Weighing equipment used for medical purposes





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Background

As part of the Non-Automatic Weighing Instruments Directive, any weighing equipment used for medical purposes sold after January 1^{st} 2003 must be of an approved type and be verified before being put in to service or following repair.

The recent project undertaken by LACORS (Local Authority Co-ordinating body on Regulatory Services) has highlighted widespread problems within the field of medical weighing. However the UKWF believes that further clarification is still needed in key areas (including calibration) to ensure the required improvements are made in a timely fashion.

The incorrect or inaccurate weighing of patients can have serious and life threatening consequences, especially where drug administration is calculated in relation to body weight. These notes are intended to provide some clarity and guidance to the subject.

The Directive, Regulations and other documents refer to weighing instruments, instruments weighing machines and scales. We will use the term "scales" from here on in these notes for clarity.

Existing equipment (put into use before 1 January 2003)

Scales put in to service before 1st January 2003 can continue in use with no further legal control.

However, such scales are:

- unlikely to be approved,
- may be weighing in **imperial units** or a mixture of **imperial** and **metric units** and
- may be of an inappropriate level of precision.

The UKWF recommends that any such equipment which does not pass the test for an inservice Class III scale be taken out of service and replaced with a suitable approved scale as a matter of urgency.

Buying new medical scales

Any new scales must be of an approved type and be verified .Manufacturers of scales for medical use must obtain approval for the design to demonstrate that the instrument type is suitable for that purpose. Then each scale must be individually verified either by the manufacturer (if they are authorised to perform self-verification) or by a trading standards officer.

The following identification markings will show that the instrument is of an approved type and has been verified:



There are various levels of precision specified for scales, namely **class I, II, III and IIII**. Medical scales are generally either **class III** or **class IIII**. This Federation recommends that only the higher precision **class III** scales are used in any medical establishments: however **class IIII** scales may be suitable for a limited number of applications (e.g. monitoring for general health and fitness in a GP consulting room),

Although there may be rare scales that still have an old approval allowing them to weigh in either **imperial** or **metric units**, we would mandate that only metric scales are used. Failure to do so could result in an error **exceeding ±100%** if the wrong units are inadvertently used. (e.g. This could result in double or half treatment doses being given to patients.) **The UKWF believes that dual imperial/metric scales be immediately removed from use unless the option to display in imperial units is permanently disabled**

Calibration, servicing & repair

Scales should, we recommend, be tested for accuracy on a regular basis, - at least annually. The scales should be tested with certified test weights at several points (at least 4) through the weighing range, up to or near full capacity. A test certificate should be issued with readings before and after any adjustment is made and a sticker applied identifying the date of calibration. This is consistent with the UKWF Calibration Code of Practice. Note calibration must be carried out by a suitably qualified weighing engineer.

Acceptable errors are defined in the N0n –automatic Weighing Instrument Regulations 2000 and a qualified service engineer will know how to apply these to assess the test results.

If a scale shows errors which exceed these limits then some form of rectification will be required and the scale should be taken out of use until that is done. In some cases this may be as simple as ensuring the scale is level or removing any obstructions.

In other cases the scale may require repair or re-calibration and in these cases re-verification will be required. The re-verification can be performed by the repairer if they are authorised to do so or by a trading standards officer and the owner or user of the scale has a legal obligation to ensure that this is done. In some instances the technical departments of some PCTs are carrying out re-calibration/repair work. The legal obligation to have the scales re-verified still applies. PCTs wishing to re- verify the scales themselves will need to obtain certification to do so from the National Measurement Office (NMO). Otherwise the PCT will need to call in a certified repairer or contact their local Trading Standards Officer to re-verify the scales before they can legally be put back into use.

Definition of medical use

Schedule 3 of the **Non-automatic Weighing Instrument Regulations 2000** includes the following applications that are subject to legal control:

- Determination of mass in the practice of medicine for weighing patients for the purpose of monitoring, diagnosis and medical treatment.
- Determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories.

Applications that are not in the practice of medicine, e.g. slimming clubs or sports centres, would not be included within these definitions.

Recommended maximum scale interval for specific applications

| | Adults | Young Children | Babies |
|---|----------|----------------|---------|
| Checking weight for records | 500 g | 200 g | 50 g |
| Regular monitoring to assess weight change | 200 g | 100 g | 10/20 g |
| Measuring weight to assist medical diagnosis | 200 g | 50/100 g | 10/20 g |
| Measuring weight for critical treatment e.g. dialysis | 50/100 g | 20/50 g | 5 g |
| Recording birth weight | | | 20 g |
| Measuring weight before and after breast feeding | | | 10 g |

Using Medical Weighing Equipment

It is vitally important that weighing scales are used under suitable conditions. Staff should be appropriately trained to use weighing equipment.

All scales must be level and on a suitably firm surface. Use on carpets or other flexible surfaces is not recommended. If scales are moved from one location to another, operators must ensure suitable adjustments are carried out to any adjustable feet to ensure the scale is stable and level.

Before commencing weighing, operators must ensure the scale reading is set to zero. After weighing has taken place, operators should then ensure the scale indication has returned to zero. If it does not, then they should consult a qualified scales engineer.

The scales must be free to operate unimpeded without the risk of weight (force) transfer to or from adjacent structures, which will affect accuracy. Patients must only be in contact with the load receptor (weighing platform) and must not be allowed to lean on or hold onto structures such as the column of the scales, that are not part of the active (live) part of the weighing machine.

When carrying out repeat weighings on patients, operators must ensure readings are taken under identical circumstances (e.g. tare items such as clothes, shoes etc have a major impact on weight).

For critical weighing situations (especially those involving drug administration relating to body weight), it is recommended that at least two repeat weighings are made in order to ensure the correct weight reading is used for treatment calculation; and a check made by a second person to ensure errors e.g. mis-reading decimal points, are not made. If readings do not show repeatability within ± 2 scale divisions, the scale should be taken out of use and the patient reweighed on alternative scales. The original scale should remain out of use until checked by a qualified scales engineer.