Estates and Facilities Alert

Action

Ref: EFA/2010/010 Issued: 19 October 2010 at 10:30

Device

Automated thermal washer disinfectors with independent monitoring

Problem

There is a risk of infection if surgical instruments are processed in a faulty or incorrectly set up automated thermal washer disinfector with inadequate or disabled independent monitoring.

Action

If an automated thermal washer disinfector (WD) is equipped with an independent monitoring system, it should:

- indicate to the operator the status of critical parameters;
- provide a permanent record of critical parameters for every load.

Action by

Managers and staff involved in

- the procurement, installation, commissioning, use, monitoring, validation/testing, maintenance or auditing of automated thermal washer disinfectors;
- the management of installations and service contractors.

Contact

Enquiries about specific WDs and monitoring systems should be addressed to

- the particular manufacturer or supplier;
- the Authorising Engineer (Decontamination).

Background

Independent WD monitoring systems vary from the traditional paper chart recorder to sophisticated microprocessor systems which will abort and 'fail' a cycle in the event of critical parameters being outwith the required values. While the level of monitoring is open to choice, it typically includes water temperature and pressure as well as logging cycle number, time and date to provide traceability.

An independent monitoring system may be supplied as part of the WD or added / changed later by a third party. Manufacturing rights for the WD and/or monitoring system may change and a third party contractor may take responsibility for maintenance and repair, sometimes making it difficult to trace history and responsibility should problems arise.

Problem

Incidents have been reported (from two separate Central Decontamination Units) involving the release of surgical instruments to the next stage of the decontamination process despite failure to meet the required conditions in an automated thermal washer disinfector (WD). The problems were only noticed later during planned revalidation tests.

These particular reports involved WDs with insufficient circulation water for the rinse and disinfect stages. The loads underwent terminal sterilization and, although the risks (to staff and patients) were considered to be relatively low on these occasions, a limited number of loads were recalled. The sites were registered and audited for compliance with the Medical Devices Regulations.

In the absence of WD self monitoring, the problems should have been picked up by the independent monitoring system. However, during the investigations, the independent monitoring was found to be either incorrectly set or inoperative.

Action

1. Any safety or monitoring feature (whether built in or independent) should comply with defined regulatory requirements[1,2] and be capable of being challenged / tested to ensure that it is functioning correctly and fit for purpose.

2. Procedures, training and defined responsibilities should be in place to:

   a) permit the release of each load only if all critical parameters are satisfactory, both on the WD and the independent monitoring system;

   b) permit the release of each load by a documented and signed off batch release procedure, especially should the independent monitoring system be partially or wholly inoperable;

   c) log cycle number and error codes for any failed cycle to aid further investigation;

   d) retain permanent records in line with legal and local policy requirements;

   e) carry out daily testing and maintenance checks on the flow and distribution of water and aqueous solutions throughout the chamber(s) and load, especially the spray system, and record in the log book[3];

   f) test the safety features weekly, quarterly and yearly to ensure that they are functional[3];

   g) test the WD and independent monitoring system during commissioning and subsequent validation tests, and following maintenance or repair, obtaining advice as required about the extent of the testing from an Authorising Engineer (Decontamination) as identified in Health Technical Memorandum guidance[3,4].

Suggested Onward Distribution

- Central Decontamination Units
- Estates/Facilities
- Health & Safety
- Infection Control Staff
- Microbiology
- Risk Management

Additional information for Northern Ireland

The above sections of this Alert were compiled by Health Facilities Scotland and distributed nationally without modification.

References

1 BS EN ISO 15883-1:2009, *Washer-disinfectors. General requirements, terms and definitions and tests,* BSI

2 BS EN ISO 15883-2:2009, *Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*, BSI

3 Health Technical Memorandum HTM 2030, *Washer Disinfectors* Parts 2 and 3,

4 Health Technical Memorandum HTM 01-01, *Decontamination of reusable medical devices,* Part A – *Management and environment*, Department of Health Estates & Facilities Division 2007

Action required by this alert should be underway by: 23rd Nov 2010
Action required by this alert should be completed by: 25th Jan 2011

Enquires should quote reference number EFA/2010/010 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523868
Fax: 02890 523900
E-mail: NIAIC@dhsspsni.gov.uk
Website: http://www.dhsspsni.gov.uk/niaic

How to report adverse incidents

Incidents relating to medical devices, estates equipment and plant in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible. Further information about reporting incidents can be found in DB(NI)2010-001; and downloadable report forms are available from the NIAIC's website (http://www.dhsspsni.gov.uk/niaic).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.
(An answer phone service operates outside normal office hours)

Estates and Facilities Alerts are available in full text on the NIAC website
Further information about SABS can be found at http://sabs.dhsspsni.gov.uk
This Alert can be found on the following websites
http://www.dhsspsni.gov.uk/niaic and http://sabs.dhsspsni.gov.uk