

# The Development of a Quality Management Framework for Evaluating Medical Device Reprocessing Practice in Healthcare Facilities

Bailey Lorv, Robin Horodyski, Cynthia Welton, John Vail, Luca Simonetto, Danilo Jokanovic, Richa Sharma, Angela Rea Mahoney, Shay Savoy-Bird and Shalu Bains

## Appendix 1: MDR service standards and KPIs

MDR service standards					
Category	Service standard	Target compliance	Additional details	Review schedule	Applicable standards
Program operations	Maintenance and availability of standard operating procedures (SOPs)	100% of necessary SOPs are documented, maintained and available to staff	SOPs for all MDR processes, such as infection prevention and control and occupational health and safety requirements, are documented, available, maintained and reviewed routinely	Annual	AC: 4.1, 4.3, 5.5, 5.8, 8.2, 9.6, 13.7 CSA Z3140.0, Z314.8
Program operations	Daily review of booked medical and surgical procedures	Review is completed daily 100% of the time	Scheduled procedures are previewed by the MDR Supervisor, the day before at a defined time suitable for operations. This preview is to confirm delivery and availability of required sterile instrumentation par level (with communication to affected departments of potential deficiencies and intended resolution of same).	Monthly + annual	AC: 4.1 CSA Z314.0
Program operations	Daily review of instrument par levels	Review is completed daily 100% of the time	Instrumentation par levels for procedures that require sterilized instruments are previewed the day before, and when applicable a week in advance, by the MDR Supervisor at a daily defined time suitable for operations and with communication to affected department(s) to support refinement or adjustment of upcoming scheduled work.	Monthly + annual	AC: 4.1, 12.1 CSA: Z314.0

MDR service standards					
Category	Service standard	Target compliance	Additional details	Review schedule	Applicable standards
Program operations	Daily supervisor huddles with MDR and or staff	Daily huddles are completed daily 100% of the time	MDR Supervisor will communicate throughout the day any identified deficiencies and intended resolution of the same; beginning with a morning daily huddle by a defined time suitable with the OR charge nurse and or designated clinical leader.	Monthly + annual	–
Program operations	Daily maintenance & inspection	Daily audits to confirm clean and dirty work areas are kept separate 100% of the time.	Perform daily audits to confirm clean and dirty work areas are kept separate with monthly and annual reporting. Supervisors perform visual confirmation of distinction of clean and dirty work areas, and complete a daily checklist document.	Monthly + annual	AC: 3.3, 3.4 CSA: Z314.0
Program operations	Prepare recall report during event of instrument recall	100% completion of a recall report following circumstances requiring a recall	For any circumstance requiring recall of a load, a “recall report” must be submitted to MDR leadership that includes identification of which trays were successfully recalled and which were not.	Monthly + annual	AC: 12.7, 12.8 CSA: Z314.0
Program operations	Manufacturer’s instructions for use (MIFU) availability	100% of MIFUs for all instruments are reviewed and updated annually	All Manufacturer’s Instructions for Use (MIFU) are readily available for routine use by staff in the performance of their MDR duties.	Annual	AC: 4.5 CSA: Z314.0
Program operations	Documentation of daily biological indicators (BI) testing	100% completion of documented daily BI testing	Audits and reports on process and outcome of daily biological indicators tests are completed and documented.	Monthly + annual	AC: 6.1, 7.6 CSA: Z314.23, Z314.3
Program operations	Daily Bowie-Dick test in sterilizer	100% completion of daily Bowie-Dick test in sterilizer with documentation	A Bowie-Dick test load is performed daily.	Monthly + annual	AC: 6.1 CSA: Z314.0
Program operations	Biological indicator (BI) use whenever change in sterilization process is implemented	100% completion of documented BI testing following a change implementation	Validation via biological indicators for every family of trays whenever a change is implemented (e.g. change in wrapper, change in steam, etc.).	Annual	AC: 9.2, 7.6, 6.1, 7.2 CSA: Z314.23, Z314.3
Program operations	Immediate-use steam sterilization (IUSS) biological testing records	100% completion of daily biological testing for all IUSS	All sterilizers used for emergency sterilization have daily documented records of first of the day mandatory biological testing, per manufacturers instruction.	Monthly + annual	–
Program operations	Bowie-Dick and biological indicator (BI) testing following major equipment or environment change	100% completion of documented Bowie-Dick and BI testing following a major equipment or environmental change	Three (3) consecutive test loads with Bowie-Dick followed by three (3) consecutive test loads of biological indicators (for a total of six (6) tests) will be performed to validate efficacy after a major equipment repair or steam change.	Annual	AC: 9.2, 7.6, 6.1, 7.2 CSA: Z314.23, Z314.3
Program operations	Biological indicator (BI) use in every production load	100% of production loads have documented BI use	Biological indicators will be included in every production load.	Monthly + annual	AC: 9.5, 9.6
Program operations	Routine / preventative maintenance	100% completion of preventative maintenance and cleaning program records (both planned and unplanned)	Documented records of preventative maintenance and a cleaning program, for decontamination, environmental cleaning, and routine cleaning for MDR equipment are provided to MDR leadership annually, including immediate reporting of any planned or unplanned equipment repairs.	Monthly + annual	AC: 7.2 CSA: Z314.0
Employee certification, education and development	Staff orientation	100% of new staff participates in formal orientation process	All new staff participates in formal orientation process that includes but not limited to, in class, practicum, tests, quizzes, return demonstration and supervision by a preceptor.	Annual	AC: 2.1, 2.2 CSA: Z314.0

