COLLEGE OF PHYSICIANS AND SURGEONS OF BRITISH COLUMBIA

Diagnostic Accreditation Program

ACCREDITATION STANDARDS

Equipment and Supplies

Diagnostic Accreditation Program
College of Physicians and Surgeons of British Columbia
300–669 Howe Street
Vancouver BC V6C 0B4

Introduction

Medical imaging equipment and supplies are appropriately operated, validated for clinical use with acceptance testing, maintained with robust quality assurance procedures and have the specifications required for safe and quality patient care. For specific acceptance testing and quality control testing requirements, please refer to the modality standards chapters.

Equipment operation

No.		Description	Risk	Reference	Change
DES1.0		**EQUIPMENT IS SAFELY OPERATED, AND MAINTAINED AND MONITORED IN A MANNER THAT ENSURES PERFORMANCE SPECIFICATIONS ARE MET.**			
DES1.1		**There is a current inventory log for all medical imaging systems and ancillary equipment.** *Guidance: Medical imaging systems include all primary systems and any acquisition accessories (i.e. probes, DR detectors). Ancillary equipment refers to any key equipment utilized in the imaging chain that is not an expendable or a supply (i.e. digitizers, fixed hot lab equipment, probe HLD system, displays).*			
DES1.1.1	**M**	The medical imaging systems/ancillary equipment inventory log includes the name.	L	Equip-QA-RPS-AC-23	Revised
DES1.1.2	**M**	The medical imaging systems/ancillary equipment inventory log includes manufacturer.	L	Equip-QA-RPS-AC-23	Revised
DES1.1.3	**M**	The medical imaging systems/ancillary equipment inventory log includes serial number or another identifier.	L	Equip-QA-RPS-AC-23	Revised
DES1.1.4	**M**	The medical imaging systems/ancillary equipment inventory log includes date of installation.	L	Equip-QA-RPS-AC-23	Revised
DES1.1.5	**B**	The medical imaging systems/ ancillary equipment inventory log includes condition of equipment at the time it was acquired (e.g. new, refurbished).		Equip-QA-RPS-AC-23	
DES1.2		**Medical imaging systems and ancillary equipment are appropriately operated.**			Revised
DES1.2.1	**M**	An orientation and training program is provided to those who use medical imaging systems and ancillary equipment to ensure safe, consistent, and accurate operation.	H	Equip-QA-RPS-AC-23	
DES1.2.2	**M**	Medical imaging systems and ancillary equipment are operated by competent staff with the necessary education, knowledge, skills and certification.	H	Equip-QA-RPS-AC-23	Revised
DES1.2.3	**M**	Medical imaging systems and ancillary equipment are used only as intended by the manufacturer.	H	Equip-QA-RPS-AC-23	Revised

