

Estates and Facilities Alert



Action

Ref: EFA/2010/001 Issued: 15th March 2010 at 14.00
Gateway Reference: 13924

Device

MEDICAL PATIENT WEIGHING SCALES

Problem

Medical weighing equipment used in healthcare premises may be inaccurate, inappropriate or not used correctly, leading to potential errors in diagnosis, treatment or medication of patients.

Action

Healthcare providers should review the LACORS (Local Authorities Coordinators of Regulatory Services) final report, published in July 2009, and draw up an action plan to address the report recommendations where they consider a risk to patient safety may exist.

Action by

Chief Executive/Board Member with special responsibility for health and safety, in accordance with local procedures, should ensure that this alert is brought to the attention of appropriate staff.

Contact

Further advice can be obtained from LACORS (Local Authorities Coordinators of Regulatory Services), local Trading Standards Departments, or the UK Weighing Federation.

Website details can be found on page 2 of this alert.

Problem

1. Medical weighing equipment used in healthcare premises may be inaccurate, inappropriate or not used correctly, leading to potential errors in diagnosis, treatment or medication of patients.
2. LACORS conducted a National Medical Weighing Project during 2008/9 within the acute healthcare sector of the NHS, and identified a number of shortcomings. They published a report in July 2009, identifying a number of recommendations for the NHS. The report is attached as a PDF and summarised for information in Appendix 1. The Department of Health (England) response is given in Appendix 2.

Action

3. Healthcare providers should review the LACORS final report published in July 2009, and draw up an action plan to address the recommendations of the report by the 30th July 2010 (England only). (see Appendix 1)
 - a) To comply with the action complete date on page 3 (England only), there will need to be in place a prioritised action plan with realistic timescales for replacing equipment. A maximum period of 12 months to replace equipment is considered a reasonable timescale.
 - b) Where the organisation considers that a risk to patient safety may exist, measures should be taken to remove this risk, or reduce it as low as reasonably practicable within a very short period.
 - c) Where the organisation identifies equipment that is not compliant with current legislation, arrangements should be made to replace the equipment. Responsibility for replacing existing equipment rests with local management. Additional guidance can be found in Appendix 1 on prioritising replacement of medical weighing equipment.
 - d) Where a decision is taken to replace medical weighing equipment, a phased approach should be considered based on the following priorities:
 - Unapproved, domestic type bathroom scales (e.g. purchased locally from high street outlets);
 - Dual reading scales unless converted to read metric only;
 - All dial type bathroom scales and Class III scales.

Suggested Onward Distribution

- | | | | |
|------------------------|---------------------------|-------------------|--|
| • Accident & Emergency | • Health Centres | • Oncology | • Radiotherapy |
| • Anaesthetics | • Hospices | • Outpatients | • Risk Management |
| • Care Home Services | • Intensive Therapy Units | • Paediatrics | • Stores |
| • Community Care | • Maternity | • Pharmacy | • Supplies/Procurement |
| • District Nursing | • Medical Physics | • Practice Nurses | • Wards |
| • Estates/Facilities | • Neonatal | • Private clinics | • Independent Health and Social Care Providers |
| • Health & Safety | • Nursing | • Radiography | |

Contacts

- Local Authorities Coordinators of Regulatory Service (LACORS) – www.lacors.gov.uk
- Local Trading Standards Departments – www.tradingstandards.gov.uk
- UK Weighing Federation – www.ukwf.org.uk

Information for UK

LACORS (the Local Authorities Coordinators of Regulatory Services) is accountable to its Board of Directors, which is made up of senior councillors nominated by the four UK local authority associations.

- The Local Government Association (LGA)
- The Welsh Local Government Association (WLGA)
- The Convention of Scottish Local Authorities (COSLA)
- The Northern Ireland Local Government Association (NILGA)

Information for England only

This alert supplements previous alerts DH (2008) 05, DH 2008/05U, Ref. DH 2008/05(2U) issued in 2008.

Action required by this alert should be **underway by: 31/March/2010**

Action required by this alert should be **completed by: 30/July/2010**

Enquires should quote reference number EFA/2010/001 and be addressed to:

Defects & Failures
Department of Health
Estates & Facilities Division 3N12
Quarry House
Quarry Hill
Leeds
LS2 7UE
Email: mb-defects&failures@dh.gsi.gov.uk

HOW TO REPORT DEFECTS & FAILURES

Defects and failures relating to non-medical equipment, plant and buildings should be reported to the Department as soon as possible. Advice on how to report can be found in DH (2008) 01. Defect and failure reporting forms and an on-line reporting facility are available on the NHS Information Centre website at www.ic.nhs.uk

This Alert can be found on the following websites
<http://www.dh.gov.uk> and <https://www.cas.dh.gov.uk>

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Addressees may take copies for distribution within their own organisations

APPENDIX 1

LACORS NHS National Medical Weighing Project

Introduction

LACORS (Local Authorities Coordinators of Regulatory Services) recently completed a survey in the NHS to look at the use of weighing equipment in the medical environment. A copy of the report is available on the LACORS website www.lacors.gov.uk

The survey highlighted a number of concerns culminating in a series of recommendations to the Department of Health.

