# Five Year Summary of Ontario Hospitals Health Canada Inspections - Review of Observations
**Produced by ORBCoN**
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| Fiscal Year | Requirement (#) with highest number of citations | Specific HC Observation | Summary of Findings | Available ORBCoN Resources |
|---|---|---|---|---|
| 2024-25 | 95 - Operating Proocedures | **Critical supply SOP not updated to reflect current practices.**<br><br>**Not all Internal audits listed to be done in a defined period were not performed.** | Ensure the reviews/audit frequency as defined within an SOP are performed - include these details (month performed/frequency) in the audit checklist to ensure it is not missed.<br><br>Make sure your SOP does not over promise and under deliver.<br><br>If an audit is missed, there should be a root cause /documentation listing why (e.g., risk assessment). | Blood Regulation Audit Checklist (in development) |
| | 101 - Equipment | **There was no documentation to demonstrate that the establishment took appropriate actions following the preventative maintenance service provider's recommendations.**<br><br>**The preventative maintenance report did not include all tasks required as per the Quarterly and Annual Maintenance Logs.** | Validation records for storage equipment including transport containers must be completed and available. This information must include documentation that it has been qualifed for hospitals intended use.<br><br>Records were not available to indicate corrective actions required post maintenance were completed. | ORBCoN's Operational Verification Protocol |
| | 108 - Investigation & Reporting | **Not all incidents and non-conforming events were defined and investigated as errors and accidents - consequently not included in the annual report.** | 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 report. This should include minor issues (e.g., missing tamper proof seal, wrong packing configuration).<br><br>External provider's maintenance checklist must clearly list all maintenance performed. | Blood Regulation Inspection Peer group - BRIPG<br><br>Blood Regulation Audit Checklist (in development)<br><br>Annual Report Template (in development) |
| 2023-24 | 94 - QMS | **Insufficiencies in the processes for:**<br>**-preventive maintenance of critical equipment.**<br>**-Internal auditing**<br>**-ensuring an internal audit is not performed by persons responsible for that process.** | **Level 2 Risk -was assigned to this non-conformance.** Risk assessment is based on a 1-4 scale with the lower values being considered critical and may decrease patient safety practices.<br><br>Clearly outline audit process and designates. | Blood Regulation Audit Checklist (in development) |
| | 96 - Operating Proocedures | **Some SOPs not kept up-to-date and some steps were not followed in the order outlined in the SOP** | **Keep it simple**<br>-Create flowchart, summary sheet or checklist where possible<br>-Pay attention to the details (e.g., recording, frequency, MRP...)<br>-Date effective must be prior to implementation date<br>- Reviewed/update all SOPs are on a regular basis to ensure current, complete, and all relevent resources/apendices are accurate.<br>-Include Max and Min values if applicable<br>-Ensure there is a clear mechanism of notification of change in SOP or process prior to staff performing the process or procedure.<br>-Perform direct observation of staff to ensure process is followed as written. | Blood Regulation Inspection Peer group - BRIPG |
| | 117 - Records | **Records were not always accurate, complete, legible, indelible and/or readily retrievable.** | **Attention to details:**<br>-Ensure all tasks are intialed as completed<br>-Clearly indicate pass or fail / performed or not performed<br>-Reports to be signed off as indicated in the SOP<br>-Training records not complete<br>-Periodic review must correlate to an SOP with a specific frequency. | Blood Regulation Inspection Peer group - BRIPG |
| 2020-2022 | **There were no inspections performed in Ontario due to Covid Pandemic** | | | |
| 2019-20 | 94 - QMS<br>96 - SOP<br>98 - Personnel<br>117 - Records | **Detailed information not collected for summary** | | |