No.		Description	Risk	Reference	Change
DES1.2.4	**M**	The manufacturer's instructions for use, MIFUs, for medical imaging systems and ancillary equipment are readily available to staff.	L	Equip-QA-RPS-AC-23	Revised
DES1.2.5	**M**	Medical imaging systems and ancillary equipment are located and stored in a safe and secure location.	M	Equip-QA-RPS-AC-23	Revised
DES1.3		**The medical imaging service investigates and resolves problems involving medical imaging systems and ancillary equipment.**			Revised
DES1.3.1	**M**	Roles and responsibilities for reporting, investigating and resolving medical imaging system/ancillary equipment problems are defined and communicated.	M	Equip-QA-RPS-AC-23	Revised
DES1.3.2	**M**	There is a support model that includes service provider contact process and information for each medical imaging system/ancillary equipment (i.e. contact list for each modality or device).	M	Equip-QA-RPS-AC-23	Revised
DES1.3.4	**M**	Investigations and corrective actions are documented and retained for the lifetime of the medical imaging system/ancillary equipment.	M	Equip-QA-RPS-AC-23	Revised
DES1.3.5	**B**	Actions to prevent medical imaging system/ancillary equipment problem recurrence are identified, as applicable.	M	Equip-QA-RPS-AC-23	Revised
DES1.3.6	**M**	Manufacturer-issued defects, recalls and safety advisories are acted upon, as advised by the manufacturer.	H	Equip-QA-RPS-AC-23	Revised
DES1.3.7	**M**	There is a process for resolving medical imaging system/ancillary equipment non-compliance or quality issues with the service provider in a timely manner.	M	Equip-QA-RPS-AC-23	Revised
DES1.3.8	**M**	If a medical imaging system/ancillary equipment is not safe for clinical use, it is clearly labeled and removed from service.	H	Equip-QA-RPS-AC-23	Revised
DES1.3.9	**M**	If a medical imaging system/ancillary equipment exhibits performance limitations but is safe for clinical use, it is identified and limitations are communicated to relevant staff.	H	Equip-QA-RPS-AC-23	Revised
DES1.3.10	**M**	Medical imaging systems and ancillary equipment that exhibits performance limitations but is safe for clinical use, is identified and limitations are communicated to relevant staff.	M	Equip-QA-RPS-AC-23	Revised
DES1.3.11	**B**	Repairs are conducted in a suitable location that provides the necessary staff protection (e.g. radiation safety considerations).		Equip-QA-RPS-AC-23	Revised

No.		Description	Risk	Reference	Change
DES1.3.12	**B**	There is a policy or procedure for medical imaging systems and ancillary equipment lifecycle planning. *Guidance: Lifecycle planning identifies what conditions should be reviewed in determining when a replacement or upgrade is required, risk management, procurement processes, financial planning, defined timeframes and responsibilities. For more recommendation on equipment lifecycle planning, you may wish to review the CAR lifecycle guidance, available from https://car.ca/wp-content/uploads/car-lifecycleguidance-summary.pdf.*			New

Acceptance testing

No.		Description	Risk	Reference	Change
					Revised
DES2.0		**ACCEPTANCE TESTING GENERAL REQUIREMENTS**			
DES2.1		**Acceptance testing is performed after purchase and prior to clinical use of new, relocated or significantly retrofitted medical imaging systems.** *Guidance: For repaired or replaced medical imaging system components see DES2.4.*			Revised
DES2.1.1	**M**	Acceptance testing is performed prior to clinical use for all new, relocated or significantly retrofitted medical imaging systems. *Guidance: Relocated imaging systems refer to fixed systems which are transported to another fixed location (e.g. to another facility or to another room). Systems designed for intra-facility portable imaging do not require acceptance testing after each time the system moves within the facility (e.g. portable X-ray systems).*	H	Equip-QA-RPS-AC-23	Revised
DES2.1.2	**M**	The tester is independent of the manufacturer.	H	SC-35	
DES2.1.3	**M**	Results from acceptance testing are used to establish baseline values of equipment performance.	H	Equip-QA-RPS-AC-23	
DES2.1.8	**M**	Acceptance testing records are retained for the lifetime of the equipment.	H	Equip-QA-RPS-AC-23	New
DES2.3		**The DAP is notified of all new, relocated or significantly retrofitted medical imaging systems prior to clinical use.**			New
DES2.3.1	**M**	Prior to clinical use of new, relocated or significantly retrofitted medical imaging systems, a Notification of Significant Change (NOSC) form must be submitted to the DAP for approval along with either I. satisfactory acceptance testing report, or II. Urgent Clinical Use Requirement – Provisional Acceptance Agreement (UCU-PAA). *Guidance: All acceptance testing must be satisfactorily completed prior to clinical use, the UCU-PAA is to be utilized in urgent circumstances when the delay in receiving the completed acceptance testing report would significantly disrupt service delivery. See UCU-PAA form for full details. In non-urgent circumstances the completed acceptance testing report must be submitted to the DAP prior to clinical use.*	H	Equip-QA-RPS-AC-23	New

