**Scope:**

McMaster University research laboratories use autoclaves as part of their daily operations. It is essential that all autoclaves and related areas be inspected to review activities to ensure that specific requirements have been met.

Autoclaves having characteristics which place them under the Technical Standards and Safety Authority (TSSA) Regulation respecting Boilers and Pressure Vessels must comply with all applicable sections.

Additionally, autoclaves used for decontamination of biohazardous waste or contaminated items are to comply with the relevant sections of the Canadian Biosafety Standard (CBS).

**Responsibilities:**

The supervisor is accountable to ensure that user training is completed, that testing, certification, calibration, and maintenance is in place for each autoclave that they operate and that the relevant records are available for inspection.

The supervisor is accountable for notifying the Biosafety Office of any new or existing autoclave(s). The supervisor is accountable for notifying the central campus Facilities Services Director of Energy Management and Utilities prior to permanently removing an autoclave from operation or use, and to complete and submit the form published by the designated administrative authority.

Workers are responsible for following procedures as set out by their training and by their Supervisors through written standard operating procedures. Workers are responsible for reporting to their Supervisor any issues that arise with respect to the equipment, infrastructure or procedures.

The Research Compliance Auditor is responsible for auditing associated autoclave documentation and immediate support areas on a regular basis. Immediate support areas may be laboratories undergoing scheduled biosafety audits.

**Definitions:**

*Certificate of inspection -* a certificate issued under the TSSA Regulation in respect of an inspection of a boiler or pressure vessel.

*Cycle number* – the number printed on the tape; determined by the autoclave control panel.

*Cycle name* – ensure a legend of cycle parameters is posted at the unit.

*Insurer -* a person licensed under the *Insurance Act* to undertake boiler and machinery insurance as defined by that act.

*Load number* – the number in the log; determined by the users.

*Log* – format of documentation used to record autoclave parameters and results as prescribed; may be individual sheets or bound books.

*Medium –* form of stored record (i.e. paper, magnetic tape, disk, etc.)

*Pressure vessel* - any enclosed unfired vessel that contains gas, vapour or liquid under pressure.

*Repair -* any work necessary to restore a boiler or pressure vessel to a safe and satisfactory operating condition that does not result in a deviation from the original design.

*Supervisor -* a person who has charge of a workplace or authority over a worker. Although supervisors may delegate responsibilities under this program, supervisors are accountable for ensuring that the requirements of this program are met.

*Worker -* any person who performs tasks assigned by a supervisor.

**Monitoring, Maintenance, Repair and Inspection:**

Autoclave monitoring is an important aspect of a safe and properly functioning autoclave, since over time the accuracy of measurements can drift and inaccurate readings can affect quality. Manufacturer’s recommendations for preventative maintenance are to be followed and all regular maintenance and repairs are to be performed only by fully qualified service personnel.

Autoclaves are considered unfired pressure vessels. Autoclaves that fall under the TSSA Regulation on Boilers and Pressure Vessels are those that have a maximum working pressure greater than 15 psi (103 kPa), a capacity greater than 1.5 cubic feet (42.4L), and an internal diameter greater than six (6) inches (152mm). Autoclaves falling under the TSSA Regulation must undergo inspection at the time of installation, change in fittings or piping, and at least once in every 12 months thereafter. The inspection must be conducted by the TSSA if uninsured, or by the Insurer that provides Boiler and Machinery Insurance coverage as required by the Boilers and Pressure Vessels Regulation. No person shall operate an autoclave that falls under the TSSA Regulation unless it has been inspected by a Boiler Inspector holding a valid Certificate of Competency and a certificate of inspection has been issued. Prior to permanently removing an autoclave from operation or use, the supervisor is to notify the Facilities Services Director of Energy Management and Utilities <http://facilities.mcmaster.ca/aboutus.html#utilities> and to complete and submit the form published by the designated administrative authority. Management of TSSA inspections is through Facilities Services Director of Energy Management and Utilities even if the McMaster-owned autoclave is within a hospital.

