



11 May 2017

Registered Managers
Registered Responsible Persons
All registered establishments

Dear Sir/Madam

Re Acting on Safety Information from, and Reporting of Adverse Incidents to the Northern Ireland Adverse Incident Centre (NIAIC), Department of Health (DoH)

RQIA wrote to all registered providers in December 2009 and again in May 2013 regarding your responsibilities around NIAIC.

The purpose of this letter is to remind you of these responsibilities and to bring them to the attention of those new to regulation since then. It is also intended to make you aware of changes to the NIAIC website address and to provide an update regarding their notification system for safety information.

NIAIC

The NIAIC operates as a function of the DoH, formally the Department of Health, Social Services and Public Safety (DHSSPS). The objective of the NIAIC is to take all reasonable action, within its remit, to safeguard the health of healthcare users and staff. This is achieved through the voluntary reporting and investigation of adverse incidents involving medical devices, non-medical equipment, plant and building elements and the provision of relevant safety guidance in these areas.

Reporting adverse incidents to NIAIC

The NIAIC run an open reporting forum of adverse incidents in the healthcare environment. This has proven in many instances to offer learning and improvements in safety. Therefore part of the NIAIC's work is encouraging a shift to a safety culture, where open reporting and balanced analysis is encouraged in principle and by example. This is in contrast to a blame culture, which encourages people to cover up errors for fear of retribution. Open reporting and a balanced analysis allows for a focus on the true cause of the incident and enables improvements to be made.

All healthcare staff are encouraged to report any event involving a medical device, estate infrastructure or equipment, which has the potential to cause unexpected or unwanted effects and involves the safety of healthcare users and staff or any other persons.

NIAIC safety information

The NIAIC issues relevant safety information to help prevent recurrence and avert injury to healthcare users and staff as result of information from the manufacturer's and the outcome of investigations. This normally takes the form of either national Medical Device Alert's (MDA's) or Estates and Facilities Alert's (EFA's). The NIAIC also produce Northern Ireland Alerts (NIA's), which provide specific advice for the Devolved Region. The NIAIC has recently updated its Safety Alert Broadcast System (SABS) and this new system provides similar functionality to its predecessor and is known as the Northern Ireland Central Alert System (NICAS). Safety information is published regularly on the NIAIC section of the DoH website with notifications on NICAS. Full text and actions can be accessed by clicking on the active links on these sites.

Requirement on registered establishments

To ensure that registered providers can receive and act upon alerts in a timely manner, robust arrangements should be in place within the regulated establishments and agencies to receive and analyse safety alerts.

All registered organisations should have a nominated person(s) with sufficient knowledge and competence to assess and determine the relevance of published alerts for the relevant equipment held and used in their establishments and agencies.

The following should be carried out by the nominated person(s):

- Visit the NICAS website at suitable frequencies and access newly published safety information. It is recommended that this is carried out at least weekly
- Keep a record log of all visits to the website
- Print or retain a copy of any safety information, which relates 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
- Manage the reporting of adverse incidents involving medical devices or equipment to NIAIC

The above information should be retained for reference purposes and should be available for inspection by RQIA Inspectors who may request to see these records during the course of inspections.

Registered establishments operated by 'larger' groups or organisations

Some organisations including Health and Social Care (HSC) Trusts and larger independent health and care providers may already have, or may wish to implement central arrangements for distributing NIAIC safety information within their organisations. Registered managers of such establishments should confirm with their respective organisations that these satisfy the arrangements outlined above.

NIAIC website details

The web address for NICAS - safety information notification is:-

<https://applications.health-ni.gov.uk/NICAS/Public/Alerts.aspx>

The NIAIC website address is:-

www.health-ni.gov.uk/niaic

Blank adverse incident reporting forms can be found at the address given below:-

<https://www.health-ni.gov.uk/articles/reporting-adverse-incident>

Further guidance on NIAIC reporting adverse incidents and distribution of safety information can be found at:-

<https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/niaic-guidance-for-reporting-adverse-incident-dbni-2010-001.pdf>

The web address provided on previous RQIA correspondence

www.dhsspsni.gov.uk/index/hea/niaic.htm should be updated with the NICAS link given above.

Action and queries

There is no need to contact RQIA as a result of this letter. If however you have any queries regarding any of the above, please contact your aligned RQIA inspector in the first instance.

Yours sincerely



Kathy Fodey
Director of Regulation and Nursing, RQIA

cc Robert Sergeant, NIAIC
Dr Lourda Geoghegan, RQIA
Phil Cunningham, RQIA
John Black, RQIA
Fiona Goodman, RQIA
Elaine Connolly, RQIA