



MS Legal metrology programme 2002 – 2005

Project 2.2.5 deliverable a – a report on Consultation on effect of Non-automatic weighing Instruments Regulations 2000 SI 2000/3236 on medical weighing instruments put into use after 1 January 2003

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Annex A - Consultation letter

(i) EXECUTIVE SUMMARY AND PROPOSED ACTIONS

1. The purpose of the Review was to consider whether the accuracy class for non-automatic weighing instruments used in the determination of mass in the practice of medicine should be specified in the Non Automatic Weighing Instruments Regulations 2000 (S.I.2000 No 3236). Section (ii) below describes the purpose of the review in more detail.
2. A copy of the consultation letter that was sent to interested parties is attached at Annex A.
3. Comments on the Review were received from
4. Independent Midwives Association, Medical Devices Agency, SECA Weighing and Measuring Instruments, H Fereday and Sons, Simpson Scales and The Royal College of Anaesthetists.
5. Suggested actions stemming from the Review are:-

to restrict use of Class III instruments to GPs' surgeries and nursing and care homes not providing a medical service – SECA, H Fereday and Sons

to restrict use to Class III machines - Simpson Scales

to permit free choice by users – The Medical Devices Agency

(ii) PURPOSE OF CONSULTATION

The consultation anticipated the legislative change introduced by Directive 90/384/EEC which requires that new non-automatic weighing instruments used in the “determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment” must comply with the conformity assessment procedures applicable to non-automatic weighing instruments from the end of the transitional period i.e. from 1 January 2003. Existing instruments (i.e. those in service before 1 January 2003) are not affected can remain in use.

The Directive specifies four classes of accuracy, but the implementing regulations (currently the Non-Automatic Weighing Instruments 2000) are silent as to which class or classes may be used for medical purposes, therefore any class may be used. The consultation was an attempt to determine whether this matters in relation to the medical decisions taken as a result of the weighing, for example change of diet or quantity of drugs administered. Some of these instruments are subject to the Medical Devices Directive, eg hospital beds with a weighing function; others such as scales in doctors' surgeries are not. The result of the investigation will enable NWML to conclude whether the use of any class of instrument is satisfactory for medical scales.

The purpose of the letter was to establish whether any of the four classes of accuracy specified in the Directive should be permitted to be used for any medical weighing or whether a suitable class should be identified and specified for specific uses.

NWML wanted to be in a position to give:-

pre-purchase advice for hospitals, etc, as to suitability of classes of accuracy for particular purpose of use;

(i) advice on service/maintenance contracts and the levels of accuracy they should contain;

(ii) advice/training in the use of weighing instruments;

(iii) advice on a co-ordinated programme of inspection and how to do it in the surgery/hospital environment;

(iv) determine whether legislation should be introduced to prescribe the class of weighing instrument to be used in particular circumstances.

(iii) COMMENTS RECEIVED, ANALYSIS OF THEM AND CONCLUSION

Independent Midwives Association

Currently use spring scales and see no need to use more accurate scales. Regard new legislation as unnecessary and retrograde step leading to greater expense which is unnecessary for normal births, although may be applicable to intensive neonatal units.

Medical Devices Agency

Different degrees of accuracy required for different purposes e.g. weighing in GP surgery different than for neonate or patients for dialysis or on diuretic for heart failure. Question whether NWML should issue guidance on most appropriate type of machine for particular medical purposes. Consider that the same level of accuracy should apply to scales used for weighing patients as for nursing homes and mobile/visiting healthcare facilities. Maximum scales intervals sensible except for neonatal monitoring.

Recent exercise with Royal College of Paediatrics and the Neonatal Society about the level of accuracy for baby weighers concluded that they should weigh around 50g for purposes of monitoring progress.

Weighing scales in healthcare establishments are generally badly maintained and where a high level of accuracy is required should be tested on a weekly basis. In other circumstance maintenance should follow the manufacturer's instructions for use.