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Employee certification, education and development	Manager and supervisor certification	100% certified within 1 year of employment	Managers and supervisors are MDR and MDRT certified within one year of employment.	Annual	AC: 1.4, 2.4 CSA: Z314.0
Employee certification, education and development	Technician certification	100% certified upon hire	Technicians are MDRT certified via a recognized educational institution.	Annual	AC: 1.4, 2.4 CSA: Z314.0
Employee certification, education and development	Documentation of staff education, training, skill and experience	100% of staff has completed documentation of education, training, skill and experience	Maintain appropriate documentation of staff education, training, skill and experience.	Annual	AC: 2.7 CSA: Z314.0
Employee certification, education and development	Manager and supervisor leadership training	100% completion of training annually	Managers and supervisors participate in annual, documented leadership training.	Annual	AC: 2.5, 2.6 CSA: Z314.0
Employee certification, education and development	Staff ongoing education and training	100% of staff participates in ongoing education and training	All staff participates in ongoing education and training pertaining to the roles and that this training is documented. Scheduled and annual training, including, in-servicing of staff, and introduction of changes necessary for competent personnel work performance, should be identified and documented.	Annual	AC: 2.5, 2.6 CSA: Z314.0
Employee certification, education and development	Staff performance review and competency assessment	100% of staff participates in annual performance review and competency assessment	Managers, supervisors and technicians have a documented annual performance and competency review.	Annual	AC: 2.5, 2.6 CSA: Z314.0
Employee certification, education and development	New equipment and instrumentation education	100% education completed on new equipment and instrumentation	There is documented staff education for the introduction of new equipment and instrumentation.	Annual	AC: 2.3 CSA: Z314.0
Employee certification, education and development	Immediate-use steam sterilization (IUSS) procedure training	100% of applicable staff are oriented and trained on IUSS	Staff are oriented and trained (with documented mandatory ongoing education) following manufacturer's instructions-for-use, to ensure effective sterilization.	Annual	–
Performance improvement	Incidents reported and followed-up	100% of incidents investigated, mitigated and closed as per corporate policy	All incidents requiring attention or action are documented immediately and reported to the onsite Supervisor/Manager or delegate. Results of investigation and change management to mitigate future occurrences are reported within a timeline specified by corporate policy. Incidents should be documented, trended, reported monthly and summarized in an annual report on adverse events with corrective actions. Incidents for reporting include, but are not limited to: reprocessing equipment failure, soiled, broken and/or non-functioning, missing, or incorrect instrumentation, compromised sterility, and/or mislabelled items.	Monthly + annual	AC: 2.6, 4.9 CSA: Z314.0
Performance improvement	Client feedback improvement cycles	100% completion of annual feedback cycle on quality improvement opportunities	Maintain a customer focused approach, soliciting feedback annually on requirements and other quality improvement opportunities.	Annual	AC: 1.0, 1.1, 13.3 CSA: Z314.0

