

Memo: SHA Equipment Maintenance, Calibration, and Documentation for Research Use

DATE: 23-Sep-26

TO: Research Principals, Investigators, Study Personnel, and Sponsors

FROM: SHA Research Department, Insights for Better Health, Digital Transformation and Information for Better Health

RE: Equipment Maintenance, Calibration, and Documentation for Research Activities Conducted within Saskatchewan Health Authority Facilities

This memo provides a summary of current Saskatchewan Health Authority (SHA) practices related to equipment maintenance, calibration, and documentation, particularly as they relate to equipment used in clinical research. It also outlines a proposed approach to improve clarity, consistency, and accessibility of information supporting regulatory and operational requirements.

Background

Questions have recently arisen regarding maintenance and calibration documentation for equipment used in research studies conducted within Saskatchewan Health Authority (SHA) facilities. Specifically, clarification has been requested regarding equipment maintenance practices, availability of supporting documentation, and responsibilities related to equipment used in clinical research.

To support a consistent understanding across research and operational stakeholders, Research Services consulted with Clinical Engineering leadership in Regina and Saskatoon. The purpose of this memo is to summarize current practices and identify opportunities to strengthen coordination between research and operational departments.

Given the multi-departmental nature of equipment oversight within SHA, it is important to ensure that any documentation or statement reflects validated operational practices and does not inadvertently misrepresent responsibilities, processes, or regulatory alignment.

Equipment Maintenance and Calibration Practices

Equipment used within SHA facilities is maintained through a combination of internal Clinical Engineering services and external vendor service agreements, depending on the type of equipment.

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In general, smaller SHA-owned clinical devices are maintained by SHA Clinical Engineering departments. Larger diagnostic and specialized equipment, such as MRI, CT, ultrasound, and X-ray systems, are typically maintained through contracted service providers.

Maintenance, inspection, testing, and calibration activities are performed according to manufacturer recommendations, accreditation requirements, applicable standards, and operational risk assessments. Calibration is completed where specified by manufacturers, operational standards, quality assurance programs, or regulatory requirements. These practices are intended to support safe clinical operations and ensure equipment performs as intended within the healthcare environment.

Availability of Maintenance and Calibration Records

Maintenance and calibration records are generally available for equipment maintained by either SHA Clinical Engineering or contracted service providers.

For SHA-maintained equipment, records can typically be requested directly through Clinical Engineering with reasonable advance notice. For equipment maintained through external vendors, records may also be available; however, retrieval timelines may be longer depending on the service provider and age of the records requested.

Researchers and study teams should recognize that documentation requests associated with audits, monitoring visits, sponsor inquiries, or regulatory inspections may require coordination with operational departments as well as Clinical Engineering and should plan requests accordingly.

Research Considerations

Where maintenance history, calibration status, or equipment performance is critical to study endpoints, data integrity, sponsor requirements, or regulatory compliance, these requirements should be identified during study planning and communicated to operational departments before study initiation and should be part of the Operational Approval request.

Research teams remain responsible for ensuring that study-specific requirements are understood and that any required documentation is requested sufficiently in advance to support study activities, monitoring, or audits.

The existence of maintenance records does not necessarily imply immediate accessibility, particularly where records are maintained by external service providers or relate to equipment that has been decommissioned or replaced.

Best practice for research includes the researcher retaining in the study file a certified copy of any maintenance records required for long-term storage. This is particularly recommended where the measurements are critical to the study outcomes. This practice eliminates the potential for discrepancies between SHA retention practices and research requirements.

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Key Takeaways

SHA maintains processes for the servicing, maintenance, and calibration of equipment through Clinical Engineering departments and contracted service providers. Documentation is generally available through the appropriate operational channels, subject to retrieval timelines and record availability.

Researchers are encouraged to retain their own certified copies of required maintenance documents, particularly where the measurements are critical to the study outcomes.

Continued collaboration between research teams, operational departments, and Clinical Engineering will help ensure that equipment used in research studies continues to meet operational requirements while supporting sponsor, audit, and regulatory expectations.

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