Manufacturer/Distributor Reprocessing Information

Related IPC Standard:	Cleaning, Disinfection, and Sterilization of Reusable Medical Devices for all Health Care Facilities and Settings, January 16, 2008, Standard 4.4.1, 4.4.2, page 12.
Purpose:	It is the responsibility of manufacturers/distributors to provide written instructions for the use and reprocessing of reusable medical devices. This information sheet provides guidance for what to do if there are concerns about the manufacturer's instructions for use or reprocessing, or about the validity of the information provided by the manufacturer.
Primary Audience:	Reprocessors and/or end users of medical devices
Secondary Audience:	IPC professionals and Medical Officers of Health

What validation information should the manufacturer or distributor of the medical devices provide?

- Upon request by the purchaser of the medical device, the manufacturer or distributor should provide, in addition to the parameters in standard 4.41 and 4.4.2:
    - Names of suppliers of equipment, tools, cleaning agents, disinfectants, sterilants or other products suitable for use in reprocessing and testing of the medical device;
    - Information (validation data) that confirms that the medical device in question will be clean and sterile when reprocessed as directed;
    - Information (validation data) for sterilizing the medical device while in its container, if the medical device is sold in a container in which it is to be sterilized[1].

What steps can be taken if a health care provider continues to have concerns about the information the manufacturer or distributor has provided?

- The health care provider should write to the manufacturer requesting a declaration to confirm that the manufacturer's recommended process for cleaning and sterilizing the medical device will yield consistent results.

- If the health care provider does not receive a satisfactory response, a complaint may be filed on the Health Canada hot line at 1 800 267-9675. A Health Canada inspector will follow up on the reported issue. Health Canada assesses adequacy of instructions for use based on the document referenced below[1]. In the case of complaints, Health Canada will enforce the Safety and Effectiveness and labelling requirements of the *Medical Devices Regulations*.

- In the interest of communication and coordination, the health care provider is asked to notify Alberta Health and Wellness if a complaint is filed with Health Canada. Please send e-mail notification to Bernice.Heinrichs@gov.ab.ca or Barb.Hansen@gov.ab.ca.

- In the interim, if there are concerns about manufacturer's instructions or validation information, do not reprocess the device, do not use devices reprocessed using the instructions in question and consider using single-use alternatives.

[1] Health Canada (2006) Draft Guidance Document – Information to be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices, 2.3.2.