

Incident Reporting and Investigation Centre (IRIC) Annual Report 2025-26

Annual Report for the Period 01 April 2025 to 31 March 2026

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Executive Summary

The Incident Reporting and Investigation Centre (IRIC) continued to deliver its national remit during 2025–26 by supporting safer use of medical devices, in vitro diagnostics (IVDs), software as a medical device (SaMD), estates and facilities assets, social care equipment and personal protective equipment (PPE) across Scotland’s health and social care system. Working under the framework set out in Director Letter DL(2024)32 and aligned with Scottish Health Technical Note (SHTN) 00-04, IRIC focused on strengthening reporting, enhancing learning and reducing preventable harm.

On behalf of Public Services Delivery Scotland, IRIC completed 3 tasks requested by Chief Medical Officer ([SGHD/CMO\(2024\)1](#)) in connection with preparing Scotland for changes to the Medical Devices Regulations and Policy. This includes:

- The publication of revised national SHTN 00-04 - [Guidance on the Management of Medical Devices in Health and Social Care](#) to reflect the changes in Medical Devices Regulations (MDR) and developments in the medical devices landscape in Scotland.
- In conjunction with Incident and Safety Officers Network (ISON), produce a report on gap analysis on In House Manufacture by Health Institutions. This includes the extent to which ISO 13485 or equivalent QMS is being implemented.
- Develop a Monitoring and Improvement Framework to measure NHS boards/local authorities (LAs) compliance against [Guidance on the Management of Medical Devices in Health and Social Care](#) (which includes appropriate MDR requirements). This is now published.

During the year, IRIC received 401 adverse incident reports, a small reduction from the previous year. Medical devices again accounted for the majority of submissions, reaffirming the importance of sustained vigilance as technologies evolve. Incidents in estates, facilities, PPE and social care equipment remained low, with some areas demonstrating notable year-on-year reductions. Variability across regions highlighted both improving local practices and the positive impact of increased awareness in NHS boards where reporting rose.

IRIC issued 28 safety communications, matching overall activity from the previous year but with a shift in emphasis. The reduction in Safety Action Notices, alongside the doubling of Safety Bulletins and publication of two National Patient Safety Alerts, reflected a focus on early learning, proactive intelligence sharing and alignment with UK regulatory signals.

Demand for IRIC’s specialist advice increased, with 129 enquiries submitted by NHS boards, local authorities, manufacturers and national partners. Engagement through the Incidents and Alerts Safety Officer Network (IASON) strengthened national coordination with continuing engagement on Scan for Safety, National Medical Equipment Management

System (NMEMS) and Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland. Learning and Development also saw good engagement including exceeding 2,000 completions of the IRIC e-learning module on Turas.

A comprehensive events programme supported system-wide education on emerging risks, operational changes and priority safety themes. Collectively, these activities demonstrate IRIC's enduring role in supporting safe, effective and resilient use of equipment across Scotland.

1. Introduction

- 1.1. The Incident Reporting and Investigation Centre (IRIC) plays a national role in improving safety related to medical devices, in vitro diagnostic devices (IVDs), estates, facilities, social care equipment and personal protective equipment (PPE) across Scotland's health and social care services. It's important to recognise that these products can introduce safety risks and consequently, fostering an open culture of adverse incident reporting is essential for learning and prevention.
- 1.2. A Scottish Government directive, Director Letter [DL\(2024\)32](#) (issued 16 December 2024), defines the responsibilities of NHS boards and local authorities, and clarifies the national remit of both IRIC and the Incidents and Alerts Safety Officer (IASO) function.
- 1.3. IRIC provides national adverse incident and safety alert services. While individual organisations remain responsible for resolving incidents locally, reporting to IRIC supports national trend monitoring. When recurring issues are identified, IRIC investigates and issues safety alerts to prevent similar incidents across Scotland.
- 1.4. The IASO role underpins this system through four key functions:
 - managing reporting systems for incidents, near misses and safety concerns.
 - handling safety alerts, notifications and manufacturers' field safety notices.
 - developing and coordinating the Incidents and Alerts Safety Officer network (IASON).
 - Delivering education, training and information.
- 1.5. Further guidance is available in [DL\(2024\)32](#), Scottish Health Technical Note ([SHTN](#)) 00-04 (version 3, issued 27 August 2024), and the [IRIC webpages](#), including how to report adverse incidents and IASO contact details.