Medical devices used for medical weighing include:-

Hospital beds (450kg max weight limit)

Patient hoists (250kg max weight limit)

Chair type or standing scales (+/- 0.5kg)

Consideration should also be given to devices intended to be used as work equipment where the accuracy could affect the appropriate work being done and the Provision and Use of Work Equipment Regulations and the Lifting Operations and Lifting Equipment Regulations where the weigh scales used in hoists can transmit the patient's weight/weight bear and may need to be considered as a component part of the device. These Regulations are enforced by HSE.

SECA Weighing and Measuring Instruments

SECA offer twice yearly maintenance for scales supplied directly – but others may do no testing - suggest licensing of qualified weighing machine technicians to overcome problem.

Most hospital patients are weighed and this will be used to determine treatment – baby and toddler scales should be accurate to 10 g or better, adult scales to 100g or better, obese scales to 200g or better

Mobile/Community nursing - equipment may be used in court cases involving infant fatalities and abuse and should be Class III and have scale accuracy of 10 division or better

Nursing homes should be Class III and tested and calibrated to ISO 9001.

H Fereday and Sons

They produce the following type of medical scales including those used for weighing babies and young children, adults, adults, babies and young children, and mobile weighing instruments with chairs for patients with standing difficulties. All of these are Class III instruments.

Outside their production are bathroom scales of class IV accuracy, baby-weighing equipment incorporated in incubators and portable baby scales for use by midwives in the home.

The in-service error allowances vary significantly for instruments of identical capacity and weighing interval depending on whether the instrument is classified Class III or Class IIII. Whilst Class III may have sufficient accuracy for a medical decision to be properly made, the similar Class IIII instrument may not be fit for the medical purpose which could, for example, be the close monitoring of weight during dialysis.

An instrument could have a variable reading but within allowable in-service tolerance. In an extreme case a patient weighing 50kg on a typical Class IIII 1kg interval instrument could in successive weighings have their weight recorded as 48kg or 52kg – a difference of 8% but with the instrument conforming to the Regulations. Such a variation may be unlikely on a single instrument but it is quite likely that different instruments within the same department could easily show that degree of variation.

Class IIII equipment, because of its relatively coarse error allowances is not appropriate for medical use apart from recording patients' weights in their records – mostly by GPs.

The error allowance for Class IIII is too high to be sufficiently accurate for diagnosis and medical treatment especially for close monitoring for purposes such as dialysis and weight reduction.

Because weighing instruments are frequently moved between departments only Class III instruments should be used in hospitals to avoid instruments intended for non-medical applications being used for such purposes. Weighing instruments in use in nursing homes and care homes are not generally being used for medical purposes and Class IIII would therefore be appropriate in these establishments. Where there are resident medical staff monitoring weight for treatment purposes Class III should be used. Class III should also be available where a doctor visits a care/nursing home and treatment is dependent on weight.

All instruments used in institutions or on premises where medical care is undertaken, apart from GP surgeries should conform to Class III.

NWML should issue advice that instruments should be checked annually to ensure that accuracy remains within service tolerances.

Legislation should be introduced to limit the use of Class III instruments.

Simpson Scales

They have sales and maintenance contracts with every Health Board in Northern Ireland covering hospitals, health centres and associated community nursing. Machines are checked and calibrated using certificated weights and, when requested, certificates are issued for each machine. See main problem as the supply of machines by companies not providing service contracts whether equipment supplied is untested or calibrated. See licensing of qualified weighing machine technicians as a way to solve the problem.

Estimate 99.9% of patients in hospital are weighed to determine treatment. Baby and toddler scales should be required to display weight by 10g or better, adult scales by 100g or better and obese scales by 200g or better. For Mobile/Community Nursing they recommend Class III with a 10g or better division and point to the fact that the readings have been used in court cases involving infant fatalities. Nursing Homes should be Class III calibrated and tested to ISO 9001.

