

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/44

Issued: 20th July 2006

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Devices in cardiac catheterisation and interventional radiology laboratories, including devices suspended from the ceiling.</p>	▶ ①
<p>Problem: The MHRA has received reports of adverse incidents where devices have not been maintained, leading to their failure. In some cases there has been no maintenance on the devices for several years. Specifically, a lack of maintenance has been found for suspension arms supporting ceiling-suspended lead acrylic screens, theatre lamps and power injectors.</p>	▶ ②
<p>Action by: Directors of cardiology, directors of radiology and staff working in cardiac catheterisation and estates staff.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Ensure that an appropriate maintenance contract is in place for every item in these laboratories that needs one. • Review procedures to ensure that new items are included in the maintenance programme. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Devices in cardiac catheterisation and interventional radiology laboratories, including ceiling-suspended radiation protection shields, theatre lamps, and power injectors.

2. PROBLEM:

Some devices have not been maintained as specified by the manufacturers' user instructions and as required under Statutory Rule 1993 No.19 "Provision and Use of Work Equipment Regulations (Northern Ireland)" 1993 . One example was a ceiling-suspended radiation screen where maintenance on the supporting arm had been inadvertently overlooked by hospital staff and equipment suppliers. The lack of maintenance may have contributed to the failure of a knuckle joint, which in turn caused the arm to collapse.

3. ACTION BY:

Directors of cardiology, directors of radiology, staff working in cardiac catheterisation and estates managers.

4. ACTION:

Ensure that arrangements have been made to provide maintenance for all devices in the laboratory that need it. This may be achieved by correlating an equipment inventory for the laboratory with the manufacturer's maintenance schedules, and contracting with a maintenance provider to carry it out. The provider may be an external party, such as the X-ray equipment service agent, or a trained in-house provider.

Maintenance of medical devices is also addressed in NIAIC publications DB 9904 (NI) and DB 2000/02 (NI) (both currently under revision).

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:

- Cardiology service managers
- Clinical directors of cardiology
- Clinical directors of radiology
- Estates departments
- Health & safety managers
- Independent Health and Social Care Providers – Private Hospitals through RQIA
- Medical physics/EBME
- Purchasing managers
- Radiology service managers
- Risk managers
- Superintendent radiographers
- Supplies managers

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2006/44 and be addressed to:

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

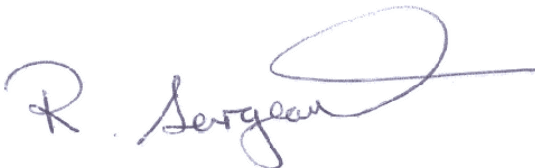
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



Robert Sergeant
NIAIC Operational 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)2006/01. 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

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