

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/34

Issued: 7 July 2004

For:

IMMEDIATE ACTION	
ACTION	
<b>UPDATE</b>	✓
INFORMATION REQUEST	

	Section
<b>Medical Device/Equipment:</b> Flexible endoscopes	▶ ①
<b>Problem:</b> Risk of transmission of infection because of inadequate decontamination	▶ ②
<b>Action by:</b> <ul style="list-style-type: none"> <li>• Chief Executives – Boards and Trusts</li> <li>• Decontamination Leads</li> <li>• Professionals who use endoscopes</li> <li>• Staff who reprocess endoscopes</li> <li>• Staff with responsibility for the specification and procurement of endoscopes and reprocessing equipment</li> <li>• Staff with responsibility for the training of other staff in the use of endoscopes and reprocessing equipment</li> <li>• Infection Control Team</li> <li>• Risk Management Team</li> </ul>	▶ ③
<b>Action:</b> This MDEA is an update of guidance to HPSS Trusts and Private Clinics.	▶ ④
<b>Distributed by NIAIC to:</b> <ul style="list-style-type: none"> <li>Chief Executive of each HSS Board</li> <li>Chief Executive of each HSS Trust</li> <li>Chief Executive of each Agency</li> <li>NIAIC Liaison Officers</li> </ul> <b>For onward distribution see Section 5</b>	▶ ⑤
<b>Contacts</b> NIAIC contact for technical aspects	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None Required	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## **1. DEVICE/EQUIPMENT:**

Flexible endoscopes

## **2. PROBLEM:**

Within endoscopy differing levels of decontamination are used. They are cleaning followed by high-level disinfection or cleaning followed by sterilization, depending on the device, the clinical procedure and chemicals used to achieve high-level disinfection. Examples of inadequate decontamination practices identified that could result in an increased risk of transmission of infection between patients include: -

- the use of connection sets that were not designated for a particular endoscope and the liquid-chemical processor or automated endoscope reprocessor (AER). Connection sets must be fully compatible with both the endoscope and the processor.
- failure to decontaminate specific channels that had not been used during the procedure. Endoscopes with channels that may not be used during every procedure (e.g. auxiliary irrigation channel) must be included in the decontamination cycle (manual or automated) after every use of the endoscope.
- failure to manually decontaminate specific channels prior to automated reprocessing. Some endoscopes have channels such as elevator wire channels that cannot be decontaminated in some liquid-chemical processors or AERs. In such cases, these channels must be manually cleaned and decontaminated using a high-level disinfectant following the manufacturer's instructions after every use of the endoscope. The manual high-level disinfection process is required by law to be risk assessed to ensure the health and safety of employees. Should this assessment indicate that the risks of manual high-level disinfection are unacceptable for health and safety reasons, the endoscope should be decommissioned and not used.
- failure to decontaminate endoscopes that are not frequently used such as endoscopes used for emergency intubation. All endoscopes must be adequately decontaminated after each patient episode.
- the inappropriate use of alcohol as a disinfectant when a high-level disinfectant should have been used. Alcohol is not a sterilant or high-level disinfectant. It has bactericidal, fungicidal properties and is active against many viruses and has been shown to be tuberculocidal. It does not however penetrate well into organic matter. Isopropyl alcohol is recommended only as a drying agent following decontamination.

## **3. ACTION BY:**

- Chief Executives
- Decontamination Leads
- Professionals who use endoscopes
- Staff who reprocess endoscopes
- Staff with responsibility for the specification and procurement of endoscopes and reprocessing equipment
- Staff with responsibility for the training of staff in the use of endoscopes and reprocessing equipment
- Staff with responsibility for inspection and maintenance of endoscopes and reprocessing equipment

## **4. ACTION:**

The following is recommended for all organisations providing endoscopy services: -

1. Chief Executives to ensure that appropriate management arrangements are in place to oversee and improve where necessary the overall process of decontamination.
2. The organisation's senior member of staff with responsibility for decontamination (Decontamination Lead) should ensure that a member of staff with operational experience in endoscope reprocessing is designated to take lead responsibility for all aspects of endoscope management. Responsibility should cover all units within an organisation in which endoscope decontamination is undertaken to ensure consistency of decontamination processes in the organisation e.g. in Day Procedure Units, Outpatient Departments, Intensive Care Units, Theatres etc.

