



The Regulation and  
Quality Improvement  
Authority

June 2013

Registered Managers  
All registered establishments

Dear Sir/Madam

**Re Medical Device and Equipment Alerts (MDAs and MDEAs) and Reporting of Adverse Incidents to the Northern Ireland Adverse Incident Centre (NIAIC)**

RQIA wrote to all registered managers in December 2009 regarding medical device and equipment alerts (MDAs and MDEAs).

The purpose of this letter is to remind providers of their responsibilities around this and to bring it to the attention of those new to regulation since then.

**Northern Ireland Adverse Incident Centre (NIAIC)**

The DHSSPSNI operate NIAIC which investigates and reports on adverse incidents involving medical devices, equipment, plant and building items used in HPSS in Northern Ireland.

NIAIC issues warning notices and guidance to help prevent recurrence and avert patient, staff, client or user injury.

These are normally in the form of medical device and equipment alerts (MDAs and MDEAs) which are published regularly on their website.

**Arrangements for dealing with medical device and equipment alerts (MDAs and MDEAs)**

To ensure that registered managers can receive and act upon alerts in a timely manner, robust arrangements should be in place within establishments for accessing alerts on the NIAIC website,

This will go some way to ensuring that the risk of harm or injury to service users and staff from exposure to defective medical devices or equipment can be reduced with minimal delay.

**Actions by registered persons and managers**

All registered persons and managers should ensure that a suitably competent member of staff is nominated to access the NIAIC section of the DHSS website and assess the published MDAs and MDEAs as well as reporting on adverse incidents involving medical devices or equipment.

Suitable I.T. equipment will need to be made available to the nominated person for this purpose e.g. computer, internet connection, printer etc.

The nominated person might be the registered manager or another senior member of staff. They should possess sufficient knowledge and competence

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to assess and determine the relevance of the published alerts to the equipment held and used in the establishment.

The following should be carried out by the nominated person:

- Visit/log on to the NIAIC website at suitable frequencies and access MDAs and MDEAs. These are published on an ongoing basis. It is recommended that the website is accessed at least weekly
- Keep a log of all visits to the website
- Print off all alerts which relate to equipment held or used at the premises
- Ensure that appropriate action is initiated or taken as outlined on the alerts and retain records of such actions
- Report any adverse incidents involving medical devices or equipment to NIAIC using the form provided on the website and retain a copy of same.

The above information should be retained for reference purposes and should be available for inspection by RQIA Inspectors who may check for compliance with above arrangements during the course of their normal inspections.

### **NIAIC website details**

The NIAIC webpage address is [www.dhsspsni.gov.uk/index/hea/niaic.htm](http://www.dhsspsni.gov.uk/index/hea/niaic.htm)  
From this webpage, all recent MDAs and MDEAs can be accessed by clicking on the 'Whats New' link on the left hand side of the page.

Alternatively, the complete up to date list of MDAs and MDEAs for 2013 can be found at

[http://www.dhsspsni.gov.uk/index/hea/niaic/niaic\\_warning\\_notices/niaic\\_medical\\_device\\_equipment\\_alerts/mdea-2013.htm](http://www.dhsspsni.gov.uk/index/hea/niaic/niaic_warning_notices/niaic_medical_device_equipment_alerts/mdea-2013.htm)

Previous years can be easily accessed from this page by selecting the relevant year on the left hand side of the web page.

Full information on the alerts including appropriate action can be accessed by clicking on the active links within.

Similarly, information on adverse incidents and reporting forms can be found in the webpage's 'Reporting Incidents' link.

### **Establishments operated by 'larger' groups or organisations**

Some organisations including HSC Trusts may already have, or may wish to implement central arrangements for distributing MDAs and MDEAs to the registered establishments which they operate.

Managers of such establishments should confirm with their respective organisations that these satisfy the arrangements outlined above.

## **Reporting adverse incidents**

Details on procedures for reporting adverse incidents to NIAIC can be found on the website at [http://www.dhsspsni.gov.uk/db2010\\_ni\\_-01.pdf](http://www.dhsspsni.gov.uk/db2010_ni_-01.pdf)

Yours sincerely

A handwritten signature in black ink, appearing to read 'P. Cunningham'.

**Phil Cunningham**  
Senior Estates Officer, RQIA

cc    **Robert Sergeant, NIAIC Operational Manager, Health Estates  
Investment Group  
Kathy Fodey, RQIA  
Dermot Parsons, RQIA  
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