Royal College of Anaesthetists

Accuracy class III is considered appropriate

No comment on instrument accuracy or test and maintenance procedures –(local matter).

NWML response to comments

The Medical Devices Agency saw no reason to distinguish between equipment used for monitoring, diagnosis and treatment and would wish to see the same level of accuracy required in nursing homes and mobile/visiting healthcare centres as are required in hospitals.

Two of the manufacturers i.e. SECA and H Fereday and Sons expressed concern about the use of inappropriate instruments and thought that the use of Class III instruments should be restricted to GP surgeries and Care/Nursing homes. This view is reflected in guidance from the United Kingdom Weighing Federation (UKWF).

Simpson Scales thought Class III scales should not be permitted for mobile/community nursing and nursing homes.

Conclusion

The strong advice of the Medical Devices Agency was against the issue of NWML guidance on the appropriate weighing instrument for particular cases however the industry has expressed a preference for a limited amount of control on instruments for weighings by GPs and in nursing and care homes. NWML does not propose to identify accuracy classes for specific medical weighing at this time.

The results of the consultation suggest that the recommendations of the UKWF offer sensible guidance on suitable accuracy levels. Guidance will also be available from local authority trading standards departments (who have responsibility for enforcing the Regulations) both pre-purchase and in the course of inspections.

NWML will review the situation if evidence of the use of instruments with an inappropriate level of accuracy emerges.

Users should adopt a suitable maintenance programme in line with the manufacturers' recommendations.

NWML

30 March 2003

Direct line 020 8943 7277

Our Ref STD 1317R

Your Ref

Date 8 November 2002

Dear Sir or Madam

NON-AUTOMATIC WEIGHING INSTRUMENTS – MEDICAL WEIGHING

1 I am writing to seek your assistance in identifying the types of weighing instruments used for medical purposes. **It would be helpful to receive a reply by 31 December 2002.**

2 Under Directive 90/384/EEC, from 1 January 2003 new non-automatic weighing instruments used in the "determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment" must comply with the conformity assessment procedures set out in the directive. Existing instruments in use at 31 December 2002 are not affected and can continue in use.

3 The Directive specifies four classes of accuracy but the implementing Regulations (currently the Non-automatic Weighing Instruments Regulations 2000) are silent as to which class or classes may be used for medical purposes. The effect of this is to permit any class to be used for medical weighing.

4 Some of these instruments are also subject to the Medical Devices Directive, eg hospital beds with a weighing function; others, such as scales in doctors' surgeries, are not.

5 All instruments brought into service after 1 January 2003 and used for medical weighing will be subject to inspection and test by authorised persons under the Regulations.

6 The details of the changes, which come into effect on 1 January 2003, are set out in the attached information document (Annex A). You may already have seen this document on circulation from us or from the Medical Devices Agency or Department of Health.

7 The purpose of this letter is to establish :-

- whether the accuracy of the weighing instrument is significant in relation to the medical decisions taken as a result of the weighing for example in relation to change of diet, the quantity of drugs to be administered or other medical treatment and, if so, in what areas;

- which accuracy class you would consider appropriate for the type of weighing carried out in the particular circumstances for which you use weighing instruments. Tables 1 and 2 of Annex B provide a comparison between the error allowances for Class IIII and Class III instruments and demonstrate what these requirements mean in practice. Your comments on the types of equipment used and the appropriate instrument characteristics for the purposes for which each instrument type is used would be helpful. You should consider a) the maximum capacity of the instrument which will depend on the maximum weight to be measured and b) the resolution or scale interval. Table 3 provides a proposal for instrument class for specific medical functions suggested by the UK Weighing Federation (Its inclusion here should not be taken as endorsement. NWML is grateful for permission to reproduce it.);

- irrespective of what may have been the initial accuracy of the instruments used, this may have deteriorated over time, do –users have procedures in place to test and/or maintain them? What is the likely nature and frequency of these checks?
- it is clear that heavily used equipment may often be unavailable for checking/maintenance what difficulties will be expected to result from the introduction of the obligation to inspect in-service equipment in the medical services eg identifying when equipment is not in use for medical purposes.