This alert is a follow up to the Safety Alert's issued in 2008, and provides advice to the NHS based on the LACORS recommendations.

Legal Position

Medical weighing equipment is covered by Schedule 3 of the Non-Automatic Weighing Instrument (NAWI) Regulations. It is regarded as equipment used for the '*determination of mass in the practice of medicine for weighing patients for the purpose of monitoring, diagnosis and medical treatment*'. The regulations make it a legal requirement to have equipment that is appropriately accurate. If CE marked as a medical device with a weighing function, the manufacturer of the equipment is expected to include the NAWI Regulations within their overall conformity assessment process under the Medical Devices Regulations. This should also include the determination of the appropriate class of scale under the NAWI Regulations based on the intended use of the medical device.

Class of weighing equipment

Within the regulations, weighing equipment falls into four classes:

Class I, Class II, Class III, Class IIII

Class I scales provide the highest degree of accuracy, and Class IIII, the lowest. As an example, Class IIII scales include bathroom scales for domestic use.

All weighing equipment for use in healthcare settings for weighing patients for the purpose of monitoring, diagnosis and medical treatment is covered by the NAWI regulations, and fall predominantly within Class III or Class IIII.

APPENDIX 1 (continued)

LACORS recommendations to the NHS

LACORS made six recommendations to the NHS:

1 – One department in each hospital or Trust should be responsible for the procurement, provision and maintenance of all medical weighing equipment for the organisation. All wards must be notified that procurement must go through this route to ensure equipment meets legal requirements and is fit for purpose.

2 – Each Trust should instigate a programme of testing for their equipment. This may be done in-house, given the relevant training or procured externally.

3 – Basic training for the use of weighing equipment should be incorporated into training and induction procedures. When new equipment is purchased, training should be given by the installer and cascaded to relevant ward staff. Training should focus on setting to zero before use, and correct weighing procedures.

4 – Any equipment found to be inaccurate (outside of legal tolerance) should be immediately removed from service and either repaired or replaced.

5 – Whilst some Class III scales might be suitable for some medical purposes, to avoid error, all new medical weighing equipment should be of Class III accuracy (or higher if appropriate).

6 – From now on, scales purchased for medical purposes should only be capable of metric display. There should be no capacity for switching or dual readouts. Trusts should be aware of the pitfalls of using switchable scales and may wish to consider replacing them or having the switches removed.

APPENDIX 2

DH Response to the LACORS recommendations

Having considered the recommendations of the LACORS report, the following advice is provided for the benefit of the NHS by the Department:

Recommendation 1 – The principle of this recommendation is accepted. The process is likely to be appropriate for an acute Trust; however, in the Primary Care setting it may be more difficult to implement. All healthcare providers are strongly advised to introduce the most appropriate system of central control for the procurement, management and maintenance of weighing scales within their organisation.

Recommendation 2 – LACORS advice is that weighing equipment should be tested annually. If the user considers the equipment may be giving inaccurate readings during the intervening period, it should be taken out of use and subjected to an interim inspection.

Recommendation 3 – For CE marked medical devices see the MHRA Device Bulletin DB 2006(05) Managing Medical Devices, which includes training and adherence to the manufacturer's instructions for use. For weighing equipment that is **not** a medical device, basic training should be incorporated into training and induction procedures. When new equipment is purchased, training should be given by the installer and cascaded to relevant staff.

Recommendation 4 – This recommendation is supported, when the inaccuracy is identified as part of the inspection programme implemented at recommendation 2.

Recommendation 5 – All new scales purchased for the purposes of weighing patients should, as a minimum, achieve a Class III standard (or higher where necessary). Where appropriate (e.g. weighing equipment forming part bed weighers), medical weighing equipment CE marked as a medical device should be used.

The Department strongly recommends that the use of weighing equipment meeting the Class III standard currently used for weighing patients for the purpose of monitoring, diagnosis and medical treatment should be taken out of service and replaced by Class III, or higher.

Recommendation 6 – Safety Alert's previously issued by DH Estates & Facilities recommended that all scales used for weighing patients should only display metric units. Where weighing equipment is in use with switchable scales (e.g. imperial and metric), **the switching facility must be disabled** to ensure that **only the metric reading is available**. Where weighing equipment is in use with dual readings not capable of being converted to read only metric units, should be replaced as a priority.