NHSScotland Guidance for the interpretation and clinical management of endoscopy final rinse water

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Contents

Introduction

In terms of reusable medical devices used within healthcare settings, flexible endoscopes have frequently been associated with outbreaks of infection.[1] NHSScotland (decontamination staff or clinical staff) are expected to follow the guidance laid out in the Scottish Hospital Technical Memorandum (SHTM) 2030 Washer-disinfectors, [2] the European Standards BS EN ISO 15883-4:2009 Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile flexible endoscopes,[3] Roles and Responsibilities of NHSScotland Decontamination Engineering Staff in the Acute Sector,[4] Endoscope Washer Disinfector Log Book, [5] and Requirements for Compliant Endoscope Decontamination Units 2014: Annex 1, Table 1.[6] Hospital Technical Memoranda 0106 [7] is not a Scottish document but is often referred to where guidance is not available within the SHTM.

This national guidance document aims to enhance patient safety and reduce risks of decontamination related Healthcare Associated Infection (HAI) by standardising the interpretation of and clinical management of endoscopy final rinse water results nationally, based on available scientific evidence, current practices and an estimation of infection risk within NHSScotland following endoscopic procedures.

Background

Health Protection Scotland as part of the SGHSCD HAI Taskforce Delivery Plan (2011 and beyond) in 2013/14 undertook a national survey of endoscope final rinse water testing, establishing current practice across NHS boards in Scotland. The survey also aimed to ascertain any variation within the clinical management of risks related to HAI associated with endoscope procedures and final rinse water results. The survey concluded that procedures used for the testing and management of final rinse water from endoscope washer-disinfectors (EWD) varies across the responding boards and that further intelligence was required to establish current practice around the clinical management of final rinse water from washer-disinfectors used to carry out decontamination of thermolabile flexible endoscopes.

To develop guidance for the clinical management of endoscopy final rinse water a data linkage exercise was performed with the aim of quantifying possible HAI risk related to endoscopy procedures. This was carried out in 2016/17 and attempted to estimate the risk of infection and identify potential infection clusters following endoscopic procedures. Data linkage was performed on endoscopic procedures carried out in Scotland with positive isolates post

procedure reported via Electronic Communication of Surveillance in Scotland (ECOSS). The data linkage study planned for publication in 2018 found the risk of infection following an endoscopic procedure in Scotland was 1.5 – 3.3% over the 5 year study period; lower than reported rates found within the literature.[1, 8, 10] From the data linkage study, national clinical risk based recommendations have been drafted for the interpretation and clinical management of final rinse water results in endoscope washer disinfectors.

Methods

The findings of the 2013/14 survey, current Scottish guidance documents and the data linkage study findings and recommendations were used to inform the development of this guidance. An updated survey was sent to all health boards in NHSScotland in 2017 to cross reference the previous 2013/14 survey information provided. The 2017 survey was undertaken via an e-mail to all Infection Control Doctors within NHSScotland and aimed to identify any health boards who may have updated their final rinse water result management processes since the 2013/14 survey.

Results

2013/14 Survey findings

Nine (64%) NHS boards responded to the 2013/14 survey. All respondents reported boards were performing microbiological testing on EWD final rinse water. The indicators of microbial contamination organisms included in the final rinse water testing varied across the boards (Table 1).

All nine boards reported testing for Total Viable Counts (TVC) however practice for other indicators was not standardised.

TABLE 1: Indicators tested in endoscope final rinse water at NHS board level (n=9)

Indicators of microbial contamination	Yes	No	Only when required	No response
Total Viable Count (TVC)	9	0	0	0
Mycobacterium species	1	3	4	1
Pseudomonas aeruginosa (PA)	3	3	3	0
Endotoxins	5	3	0	1
Other	0	0	0	9

Health boards were asked to provide the level of individual indicator (identified in Table 1) counts at which their board would request retesting of the washer-disinfector final rinse water (Table 2).

