



NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES
ACCREDITATION PROGRAM

Accreditation Standards

Equipment Management



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INTRODUCTION

All new, used and refurbished surgical, anesthesia, patient care and medical device reprocessing equipment and accessories must conform to the requirements of Health Canada and the Canadian Standards Association and it is the responsibility of the medical director to ensure that all equipment in the non-hospital facility meets these requirements.

Note: Laser and X-ray equipment requirements are addressed in their respective accreditation standards.

NHEQM1.0 EQUIPMENT MANAGEMENT

NHEQM1.1 Equipment is safely operated, maintained and monitored in a manner than ensures performance specifications are met.	
NHEQM1.1.1	<p>M There is a current inventory list of all medical and patient care equipment. <i>Guidance: The non-hospital facility maintains a current list of all medical equipment. This includes equipment owned by the facility as well as leased equipment, loaner, demo and physician-owned equipment. Equipment means instruments/devices/tools with mechanical and/or electrical components used in the diagnosis, monitoring or treatment of patients. The equipment inventory list includes the name of the item, manufacturer, serial number or other identifier, date of installation (date put into active service), condition of the equipment at the time it was acquired (e.g. new, refurbished). Examples include but are not limited to electrocautery units, anesthetic machines and monitors, tourniquets, electronic medical monitors (blood pressure, cardiac monitors), intravenous pumps, specialized surgical equipment (cameras, light cords, insufflators), scopes, reprocessing equipment, lasers, imaging equipment (ultrasound, x-ray), medical beds including stretchers and operating room tables, suction.</i></p>
NHEQM1.1.2	<p>M Equipment manufacturer's operator manuals are available for reference. <i>Guidance: A manual from the manufacturer that has installation (where appropriate), operation and maintenance instructions is available for each piece of medical and patient care equipment in the facility.</i></p>

NHEQM1.1.3	M	<p>Staff receive training in the use of equipment appropriate to their role/duties.</p> <p><i>Guidance: Staff may receive education and training of medical and patient care equipment through initial and refresher in-services, from the equipment user instruction manual and by other staff who have been trained on the proper use of the equipment (e.g. nurse demonstrates for new staff nurse how to work the patient monitor). The responsibility for ensuring that staff is appropriately trained in the use of equipment, appropriate to their role/duties, is that of the medical director. This training should be documented; for example the Canadian Anesthesiologists' Society Guidelines to the Practice of Anesthesia (2017) state that training on the safe use of all anesthesia equipment should be provided to all anesthesia department members prior to use and that training session attendance should be documented.</i></p>
NHEQM1.1.4	M	<p>Acceptance testing is performed on all equipment before initial use and after major repairs or upgrades.</p> <p><i>Guidance: All medical and patient care equipment with mechanical and/or electrical components, whether facility-owned, leased, loaner, demo or physician-owned, must be tested to ensure that the equipment is complete, safe and functioning properly before being used at the facility for the first time for patient care. This is referred to as acceptance testing and is performed by the manufacturer or a qualified biomedical technician when the equipment is received by the facility. Safety, operational and functional checks are also performed after major repairs or upgrades of medical equipment. Depending on the equipment the acceptance testing/inspection/check may also include set-up and calibration. Documentation of these acceptance tests/inspections/checks are on file for each piece of medical and patient care equipment. Examples include but are not limited to electrocautery units, anesthetic machines and monitors, tourniquets, electronic medical monitors (blood pressure, cardiac monitors), intravenous pumps, specialized surgical equipment (hand pieces, light cords, insufflators), lasers, imaging equipment (ultrasound, x-ray), medical beds including stretchers and operating room tables, suction.</i></p>
NHEQM1.1.5	M	<p>Preventative maintenance is performed on all equipment in accordance with the manufacturer's instructions for use.</p> <p><i>Guidance: All medical and patient care equipment receives scheduled preventative maintenance. The preventative maintenance activities and frequency of maintenance activities are completed as specified by the manufacturer's instructions for use. The medical director must ensure that the equipment is serviced in accordance with the manufacturer's instructions for use. Relying on vendor opinion for equipment maintenance does not satisfy this requirement.</i></p>
NHEQM1.1.6	M	<p>Preventative maintenance and repair of equipment is performed by a qualified biomedical technician or the manufacturer.</p> <p><i>Guidance: The facility medical director is responsible for ensuring that the manufacturer vendor or technician testing/inspecting/checking, repairing or performing preventative maintenance on medical and patient care equipment is appropriately qualified.</i></p>
NHEQM1.1.7	M	<p>Preventative maintenance and repair records are maintained for all equipment.</p> <p><i>Guidance: Preventative maintenance and repair records document the name of the item, manufacturer, serial number or other identifier, description of the preventative maintenance or repair activities performed, date maintenance or repair performed, name of the technician and company performing the maintenance or repair. These records are retained for a minimum period of sixteen years from the date the equipment was removed from services.</i></p>