7 As a result of this consultation NWML hopes to be in a position to give one or more of the following :-

- pre-purchase advice for hospitals, etc, as to suitability of classes of accuracy for particular purpose of use;
- advice on service/maintenance contracts and the levels of accuracy they should contain;
- advice/training in the use of weighing instruments;
- advice on a co-ordinated programme of inspection and how to do it in the surgery/hospital environment;
- determine whether legislation should be introduced to prescribe the class of weighing instrument to be used in particular circumstances.

Yours sincerely

Sue Billing

Senior Legislation Adviser

ANNEX A

WEIGHING OF PATIENTS; MAKING UP OF MEDICINES

CHANGES TO UK WEIGHING INSTRUMENTS LEGISLATION

FROM 1 JANUARY 2003

Note by the National Weights and Measures Laboratory

Introduction

From 1 January 2003, the Non-Automatic Weighing Instruments Regulations 2000 *may* apply to non-automatic weighing instruments that you use. A non-automatic weighing instrument is one where an operator is involved in some part of the weighing process. From that date, you will need to ensure that the instruments meet the requirements of the Regulations where instruments are brought into use for any of the purposes in list A or B below (the words in quotation marks are taken directly from Directive 90/384/EEC).

List A:

- "Determination of mass for commercial transactions"
- "Determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment".
- "Determination of mass for the application of laws or regulations; expert opinions given in court proceedings"
- **"Determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment"**, which covers those activities where medical staff are responsible for the weighing of patients. Examples are the use of weighing instruments in hospitals, health centres or taken into the community for medical purposes. Medical staff includes all persons that lawfully carry out the medical weighing tasks concerned in their Member State. Medical weighing tasks might include, for example, bed-weighers and baby-weighers.
- **"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"**, where medical laboratories are laboratories that carry out analyses at the request of medical practitioners and pharmaceutical laboratories are quality control laboratories of manufacturers of medicinal products for human use. Pharmaceutical laboratories do not include the research and development laboratories of manufacturers of these medicinal products.
- "Determination of price on the basis of mass for the purposes of direct sales to the public and the making up of pre-packages"

Requirements relating to instruments covered by List A - generally type examination, followed by one of the verification options

List B "All other applications other than those listed in" [List A above]

- Sports and sporting records;
- Domestic use (kitchen, bathroom, ...);

- Geological surveys;
- Veterinary medicine;
- **Medical practice, except for the weighing of live patients;**
- Goods inwards inspection, etc (checking scales);
- Weighing of goods for customer information only and not for the final determination of mass (not to be confused with self-service scales that are used for the final determination of mass);
- Weighing for any non-List A purpose against payment. The payment represents a situation of commercial transaction for the determination of mass, which does not convert the use into a List A use. (E.g.: coin-operated person weighers).
- The use in quality systems. The metrological requirements that a measuring instrument, used in the operation of a quality system, needs to fulfil are, inter alia, that it has appropriate accuracy and is properly calibrated and periodically recalibrated against traceable metrological standards by a metrological laboratory. These requirements apply regardless of the status of the system (private agreement between two parties, mandatory certification procedure, ...). Although they do not exclude the use of legal measuring instruments, they do not render them mandatory either.

Also the use of instruments by

- Metrological enforcement agents
- Metrological experts (eg national metrology laboratories, ...);
- Government or public authority laboratories, forensic laboratories, ...

Requirements relating to instruments covered by List B - must bear the manufacturer's mark or name and the maximum capacity in the form Max [n] kg, g, etc

Who will be affected?