TABLE 2: Levels of indicator used to trigger retesting of washer-disinfector at NHS board level (n=9)

Indicator of microbial contamination	>0 CFU/100ml	>10 CFU/100ml	>30 CFU/100ml	Unknown
Total Viable Count (TVC)	NA	5	1	3
Mycobacterium species	1	NA	NA	8
Pseudomonas aeruginosa (PA)	3	NA	NA	6
Other	0	0	0	9
Endotoxins	0 Endotoxin unit EU/ml	0 Endotoxin unit EU/ml	0 Endotoxin unit EU/ml	9 Endotoxin unit EU/ml

From the varied responses received nationally regarding risks associated with the clinical management of endoscopy final rinse water test results Infection Control Doctors were questioned regarding the triggers they used which would result in a washer-disinfector being taken out of use.

Of the 6 board respondents in 2014;

- 100% of respondents reporting >100 TVC/100ml would result in the washer-disinfector being taken out of use until samples returned to acceptable levels.
- One board routinely testing for Mycobacterium species reported that two consecutive positive samples would result in machine being taken out of use.
- *Pseudomonas aeruginosa* >0 CFU/100ml was reported by all boards routinely testing as a trigger to stop using washer disinfector and carrying out retesting.

None of the nine boards that completed the questionnaire provided any information on patient notification.

2017 Health board survey findings

The follow up survey in 2017 provided detail around standard operating procedures (SOPs) for positive endoscopy final rinse water results. Response was poor and only six health boards responded (the full detail is tabled in Appendix 1 for TVC count results and Appendix 2 for *Pseudomonas aeruginosa* results) including local actions. Only three of the respondents were able to provide information of rinse water testing as a standard operating procedure. General findings were similar for all health boards. Two health boards had a risk assessment attached to specific scopes and actions to be considered for TVC count results. One health board had developed a more detailed approach for endoscopy final rinse water results based on the model of EWD and/or associated reverse osmosis (RO) units.

Laboratory testing of endoscopy rinse water varies throughout NHSScotland. Some health boards have laboratories which undertake water testing with other boards using private laboratories. Regardless of laboratories being affiliated to a health board or private facilities the local actions shared by health boards are listed below.

TVC final rinse water results of <1 cfu/100ml

Respondents stated no further action is required and routine reprocessing of all scopes should be performed. Results should continue to be monitored.

TVC results between 1 – 9 cfu/100ml

Respondents stated results should be monitored but all scopes can continue to be reprocessed. If positive results persist inform estates, the authorising engineer (decontamination) (AE(D)) and the local infection prevention and control team (IPCT) for possible action.

TVC results between 10 – 100 cfu/100ml

All respondents described this result as unacceptable and that engineering action would be required. Therefore estates, AE(D) and the local IPCT should be contacted for advice. Meantime final rinse water should be resampled.

There was variation in responses for clinical actions for this level of test result. One board would undertake a risk assessment to investigate potential problems with the EWD or water supply and superchlorinate the system. The infection control doctor (ICD) would be notified and advise as to the clinical management to be taken. One board had developed a risk matrix to assess possible infection risk to patients based on water results and endoscope activity. Only low risk scopes (see Appendix 1) would be reprocessed in the EWD until resample results were available. One board provided a very detailed plan of action for TVC test results within the 10 –100 cfu/100ml for reverse osmosis units and stand alone EWD (see Appendix 1).

TVCs >100cfu/100ml

All respondents described this result as unacceptable and that engineering action would be required. Therefore estates, AE(D) and the local IPCT should be contacted for advice.

There was variation in responses for clinical actions for this level of test result. One board would undertake a risk assessment to investigate potential problems with the EWD or water supply. Consideration would be given to removing the EWD from service until the water quality had improved. One respondent would continue with colonoscopies, nasolaryngoscopes, small intestine, choledocoscopes and gastroscopes but would stop using the EWD for duodenoscopes, cystoscopes, urethroscopes and bronchoscopes. One respondent would resample rinse water. If second sample positive sanitise reverse osmosis unit and resample. If the third sample returns positive estates and ICD would be contacted for advice. See Appendix 1 for details.