2. Adverse incidents

- 2.1. During 2025–26, Incident Reporting and Investigation Centre (IRIC) received 401 adverse incident reports, representing a reduction compared with the previous reporting period. This decline suggests changes across the system and highlights both progress and areas where ongoing attention is needed.
- 2.2. As in previous years, incidents involving medical devices made up the vast majority of reports. This is expected given the widespread use of medical technology in day-to-day care, and demonstrates the importance of maintaining strong reporting cultures around these devices. Incidents relating to estates and facilities, social care equipment and personal protective equipment remained relatively low overall, with some categories showing noticeable reductions. These trends may reflect improvements in local practices, changes in service activity or the successful implementation of safety measures.
- 2.3. Incident volumes varied across different parts of Scotland. Some areas recorded fewer incidents than in the previous year, which may indicate improvements in equipment management, effective local learning or reduced exposure to certain risks. Other areas saw increases, which can often be linked to heightened reporting awareness, service changes or the introduction of new technologies. These variations are a normal part of a complex system and emphasise the importance of continually reviewing incident data to identify emerging patterns.
- 2.4. As equipment and technologies continue to evolve, IRIC remains committed to providing expert support, strengthening learning and helping services across Scotland maintain high standards of safety.

Incident workstreams

Table 2.1 - Incident reports received in 2025-26 and previous year broken down by workstream

Workstream	2024-25	2025-26	Variation
Medical devices	388	372	-16
In vitro diagnostic medical device	1	1	0
Software as a medical device	1	4	3
Estates and facilities	42	22	-20
Social care equipment	4	1	-3
Personal protective equipment (PPE)	1	1	0

Workstream	2024-25	2025-26	Variation
Totals	437	401	-36

- 2.5. Incident activity decreased overall, with adverse incidents falling from 437 to 401. Medical device issues remained the dominant category, while estates, social care and PPE incidents stayed low.

3. Safety alerts

- 3.1. Safety alerts are distributed to health boards and local authorities via their Incidents and Alerts Safety Officer (IASO).

Table 3.1 Safety alerts issued in 2025-26 and previous year broken down by format

Format	2024-25	2025-26	Variation
Safety action notice	5	2	-3
Incident Reporting and Investigation Centre (IRIC) safety bulletin	2	4	2
Safety information message	13	12	-1
Estates and facilities notice	1	1	0
Medicines and Healthcare products Regulatory Agency (MHRA) device safety information	7	7	0
National patient safety alert	0	2	2
Totals	28	28	0

- 3.2. During 2024–25 and 2025–26, IRIC's safety alert system maintained a consistent level of activity, issuing 28 safety communications in each year. Although the overall volume remained stable, the distribution of alert types shifted, reflecting changes in the way safety information was shared and how risks were managed across health, social care, estates and facilities services.
- 3.3. The number of Safety Action Notices decreased from five to two, indicating fewer incidents requiring urgent or mandatory action. In contrast, the use of IRIC Safety Bulletins doubled from two to four, demonstrating an increased emphasis on disseminating learning, supporting early intervention, and strengthening system-wide intelligence. Safety Information Messages continued to form the largest category of communication, with a modest reduction from 13 to 12.
- 3.4. Outputs driven by external partners remained stable. MHRA Device Safety Information remained at seven each year, demonstrating a consistent flow of device-related intelligence, while Estates and Facilities Notices remained constant at one. Notably, two National Patient Safety Alerts were issued in 2025–26, reflecting emerging issues requiring coordinated national action.
- 3.5. Overall, the safety alert profile shows a maturing and responsive safety system. Despite steady activity levels, the shift towards bulletins and national alerts highlights an increased

focus on shared learning, improved risk detection and continued alignment with UK-wide safety mechanisms. This evolution supports Scotland's health and social care community to act early, manage risk effectively and strengthen the resilience of equipment and facilities across the system.

