From: [redacted] (NHS NATIONAL SERVICES SCOTLAND)
Sent: 21 February 2019 17:51
To: [redacted] (NHS GRAMPIAN) <[redacted]@nhs.net>
Subject: Closure of INV826 OCC1020 Dr Weigert Unvalidated Chemical Detergent used in Endoscope Reprocessors & Washer Disinfectors

To [redacted], NHS Grampian

Dear [redacted]

Closure of INV826 OCC1020 Dr Weigert Unvalidated Chemical Detergent used in Endoscope Reprocessors & Washer Disinfectors

IRIC is closing this case. In summary:

- **Steelco WDs in Aberdeen Dental LDU** The Endoclean was procured in the belief that this was simply a rebrand of MediClean Forte. During the time of Endoclean was placed in WD and the time of discovery, the WDs were not used to process instruments due to the refurbishment of the decontamination unit. NHS Grampian confirmed no instrument was processed in Steelco WD using Endoclean.

- **Wassenburg EWD in ARI EDU**

During the period of incidents, endoscopes were subjected to manual pre-cleaning followed by cleaning and disinfection process in automated EWDs despite using the chemical previously has not been validated for these machines. On August 2017 the cleaning efficacy test of Endoclean on 8 EWDs on-site were undertaken, in accordance with HTM 2030, by Medical Devices UK. The testing parameters (i.e. temperature, time and concentration of detergents) were in the same range (e.g. as those used routinely including during incident on early June 2017. The results of the cleaning efficacy test on endoscopes found satisfactory (. This demonstrated Endoclean has similar cleaning performance as MediClean Forte and was able to satisfactorily clean the endoscopes in EWDs setting during the incident. Thus the risk on patients due to this incident was minimal. However, it is always advised the validation must be carried out prior to use.

Recommendations

- to develop change management process covering stages from planning, review, approval, implementation (procurement, training, execution) and post-review. This may cover trial and proposed change of chemicals, other consumables, equipment, facilities etc. It's recommended to involve the appropriate specialist (depending on products/services) e.g. in decontamination, procurement, infection control/microbiologist, AE(D), estates/facilities, risk, medical physic etc;

- to specify the chemical name, temperature and contact time and other cycle in the reference document e.g. SOP or Work Instruction and training material.(if any) This information should be made available for the staff carries out the relevant duties;

- to check the items against the reference documents prior to purchase, distribution, receipt on-site and prior to use;

- to improve storage of chemicals and others i.e. not to store the items which are not used within the units or secure restricted access;
- to complete change chemical form and signed by supervisor;
- to obtain a written confirmation from the manufacturer that the brand name has been changed and that the chemical compositions and other physical chemical characteristics remain the same as the original product;
- even in the case where the chemical name has been simply rebranded, the label on the cabinet should be changed with the new name.

Conclusion

Based on the records reviewed, over the three days examined, it is concluded that manual wash of the endoscopes was taking place.

Best regards

[redacted]
Health Facilities Scotland, direct dial [redacted]

http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric-1/