Health Facilities Scotland
Incident Reporting and Investigation Centre (IRIC)

# IRIC Adverse Incident Report Form

adverse incidents | near misses | safety concerns

NHS National Services Scotland

**Phone:** 0131 275 7575 **Email:** nss.iric@nhs.scot **Web:** incidents and alerts

**SUBJECT:**

* Indicates a mandatory field. For more information about using this form click here.

| **1. Reporter details** | |
|---|---|
| Your Ref | |
| Your role* | Select from list |
| Profession* | Select from list |
| First name* | |
| Last name* | |
| Email address* | |
| Telephone number | |

| **2. Workplace details** | The organisation which delivers the service where the incident happened |
|---|---|
| Organisation name | Select from list |
| Incident location | Select from list |
| Incident location (if not on list) | |

| **3. Local contact** | Please give details of someone who can be contacted by us or the manufacturer |
|---|---|
| Designated contact* | Select from list |
| First name | |
| Last name | |
| Email | |
| Other contact information | |

| **4. Product information** | Please don't send contaminated devices by mail - contact IRIC to make alternative arrangements |
|---|---|
| Workstream* | Select from list |
| Operator of the device | Select from list |
| Device manufacturer name | |
| Equipment description* | |
| Type of device | Select from list |
| Any additional device or accessory that may also have been involved | Select from list |
| Unique device identifier (UDI) | |

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| 4. Product information (continued) | |
|---|---|
| Model | |
| Catalogue number | |
| Serial number | |
| Lot or batch number | |
| Firmware version | |
| Software version | |
| Where is the device now? * | Select from list |
| Location if quarantined | |
| Containment / corrective actions | |
| Manufacturer/supplier contacted? | ◯ Yes ◯ No ◯ Unknown |
| Manufacturer's case Ref (if contacted) | |

| 5. The incident | Please give as much information as possible about what happened |
|---|---|
| Date incident occurred* | |
| Please describe what happened* | |
| Suspected problem | Select from list |
| Was any injury or illness involved? | Select from list |
| Health impact | Select from list |
| Additional comments | |
| Persons who were put at risk (tick all that apply) | ☐ Patient ☐ Service user ☐ Staff ☐ Contractor<br>☐ Visitor ☐ Carer ☐ Other ☐ None |

## When to use of this form

This form is only to be used when it is not possible to use the standard webform, e.g. when local IT security measures prevent access. Refer to the IRIC website for more information on reporting adverse incidents.

This form can be used to report adverse incidents, near misses or safety concerns involving medical devices, in vitro diagnostic medical devices, estates, facilities, social care equipment and personal protective equipment used in Scotland's health and social care services. We will normally send you an email acknowledgement within three working days of receiving your report. However, please get in touch at nss.iric@nhs.scot if you haven't heard from us after five working days.

## What we do with information you send us on this form

All incident reports become live data points on our trending system as soon as they are received. This helps us identify and prioritise the most pressing issues. However, we also individually assess and triage each incident report so, depending on the circumstances, we may open an investigation without waiting for a trend to develop. You can find out more by clicking here: Incident Trending.

Regardless of how we triage your incident report we always recommend you do two things:

- report the incident to your local adverse event management system (often referred to as Datix)
- raise a complaint with the equipment supplier and send us a copy of their reply.

## Who we share incident information with

We may share information on this form, e.g., with manufacturer or regulatory bodies, for the purposes of investigation and safety surveillance. We work in partnership with the Medicines and Healthcare products Regulatory Agency (MHRA) and we are responsible for informing them about medical device incidents occurring in Scotland.