

Action

Ref: NIA-2021-001

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Valid until: **Superseded**

Reporting of Medical Device and Estates Adverse Incidents and disseminating safety information distributed by the NIAIC

Information

You are reminded that:-

- In the interests of patients, staff and visitor safety **all** regulated healthcare providers, including Ophthalmic, Pharmaceutical & Dental practices and GP surgeries should report Adverse Incidents (AIs) involving medical devices and estates defect and failures directly to the Northern Ireland Adverse Incident Centre (NIAIC). The aim of reporting and any subsequent investigation is to assist manufacturers identify learning that can be shared across other healthcare service providers and work towards reducing the risk of similar incidents reoccurring, thereby improving safety for all.
- Ensure that all adverse incidents are reported on the most up to date AI Form and it is completed with the all the information available. It is essential that the form includes an email address for all correspondence; precise details on the device/equipment involved with enough to uniquely identify the product and its manufacturer and an accurate description of the failure.

NB: NIAIC 's email address was changed in 2018 to niaic@health-ni.gov.uk from the old Department dhsspsni.gov.uk domain, this is now obsolete.

- Details on reporting adverse incidents can be found in document "Reporting Adverse Incidents and disseminating Safety Information". An electronic copy and the Adverse Incident Form can be downloaded at the following address:-
<https://www.health-ni.gov.uk/publications/niaic-adverse-incident-reporting-guidance-and-forms>
- All organisations should have procedures in place to:
 - a) access Alerts issued via the Northern Ireland Central Alert System (NICAS)
 - b) assess the relevance of the safety information to the organisation at an appropriate level
 - c) disseminate relevant information to the appropriate staff for the necessary action

Distribution

- All staff

Enquiries

- Enquiries should be directed to NIAIC quoting the alert reference number NIA-2021-001.

Northern Ireland Adverse Incident Centre

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