The current certificate of inspection must be kept in good condition and must be posted near the autoclave at all times. If there is no valid certificate of inspection posted, the autoclave falling under the TSSA Regulation on Boilers and Pressure Vessels should not be used. Copies of service records should be made available for inspection by internal/external auditors. If an autoclave is not working properly, discontinue use immediately, post a sign alerting others not to use the autoclave, and notify the responsible person(s). Users are not to make repairs.

**Training:**

It is required that workers be trained in the hazards associated with autoclave usage regardless of the types of material(s) being sterilized or decontaminated prior to use. Training is achieved by successfully completing both Autoclave Awareness training available through the Mosaic system as well as autoclave specific hands-on training provided by the responsible person for your autoclave.

Training must be documented and kept on file. The training record should include the name of trainee, date of training, type of training, and signatures at a minimum.

**Quality Assurance:**

Autoclaves for decontamination and processes are to be validated through the use of representative loads in conjunction with application-specific biological indicators, chemical integrators, and/or parametric monitoring devices consistent with the technology/method. Once effective decontamination parameters have been established through validation, it is important that decontamination processes and procedures be monitored (verified) on a regular basis to confirm that established parameters have been met.

Verification is the routine monitoring of equipment and processes to ensure they are functioning properly and continue to meet the parameters established during validation. The information captured during verification should include the cycle parameters (e.g., temperature, time, description of the size and type of load, and a short description of the procedure. For each run performed, the parameters captured may include time and temperature charts and biological indicator results. If a biological indicator is used, results of a positive control from the same lot should also be captured. A local risk assessment (LRA) will help determine the procedures for routine monitoring (e.g., daily, weekly, monthly, etc.), taking into consideration the frequency of use.

**Data Review and Analysis:**

Prior to operating the autoclave, ensure the date and time are correct on the unit and printer paper is present and printout is legible. At no time, should the autoclave be run without adequate paper or ink. Rolls of regular or thermal tape typically come with coloured roll-end indicators at which time the roll must be changed immediately. If a battery is present in the control panel it is to be replaced on a regular basis as outlined in manufacturer’s guidelines. An autoclave load must not be run if any of these are not present.

When the autoclave load has been completed, verify parameters have been achieved by checking cycle information on the printout. In the event of a failed load, re-process the load. If unable to re-process immediately after failure, leave the load inside the unit, place a sign on the unit indicating out of service and report to your supervisor.

**Records:**

Maintaining records provides evidence that a specific activity was performed and provides documentation of the results. The load number in the log is to be recorded on the corresponding autoclave tape and record the cycle number for each load run in the log. This will ensure the log matches the tapes. Autoclave tapes must not be discarded.

The supervisor or designate is responsible for maintaining documentation records of any training/retraining, inspections and corrective actions, equipment maintenance, repair, testing, certification, calibration, and verification of decontamination equipment and processes. It is important that records are legible and clearly identify the activity, product, or service included.

Records are to be kept on file ensuring the medium and storage environment are suitable (consider presence of water, heat, light, dust, vermin, etc.). The records must be easily retrievable for inspection if/when requested by internal/external auditors. The records should be catalogued in such a manner which enables searching by at least one parameter (cycle #, load #, date, etc) can be accomplished.

Please contact the Research Compliance Auditor if you require assistance in setting up a records management system.

**Record Retention:**

Below provides a comprehensive list of the types of records that must be kept on file.

