**Audit Checklist: Autoclave Operation**

**Document Number: 208**

*The purpose of this document is to standardize the specific audit procedures to be used for the facility. This document should be customized to meet your facility’s needs.*

1. **Purpose**

This document is intended to guide managers who have to check that autoclaves are being operated safely, that waste is being treated effectively, that regular maintenance procedures are carried out on time and that any repairs or problems are properly addressed.

1. **Scope**

A waste management system should include well-defined processes and procedures and all involved should be trained accordingly. To make sure that these procedures are being applied, managers should undertake regular checks on the autoclaves, their records and the practices undertaken. The manager should regularly check that all is running well and inspect logs, equipment, etc.

In addition, there should be periodic audits which are more systematic and often carried out by an independent expert or company. The auditor should review the logs and records and visually inspect the waste storage and treatment areas at the time of the audit. Audit results should be filed for a minimum of three years, so that any persistent problems can be identified and the effects of any changes can be tracked, and for reference by the regulatory authorities. Whenever possible, the health care facility should make audit results public.

Staff should not have any warning of an audit. If they are able to anticipate one, they may adjust their behavior so the auditor will not get an accurate impression of actual practices.

This document provides a checklist of the items and issues that an auditor should investigate. The auditor should produce a report including a summary and a discussion of the data collected, and highlight any areas that need improvement.

1. **Definitions**

Refer to Doc 524: Infectious Waste Autoclave Operation, Testing and Maintenance – Guidance for definitions.

1. **Responsibilities**
	1. The management should:
		1. Work with the auditor to define the terms and objective of the audit.
		2. Make sure that the auditor has access to all records, working areas and staff that they require.
		3. Ensure that any recommendations resulting from the audit are implemented without delay.
	2. Autoclave and other waste treatment staff should:
		1. Continue with their tasks as normal during the audit.
		2. Answer any questions the auditor has fully and provide any other information that is requested.
2. **Materials and Equipment**

The auditor may need to refer to the following documents. Copies should be made available.

* + - National or regional medical waste treatment guidelines
		- Facility healthcare waste management policy
		- Facility safety procedures
		- Standard operating procedure(s) for autoclave use and maintenance
		- Waste register
		- Autoclave Operation Log
		- Autoclave Maintenance Log
		- Collection records where final disposal is off-site
		- Facility and/or equipment authorization (such as a permit or a license from the regulatory authorities) and may include permission to dispose of waste, wastewaters or emit waste gases to atmosphere
		- Previous audit/inspection reports
1. **Hazards and Safety Concerns**
	1. There are several hazards associated with the use of autoclaves:
		1. Substantial heat and pressure generated by the autoclave
		2. Heat from steam, hot liquids and other materials, including containers, the autoclave chamber and door
		3. Falling items e.g., heavy containers of waste being put into/removed from autoclave
		4. Infectious waste, including untreated waste and waste from a failed treatment cycle
		5. Sharps, when glassware has broken or has been placed in bags rather than puncture-proof containers
	2. Do not touch the sides or back of older autoclaves; they have little or no heat shielding and may cause burns.
	3. Do not stack or store combustible materials (e.g., cardboard, plastic materials) or flammable liquids next to the autoclave.
	4. Never autoclave materials that contain toxic agents (e.g., disinfectants), corrosives (e.g., acids, bases, bleach, phenol), solvents or volatiles (e.g., ethanol, methanol, acetone, chloroform), or radioactive materials.
2. **Procedures**
	1. Clearly define the objectives of the audit beforehand. The purpose of auditing the autoclaving process is to:
		1. Check that the waste is being properly disinfected.
		2. Check that the maintenance is being carried out appropriately.
		3. Make sure safety systems are in place.
		4. Check that all incidents have been recorded and investigated, that actions are taken to prevent a recurrence and that they are reported in terms of legal and organizational requirements.
		5. Ensure that legal requirements are complied with.
	2. Auditing tips
		1. Introduce yourself, let people know why you are doing the audit and why it is so important to comply with the requirements.
		2. List the people interviewed in the “comments” column of the checklist.
		3. List the sample documents checked in the “comments” column, such as training done, reports, etc.
		4. Check that people understand the reasons for the requirements for safe work, including emergency response and incident reporting.
		5. Thank those who participated and explain how the findings will be reported and communicated, including the time frames.
3. **Reporting and Recordkeeping**
	1. Any failures and other incidents must be reported immediately to the relevant manager and department for action.
	2. Where prescribed by local legal requirements, the relevant authorities must be notified of any failures or incidents involving autoclaves.
	3. The results of the audit must be documented and submitted to the overseeing committee, such as the Infection Prevention Committee or Laboratory Biosafety Committee or Laboratory Quality Management Committee.
4. **References**