In order to determine whether you will be affected, you simply need to answer the following two questions:

- Will the instrument be used for one of the purposes detailed in the lists?
- Will the instrument be first brought into use after 31 December 2002?

If the answer to both of these questions is yes, then the Regulations will apply to your instrument. Unlike the provisions of the Weights and Measures Act 1985 there is no exemption in the Regulations for Crown bodies, eg government departments. You may wish to seek your own legal advice, if there is any doubt as to whether the Regulations would apply. Alternatively you may wish to contact the Trading Standards Department within your Local Authority for advice. Trading Standards Officers are responsible for enforcing many of the requirements within the Regulations. If you do not know where to find them, you can use the postcode find facility on www.tradingstandards.gov.uk .

If the Regulations apply, what will you need to do?

You will need to ensure that any instruments you purchase after 31 December 2002 comply with the requirements of the Regulations. Perhaps the simplest way for you to do this is to ask the instrument's supplier to confirm that it meets the requirements of the above Regulations, and that in the case of List A uses it bears the necessary symbols, which are:

i) the 'CE' marking;

ii) the 'M' (black 'M' on a green background); and

iii) a four digit number (the identification number of one of several bodies who are authorised to test instruments and/or approve quality systems that confirm that they accord with the Directive on which the Regulations are based).

What about subsequent maintenance and repair?

You should avoid making alterations, adjustments, repairs or replacements to instruments that bear the symbols described above. Some may also bear seals. Such changes may affect the function, accuracy or compliance of the instrument with the Regulations. You should seek the advice of the Trading Standards Department or the instrument's manufacturer. Some manufacturers are authorised to both repair and re-seal instruments with a re-qualification sticker. In other cases the affixing of the re-qualification sticker will be carried out by an approved body/Trading Standards Department.

Does this affect instruments which were brought into use prior to the deadline?

No it does not. You will be able to continue to use any instruments that you have had in use prior to 1 January 2003; and they will not be affected by this change. However, you should note that such instruments may be subject to the requirements of other Regulations.

Where can I obtain copies of the Regulations/further information?

This note gives general guidance only. You can obtain a copy of the Regulations themselves from The Stationery Office Limited. The reference number for the Regulations is: statutory instrument S.I. 2000/3236. Orders may be placed via telephone number 0870 600 55 22 or facsimile number 0870 600 55 33. Alternatively copies may be ordered through booksellers. The Regulations can also be found on the HMSO website at www.legislation.hmso.gov.uk/si/si2000/20003236.htm .

General information regarding legal metrology can be found at www.nwml.gov.uk . Email enquiries to info@nwml.gov.uk . NWML telephone 020 8943 7272; fax 020 8943 7270.

NWML

Teddington

August 2002

ANNEX B

UK WEIGHING FEDERATION PROPOSALS

TABLE 1

Comparative error allowances between Class III and Class III weighing instruments