NHEQM1.1.8	M	Biomedical inspection of anesthetic machines is performed annually or more frequently as required by the manufacturer. <i>Guidance: Safety, operational and functional checks are performed in accordance with the manufacturer's instructions annually, at a minimum, or more frequently as required by the manufacturer. These checks are performed by the manufacturer (vendor) or a qualified biomedical technician and documentation is on file.</i>
NHEQM1.1.9	M	Biomedical inspection of anesthetic monitors is performed annually or more frequently as required by the manufacturer. <i>Guidance: Safety, operational and functional checks are performed in accordance with the manufacturer's instructions annually, at a minimum, or more frequently as required by the manufacturer. These checks are performed by the manufacturer (vendor) or a qualified biomedical technician and documentation is on file.</i>
NHEQM1.1.10	M	Biomedical inspection of the defibrillator/automated external defibrillator is performed annually. <i>Guidance: A safety, operational and functional check is performed annually, at a minimum, by the manufacturer or a qualified biomedical technician and documentation is on file.</i>
NHEQM1.1.11	M	Biomedical inspection of patient monitoring equipment is performed annually. <i>Guidance: A safety, operational and functional check is performed annually, at a minimum, by the manufacturer or a qualified biomedical technician and documentation is on file. Examples of patient monitoring equipment include cardiac monitors, non-invasive blood pressure monitors, pulse oximetry monitors, nerve stimulators.</i>
NHEQM1.1.12	M	Biomedical inspection of medical equipment is performed annually. <i>Guidance: Preventative maintenance is performed annually, at a minimum, by the manufacturer or a qualified biomedical technician and documentation is on file. Examples of medical equipment include electro-cautery units, laparoscopic light sources, insufflators, phacoemulsification machines, microscopes, tourniquets, suction equipment, laser equipment, infusion pumps, diagnostic imaging equipment (ultrasound, X-ray), operating room/procedure room tables, electrically operated beds/chairs.</i>
NHEQM1.2		Facility personnel investigate and resolve problems involving all equipment.
NHEQM1.2.1	M	Equipment that is not functioning properly or poses a safety risk is clearly labeled and removed from service. <i>Guidance: There is a process for managing equipment that is not functioning properly or poses a safety risk. This process includes reporting the equipment problem to the facility leadership as well as clearly labeling and removing the equipment from service while awaiting repair or disposal. Equipment awaiting repair or disposal is stored in a separate area away from equipment that is good-working order. Equipment problems/incidents that reach the patient, both no harm and harm events, are reported to the College in accordance with the bylaws for patient safety incidents.</i>

NHEQM1.2.2	M	<p>A regulated health professional is responsible for monitoring and managing equipment recalls and safety advisories</p> <p><i>Guidance: A named regulated health professional is responsible for regularly reviewing health alert networks as part of the facility's quality monitoring and risk management processes. Health alert networks include the Canadian Agency for Drugs and Technologies in Health (CADTH), Canadian Patient Safety Institute Global Patient Safety Alerts, the Institute for Safe Medication Practices Canada (ISMP Canada), Health Canada's MedEffect™. When a health alert networks review is conducted, the date, name, signature and title (e.g. MD, RN) of the regulated health professional completing the review and the action taken is documented in a log. Facility leadership is notified when there is a recall or safety advisory involving equipment or medication which is in use at the facility and actions taken as a result of the recall or safety advisory (http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index-eng.php). If no action is needed and/or the alert is not applicable to the facility then no action needed or not applicable is documented in the log for the review.</i></p>
NHEQM1.2.3	M	<p>There is a process to manage and prioritize the replacement or upgrade of medical and patient care equipment.</p> <p><i>Guidance: Eventually all medical and patient care equipment needs to be replaced as a result of wear and tear, technological progress, changes in clinical practice or end of manufacturer support. Facility equipment needs are to be reviewed annually and equipment replaced or upgraded as necessary. The facility equipment review process is documented and should include the following considerations: the age of the equipment, availability of parts and/or technical support, reliability of the equipment (frequency of service interruption), clinical obsolescence, type of equipment (critical-life sustaining, non-critical) and the impact of not replacing the equipment.</i></p>
<p>NHEQM1.3 Policies and procedures contain all the information necessary for the safety of patients, staff and visitors.</p> <p><i>Intent: Policies and procedures ensure that activities/procedures are performed consistently and accurately by all personnel within the non-hospital facility.</i></p>		
NHEQM1.3.1	M	<p>There is policy and procedures for the management and maintenance of equipment.</p>
NEHQM1.3.2	M	<p>There is policy and procedures for the investigation and resolution of equipment performance issues.</p>



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