No.		Description	Risk	Reference	Change
DES2.4		**Repaired or replaced medical imaging system components have the necessary testing performed prior to clinical use.**			New
DES2.4.1	**M**	Component specific acceptance testing is performed for repaired or replaced medical imaging system components prior to clinical use. *Guidance: Component specific acceptance testing is a set of quality control testing which ensures the equipment component meets regulatory standard and manufacturer's specifications. Depending on the system component this may require full or partial acceptance testing of the system, as defined by individual(s) with appropriate technical or medical expertise (e.g. medical physicists, biomedical personnel, application specialist, etc.).*	H	Equip-QA-RPS-AC-23	New

Quality assurance

No.		Description	Risk	Reference	Change
					Revised
DES3.0		**QUALITY ASSURANCE GENERAL REQUIREMENTS**			
DES3.1		**Quality control procedures are performed to monitor the performance of imaging equipment.** *Guidance: Quality control testing procedures and frequency of testing are defined in the modality-specific accreditation standards.*			Revised
DES3.1.1	**M**	There is a designated person(s) responsible for monitoring and reviewing QC on a regular basis. *Guidance: The facility determines who is trained and knowledgeable to perform and monitor QC procedures. Some QC procedures may be designated to individuals. For example, technologists may perform some frequently scheduled QC procedures, QC coordinators, equipment service providers, consultants, and biomedical service engineers may perform more specialized procedures and Medical Physicists may perform or provide consultation for all or some of the QC procedures.*	M	Equip-QA-RPS-AC-23	
DES3.1.2	**M**	Staff have the necessary training, reference and education materials available to ensure QC is performed according to manufacturer's recommendations or recognized best practices.	M	Equip-QA-RPS-AC-23	
DES3.1.3	**M**	QC records are retained for a minimum of three years. *Guidance: As far as practicable, recorded data must be indicated as data points on a control chart when the measurement is made. In this form, trends can be more easily detected. A logbook, excel document or other easily identifiable method of recording must be used and records must be kept for a minimum of three years.*	M	Equip-QA-RPS-AC-23	New
DES3.2		**Quality control testing equipment is maintained and monitored.**			

No.		Description	Risk	Reference	Change
DES3.2.1	**M**	All equipment used for acceptance and quality control testing is evaluated for their functionality and performance on a regular basis according to manufacturer's recommendations. *Guidance: All sensitometric and densitometric equipment, dose meters, and tube voltage meters are calibrated on a regular basis according to manufacturers' recommendations. All phantoms and other equipment used for the assessment of image quality, dose and system performance are to be checked for damage or any condition which may affect their use.*	M	Equip-QA-RPS-AC-23	
DES3.2.2	**M**	Testing equipment is operated following manufacturer's recommendations.	M	Equip-QA-RPS-AC-23	
DES3.3		**Equipment failures and out of range QC values are promptly reviewed and investigated.**			Revised
DES3.3.1	**M**	There is a policy or procedure to respond to equipment failures and when equipment performance deviates beyond set limits.	M	Equip-QA-RPS-AC-23	Revised
DES3.3.2	**M**	Corrective action is taken to repair or replace equipment with test failures and or out of range QC values.	M	Equip-QA-RPS-AC-23	Revised
DES3.3.3	**M**	Equipment failures and out of range QC values, testing investigations and corrective actions are documented and retained for the lifetime of the equipment.	M	Equip-QA-RPS-AC-23	Revised
DES3.4		**There is a preventative maintenance program in place for the imaging equipment.**			Revised
DES3.4.1	**M**	Documented preventative maintenance is performed by service staff that have the necessary training and applicable materials available to ensure preventative maintenance is performed according to manufacturer's recommendations or industry accepted best practices.	M	Equip-QA-RPS-AC-23	Revised
DES3.4.3	**M**	Maintenance personnel ensure that the record of all repair and maintenance procedures are properly recorded and when required, communicated to relevant staff.	M	Equip-QA-RPS-AC-23	
DES3.4.4	**B**	Maintenance personnel review the maintenance procedures periodically and update them to ensure optimum patient and operator safety.		Equip-QA-RPS-AC-23	
DES3.4.5	**M**	Preventative maintenance records are retained for the lifetime of the equipment.	M	Equip-QA-RPS-AC-23	New

