturer of the sterilizer.

The following recommendations were provided to address these concerns:

- Manufacturers should provide clearly legible instructions for disassembly, cleaning, disinfection, assembly and sterilizing, that are specific to the device in question, where appropriate. These instructions should include schematics. Generic instructions are not sufficient.
- Manufacturers should inform users of the maximum recommended number of reprocessing times for implants (i.e. screws, plates) – and an indication to enable users to identify when replacement is required.
- Manufacturers should provide appropriate cleaning tools needed for proper processing of a device. Manufacturers should also be able to validate all cleaning and sterilization instructions regardless of the Medical Device Class. When these instructions are updated or changed, these new procedures should be communicated to the current users in a systematic documented manner.
- Manufacturer should provide means to facilitate tracking of limited use devices during reprocessing to ensure that use does not exceed lifespan. This requires a unique identifier for each medical device to which this applies and a method to track their use and functionality.
- The manufacturer or vendor should provide comprehensive in-service training for the OR and Sterile Reprocessing staff for newly introduced complex medical devices entering the health care facility. Manufacturer must ensure that the individual providing training is competent and had previously been trained in correct procedures.
- HC should review the cleaning and sterilizing instructions to ensure they are adequate and appropriate.

After the presentation some discussion ensued. Members indicated concerns regarding the commonly used biological and chemical indicators. Members noted that sterilization validation by users should not be a substitute for requirement that manufacturers provide/create appropriate process challenge packs to verify sterility of sets.

However, it was agreed that they need to follow manufacturers' instructions until new ones are provided. It was noted that Chemical Indicators (CI) should not be used in lieu of Biological Indicators (BI).

Issues with Extended Sterilization Cycles

Susan Lafferty described the issues. The presentation is available upon request.

The presentation recapped the main issues with respect to extended sterilization cycles. It was noted that up to 10 different extended cycle times greater than standard hospital cycles are now being recommended by various device manufacturers (e.g. Range of 5 to 40 minutes).

It was noted that large sterilizers are designed to accommodate loads of multiple devices with similar requirements for sterilization. To accommodate extended cycles, changing of settings on sterilizer equipment for each load can lead to human error resulting in the wrong cycle being selected, when one is required to change cycles multiple times. It was stated that packaging for containment of devices or sets (e.g. reusable and single use wraps, pouches, rigid containers and their filters) has not been validated for use in extended cycles.

Currently, marketed biological and chemical process indicators are not designed or validated for every extended cycle. There is a need to develop BIs and CIs in an appropriate challenge “Test Pack” specific to each extended cycle. A BI (or CI) in a test pack that has been validated for a standard hospital cycle (e.g. 4 min @ 135°C) cannot be used to monitor an extended cycle (e.g. 18 min @ 132°C).

It was noted that it is difficult to obtain a rationale or validation from the device manufacturer supporting the need for an extended cycle.

To address these issues and concerns the Panel recommends to:

- Standardize to a minimum number of cycles e.g. one extended cycle, the length of time to be determined, in addition to the 3 or 4 minute cycle routinely used to allow BI and CI manufacturers to develop products specific to these cycles to decrease likelihood of human error to increase productivity to decrease likelihood of sterilization failure
- When a device manufacturer develops extended cycle recommendations, the type of appropriate packaging to be used *for the extended cycle* (reusable or single use wrappers, rigid containers or pouches) should be included in the validation process. Packaging manufacturers should validate their products for extended cycle times.
- Device manufacturers must work together with sterilizer manufacturers to ensure that the recommended extended cycle meets capabilities of the sterilizer, the packaging, and process monitors to be used.

Members noted that health care centres across Canada seem to have different policies with respect to extended cycles. It was agreed that where possible, there should be an effort to harmonize these policies.

It was stated that there are no specific standards at this time to address this issue. Members stated that this issue was discussed at a CSA meeting and it was agreed that there is a need for an extended cycle standard. It was noted that extended cycles are not covered by AAMI either. Members agreed that international harmonization would be needed.

Members agreed that such settings should be determined by the various Standards Associations. However, in the interim, perhaps the manufacturers could provide one or two validated extended cycles with their instructions to minimise error.

It was noted that there is a need to break down device sets into manageable sections. It was agreed that health care professionals need to work with manufacturers to recommend set cycles. They need to work with both the sterilizer companies and medical device companies to achieve the needed result.

