

Disposal of Medical Devices

OVERVIEW OF ISSUE

Hospitals routinely dispose of medical devices, from single-use devices to obsolete equipment. Improper disposal of devices, whether by a hospital or its third-party contractor, could lead to liability exposure and/or regulatory scrutiny. This risk note highlights some of the risks associated with the disposal of devices, as well as some risk mitigation strategies.

THINGS TO CONSIDER

The Environment

- As one example, sharps wastes can be considered pathological waste under the Waste Management Regulation made under the Environmental Protection Act. This Regulation deems pathological waste to be hazardous, and it contains requirements for the registration and manifesting of pathological waste generated by hospitals. Hospitals generating such waste must pack and mark it to meet the transport requirements of the Transportation of Dangerous Goods Act (Canada). Also, hospitals should conduct due diligence before retaining third-party contractors to dispose of pathological waste to ensure they comply with the legal requirements for disposal. Hospitals might be exposed to regulatory scrutiny and statutory liability if they or their third-party contractors fail to adhere to the regulatory requirements for proper disposal of pathological waste. For example, the Ministry of the Environment can issue an order that waste disposed of in an unapproved site be removed and that the site be restored. The order can be issued to “an owner or previous owner or a person who otherwise has or had charge and control of the land or building or waste”. Although hospitals cannot contract out of statutory liability, contractual terms may be used to mitigate the impacts.

KEY POINTS

Regulatory Risk

- Some devices might be contaminated with biological, chemical or other hazardous materials. Disposal of such devices must comply with environmental laws that govern the discharge of contaminants into the natural environment.
- Some devices can be considered workplace hazards. Disposal of such devices must comply with occupational health and safety laws that govern workplace safety.
- Some devices might store patients' personal health information. Disposal of such devices must comply with health privacy laws.
- Some devices might have radioactive components. Disposal of such devices must comply with the unique legislative regime governing such devices.

Litigation Risk

- Patients, employees, professional staff, contractors, volunteers, visitors or others might initiate legal action for any harm suffered from the improper disposal of devices.

Risk Management Strategies

- Follow the manufacturer's instructions for the decommissioning and disposal of devices.
- Ensure compliance with the laws, regulations and guidelines relating to the specific device.
- Ensure that personal health information is removed or deleted.
- Conduct due diligence when engaging third-party contractors to dispose of devices.
- Incorporate terms in agreements with third-party contractors who are engaged to dispose of devices (such as representations and warranties, and indemnification and insurance provisions) to mitigate risks.

Disposal of Medical Devices

Workplace Safety

- The Health Care and Residential Facilities Regulation made under the Occupational Health and Safety Act sets out requirements for handling many types of hazardous materials found in healthcare facilities. Hospitals' workplace safety obligations extend to third-party contractors. This means that a hospital cannot contract out of its health and safety obligations to waste disposal contractors relying on their specific expertise in the area. Mishandling of hazardous materials by a hospital employee or by a waste disposal contractor might expose the hospital to regulatory scrutiny and statutory liability. A successful prosecution could lead to significant fines.

Sterilization, Cleaning and Disinfection Before Disposal

- For guidance on sterilizing, cleaning, and disinfecting devices that require such treatment before disposal, refer to the best practices published by Ontario's Provincial Infectious Diseases Advisory Committee (PIDAC).

Radiology Equipment

- Radiology equipment is governed by a complex regulatory regime. Briefly, when radiology equipment is to be disposed of, communication with the manufacturer or supplier should be made about whether the equipment or its components can be recycled or returned. Once a decision has been made to dispose of the device, an assessment must be made to determine if any equipment components contain hazardous materials. For example, the X-ray systems high voltage transformer(s) might contain polychlorinated biphenyls (PCBs) and lead might be present in the X-ray tube or other shielding. To ensure equipment is not unsafely operated after disposal, it should be made inoperable before disposal. The cables that power the equipment and other electrical connections should be disconnected and removed.

Patient Privacy

- Before disposing of a device that captures personal health information in its software, the hospital should contact the manufacturer or supplier on how to ensure that all personal health information and other data is removed or deleted.

Contractor Due Diligence and Agreement Terms

- Hospitals might retain the services of third-party contractors to dispose of devices. These contractors range from general waste disposal contractors to specialized individuals with specific expertise, such as biomedical technologists or a radiation technician. Agreements with such contractors should contain representation and warranties as to their expertise, and covenants that they will comply with applicable laws, regulations and guidelines. There should also be robust limitation of liability, indemnification and insurance provisions favouring the hospital in the event of adverse outcomes.
- However, even the most stringent contractual protections might not insulate hospitals from regulatory scrutiny and statutory liability, which may be imposed notwithstanding the fact that any non-compliance was committed by a contractor. Risk can be mitigated by a proper contractor diligence program. A contractor diligence program that a court or regulatory authority would find proper and sufficient should: reflect knowledge of the legal requirements as applicable to the specific devices to be disposed of; have in place a pre-qualification assessment that inquires into a contractor's policies, practices, capacities and track record (in that regard, a generalized questionnaire may not be sufficient); continuously monitor contractors to ensure ongoing compliance; and establish channels of communication and coordination of work.
- If any impropriety is uncovered by due diligence, a hospital might consider alerting regulatory authorities. If done in a responsible and discrete manner, in a way that does not breach any contractual obligations of confidentiality owed by the hospital, such whistleblowing could be a defense or a mitigating factor to civil or regulatory liability.

Disposal of Medical Devices



REFERENCES

- Environmental Protection Act, Revised Statutes of Canada. (1990, c. E-19).
- General – Waste Management, R.R.O. (1990). Regulation 347.
- Health Canada (2008). Safety Code 35: Safety procedures for the installation, use and control of x-ray equipment in large medical radiological facilities.
- Health Care and Residential Facilities. (1990). Ontario Regulation 67/93.
- Occupational Health and Safety Act, Revised Statutes of Canada. (1990, c. O.1).
- Provincial Infectious Diseases Advisory Committee (PIDAC). (2013). Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings (3rd ed.). *Public Health Ontario*.