***Pseudomonas aeruginosa* results (>0 cfu/100ml)**

The actions required by all health board respondents for *Pseudomonas aeruginosa* are more clearly defined. The acceptable limit reported by all health boards is 0 cfu/100ml where reprocessing of all scopes would be expected. For positive *Pseudomonas aeruginosa* results (>0 cfu/100ml) one board would investigate immediately and take repeat samples. Laboratory staff must identify and report any presumptive *Pseudomonas aeruginosa* colonies and results should be reported to the ICD.

One board would suspend decontamination of bronchoscopes, cystoscopes, urethroscopes and endoscopic retrograde cholangiopancreatography (ERCP) scopes in the EWD until the affected washer-disinfector final rinse quality has been restored. No further detail was provided regarding attainment of negative sample results and the decision process for returning the EWD to use other than advice of ICD/IPCT.

The third board response again provided detail around actions dependant on the EWD and/or RO unit, the detail of which can be seen in Appendix 2. The general principles described were to switch to an alternative RO unit if possible to continue the decontamination of scopes. If not possible, scopes should not be reprocessed. Any scopes processed prior to the positive result must be recalled and reprocessed in another EWD. Recall scopes reprocessed through affected bath that are in HEPA storage units and endoscopy departments. The IPCT, ICD, decontamination lead and estates should be contacted. Track all scopes processed in this bath from previous water test. If any scope has been used for ERCP procedures on a patient, carry out a clinical risk assessment. Disinfection should be performed on the EWD bath and RO unit (if applicable) and repeat final rinse water samples taken. A review of planned maintenance data on water line filters should be performed and consideration should be given to replacing the filters. Three consecutive culture negative *Pseudomonas aeruginosa* results are required before releasing the unit back to service.

Conclusions and Recommendations

The findings of the health board survey have shown endoscopy practice in NHSScotland follows the national guidance laid out within SHTM 2030, and the European Standards BS EN ISO 15883-4 for TVC and *Pseudomonas aeruginosa*, testing. However despite this; variation in the clinical response to final rinse water test results is evident across NHSScotland.

Taking a washer-disinfector out of use can have a negative impact on patient services with the cancellation of procedures and delayed treatment being possible consequences. However the continued use of a washer disinfector where there is an indication that the decontamination of flexible endoscopes processed by the washer disinfector may not have achieved the desired decontamination level and may pose an infection risk to patients.

The aim of this project was to produce national guidance on how final rinse water test results should be interpreted and standardise any remedial actions which should be taken on finding