Issues With Loaned and Leased Instrument Sets

Issues were presented by Susan Hadfield. The presentation is available upon request.

Examples of such devices were provided. The main issues with respect to leased and loaned equipment were described. It was noted that some of these devices have no medical device license. These complex multi-component sets usually arrive on request of a surgical team with no content list, no validated reprocessing instructions and no schematics.

It was noted that some sets do not arrive in time to allow for safe reprocessing. Containers used for these sets are frequently overfilled, multi layered and overweight. Vendors of consignment sets do not supply an adequate inventory to allow for safe reprocessing between procedures. In some cases these sets arrive at the health care facility soiled.

The life cycle of certain implants (i.e screws and plates), metal fatigue, has not been determined by the manufacturer. These implants are subjected to the rigours of repeated reprocessing (such as metal fatigue) for years and there is no tracking mechanism to monitor repeated use.

Panel recommends that:

- Health Canada inform distributors of loaned and consignment sets that a medical device license is required. The manufacturer or distributor should be required to supply sterilization validation for modular sets and validated instructions must be specific to the set.

- Every loaned or shared device should be accompanied by an inventory list, instructions for use and validated written instructions for reprocessing or routine maintenance and be traceable as described in CSA Z314.22-04, *Management of loaned, shared and leased devices*. Z314.15-03, *Warehousing, Storage and Transportation of Clean and Sterile Medical Devices* should be followed for proper handling of the device.

Panel members would like to request that manufacturers provide appropriate training to OR & SPD staff for the new loaned sets to ensure proper handling of the sets.

It was suggested that the HC develop a Guidance to ensure that the issue of loaned or leased equipment is addressed for all classes of devices.

Reprocessing Issues with Reusable Medical Devices - Discussion With Manufacturers

Michelle Alfa presented the list of issues compiled by the Panel and which are appended to this record. MEDEC representatives provided their views and recommendations on these issues. Presentations are available upon request.

It was stated that some of the current challenges include the complexity of device design, availability of the manufacturer's validated cleaning instructions and the competence of reprocessing personnel. For proper handling of devices the users require:

- Medical device specific instructions for reprocessing
- Compliance with ISO 17664: requirement regarding validated cleaning methods
- Compliance with ISO 17664-06: requirement on rationale for non-standard cycles
- BIs & CIs for monitoring extended steam sterilization cycle
- Manufacturer recommendation of cleaning detergents that have been validated
- Break down of Instrument sets with excessive weight & mass
- Solution to the "sterile crud" Issue
- Solution to container issues
- Solution to issues about loaner and specialty equipment sets
- Proper tracking means for single use and limited use medical devices
- Appropriate manufacturer in-service training
- Improved manufacturer-user communication

MEDEC agreed that proper cleaning and sterilization of reusable devices in Canadian healthcare facilities is critical in preventing patient and healthcare worker exposure to infectious agents. Communication and implementation of the manufacturers' validated processes should be optimized with a view to developing best practice solutions that ensure patient safety.

Cleaning and sterilization of reusable devices is a shared responsibility between manufacturers and healthcare facilities. Manufacturers must provide instructions for reprocessing. Hospitals should ensure adequate training for reprocessing staff and the development and implementation of a reprocessing protocol.

Manufacturers must provide clear and accurate instructions that explain proper reprocessing procedures for reusable devices and any relevant standards that may be applicable.

Healthcare facilities that reprocess reusable medical devices should ensure those devices are reprocessed according to the manufacturers' recommended procedures. They should implement reprocessing protocols that ensure personnel are trained and knowledgeable on all relevant procedures recommended by the various manufacturers of the reusable devices. Healthcare facilities should validate their ability to meet manufacturers' specified cleaning and sterilization parameters for reusable devices.

One standard sterilization parameter for all reusable devices is neither practical nor sustainable. It is important that healthcare facilities recognize the variation among devices, and that a "one process fits all" approach will not work and may in fact place patients at increased risk. All devices should be sterilized according to manufacturers' specifications for the safest possible outcomes.

MEDEC agrees that in order to address these issues they would require participation and cooperation of all stakeholders. Industry continues to be interested in participating and co-operating to develop collaborative solutions to address these issues.

