Three Year Summary of Ontario Hospitals Health Canada Inspections - Review of Observations
Produced by ORBCoN
April 16, 2026

Fiscal Year	Requirement (#)	Specific HC Requirement Statement	Summary of Findings	Available ORBCoN Resources
2025-26	94 - Quality Management System	*** The system for identifying and investigating errors and accidents was not sufficient.** *** The quality control program was not sufficient.** *** The internal audit did not assess if all regulated activities complied with the Blood Regulations.** *** The system that identifies, documents and tracks all critical equipment or supplies was not sufficient.**	***Risk Level 2** - Errors/Accidents of regulated activities were not defined in electronic system for tracking incidents, therefore, blood safety related incidents were not consistently identified, documented, or trended. ***Risk Level 2** - Several QC or equipment log sheets had variables recorded that were not within established parameters and lacked comments, assessments or documented corrective actions. (i.e., temperatures of storage equipment noted outside of specified range with no comments to indicate action taken). *Internal auditing did not include an assessment of all regulated activities. It could not be confirmed that all washing, pooling, irradiating, aliquoting, accepting blood, issuing/distributing blood and storage processes were audited. *SOP did not identify all critical equipment, and maintenance and calibration schedule missed required PM activities.	Annual Report template for tracking of E/A's Audit summary reports
	95/96 - Operating Procedures	*** Some processes were not described in operating procedures.** *** Some operating procedures were not kept up-to-date.**	*** Risk Level 2** - Procedures did not specify contingency methods if critical equipment was not available for registered transformation methods. An interim solution was not documented or had an associated approved process. *** Risk Level 2** - SOP's for reporting adverse reactions contained incomplete instructions pertaining to reporting to Health Canada. *Two different cooler types in use for red cell products were validated for different maximum lengths of time. SOP instructions for acceptable return did not specify the different cooler types.	
	100 - Equipment	**The validation, calibration, cleaning, or maintenance of critical equipment were not always sufficient.**	* Maintenance, cleaning, calibration/verification, and PM's for critical equipment was not performed as written in SOP's or as recommended by manufacturer. * Equipment identified as requiring replacement, was not immediately removed from service. * There was no documented information or follow up regarding why these non conformant actions were not completed.	
2024-25	95/96 - Operating Proocedures	*** Some operating procedures were not always followed.** *** Some operating procedures were incomplete.**	* Critical supply SOP not updated to reflect current practices. * Internal audits were not performed as described in procedures or by the timeframe interval determined. * SOP for equipment and maintenance did not specify how to address issues identified by preventative maintenance service provider.	Blood Regulation Audit Checklist (in development)
	101 - Equipment	**The validation, calibration, cleaning, or maintenance of critical equipment were not always sufficient.**	*** Risk Level 2 -** Validation records for storage equipment including transport containers must be completed and available. This information must include documentation that it has been qualified/verified for hospitals intended use. * Records were not available to indicate corrective actions required post maintenance were completed. * The preventative maintenance report did not include all tasks required as per Quarterly and Annual Maintenance Logs. External provider's maintenance checklist must clearly list all maintenance performed.	ORBCoN's Operational Verification Protocol
	108 - Investigation & Reporting	*** The annual report summarizing all error and accident investigations the establishment conducted in the past 12 months was incomplete.** *** The annual report did not include the analysis of the error and accident investigations.**	* All errors and accidents in relation to a regulated activity, including those determined not reportable to Health Canada by the investigating site must be included in the year end (annual) report. (e.g., missing tamper proof seal, wrong packing configuration). The annual report requires analysis to identify trends for additional corrective/preventative actions. * Not all incidents and non-conforming events were defined and investigated as errors and accidents - consequently not included in the annual report.	Annual Report Template
2023-24	94 - QMS	*** The program for the preventive maintenance of critical equipment was not sufficient.** *** The internal audit system was not sufficient.** *** The internal audit was conducted by someone who had direct responsibility for the process being audited.** *** The document control or records management system was not sufficient.**	**Level 2 Risk -was assigned to this non-conformance.** * There was no documented process in place to outline the actions to be taken when the PM for equipment was not performed as per the required frequency. In addition, the PM reports did not state an overall designation of pass or fail. * Audit procedures were not followed as stated in the policy. * The auditor that conducted the internal audit had direct responsibility for the procedures or processes that were being audited. * Current versions of procedures were not always uploaded/generated after the review was done. The published or go live date of procedures was not always the same as the date that the procedures were effective, resulting in staff viewing outdated procedures.	Blood Regulation Audit Checklist (in development)
	96 - Operating Proocedures	*** Some operating procedures were incomplete.** *** The operating procedure did not meet some requirements.** *** Some operating procedures were not kept up-to-date.**	* Operating procedures for error and accident investigations had inaccurate information regarding reporting to Health Canada or did not include all information for reporting to Health Canada * Operating procedures were incomplete as they did not include minimum and maximum number of components to be shipping in E38 and J82 containers as per validations. * Ambiguity in notification of staff to changes in an SOP. All personnel responsible for carrying out a procedure must be trained prior to performing any task associated with a new or revised operating procedure which include changes in laboratory processes or analytical changes with minimum impact on clinical outcome. * Periodic review of SOP's did not include a frequency in which they were to be reviewed. In addition, despite a document control system notifying of a scheduled review, this was not performed.	
	117 - Records	**Records were not always accurate, complete, legible, indelible and/or readily retrievable.**	* Documentation of temperatures, dates/times, or component unit numbers on critial equipment (plasma thawers, freezers, incubators, irradiator) logs were not legible * Doumentation was incomplete - the rquired responses were not provided (intials, outcome) *Electronic records did not state the date the activity/review/sign off was performed. Instead the date the document was uploaded was used as the date of record, but did not always reflect when the action was actually completed. * Training records were missing method of training / initials / training outcome.	