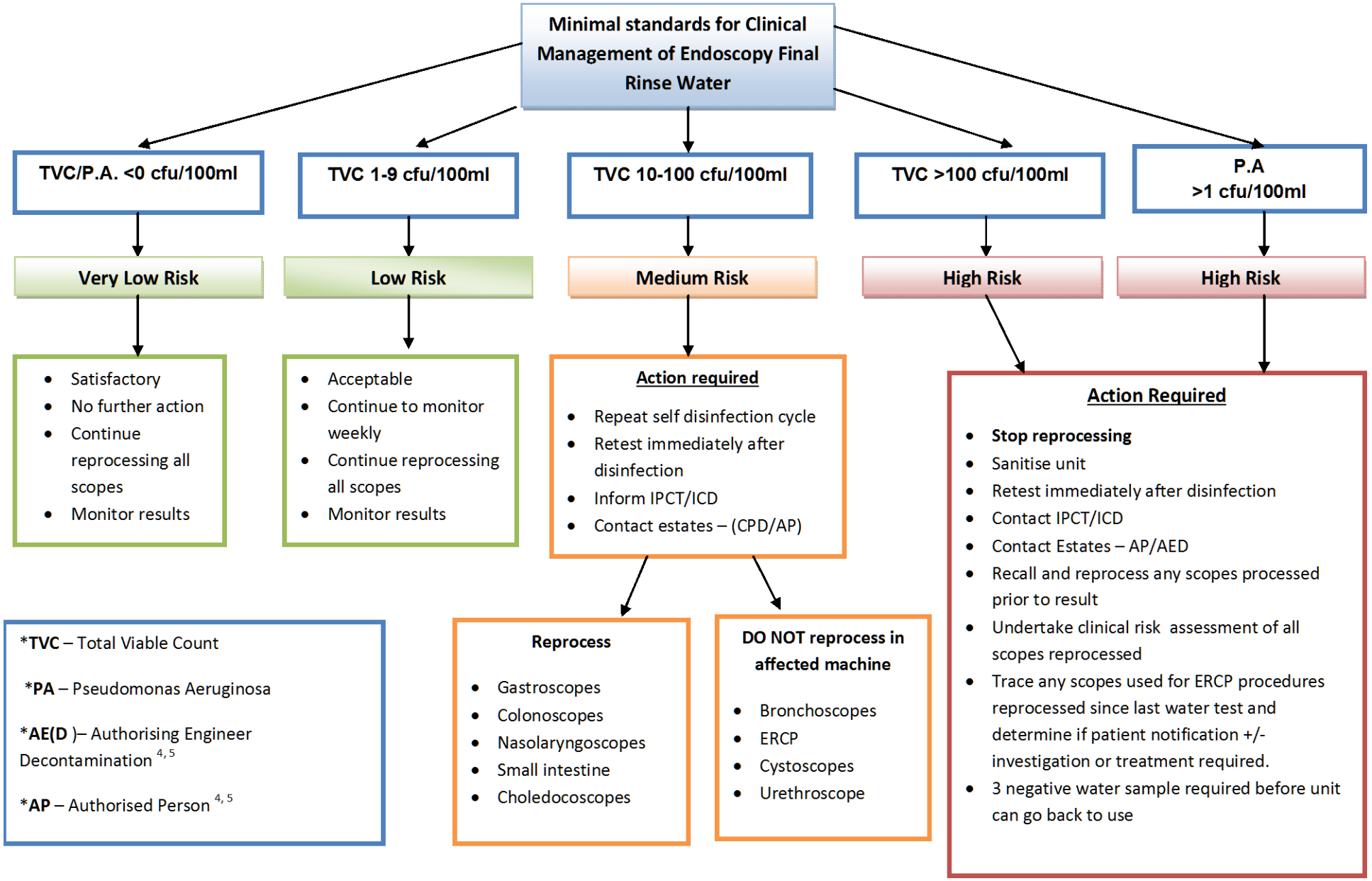
indicators of microbial contamination. The data linkage study, found a low risk of infection following an endoscopic procedure. The subsequent cluster analysis of the data did not identify any infection clusters within NHSScotland despite the variation in how positive final rinse water results are managed. The findings of the data linkage study, the supporting literature review (unpublished) [10] and the HPS national surveys suggest it is appropriate to recommend a national minimum standard to be developed for the interpretation and management of EWD final rinse water results. The minimal standard (Figure 1) can be adopted by health boards however if required can be adapted by health boards where more detailed processes are in place.

To assist staff in following the proposed minimal standard, an algorithm format has been developed for ease of use. This can be placed in a convenient place for staff to access when results are being interpreted.

Recommendations

- Testing laboratories should use the methodology in BS EN ISO 15883 (2006) to assess the final rinse water TVC/*Pseudomonas aeruginosa* PA in the endoscope washer-disinfector.
- Testing laboratories should be accredited for testing of endoscopy rinse water.
- Staff responsible for undertaking testing of final rinse water should be trained in the aseptic process for collection and transportation of samples as described in SHTM 2030 and BS EN ISO 15883.
- Weekly microbiological testing should be undertaken as described in SHTM 2030.
- Where positive TVC counts of >10 cfu/100ml are identified on subsequent tests the testing laboratory should provide detail on the number and type of indicators of bacterial contamination found on the second result.
- Where positive TVC counts of >100 cfu/100ml are identified the testing laboratory should provide detail on the number and type of indicators of bacterial contamination found.
- Health boards should monitor results and analyse trends.
- As a minimum, health boards should follow the guidance for clinical management of endoscopy final rinse water described in the algorithm below.