None

# Related Documents

* Doc 524: Infectious Waste Autoclave Operation, Testing and Maintenance – Guidance
* Doc 530: Autoclave Operation - SOP
* Doc 532: Autoclave Operation Log
* Doc 543: Autoclave Validation and Challenge Testing - SOP
* Doc 533: Autoclave Validation and Challenge Test Log
* Doc 531: Autoclave Inspection and Routine Maintenance – SOP
* Doc 208: Audit Checklist: Autoclave Operation
1. **Attachments**
	1. Autoclave Audit Checklist

**Attachment 11.1: Autoclave Audit Checklist**

| **Item** | **Yes** | **No** | **Comments** |
| --- | --- | --- | --- |
| **Waste storage and segregation** |
| 1 | Storage area clean and tidy | Yes | No |  |
| 2 | Storage area accessible only to authorized personnel | Yes | No |  |
| 3 | Storage area protected from pests | Yes | No |  |
| 4 | Biohazard warning sign in the waste storage area and on waste containers | Yes | No |  |
| 5 | Storage area properly ventilated | Yes | No |  |
| 6 | Infectious waste in robust containers with closed lids | Yes | No |  |
| 7 | Infectious sharps waste in puncture proof containers | Yes | No |  |
| 8 | Waste bags no more than ⅔full | Yes | No |  |
| 9 | Sharps containers no more than ¾ full | Yes | No |  |
| 10 | Only infectious waste sent for autoclaving | Yes | No |  |
| 11 | Toxic, corrosive and hazardous chemicals are excluded from materials for autoclaving | Yes | No |  |
| 12 | Waste autoclaved within acceptable time limits | Yes | No |  |
| 13 | Waste containers tagged with autoclave tape to show which have been autoclaved | Yes | No |  |
| 14 | Treated waste stored properly and away from untreated waste | Yes | No |  |
| **Autoclave status and operation** |
| 15 | Autoclave in an appropriate location | Yes | No |  |
| 16 | Access restricted to authorized personnel | Yes | No |  |
| 17 | Treatment area clean and uncluttered | Yes | No |  |
| 18 | Treatment area properly ventilated | Yes | No |  |
| 19 | Autoclave is free of leaks (can be indicated by water or water stains on the floor, water stains around joints and seals) | Yes | No |  |
| 20 | Door seal in good condition | Yes | No |  |
| 21 | Staff wearing the correct PPE | Yes | No |  |
| 22 | PPE clean and in good condition | Yes | No |  |
| 23 | Staff understand operational and safety procedures | Yes | No |  |
| 24 | Spill kit/emergency response supplies and equipment available | Yes | No |  |
| 25 | Pressure and temperature gauges on the autoclave are operational | Yes | No |  |
| 26 | Chamber trap strainer present and clean | Yes | No |  |
| **Challenge testing** |
| 27 | Challenge tests regularly run | Yes | No |  |
| 28 | Challenge tests conform to UNDP/GEF guidelines | Yes | No |  |
| 29 | The autoclave passes all challenge tests | Yes | No |  |
| 30 | Appropriate action taken if a challenge test is failed | Yes | No |  |

| **Item** | **Yes** | **No** | **Comments** |
| --- | --- | --- | --- |
| **Documentation** |
| 31 | Autoclave manual available in autoclave room | Yes | No |  |
| 32 | Autoclave user log available in autoclave room | Yes | No |  |
| 33 | Autoclave maintenance log available in autoclave room | Yes | No |  |
| 34 | Logs consistently and clearly filled in | Yes | No |  |
| 35 | Amounts of waste treated tally with the records of infectious waste collected within the healthcare facility | Yes | No |  |
| 36 | Responsible person’s letter of assignment available for inspection | Yes | No |  |
| 37 | Identified problems properly resolved | Yes | No |  |
| 38 | Annual inspection certificate (should be posted on the wall) | Yes | No |  |
| 39 | Emergency numbers and emergency exit route (should be posted on the wall) | Yes | No |  |
| 40 | Standard operating procedure (should be posted on the wall where possible) | Yes | No |  |
| 41 | Spill and injury response procedure available | Yes | No |  |
| 42 | Regulatory authorizations (permits, consents, licenses, etc.) available  | Yes | No |  |
| 43 | Permit to work (where appropriate) | Yes | No |  |
| **Training** |
| 44 | Personnel training files up to date and available | Yes | No |  |
| 45 | Relevant personnel trained, including refresher training | Yes | No |  |
| 46 | Relevant personnel understand hazards and how to minimize risks | Yes | No |  |
| 47 | Spill and injury response procedure is known and understood by all relevant personnel, including the procedure to follow in the event of potential exposure to pathogens | Yes | No |  |
| 48 | Operators have been vaccinated with all routine immunizations given to the public in that country, including tuberculosis and tetanus. In addition, all waste workers should be vaccinated against hepatitis A and B. | Yes | No |  |