

Alert: Improper Reprocessing of Transvaginal Ultrasound Probes

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The Saskatchewan Infection Prevention and Control Program were alerted to breaches in the reprocessing of transvaginal ultrasound probes through a recent Accreditation Canada survey. Reprocessing of transvaginal ultrasound probes requires appropriate cleaning followed by high-level disinfection according to the manufacturer's instructions. Improper reprocessing of medical devices/equipment is a patient safety issue that places patients at increased risk for infection. At this time, RHAs are encouraged to review their health regions' procedures for reprocessing transvaginal ultrasound probes to ensure they are meeting Accreditation Canada and the Canadian Standards Association (CSA) standards for reprocessing and to ensure they are performing all necessary steps required for appropriate reprocessing of medical devices/equipment.

Please review the following standards and use them as a reference when evaluating your health region's procedures for reprocessing transvaginal ultrasound probes:

- CSA Standard Z314.0 Medical device reprocessing – General requirements
- CSA Standard Z314.8 Decontamination of reusable medical devices
- CSA-Z17664 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- Accreditation Canada Diagnostic Imaging Services Qmentum Standards, 2014

Highlighted below are three main areas of concern, with reference to the corresponding CSA standard and corrective action options, if deficient in any of these areas.

1. Procedures for cleaning/disinfection:

- According to *CSA Z314.0 Clause 5.3.1 Manufacturer's instructions*, "the healthcare setting shall obtain device-specific manufacturer's instructions for reprocessing. They shall be received in printed form (e.g., in binders, manuals, or monographs) or in electronic format, so as to facilitate device maintenance, as well as personnel training and education. The manufacturer information or manufacturer's instructions shall be placed in a location where they are readily accessible to those needing access, and they shall be updated as required.

Options:

- Contact the vendor rep and request appropriate reprocessing instruction for ultrasound probes as indicated above;
- Ensure instructions received by the manufacturer meet requirements outlined in *CSA-Z17664 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*; and
- Ensure that instructions provided by the manufacturer are reviewed regularly and are clearly posted for all personnel reprocessing ultrasound probes.

2. Education and Training for Personnel:

- According to *CSA Z314.8 Clause 12.2.1 Education and Training*, “ultrasound transducer probes shall only be handled and reprocessed by personnel who are qualified by education, training, and demonstrated competency and experience for each of the tasks they perform. Personnel who have not been fully trained or who have not demonstrated ongoing competency shall not reprocess transducer probes.”
- Further to this, according to *CSA Z314.0 Clause 6.2.2 Reprocessing personnel*, “all personnel involved in reprocessing medical devices shall be prepared for the functions that they perform through appropriate education and training in a formal medical device reprocessing program recognized by the healthcare setting.”

Options:

- If the health region has not recommended a training program for diagnostic imaging personnel, the RHA may contact the vendor and request on-site training.
- If training and education is provided by the vendor, ensure that all of the training requirements indicated in *CSA Z314.0 Clause 6.3.2* are incorporated into the training program. Maintain all records of training and continuing education.

3. Competency Assessment for Personnel:

- According to *CSA Z314.0 Clause 6.4 Competency assessment*, “ongoing competency assessment shall be performed and documented as stated in the quality plan. Competency review (content and frequency) shall be based on a risk assessment.” Furthermore to this, *CSA Z314.8 Clause 12.2.2.2 Qualification of personnel*, “following training, personnel shall be competency tested and the results documented before they begin their duties. Competency testing shall be performed at regular intervals as defined by the healthcare facility.”

Options:

- Develop policies and procedures related to training, education, and competency checklists for all diagnostic imaging personnel reprocessing ultrasound probes. Ensure these policies include the frequency of training and documentation of such training.
- Refer to *CSA Z314.0 Clause F6* for examples of competency checklists.