

Safety Information Message

Reference: SIM2210

Issued: 01 September 2022

Review Date: 01 September 2023

IPEM guidance for health institutions on in-house manufacture and use, including software (2nd Ed.)

Summary

The Institute of Physics and Engineering in Medicine (IPEM) has updated its guidance on in-house manufacture and use of medical devices¹. It provides guidance on what constitutes 'in-house manufacture and use' within the same health institution as well as best practice guidance when undertaking these activities. This document is specifically referenced in para 6.43 of SHTN 00-04 *Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services*².

Action

Identify services which undertake in-house manufacture and use of medical devices, including software, and ensure they read and consider IPEM's updated guidance.

Suggested onward distribution

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

References

1. [Best-practice guidance for the in-house manufacture of medical devices and non-medical devices, including software in both cases, for use within the same health institution, 2nd edition, July 2022](#)
2. [SHTN 00-04 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services v2.0, Health Facilities Scotland, June 2021.](#)

Enquiries

Enquiries and adverse incident reports should be addressed to: Incident Reporting & Investigation Centre (IRIC), NHS National Services Scotland, Tel: 0131 275 7575 Email: nss.irc@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in [CEL 43 \(2009\)](#), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities*, issued 30 October 2009.

Report an incident: Information on [how to report an adverse incident](#)

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