Safety Action Notice

Reference **SAN(SC)18/03** Issued **26 February 2018** Review Date **25 February 2019**

NHS Boards & local authorities (health institutions) exemption to the new in vitro diagnostic medical device regulation (IVDR) and medical device regulation (MDR)

Summary

NHS Boards and local authorities may come within scope of the new in vitro diagnostic and medical device regulations. MHRA is consulting stakeholders who may be eligible to apply for exemption. To get the best range of views and allow health institutions to test and model the guidance, MHRA's consultation will run for over 12 months and is not scheduled to close until 31st March 2019.

Action

1. This notice should be brought to the attention of all appropriate managers and governance committees, e.g. medical devices committees.
2. A responsible person, with authority at corporate level, should be nominated to:
   a) ensure the implications and requirements of the health institution exemption are adequately assessed,
   b) respond to the MHRA consultation,
   c) ensure the organisation is ready to take any actions that may be required.

Action by
- NHS Boards
- Local authorities

Deadlines for action
Actions underway: 19 March 2018
Actions complete: 04 May 2018

Problem / background

NHS Boards and local authorities (health institutions) are significant providers of medical devices in Scotland, and it is likely some of their activities will come within scope of the IVDR or MDR. MHRA is consulting stakeholders to develop a simple process with associated guidance that UK health institutions could use to apply for exemption.

The new EU Regulations for in vitro diagnostic medical devices (IVDs) and medical devices (MDs) will continue the exemption for manufacturing or modifying and using IVDs or MDs within the same health institution in Member States (also known as 'in house manufacture').

Health institutions wishing to apply the exemption in the new Regulations will need to ensure that products meet the relevant General Safety and Performance Requirements. In addition, health institutions will need to have

- an appropriate quality system in place;
- a justification for applying the exemption;
- technical documentation in place.

Some of this information will need to be publicly available.

The new IVD and MD Regulations define a health institution as 'an organisation whose primary purpose is the care or treatment of patients or the promotion of public health'. This includes hospitals, laboratories, local authorities and public health institutes supporting the health care system and/or addressing patient needs, but may not treat or care for patients directly.

Any health institution may be considered to have manufactured a device if it has, for example, rebuilt an existing device, fully refurbished a device, put together combinations of devices, used a device for a purpose other than that intended by the manufacturer, etc. This list is not exhaustive and there are other ways in which health institutions may find they are within scope of the regulations.

MHRA Consultation URL

The MHRA consultation can be accessed online using the following URL:

https://www.gov.uk/government/consultations/health-institution-exemption-for-ivdrmdr

Suggested onward cascade

Clinical Governance, Central Decontamination Units, Dental Laboratories, Device Managers, Health & Safety, Loaned Equipment Stores, Community Equipment Stores, Local Decontamination Units, Medical Physics/Clinical Engineering, Wheelchair Services, Prosthetic Services, Orthotic Services, Rehabilitation Medicine Services, Risk Management, Supplies/Procurement

Enquiries

Enquiries related to the draft guidance should be raised directly with MHRA: hie@mhra.gov.uk.

Any other enquiries (and adverse incident reports) in Scotland should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Report options are available on the HFS website: How to report an Adverse Incident
Further information about reporting incidents can be found in CEL 43 (2009) or by contacting IRIC at the above address.