Figure 1: Algorithm for Clinical Management of Endoscopy Final Rinse Water



Appendix 1: 2017 survey - Endoscopy final rinse water TVC results management

Health board response	TVC <1 cfu/100ml	TVC 1 – 9 cfu/100ml	TVC 10 – 100 cfu/100ml	TVC >100 cfu/100ml
1	Satisfactory	Acceptable – No action	Unacceptable Risk assessment Sanitise/self disinfect Report to ICD.	Risk assessment required Consider taking EWD out of service until water quality improved.
2	Satisfactory - No action Continue with all scopes	Acceptable - No action Continue with all scopes	Unacceptable Engineering action required **Continue with** colonoscope, nasolaryngoscope, small intestine, choledocoscope gastroscope, **DO NOT CONTINUE** with - Duodenoscope, Cystoscope, Urethroscope, Broncoscope in EWD.	Unacceptable Engineering action required. **Continue with** colonoscope, nasolaryngoscope, small intestine, choledocoscope, gastroscope **DO NOT CONTINUE** with - Duodenoscope, Cystoscope, Urethroscope, Broncoscope in EWD.
3 Stand-alone RO system with back up.	Satisfactory - No action Continue with all scopes	Satisfactory - No action Continue with all scopes	**10 – 33 cfu/100ml** Acceptable no action **34 – 68 cfu/100ml** Switch to alternative RO Unit. Resample water. **>68 cfu/100ml** Resample water.	Same as action for >68 cfu in previous section

			2nd sample >68/100ml Sanitise RO Unit. Resample. **3 consecutive results >68** contact Estates and ICD lead for advice.	
3 EWD with integral RO unit	Satisfactory - No action Continue with all scopes	Satisfactory - No action Continue with all scopes	**10 – 33 cfu/100ml** Acceptable no action **34 – 68 cfu/100ml** Resample water. Continue reprocessing scopes. If adverse results continue contact estates and ICD. **>68 cfu/100ml** Resample water. Continue reprocessing scopes. **2nd sample >68/100ml** Sanitise RO Unit Resample. Continue reprocessing. **3 consecutive results >68** contact estates and ICD for	Same as action for >68cfu in previous section

			advice.	
3 EWD Baths	Satisfactory - No action Continue with all scopes	Satisfactory - No action Continue with all scopes	**10 – 40 cfu/100ml** Acceptable no action **41 – 81 cfu/100ml** Resample water. Continue reprocessing scopes. If adverse results continue contact estates and ICD for advice **>82 cfu/100ml** Resample water. Continue reprocessing scopes. **2nd sample >82/100ml** sanitise, resample, continue reprocessing. **3 consecutive results >82** contact estates and ICD for advice.	Same as action for >82cfu in previous section
3 (integral RO unit)	Satisfactory - No action Continue with all scopes	Satisfactory - No action Continue with all scopes	**10 – 40 cfu/100ml** Acceptable no action **41 – 81 cfu/100ml** Resample water. Continue reprocessing scopes. If adverse results continue	Same as action for >82cfu in previous section

			contact estates and ICD for advice **>82 cfu/100ml** Resample water Continue reprocessing scopes. If 2nd sample >82/100ml sanitise, resample, continue reprocessing. If 3 consecutive results >82 contact estates and ICD for advice.	
DOH Department of Health	Satisfactory	Regular Acceptable	Risk assessment & investigate. Superchlorinate or repeat EWD self-disinfect Bacterial count >10 cfu/100 mL identification of species is advised. Significant proportion of microbes appear the same species from their colonial morphology, carry out oxidase test to presumptively identify Pseudomonas spp. If positive, further investigations are required to determine whether Pseudomonas aeruginosa is present.	Risk assessment required to consider taking EWD out of service until water quality improved

Appendix 2: 2017 Survey - Endoscopy final rinse water Pseudomonas aeruginosa results management

