

Dear Colleague

IMPLEMENTATION OF NHS SCOTLAND SCAN FOR SAFETY PROGRAMME 2024 -2026

Purpose

1. To:

- i. Alert NHS Boards to expected new regulatory requirements in relation to the traceability of medical devices;
- ii. Remind NHS Boards about the availability of **time-limited** assistance available from the Scottish Government to prepare for these new requirements; and,
- iii. Require all NHS Boards to work with the Scan for Safety Programme Implementation team to deliver by March 2026.

Summary

2. Traceability of medical devices, patient safety and determining real world clinical outcomes are long term issues expected to underpin a new UK medical device regulatory framework, which is planned at present to come into effect from 2025.

3. The [revision of the UK medical device regulations \(UK MDR\), by the UK Medicines and Healthcare products Regulatory Agency \(MHRA\)](#), will introduce new and additional legislative obligations on NHS Boards in relation to high risk implantable devices such as pacemakers, hip and knee joints and mesh. As set out in a [UK position statement published in June 2022](#), NHS Boards will be required to put systems in place to collect and store Unique Device Identifier (UDI) information for high risk implantables linked to the patient to ensure traceability. A change in UK administration in 2024, should that occur, is not presently expected to alter the need or broad timescale for new regulations, as the underlying requirement for regulatory change arises from UK departure from the EU.

4. To help Boards adapt to these expected requirements, the Scottish Government established the NHS Scotland Scan for Safety Programme, led by NSS, to support NHS Boards to put in

**From the Chief Medical
Officer for Scotland
Professor Sir Gregor Smith**

**The Chief Nursing Officer for
Scotland
Alex McMahon**

**Director of Health and Social
Care Finance, Digital &
Governance
Richard McCallum**

**Chief Operating Officer NHS
Scotland
John Burns**

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For action

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

For information

NHS Board Heads of Procurement
NHS Board Nurse Directors
NHS Board Scan for Safety Leads
NHS Boards Scan for Safety Clinical
Leads
NHS Board Employee Directors
NHS Board Directors of Planning
NHS Board Deputy Finance Directors
NHS Board eHealth Leads
NHS Board Medical Device Committee
Chairs

Further Enquiries to:

Policy: Kerry Chalmers, Medical
Devices and Legislation Unit
St Andrew's House
EDINBURGH EH1 3DG

Email: kerry.chalmers@gov.scot

Programme:
NSS.ScanForSafetyProgramme@nhs.scot

place a digital Point of Care (PoC) scanning system across all Health Boards in Scotland. However, support for NHS

Boards through this programme will only be available until March 2026. Following this any Boards who have not implemented the national system through the Scan for Safety Programme, will be required to make their own arrangements to meet their regulatory obligations as set out in the Medical Device Regulations.

Target for NHS Scotland Scan for Safety Programme

5. The key target for the Programme is that 75% of high-risk implantable devices used in acute care can be tracked electronically by March 2026. NHS Boards are expected to take this further in each of their Boards to achieve up to 100%, and in any case to comply with regulatory requirements.

Efficiency Savings and Benefits for NHS Boards

6. In advance of the rollout of Point of Care (PoC) scanning, a National Inventory Management System (IMS) has been deployed to improve visibility and stock management. This system allows Health Boards to effectively manage stock and provide accurate information about levels of use across their supply chain. Point of Care scanning is the next phase of implementation and utilises the additional functionality enabling the capture and retention of core medical device data, procedure and staff details linked to the individual patient.

7. In addition to efficiency savings previously made by NHS Boards through implementing the IMS, there are additional efficiency savings that can be made by Boards in implementing the Scan for Safety Programme. The Programme team within NSS is currently compiling estimated savings by Board for local validation and will share these with Heads of Procurement and Directors of Finance once the validation has been completed.

8. As well as the operational efficiency benefits highlighted above, further benefits have been identified by the Programme team in areas such as Patient Safety and Clinical Productivity. These include the ability to track medical devices quickly and easily from the point of manufacture through the supply chain to the patient, as well as reducing the amount of administrative work undertaken by clinical staff to record medical device data and update stock levels in their area.

Implementation

9. The NSS Programme team is currently engaging with each NHS Board through their appointed Scan for Safety lead, with the intention to implement in four Health Boards in FY 24/25 (so far, implementation has been undertaken across four clinical specialties in NHS Lothian and NHS Golden Jubilee National Hospital). Boards will be asked to confirm they are content for implementation to take place next year and will engage with the Programme team to agree dates and local activity to be undertaken.

