

Arrangements to eliminate risks to patients and service users from equipment including medical devices

Regulations and DHSSPS Minimum Standards

Regulations and minimum standards relating to registered services require that arrangements are in place to eliminate risks to patients and service users from equipment including medical devices.

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)

Arrangements by registered establishments

Currently RQIA distributes MDAs and MDEAs to regulated establishments as part of general 'mail shots' periodically by post and by e-mail.

As of 1 April 2010 all registered persons and managers should ensure that a suitably competent member of staff is nominated to:

- 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 in a separate folder labelled 'NIAIC/MDEAs for access by staff and managers.

The folder should also be available for inspection by RQIA Inspectors who will 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

From this webpage, all new MDAS and MDEAs can be accessed by clicking on the '*Whats New*' link on the left hand side of the screen.

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.

Contact us

If you have any comments on this subject or require any further information please contact us:

- by e-mail: mdea.info@rqia.org.uk
- in writing: **MDEA Information
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- By telephone: **(028) 9051 7500** ask for the Estates team.

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