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| **TYPE OF RECORD** | **REQUIREMENT** | **MINIMUM RECOMMENDED RETENTION PERIOD** |
| Autoclave Inspection Certificate | Records of building and equipment maintenance, repair, inspection, testing, or certification, including performance verification and testing records, in accordance with containment zone function, to be kept on file as per the Canadian Biosafety Standard, Section 4.10.6. | Records and documentation pertaining to licensed activities involving human pathogens and toxins to be kept on file for a minimum of 5 years. |
| Calibration Certificate | Equipment used for performance  verification and testing of containment  systems and essential biosafety  equipment to have a valid calibration  certificate at the time of testing;  calibration certificates to be kept on file as per the Canadian Biosafety Standard, Section 4.10.7. | Records and documentation pertaining to licensed activities involving human pathogens and toxins to be kept on file for a minimum of 5 years. |
| Daily Autoclave Use Log | Records of building and equipment maintenance, repair, inspection, testing, or certification, including performance verification and testing records, in accordance with containment zone function, to be kept on file as per the Canadian Biosafety Standard, Section 4.10.6. | Records and documentation pertaining to licensed activities involving human pathogens and toxins to be kept on file for a minimum of 5 years. |
| Biological Indicator Test Result Log | Records of validation and routine verification of decontamination technologies and processes to be kept on file as per the Canadian Biosafety Standards, Section 4.10.9. | Records and documentation pertaining to licensed activities involving human pathogens and toxins to be kept on file for a minimum of 5 years. |
| Autoclave Performance Log | Records of building and equipment maintenance, repair, inspection, testing, or certification, including performance verification and testing records, in accordance with containment zone function, to be kept on file as per the Canadian Biosafety Standard, Section 4.10.6. | Records and documentation pertaining to licensed activities involving human pathogens and toxins to be kept on file for a minimum of 5 years. |
| Training Records | Training and refresher training to be documented; records to be kept on file as per the Canadian Biosafety Standard, Section 4.10.1. | Minimum of one (1) year after the individual has left the facility / organization, minimum of two (2) years for visitors. |
| Inspections and Corrective Actions | Records of regular inspections of the containment zone and corrective actions to be kept on file as per the Canadian Biosafety Standard, Section 4.10.5. | Records and documentation pertaining to licensed activities involving human pathogens and toxins to be kept on file for a minimum of 5 years. |
| Autoclave Tapes | Records of building and equipment maintenance, repair, inspection, testing, or certification, including performance verification and testing records, in accordance with containment zone function, to be kept on file as per the Canadian Biosafety Standard, Section 4.10.6. | Records and documentation pertaining to licensed activities involving human pathogens and toxins to be kept on file for a minimum of 5 years. |

**Audits:**

Autoclaves used for decontamination of waste along with associated documentation and locations will be audited on a regular basis by the Research Compliance Auditor.

**Recommended Supporting Documentation:**

Autoclave Daily Use Log

Biological Indicator (BI) Test Result Log

Autoclave Service or Maintenance Log

Autoclave Audit Checklist

**Guidance Documents:**

Canadian Biosafety Standard, 2nd Edition (CBS); <http://canadianbiosafetystandards.collaboration.gc.ca/cbs-ncb/index-eng.php>

McMaster University Health Sciences Records Management Plan, Guidelines for Deciding on the Lifespan of Records; <http://fhs.mcmaster.ca/recman/lifespan.html>

McMaster University Laboratory Handbook; <http://www.workingatmcmaster.ca/med/document/Lab-Safety-Handbook-1-36.pdf>

McMaster University Risk Management Manual (RMM):

1. Workplace and Environmental Health and Safety Policy, Number 100; <http://www.workingatmcmaster.ca/med/document/RMM-100-Workplace-and-Environmental-Health-and-Safety-Policy-1-36.pdf>
2. Health and Safety Training Program, Number 300; <http://www.workingatmcmaster.ca/med/document/RMM-300-Health-and-Safety-Training-Program-1-36.pdf>
3. Health and Safety Training Program, Number 300 – Appendix B; <http://www.workingatmcmaster.ca/med/document/RMM-300-Health-and-Safety-Training-Program-Appendix-B-1-36.pdf>
4. Safety Audits and Inspections, Number 302; <http://www.workingatmcmaster.ca/med/document/RMM-302-Safety-Audits-and-Inspections-Program-1-36.pdf>
5. Job Hazard Analysis Program, Number 324; <http://www.workingatmcmaster.ca/med/document/RMM-324-Job-Hazard-Analysis-Program-1-36.pdf>

Occupational Health and Safety Act, R.S.O. 1990, c. 0.1; <http://www.ontario.ca/laws/statute/90o01>

Technical Standards & Safety Authority (TSSA); <https://www.tssa.org/regulated/boilers/Default.aspx>