Panel members and MEDEC representatives shared similar views on medical device reprocessing problems. They felt that much could be done with the proper venue for discussion. The need for a venue in which to have constructive dialogue between manufacturers and users is critical. However, all agreed that there is a need for better definition and prioritization of these issues. Creating generic topics of discussion was considered to be the best approach, as it will be easier to bring manufacturers of a particular group of devices together to discuss specific issues. A prioritised list of issues would be a good start. CSA's involvement was also felt to be important although members recognised that these discussions do not necessarily fall within their purview. It would be best if they were kept informed.

Members of the Panel will work with MEDEC to facilitate future manufacturer-user discussions.

MEDEC representatives left the meeting.

The chair reviewed the items discussed and listed the action items:

- The introduction to the Table needs to be finalized, together with Michelle's presentation and to be shared with MEDEC- Michelle Alfa, Colleen Landers and Sue Lafferty were assigned to this task.
- A recommendation will be prepared by Michelle Alfa, Sudha Kutty and Colleen Landers to suggest possible approaches for a forum.
- The Table sub-group will arrive at 8:00am to continue work on a Table in order to complete the review. The rest of the members will join in at 10:00am.

DAY 2 PROCEEDINGS

Review of the Agenda

The agenda was reviewed and accepted with some minor changes. The regularly scheduled items were delayed in order to permit the completion of the table.

The Table sub-group met in the morning to complete the review of the Table. Members agreed to combine similar items, and ensure consistency when describing issues and making recommendations to address those issues.

Three of the Table sub-group members worked on completion of the introduction to the Table.

The revised documents were presented to the Panel for discussion and comments. All comments regarding the introduction were captured by Sue Lafferty to be incorporated in a revised document.

Progress Report on Mandate #2

The chair advised all members of the SAP that the final draft of the Table entitled "Reusable Medical Devices: Reprocessing Concerns and Scientific Advisory Panel Recommendations." has been completed. This Table contains an extensive listing of specific reusable medical device groups that are currently being used in Canada that were deemed to have unique reprocessing concerns (i.e. difficult to clean and/or sterilize despite compliance with manufacturers' recommended protocols). This table contains recommendations to both Health Canada and the healthcare facilities as to how to address these concerns.

The introduction document that was created by the Table sub-group members will be added to the beginning of this table. It also includes a list of recommendations on a number of general issues that have been identified by the Panel. A separate document entitled "Summary of Issues and Recommendations Presented to MEDEC" includes a list of issues that the Panel members feel need to be addressed by medical device

manufacturers or distributors who provide products to the Canadian market. These issues have been summarized in a tabular form and will be posted to the HC website at

Members agreed that the set of reference binders containing sample instructions for devices would be sent to Linda Jakeman for verification. The verified binders will be returned to HC and copies of these binders will be provided to the MDB and the Inspectorate in order to aid them in their review of the recommendations and plan for any follow-up action as necessary.

An Index page was created by the Table sub-group listing various publications referenced in the Table. This page will be verified by the members and added to the back of the Table. Members agreed that the Table needs to be formatted and verified for consistency to be considered final and ready for posting. It was agreed that one or two more teleconferences would be needed to complete the work on the Table and finalize all documents prepared by the Panel in order to complete its mandate. Members were tasked to review all documents and return comments to HC. Once completed, these documents will be posted and the web-links will be provided to the members.

The current problems encountered by users in reprocessing reusable medical devices and potential solutions to these problems

The chair of the Panel provided an overview of Panel achievements. The presentation is available upon request.

She presented a summary of all recommendations made by the Panel to date. For a complete list of Panel recommendations please refer to Appendix 1.

The chair stressed the importance of an ongoing dialogue between MEDEC and healthcare representatives to ensure that the issues related to medical device reprocessing and the role of Industry are addressed. She suggested establishment of a small working group that includes representatives of the SAP-RMD, and representatives of MEDEC and CSA, to facilitate planning of the initial meeting to establish the format for an ongoing dialogue.

She noted the importance of communication with all interested stakeholders, including healthcare providers, MEDEC, CSA, Health Canada, related professional organizations, and the CMA (surgeons in particular).

Closing remarks

The achievements of the Panel were applauded. Members of the Panel were thanked for their time and their efforts in this important project. Their contributions have been recognised and their work has been invaluable. The Chair thanked HC for the opportunity to bring these important issues to light.

Meeting adjourned