

Dear Colleague

Addendum to [CEL 43 \(2009\)](#): Safety Of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities

Summary

1 This letter is an addendum to CEL 43 (2009) which states (in paragraph 3) that “Chief Executives should also ensure that these procedures are extended to all contractors and private or independent service providers who provide care, staff, equipment, buildings or other services or facilities for the direct care of patients or clients”.

2 A crucial part in fulfilling this responsibility is the need to clearly lay out the relevant roles and responsibilities in every contract made with those involved in the use or provision of equipment. Examples include general practitioners, care homes, children’s homes, education establishments and those providing care etc. to service users in their own homes.

3 This addendum provides model wording for inclusion in all such contracts.

Model Wording – to be added to contracts with Private Contractors

4 Note: when using the model wording below, the terms in square brackets should be defined within the contract or the appropriate name entered at each location. Paragraph numbering and formatting may be altered to suit the completed contract.

[1.1] The [contractor] is responsible for ensuring that arrangements exist for the reporting of adverse incidents, the retaining of material evidence, the handling of contaminated items, the dissemination of safety advice and the control of risks relating to health and social care equipment (medical devices) in line with the information and guidance all as contained in Scottish Government Health Finance Directorate Letter CEL 43 (2009)¹ and any information and guidance updating, amending or replacing CEL 43 (2009), provided that such updated, amended or replacement guidance is published and publicly available on line, publicly displayed, or the content of it has been

Addressees

For action
Chief Executives,
NHS Boards

Chief Executives,
Local Authorities

For information
COSLA

Care Inspectorate

Enquiries to

Incident Reporting and
Investigation Centre (IRIC)
NHS National Services
Scotland
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EDINBURGH
EH12 9EB

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¹ CEL 43 (2009) *Safety Of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities*, Scottish Government 31 Oct 2009, available at http://www.sehd.scot.nhs.uk/mels/CEL2009_43.pdf

notified to the [contractor] by [the commissioning /contracting organisation].

[1.2] In particular, but without prejudice to the generality of the provisions of clause [1.1] hereof, the [contractor] shall:

[1.2.1] procure that its managers, staff, sub-contractors and agents are aware of the procedures for reporting adverse incidents, retaining material evidence, handling contaminated items and for implementing safety advice and the [contractor] shall procure that such procedures are implemented;

[1.2.2] monitor relevant websites for information on equipment safety and management issues e.g. MHRA^{2,3};

[1.2.3] monitor safety alerts and bulletins, and cascade within its own organisation;

[1.2.4] monitor internal cascade systems to ensure alerts are received, assessed and acted upon;

[1.2.5] discuss equipment safety issues with [the commissioning / contracting organisation];

[1.2.6] promote equipment safety by staff education and training.

Yours sincerely



Mike Baxter
Deputy Director for Capital and Facilities

² The MHRA webpage for safety warnings, alerts and recalls is currently available at <http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/index.htm>

³ Alternatively, subscribe to the MHRA Email alerting service at <http://www.mhra.gov.uk/Stayconnected/E-mailalertingservice/index.htm>