Supplies management

No.		Description	Risk	Reference	Change
DES4.0		**SUPPLIES ARE MONITORED IN A WAY THAT REDUCES OR ELIMINATES SHORTAGES AND WASTE.**			
DES4.1		**The storage and monitoring of supplies ensures an effective inventory control system.**			
DES4.1.1	**M**	Storage complies with manufacturer's recommendations.	M		
DES4.1.2	**B**	Receipt and service entry dates are recorded as necessary.			
DES4.1.3	**M**	Expiration dates are monitored.	M		
DES4.1.4	**M**	Rejected/expired goods are clearly marked and dealt with appropriately.	M		
DES4.1.5	**B**	Inventory control problems and actions taken are documented.			
DES4.1.6	**B**	There is a process for resolving non-compliance or quality issues with the vendor in a timely manner.			
DES4.1.7	**B**	Documentation of supply utilization is routinely reviewed.			
DES4.1.8	**B**	There are policies and procedures for the appropriate disposal of solutions and supplies.			

Medical imaging equipment – technical specifications and safety

No.		Description	Risk	Reference	Change
					New
DES5.0		**MEDICAL IMAGING EQUIPMENT – TECHNICAL SPECIFICATIONS AND SAFETY**			
DES5.1		**All new, used, and refurbished medical imaging equipment conforms to applicable provincial and federal legislation.**			New
DES5.1.1	**M**	X-ray emitting medical imaging systems conform to the *Radiation Emitting Devices Act (REDA).* *Guidance: Refer to REDA available from https://laws-lois.justice.gc.ca/eng/acts/r-1/index.html.*	H		New
DES5.1.2	**M**	X-ray emitting medical imaging systems conform to Radiation Emitting Devices Regulations. *Guidance: Refer to Radiation Emitting Devices Regulations available from https://laws-lois.justice.gc.ca/eng/acts/r-1/index.html.*	H		New
DES5.1.3	**M**	Medical devices must meet the requirements of the Medical Devices Regulations under the *Food and Drugs Act*. *Guidance: Refer to Medical Devices Regulations, available from https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/.*	H		New
DES5.1.4	**M**	New medical imaging systems have an active Health Canada licence. *Guidance: See Health Canada - Medical Devices Active Licence Listing (MDALL), available from https://health-products.canada.ca/mdall-limh/.*	H		New
DES5.1.5	**M**	Existing medical imaging systems have an active or archived Health Canada licence. *Guidance: See Health Canada - Medical Devices Active Licence Listing (MDALL), available from https://health-products.canada.ca/mdall-limh/.*	H		New
DES5.1.6	**M**	Medical imaging systems are DICOM compatible.	H		New

No.		Description	Risk	Reference	Change
DES5.1.7	**B**	New medical imaging systems support the IHE technical framework. *Guidance: The IHE Technical Frameworks are a resource for users, developers and implementers of healthcare imaging and information systems. They define specific implementations of established standards to achieve effective systems integration, facilitate appropriate sharing of medical information and support optimal patient care. There are numerous IHE integration profiles that include profiles for workflow, profiles for content, profiles for presentation, and profiles for infrastructure.*			New

References

Abbreviation	Reference
Equip-QA-RPS-AC-23	2023 DAP Equipment Quality Assurance and Radiation Protection Surveys Advisory Committee Recommendation

Bibliography

Health Canada. Safety Code 35. Radiation protection in radiology—large facilities [internet]. Ontario: Health Canada; 2024. Available from: https://www.canada.ca/content/dam/hc-sc/documents/services/environmental-workplace-health/reports-publications/radiation/safety-code-35-safety-procedures-installation-use-control-equipment-large-medical-radiological-facilities-safety-code/safety-code-35-safety-procedures-installation-use-control-equipment-large-medical-radiological-facilities-safety-code.pdf