Scale Interval	CLASS III - IN-SERVICE ALLOWANCE			CLASS III - IN-SERVICE ALLOWANCE			KEY
	Capacity	Capacity	Capacity	Capacity	Capacity	Capacity	
2kg	0 - 100 kg	100 -400 kg	Above 400 kg	0-1000kg	1000- 4000 kg		
	<i>+/- 2kg</i>	<i>+/- 4kg</i>	<i>+/- 6kg</i>	<i>+/- 2kg</i>	<i>+/- 4 kg</i>		
1 kg	0 50 kg	50 - 200 kg	Above 200 kg	0 - 500 kg	500 - 2000 kg		
	<i>+/- 1 kg</i>	<i>+/- 2 kg</i>	<i>+/- 3 kg</i>	<i>+/- 1 kg</i>	<i>+/- 2kg</i>	Capacity shown	
500g (0.5kg)	0 - 25 kg	25 -100 kg	Above 100 kg	0- 250 kg	250 - 1000 kg		In
	<i>+/- 500 g</i>	<i>+/- 1 kg</i>	<i>+/- 1.5 kg</i>	<i>+/- 500 g</i>	<i>+/- 1 kg</i>	Plain text	
200g (0.2kg)	0 - 10 kg	10 - 40 kg	Above 40 kg	0 - 100 kg	100 - 500 kg		Error Allowance
	<i>+/- 200 g</i>	<i>+/- 400 g</i>	<i>+/- 600 g</i>	<i>+/- 200 g</i>	<i>+/- 400 g</i>	Shown	
100g (0.1 kg)	0 - 5 kg	5 - 20 kg	Above 20 kg	0 - 50 kg	50 - 200 kg	Above 200 kg	
	<i>+/- 100 g</i>	<i>+/- 200 g</i>	<i>+/- 300 g</i>	<i>+/- 100 g</i>	<i>+/- 200 g</i>	<i>+/- 300g</i>	
50g (0.05 kg)	0 - 2.5 kg	2.5 - 10 kg	Above 10 kg	0 - 25 kg	25 - 100 kg	Above 100 kg	
	<i>+/- 50 g</i>	<i>+/- 100 g</i>	<i>+/- 150 g</i>	<i>+/- 50 g</i>	<i>+/- 100 g</i>	<i>+/- 150 g</i>	
20g (0.02 kg)	0 - 1 kg	1 - 4 kg	Above 4 kg	0 - 10 kg	10 - 40 kg	Above 40 kg	
	<i>+/- 20 g</i>	<i>+/- 40 g</i>	<i>+/- 60 g</i>	<i>+/- 20 g</i>	<i>+/- 40 g</i>	<i>+/- 60 g</i>	
10g (0.01 kg)	0 - 500 g	500g - 2 kg	Above 2 kg	0 - 5 kg	5 - 20 kg	Above 20 kg	
	<i>+/- 10 g</i>	<i>+/- 20 g</i>	<i>+/- 30 g</i>	<i>+/- 10 g</i>	<i>+/- 20 g</i>	<i>+/- 30 g</i>	
5g (0.005 kg)	0 - 250 g	250 g - 1 kg	Above 1 kg	0 - 2.5 kg	2.5 - 10 kg	Above 10 kg	
	<i>+/- 5g</i>	<i>+/- 10 g</i>	<i>+/- 15 g</i>	<i>+/- 5 g</i>	<i>+/- 10 g</i>	<i>+/- 15 g</i>	

2g	NOT	ALLOWED	0 - 1 kg	1 kg - 4 kg	Above 4 kg
(0.002 kg)			<i>+/- 2g</i>	<i>+/- 4 g</i>	<i>+/- 6 g</i>
1g	NOT	ALLOWED	0 - 500 g	500 g - 2 kg	Above 2 kg
(0.001 kg)			<i>+/- 1 g</i>	<i>+/- 2 g</i>	<i>+/- 3 g</i>

Note: The apparent difference between two machines can be significant when one operates at the upper limit and one at the lower limit of permitted error.

TABLE 2**Recommended Minimum Classes for specific applications**

Purpose	Hospitals	Hospital associated medical centres	Ante/ Post Natal Clinics	Medical Practice Treatment Rooms	GP Consulting Rooms	Mobile/ Visiting Health care	Nursing Homes
Monitoring	III	III	III	III	IIII	IIII	IIII
Diagnosis	III	III	III	III	III	III	III
Treatment	III	III	III	III	III	III	III

TABLE 3**Recommended maximum scale interval for specific applications**

	Adults	Young Children	Babies
Checking weight for records	500g	200g	50g
Regular monitoring to assess weight change	200g	100g	10/20g
Measuring weight to assist medical diagnosis	200g	50/100g	10/20g
Measuring weight for critical treatment eg dialysis	50/100g	20/50g	5g
Recording birth weight			20g
Measuring weight before and after breast feeding			10g
<i>The above figures were taken from a limited survey of medical practitioners and specialist scales distributors</i>			