Autoclave Survey

Key findings



Why did we do the survey?

- Main route for solid biological waste
- Waste partially recycled additional exposure risk
- Anecdotal inconsistency of frequency and level of servicing
- Autoclaves are high-risk equipment
- Reliable sterilisation of media, etc. required
- Guidance due for update



What did we base our questions on?

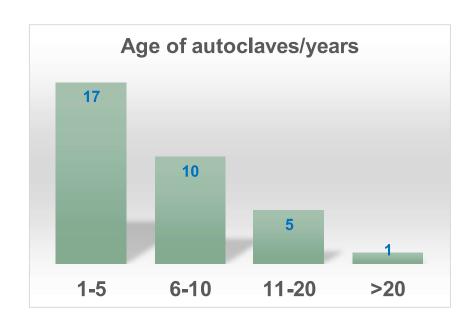
- HSE guidance PM73, Safety Requirements for Autoclaves
- BS standard BS 2646-3:2023, Autoclaves for Sterilisation in Laboratories - Part 3: Safe Use and Operation
- HTM 01-01, Management and Decontamination of Surgical Instruments Used in Acute Care – Part C: Steam Sterilisation (Department of Health, patient focussed, incl. risk from TSEs)



Use of autoclaves in biological labs at UoC

Number of autoclaves

>40% have one or two in operation



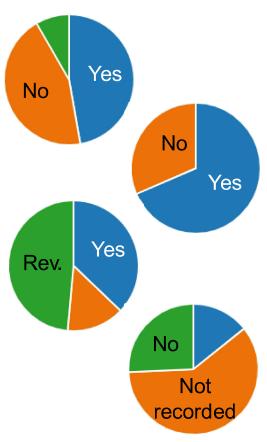
Main servicing companies

ESTS Sychem Priorclave Rodwell Astell MMM



Managing safe use of autoclaves

- 50% follow a written routine maintenance procedure
- 2/3 keep a record of training given
- Most have risk assessments in place, though review frequently required
- The vast majority do regular visual checks but often don't record them



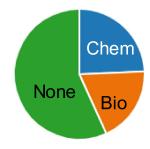


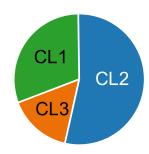
Servicing and monitoring

 Choice of performance test/validation parameters largely left to service company



 Just under half use chemical or biological indicators to monitor performance







Glossary of a few terms

- **Installation qualification** establishes that key aspects of the process equipment installation comply with specification
- Operational qualification establishes that installed equipment operates within predetermined limits
- **Performance qualification/test** establishes that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements. Set-up varies with type of items sterilised.
- **Validation** Confirmation process, through provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Evidence is result of test
- Responsible person person responsible for the operating policy and implementation of safety standards and local rules
- **User/Operator** person trained and deemed competent in their use. Training should be recorded.
- Monitoring/Indicators Use of chemical test strips or biological test kits to confirm desired parameters have been met (temperature/steam/time or kill rate)
- Make-safe process of reliably sterilising waste



Sources: ISO 17665, BS 2646, BS 1041

Guidance

- Daily checks/routine maintenance
- Which records to keep
- Legal requirements
- Contingency plans





Suggested Daily Checks

- Build-up of detritus on door interlocks, tap-in points and vent lines
- Door-locking mechanism securing bolts tight, welds not cracked, hinges adequately greased
- Seals in good condition
- No leaks
- Chemical indicators



Records

- Operating manual
- Risk assessment
- SOP, including Contingency Plan
- Training records
- Written Scheme of Examination (WSE)
- Plant History File/Maintenance History/Engineering Log
- Steriliser Process log/Usage log