Health board **Response**	**PA 0cfu/100ml**	**PA >1cfu/100ml**	**PA >100 cfu/100ml**
1	Satisfactory	Unsatisfactory. Investigate immediately and take repeat samples. Presumptive PA colonies must be ID Report to ICD	No information provided
2	Satisfactory	Pseudomonas and Environmental mycobacteria Suspend decontamination of bronchoscopes, cystoscopes, urethroscopes and ERCP in EWD until the affected washer disinfector final rinse quality has been restored	No information provided
3 Stand-alone RO system with back up.	Satisfactory	Switch to alternative RO plant Scopes processed in RO prior to +ve result - recall & reprocess Sanitise RO unit and repeat sample **if no 0.2µm filter present in EWD SEE EWD Pseudomonas response below** If bath protected by 0.2µm filter - replace filter and restart reprocess scopes If 2nd sample +ve PA contact estates & Micro decon lead for advice 3 consecutive samples culture -ve required for PA before release back to service	No information provided
3 Single RO System	Satisfactory	**STOP** reprocessing scopes in AER Any scopes processed prior to +ve result	No information provided

		must be recalled and reprocessed Sanitise RO unit and repeat sample Replace 0.2µm filter in EWD if present **(EXCLUDING ERCP scopes)** all other scopes can be reprocessed ERCP scopes should be processed off site If 2nd sample +ve PA contact estates and micro decon lead for advice. Three consecutive culture -ve samples required to release back to service	
3 EWD Baths		**STOP reprocessing scopes in AER** Any scopes processed prior to +ve result must be recalled and reprocessed Contact micro decon lead, endo manager & estates Recall scopes reprocessed through affected bath that are in HEPA storage units and endoscopy depts. **ERCP scopes only -** Track scopes processed in this bath from previous water test. IF ERCP scope with PA has been used on a patient carry out a clinical risk assessment Disinfect EWD bath and RO unit and repeat final rinse water samples Review PPM data on water line filters and consider replacements Requires three consecutive culture -ve PA results before releasing back to service.	**STOP reprocessing scopes in AER** Any scopes processed prior to +ve result must be recalled and reprocessed Contact micro decon lead, endo manager & estates Recall scopes reprocessed through affected bath that are in HEPA storage units and endoscopy depts. Track scopes processed in this bath from previous water test. Track and trace data indicates scopes have been used on patients - A clinical risk assessment is required. Disinfect EWD bath and? RO unit and repeat final rinse water samples Review PPM data on water line filters and consider replacements Requires three consecutive culture -ve PA results before releasing back to service.
3 EWD with integral RO unit		STOP reprocessing scopes in AER Any scopes processed prior to +ve result must be recalled and reprocessed	STOP reprocessing scopes in AER Any scopes processed prior to +ve result must be recalled and reprocessed

		Contact micro decon lead, endo manager & estates Recall scopes reprocessed through affected bath that are in HEPA storage units and endoscopy depts. ERCP scopes only - Track scopes processed in this bath from previous water test. IF ERCP scope with PA has been used on a patient carry out a clinical risk assessment Disinfect EWD bath and RO unit and repeat final rinse water samples Review PPM data on water line filters and consider replacements Requires three consecutive culture -ve PA results before releasing back to service.	Contact micro decon lead, endo manager & estates Recall scopes reprocessed through affected bath that are in HEPA storage units and endoscopy depts. Track scopes processed in this bath from previous water test. Track and trace data indicates scopes have been used on patients - A clinical risk assessment is required. Disinfect EWD bath and ? RO unit and repeat final rinse water samples Review PPM data on water line filters and consider replacements Requires three consecutive culture -ve PA results before releasing back to service.
Department of Health		**STOP reprocessing scopes in ISIS** **If water from ISIS contains PA** - STOP reprocessing scopes in AER Any scopes processed prior to +ve result must be recalled and reprocessed Contact micro decon lead, endo manager & estates Recall scopes reprocessed through affected bath that are in HEPA storage units and endoscopy depts. ERCP scopes only - Track scopes processed in this bath from previous water test. IF ERCP scope with PA has been used on a patient carry out a clinical risk assessment Disinfect EWD bath and? RO unit and repeat final rinse water samples Review PPM data on water line filters and consider replacements	

		Requires three consecutive culture -ve PA results before releasing back to service. **If water from ISIS is -ve PA -** Remove bath from service Run self disinfect cycle on ISIS Repeat final rinse water samples from filter bank and ISIS Contact Endo and estates managers Review data on water line filters Sanitise filter bank assembly using chlorine tabs (1000ppm) Replace filters as per manufacturers instructions Resample water and return to service pending water sample results	

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