10. Progress to Date

- Roll out of the Inventory Management System (IMS) across all territorial Boards, completed in March 2023 with local efficiency savings reinvested in local services.
- Programme data standards developed in March 2023 to allow interoperability and enable effective data sharing for product, place, patient, staff procedure and equipment.

- Supplier guidance issued to all affected NHS Scotland suppliers to ensure they are aware of the forthcoming changes and respond accordingly (this included changes to any future supplier contracts to provide NHS Scotland requirements for barcodes on packaging)
- Point of Care (PoC) scanning commenced prioritised specialties in NHS Lothian (Interventional Radiology) and Golden Jubilee National Hospital (Cardiac Surgery, Orthopaedics and Ophthalmology). Planned deployment of IMS and POC in NHS Western Isles in early 2024.

Funding

11. Funded by the SG, the Scan for Safety Programme is providing:

- All system costs:
 - Implementation costs and agree interfaces with existing systems
 - Ongoing system costs (annual licence costs)
 - Initial handset for Inventory Management and PoC scanning (approx. 890 in total for NHS Scotland)
- Subject matter expert implementation team
- Initial launch in high-risk areas (but open to discussion in individual board context) to support Board priorities: Cardiology, Vascular, Interventional Radiology, Orthopaedics
- Support with experience from previous implementation

12. NHS Boards are required to provide local support including:

- An Executive Lead to support implementation
- A Health Board Benefits owner to identify and manage local benefits
- Local implementation team, including a Project Manager to work with the S for S Programme Team

13. Boards can recover the cost of their local support from the efficiency savings that implementation will provide (see paragraph 7).

Health Board Delivery Group

14. During the initial definition phase of the programme, each Health Board was asked to identify a senior Scan for Safety Lead who would be the point of contact for their area and liaise with the programme team as required. Regular meetings are held by the programme for all Scan for Safety leads to attend, which is helping to ensure all Boards are kept up to date with developments and learning from the pilot implementations in NHS Lothian and Golden Jubilee National Hospital.

Next Steps

15. The Scan for Safety Programme team is engaging with NHS Boards to confirm the implementation schedule for April 2024 -2025. We understand the challenges that Boards face in considering how they prioritise national projects for local implementation. We must however ask that Boards take into consideration that this is a regulatory requirement in UK MDR and that Scan for Safety Programme resources are time limited.

Action for NHS Board in 2024-25

For Boards who have started Point of Care (PoC) Scanning of High Risk Implantable Devices in 2023-24 (applies to NHS Lothian, NHS Golden Jubilee and NHS Western Isles): To implement PoC technology across all specialties within the Health Board which implant Class IIb and III devices (for example pacemakers, knee/hip joints, orthopaedic screws and plates) with initial focus on Interventional Radiology, Vascular, Cardiology and Orthopaedics specialties.

For Boards due to implement Point of Care (PoC) Scanning of High Risk Implantable Devices in 24-25 (discussions underway with NHS Tayside, NHS Lanarkshire, NHS Grampian, NHS Highland and NHS Dumfries and Galloway): To work in collaboration with the Scan for Safety Programme to implement PoC scanning within the agreed specialties and following initial rollout, develop and execute a plan to expand this technology into other relevant specialties within the Board.

For Boards due to implement Point of Care (PoC) Scanning of High Risk Implantable Devices in 25-26 (applies to remaining Boards): Engage with the Scan for Safety Programme through the Health Board Delivery Group to understand the implications of local adoption, lessons learned through other Board implementation activity and ensure that the necessary activities to stand up local resources for 25-26 are completed within agreed timescales.

This is the NHS Scotland approach to deliver improved patient safety and it is expected that all Boards work with the Programme to deliver by March 2026.

For Island and smaller NHS Boards, support from the Implementation Team will be tailored to meet your requirements. It will be important that you discuss these with the Team as early as possible.

Please contact the programme team at NSS.ScanForSafetyProgramme@nhs.scot.

Yours sincerely,

Gregor Smith

Professor Sir Gregor Smith
Chief Medical Officer for Scotland

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Chief Nursing Officer for Scotland

Richard McCallum

Richard McCallum
**Director of Health and Social Care
Finance, Digital & Governance**

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