

Dear Colleague

**MEDICAL DEVICE REGULATION (MDR) PREPAREDNESS:
NHS SCOTLAND SCAN FOR SAFETY PROGRAMME**

Purpose

1. To:

- i. Remind NHS Boards of the patient safety and regulatory requirements in relation to the traceability of high risk implantable medical devices that they are required to meet;
- ii. Remind NHS Boards that the **time-limited** assistance available from the Scottish Government to prepare for these requirements is planned to end on 31 March 2027;
- iii. Outline arrangements for the Business as Usual/Target Operating Model for Scan for Safety from March 2027.

Summary

2. Traceability of medical devices, patient safety and determining real world clinical outcomes from the use of devices are long term issues and underpin the new GB medical device regulatory framework, planned by the UK Government to be in effect during 2026. The MDR framework introduces new legislative obligations on NHS Boards to improve patient safety in relation to high risk implantable devices, such as pacemakers, hip and knee joints and mesh.

3. To help NHS Boards meet their patient safety and regulatory requirements, the NHS Scotland Scan for Safety Programme, led by NHS National Services Scotland (NSS) is working with NHS Boards to put in place a digital Point of Care (PoC) scanning system and Medical Devices Data Hub (MDDH) across Boards in Scotland, by March 2027.

Target for NHS Boards

4. All Boards are required to prioritise implementation of Scan for Safety for the four key specialities (cardiac, interventional radiology, orthopaedics and ophthalmology) as this will deliver

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Addresses

For action

NHS Board Chief Executives
NHS Board Medical Directors
NHS Board Directors of Finance

For information

NHS Board Nurse Directors
NHS Board Scan for Safety Leads
NHS Boards Scan for Safety Clinical Leads
NHS Board Heads of Procurement
NHS Board Employee Directors
NHS Board Directors of Planning
NHS Board Deputy Finance Directors
NHS Board Digital Leads
NHS Board Medical Device Committee Chairs
Scottish National Audit Programme, PHS

Further Enquiries to:

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traceability of 75% of high-risk implantable devices in acute care. This approach maximises the patient safety benefit of the Programme providing rapid electronic traceability in the event of device recall or safety issue.

5. To meet the GB Regulatory requirements and improve patient safety, all NHS Boards are required to undertake further planning and implementation of the PoC system across other specialties in addition to the four prioritised specialties outlined above. As previously outlined in [DL\(2024\)3](#), **all NHS Boards are expected to have fully implemented Scan for Safety to cover 100% of their high risk implantable devices to comply with their regulatory requirements. To achieve this, Boards are required to have a clear Board plan in place outlining how this will be achieved, in order to provide assurance of regulatory compliance of MDR to their local governance structure.**

6. Support for the initial development of local plans is available from the Scan for Safety Programme team and Boards are encouraged to contact the team through their nominated Scan for Safety lead to discuss the development of local plans.

Medical Devices Data Hub (MDDH)

7. A new national clinical data collection platform to utilise information from Point of Care scanning and theatre scheduling systems, is now available to NHS Boards who have implemented PoC scanning to provide:

- Rapid electronic device traceability in the event of a device safety recall
- A national searchable clinical patient implant record

8. Further development of the MDDH platform will include:

- Patient access to accurate device information about implantable devices used in their care to be available as part of mycare.gov development.
- The ability to link MDDH data to existing national datasets to improve our knowledge of device safety and outcomes.

Focus for the Programme in 2026-27

9. As well as supporting Boards who have implemented PoC scanning in one specialty, the Programme Team is dedicated to implementation in the Boards who have yet to commence implementation:

- NHS Grampian
- NHS Tayside
- NHS Western Isles
- NHS Orkney
- NHS Shetland

Scan for Safety Business as Usual (BaU)/Target Operating Model (TOM) from 2027-28 onwards

10. From 2027-28 the Scan for Safety Programme is planned to close and move into a Business as Usual (BAU) environment, with NSS providing the following core functions:

- System maintenance and updates including ongoing licence costs for the Inventory Management System (IMS) which covers both the Point of Care scanning functionality and the IMS functionality.

- Support for NHS Boards and a central Scan for Safety Team providing subject matter expertise to NHS Boards
- Support for newly developed Data Reporting and Analytics functions to bring together medical device data with existing national data collated by Public Health Scotland.

Action for NHS Boards

11. NHS Boards are required to:

- **Prioritise the implementation of the Scan for Safety Programme in accordance with this letter. This should include each NHS Board undertaking an evaluation of their planned Board activity to progress implementation, within all specialties using implantable devices to provide assurance of regulatory compliance to their local governance structures.**
- **Note that the monitoring of NHS Board compliance is being reported directly to NHS Scotland Chief Executives by the NSS Scan for Safety Programme and that further discussion is planned on how collective assurance for NHS Board Chief Executives and SG to ensure the 100% implementation requirement is achieved.**
- **Note that a further Directors Letter will follow on the GB Medical Device Regulatory requirements for all patients being implanted with a high risk implantable device to be provided with a Patient Implant Card and Patient Information Leaflet.**

If you require any further information about the NHS Scotland Scan for Safety Programme please contact the programme team at NSS.ScanForSafetyProgramme@nhs.scot.

Yours sincerely

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