4. Enquiries

- 4.1. During 2025–26, Incident Reporting and Investigation Centre (IRIC) received 129 enquiries, an increase from 116 the previous year. This rise reflects the continuing value placed on IRIC’s specialist expertise by NHS boards, local authorities, national bodies and partner organisations across Scotland.
- 4.2. Enquiries cover a wide range of topics, including questions about medical devices, clarification on regulatory responsibilities, technical advice, and support with emerging safety concerns. The increase this year shows that services are actively seeking early guidance and assurance, helping prevent incidents before they occur.
- 4.3. Several health boards demonstrated notably higher engagement suggesting strengthened links with IRIC and a growing reliance on national advice. At the same time, enquiry numbers fell in some regions as staff managed more issues locally or faced fewer new technology-related risks during the year.
- 4.4. IRIC also received enquiries from national organisations, including government partners, manufacturers and UK-wide regulatory bodies. This highlights IRIC’s role as a trusted national contact point within wider health and care safety networks.
- 4.5. Overall, enquiry activity in 2025–26 demonstrates strong and sustained engagement with IRIC’s advisory function. The increase in requests for guidance supports the wider aim of proactive risk management, helping health and social care services address issues early, share learning and maintain safe, effective use of equipment and technologies across Scotland.

5. Incidents and Alerts Safety Officer Network

- 5.1. During 2025–26, the Incidents and Alerts Safety Officer Network (IASON) continued to strengthen Scotland’s national approach to medical device and equipment safety. Quarterly meetings brought together NHS boards, local authorities, NHS Scotland Assure, Scottish Government and Medicines and Healthcare products Regulatory Agency (MHRA) colleagues to share intelligence, address emerging risks and reinforce consistent national practice in incident reporting and alert management.
- 5.2. Updates were shared with Incidents and Alerts Safety Officer (IASOs) on progress made across key national programmes. Scan for Safety expanded point-of-care scanning, advanced the Medical Device Data Hub and worked closely with NHS boards to improve local readiness. The National Medical Equipment Management System (NMEMS) moved toward a harmonised national asset dataset, with most NHS boards completing data migration and ongoing work to refine reporting, application programme interfaces (APIs) and standard operating procedures (SOPs).
- 5.3. IRIC’s highlight reports showed strong incident reporting from many NHS boards, though local authority reporting remained low. Field Safety Notices were noted to have increased and IRIC continued to develop learning resources, including updated dashboards, Safety Bulletins, Spotlight Sessions and the IASON Manual. The IRIC e-learning module, delivered through Turas online learning resource, exceeded 2,000 completions which prompted renewed efforts to boost engagement.
- 5.4. Key risks discussed included under-reporting of Software as a Medical Device (SaMD) incidents and significant variation in Board-level handling of FSNs. Shared learning covered device-related incidents across endoscopy, electrical safety, insulin delivery and community-based equipment.
- 5.5. Close collaboration with Scottish Government and MHRA ensured alignment with national policy, regulatory developments and emerging safety intelligence.

6. Events programme

- 6.1. The 2025–26 events programme delivered a structured series of briefings, open sessions and spotlight presentations designed to strengthen knowledge, support regulatory understanding, and enhance safety practice across Scotland’s health and social care system.
- 6.2. The programme commenced in May focused on thematic learning: a session on fire incident reporting, followed by contributions from GS1 examining the continued impact of barcode standards on patient safety 50 years after their introduction.
- 6.3. In June, the programme addressed emerging cybersecurity risks, with an overview of Cylera’s healthcare Internet of Things (IoT) security and analytics platform. An August open session provided operational insight into the phased introduction of the new 10 ml CONNECT syringe barrel. Further spotlight sessions during November and December explored World Radiography Day, local safety alert systems within the Golden Jubilee National Hospital, and Medicines and Healthcare products Regulatory Agency (MHRA) oversight of manufacturers’ field safety notices.
- 6.4. In early 2026, Digital Scotland presented progress on the national transition from analogue to digital telecare services. The programme concluded in March 2026 with a session outlining the Once-for-Scotland approach to medical device incident reporting across NHS boards.