3. Ensure that endoscope users and staff responsible for endoscope reprocessing have access to sources of professional advice and reference for Microbiological, Infection Control, Health and Safety and Decontamination (Authorised Person (Sterilizers)) issues.
4. Ensure that policies and procedures for endoscope decontamination are comprehensive, current, are appropriate and that staff are adhering to these procedures. This includes: -
  - a. Confirming that you have the correct version of the instructions applicable to your liquid-chemical processor, high-level disinfectant and AER for the specific endoscope models used and check that they are all compatible;
  - b. Making available to all staff responsible for reprocessing, copies of written device-specific instructions for every endoscope model, high-level disinfectant and reprocessing system you use and check that they are all compatible;
  - c. Reviewing the written endoscope-specific reprocessing instructions from liquid-chemical processor, high-level disinfectant and AER manufacturers to be sure that they are correctly implemented at your facility.
5. Provide comprehensive quality assured training for all staff responsible for reprocessing endoscopes to ensure that they understand the importance of proper reprocessing of all endoscopes used in your organisation. Members of staff undertaking decontamination must be competent, properly trained and supervised. To achieve and maintain competency, each member of staff should periodically (at least annually) receive:
  - a. Hands-on training with each written endoscope-specific reprocessing instruction for every endoscope model and liquid-chemical processor and AER used at your facility. Work should be closely supervised until competency is documented for each reprocessing task from cleaning through to storage of the endoscope.
  - b. Individual training records, detailing an individual's core competencies and any training received, must be maintained and updated regularly. Line Managers are responsible for maintaining these records.
  - c. Hands-on training with documented competency for new models of endoscopes, high-level disinfectants or AERs before they are introduced in your facility.
  - d. Strict warnings with frequent reminders not to deviate from the written instructions for reprocessing endoscopes.
6. Implement a comprehensive quality control program. Your reprocessing program should include:
  - a. Visual inspections of the equipment systems to identify conditions that may affect the cleaning or disinfecting processes;
  - b. Decontamination equipment must be subject to validated commissioning, monitoring and maintenance by appropriately qualified staff. All decontamination processes using AERs must be validated and tested in accordance with HTM 2030.
  - c. Assurance that all manufacturer-recommended maintenance schedules and services are performed for endoscopes, liquid-chemical processors and AERs used in your facility;
  - d. Use of appropriate process monitors as recommended by your liquid-chemical processors, high-level disinfectant and AER manufacturers;
  - e. Records of the use of each endoscope, showing the patient upon who it was used, the type of procedure involved, and the system used to reprocess the endoscope;
  - f. A surveillance system capable of detecting clusters of infections or pseudo-infections associated with endoscopic procedures.
7. When considering the procurement and disposal of endoscopes and reprocessing equipment, medical device and equipment management group(s) should include membership of the necessary key staff including endoscope users and staff responsible for reprocessing to ensure appropriate examination of the manufacturers specifications. This will ensure that new endoscopes are compatible with decontamination equipment in place and new decontamination equipment can reprocess existing endoscopes.
8. When an endoscope is sent for repair or service and is replaced temporarily by an on-loan endoscope, organisations must ensure that all channels of the on-loan endoscope are identified and that it is

compatible with the high-level disinfectant in use and decontamination equipment in place. Appropriate records for traceability purposes should be maintained when on-loan endoscopes are being used.

9. Endoscopes that cannot be easily decontaminated and/or those that are in poor condition should be replaced in accordance with a planned replacement programme.
10. Decontamination equipment that does not meet the requirements of current standards and test methods is upgraded or replaced as soon as practicable in accordance with a planned replacement programme.
11. User Organisation's Medical Device and Equipment Management policies should consider the appropriateness of professional staff employed by the User Organisation using endoscopes (owned by the User Organisation) in other healthcare provider facilities.

Further advice is available in the following extant guidance. It is recommended that guidance contained in these publications should not be considered in isolation but should be considered collectively: -

NIAIC Device Bulletin DB(NI)2002/05 "Decontamination of endoscopes" .

British Society of Gastroenterology (2003). 'Endoscopy guidelines'. [www.bsg.org.uk](http://www.bsg.org.uk)

NHS Estates (1997). Health Technical Memorandum 2030 "Washer Disinfectors"

HPSS Controls Assurance Standard. "Decontamination of Reusable Medical Devices".

HPSS Controls Assurance Standard " Medical Devices and Equipment Management".

HSS(MD)15/99 Variant Creutzfeldt-Jakob Disease (vCJD) : Minimising the Risk of Transmission.

HSS(MD)16/99 Controls Assurance in Infection Control: Decontamination of Medical Devices.

Device Bulletin DB 9904 (NI) Medical Device and Equipment Management for Hospitals and Community Based Organisations.

Device Bulletin 9904 (NI) Supplement 1: Medical Device and Equipment Management for Hospitals and Community Based Organisations: Checks and Tests for newly delivered medical devices.

Device Bulletin 9904 (NI) Supplement 2: Medical Device and Equipment Management for Hospitals and Community Based Organisations: Guidance on the sale, transfer of ownership and disposal of used medical devices.

HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

Device Bulletin 2000/02 (NI) Medical Devices and Equipment Management: Repair and Maintenance Provision.

Sterilization, Disinfection and Cleaning of Medical Equipment: Guidelines on Decontamination from the Microbiology Advisory Committee to the Department of Health (MAC Manual)

## **5. ONWARD DISTRIBUTION TO:**

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Decontamination Leads
- Infection Control Doctors
- Infection Control Nurses
- Estates Managers
- Medical Directors
- Nursing Directors
- Medical & Nursing Staff
- Endoscopy Suite Managers
- Gastroenterologists
- CSSD Managers
- Surgeons
- Urologists
- Nurse Endoscopists
- Intensive Care Units
- Day Procedure Units
- Theatres
- Outpatient Departments
- Physicians
- Supplies Staff
- Directors of Public Health
- Consultants in Communicable Disease Control
- Independent Health Care Providers – Private Clinics through HSS Board R&I Units

## 6. CONTACTS:

Technical Enquires to NIAIC should quote reference number MDEA(NI)2004/34 and be addressed to:

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

Tel: 028 9052 3868  
Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

For Clinical Aspects:  
Dr Glenda Mock  
DHSSPS  
Castle Buildings  
Stormont Estate  
Belfast BT4 3SQ  
Tel: 028 9052 0710  
Email: [glenda.mock@dhsspsni.gov.uk](mailto:glenda.mock@dhsspsni.gov.uk)

For Advice and Guidance on Decontamination Processes:

John Singh  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast  
BT16 1US

Tel: 028 9052 3802  
Fax: 028 9052 3900  
Email: [john.singh@dhssps.gov.uk](mailto:john.singh@dhssps.gov.uk)

For Nursing Aspects:  
Mrs Elizabeth Qua  
Principal Nurse  
Health Estates  
Stoney Road  
Dundonald  
Belfast BT16 1US  
Tel: 028 9052 3828  
Email: [elizabeth.qua@dhsspsni.gov.uk](mailto:elizabeth.qua@dhsspsni.gov.uk)

## 7. FEEDBACK:

None Required



Brian Godfrey  
NIAIC Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2004/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*