KPIs						
Category	KPI	Measurement	KPI target	Additional details	Review schedule	Applicable standards
Patient safety	Patient safety incidents	# of patient safety incidents per month	0 patient safety incidents per month	A harmful patient safety incident is defined as an incident that results in mild, moderate or severe harm; or death (WHO International Classification for Patient Safety, 2009)	Monthly + annual	AC: 13.5 CSA: Z314.0
Patient safety	Delayed surgical cases	# of surgical cases or procedures delayed by reprocessing incidents per month	0 delayed surgical cases or procedures as a result of reprocessing incidents per month	A delayed surgical case is defined as being greater than 5 mins.	Monthly + annual	AC: 13.5 CSA: Z314.0
Patient safety	Cancelled surgeries and procedures	# of cancelled surgeries and procedures as a result of reprocessing incidents per month	0 cancelled surgeries and procedures as a result of reprocessing incidents per month	–	Monthly + annual	AC: 13.5 CSA: Z314.0
Patient safety	% of affected surgical cases	# of surgical cases affected by reprocessing incidents as % of total monthly surgical cases	Less than 3% of surgical cases affected by MDR incidents as % of total surgical cases Target of 0 surgical cases affected	Surgical cases affected by reprocessing incidents include delayed or cancelled surgeries.	Monthly + annual	AC: 13.5 CSA: Z314.0
Operational outcome	Total reprocessing error rate	# of total errors as % of monthly trays reprocessed	Less than 0.3% errors as % of monthly trays reprocessed Target of 0 reprocessing errors	Combined monthly error rate for all reprocessing errors (Errors as % of Monthly Trays Reprocessed / Cases Picked).	Monthly + annual	AC: 13.5 CSA: Z314.0
Operational outcome	Utilization of immediate-use steam sterilization	# of occurrences requiring Immediate-use steam sterilization per month	0 occurrences requiring immediate-use steam sterilization per month	Immediate-use steam sterilization occurrences are reported by the MDR Supervisor/Manager/delegate and documented at time of event, and trended with monthly reporting. Use on complete trays or implants is never to occur.	Monthly + annual	AC: 1.3 CSA: Z314.0
Operational outcome	Decontamination time	% of instruments decontaminated within 2 hours after receipt by MDR Department	100% of instruments to be decontaminated within 2 hours after receipt by MDR Department	All instruments are to be decontaminated within 2 hours of MDR Department receipt.	Monthly + annual	AC: 13.5 CSA: Z314.0
Operational outcome	Sterilization time	% of instruments to be sterilized within 8 hours after decontamination	100% of instruments to be sterilized within 8 hours after decontamination	All instruments are to be sterilized within 8 hours of decontamination.	Monthly + annual	AC: 13.5 CSA: Z314.0
Operational outcome	Instrument available for use time	% of instruments to be shelved, accounted for and available within 6 hours after sterilization	100% of instruments are shelved, accounted for and available for use within 6 hours after sterilization	All instruments are shelved, accounted for, and available for use, within 6 hours of a completed sterilization cycle.	Monthly + annual	AC: 13.5 CSA: Z314.0
Operational outcome	Tray turnaround time	% of trays turned around within 18 hours of total trays reprocessed	100% of trays turned around within 18 hours as % of total trays reprocessed	Tray turnaround time = 18hrs (Tray turnaround time = time of receipt in MDR Department to time back on shelf).	Monthly + annual	AC: 13.5 CSA: Z314.0

KPI = key performance indicator; MDR = medical device reprocessing.