



**Review of the level of accuracy required
and means of demonstrating that accuracy
for approval of dosimetry services by the
Health and Safety Executive**

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Under Regulation 35 of the Ionising Radiations Regulations 1999 (IRR99) and Regulation 14 of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPiR), the Health and Safety Executive (HSE) approves dosimetry services to carry out a number of functions specified in those regulations. The assessment of the services is carried out according to the HSE Statement on the Approval of Dosimetry Services (and REPPiR Supplement to this), the associated published Requirements for the Approval of Dosimetry Services (RADS) Parts 1 to 3 and the Supplement (2003), and the General Guidance for Laboratories providing Personal Dosimetry Services. Parts 1 and 2 of the RADS and the supplement relate to the assessment of radiation doses received by employees (Part 3 relates to co-ordination and keeping of recorded dose information). The adequacy of a service to comply with RADS is largely determined by assessment every 5 years of the dosimetry services management, laboratory and quality assurance procedures and the performance characteristics of the dosimeter or dosimetry method used. For some (but not all) types of dosimetry, HSE requires that services undertake performance tests prior to initial application for approval and periodically thereafter, currently every 18 months. The performance tests are designed to assess the performance of the service in analysing dosimeters (or biological samples) irradiated to a known level (or containing a known level of activity).

This report considers methods of assessing the accuracy and reliability of dosimetry systems, the current HSE process of dosimetry service approval and possible improvements and alternative approaches, for both external and internal dosimetry.

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EXECUTIVE SUMMARY

Under the Ionising Radiations Regulations 1999 (IRR99) and the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPPIR), HSE approves dosimetry services to carry out systematic assessments of doses from routine exposures, or of doses resulting from accidents and other occurrences. There is a range of dosimeter types and/or dosimetry methods by which radiation doses can be assessed, and a number of different dosimetry services which seek approval. The HSE process of dosimetry service approval is currently undergoing review.

The report includes a consideration of general requirements for approval or accreditation of dosimetry services; British and international standards, and other documents of relevance; and harmonization within the EU.

The report considers what is a reasonable degree of accuracy and how best to assess the ability of dosimetry services to continue to achieve that level. The overall accuracy of the assessment of dose by a given dosimetry method depends on the dosimetric characteristics of the dosimeter/dosimetry system and its suitability for the purpose, and on the quality assurance and quality management systems of a given dosimetry service, which determine the reliability and consistency of the application of the measurement method.

The assessment of the suitability for purpose of a measurement method and strategy, or dosimetry system, which involves, for external radiation, information on the energy and direction characteristics of the radiation field being measured, plus other factors (environmental conditions, dosimeter wear position, etc.), is not addressed in this report. The remaining components of overall accuracy which are addressed are:-

- (a) the more general laboratory and staff quality assurance, and quality management systems, including software quality assurance, conformity of equipment used, calibration and internal performance tests (see below);
- (b) routine external performance tests of the dosimetric reliability and consistency of the application of the method by an identifiable laboratory (system operator, actual identifiable equipment used, identifiable dosimeter calibration factor, read-out system calibration, environmental conditions for read-out, etc.), and periodic inter-comparisons between systems providing similar services;
- (c) determination of the dosimetric characteristics of the system. For external radiation dosimetry, this is achieved by type-testing- the determination of the energy and angle dependence of ($H_p(d)$) response characteristics of the type of dosimeter/dosimetry system used, repeatability and reproducibility, effect of influence quantities, and other factors linked to the measurement method. For internal dosimetry, this includes the monitoring strategy for the *in vivo*, bioassay or air concentration measurements undertaken, and the models (intake, biokinetic and dosimetric) used to determine internal dose from the measurements made, as well as factors directly related to the determination of the measurement quantity.

The present system of approval for both external and internal radiations is reviewed with comments from currently approved dosimetry services taken into account. The adequacy of the present performance tests are assessed. Then, for both external and internal dose assessment, and for each of the three aspects of overall accuracy ((a), (b) and (c) above), three options are considered:

- 1 Retain the present system with some improvements.
- 2 Introduce a more general version of present system, linked to detailed standards on quality assurance and dosimetric requirements.
- 3 Introduce a more general version of present system, linked to detailed EC guidance.

The conclusion of the authors is that the overall structure of the present system should be retained and some detailed recommendations for improvement are given, but it is recommended that the approval system should encourage the adoption of British and international standards of quality assurance, specifically BS EN ISO/IEC 17025:2005, with certification undertaken by UKAS. It is further recommended that the approval procedures should move towards having dosimetric requirements linked to British, European or international standards, or, if these become available in the medium term, to detailed EC guidance. The changes will need to take place over a period of time to allow dosimetry services to adapt to revised approval procedures and it will probably be necessary that, at least initially, ISO 17025 certification is optional. Further consultations with interested parties are to take place.

1 PROJECT BACKGROUND AND OBJECTIVES

1.1 BACKGROUND

Under Regulation 35 of the Ionising Radiations Regulations 1999 (IRR99)¹ and Regulation 14 of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR)², the Health and Safety Executive (HSE) approves dosimetry services to carry out a number of functions specified in those regulations. The assessment of the services is carried out according to the *HSE Statement on the Approval of Dosimetry Services*³, the associated published *Requirements for the Approval of Dosimetry Services (RADS) Parts 1 to 3*⁴⁻⁶, the *Supplement (2003)*⁷, and the *General guidance for laboratories providing personal dosimetry services*⁸. Parts 1 and 2 of the RADS and the supplement relate to the assessment of radiation doses received by employees (Part 3 relates to co-ordination and keeping of recorded dose information).

The HSE process of dosimetry service approval is currently undergoing review and it is therefore necessary to reconsider what is a reasonable degree of accuracy and how best to assess the ability of dosimetry services to continue to attain that level. In this research study, the HSE asked that the following questions be answered:-

- Is the current system of approval the most appropriate way to judge the level of accuracy and reliability achieved by dosimetry services? [Note that a number of international standards are available relating to personal dosimetry and the use of these within the system might provide a better means of assessing adequate levels of performance].
- Is the current system of performance tests the most appropriate way to judge the level of accuracy achieved by dosimetry services and is the current performance test requirements fit for the purpose?
- If it is concluded that the current approach should be improved, what changes should be made? (Either by reviewing and revising existing performance test criteria and/or replacing with more suitable means of demonstrating accuracy and reliability).
- Should the current period between reassessments be reconsidered where regular demonstrations of continuing performance are provided by the service?

Decisions could then be made on the overall procedure for approval, in particular were the current assessment and testing intervals still appropriate or should new procedures for assessment and demonstration of accuracy and reliability be introduced? The HSE would need to take into account the costs, benefits and feasibility of implementation of any new assessment and testing requirements- a key requirement would be to ensure that resources were used effectively.

1.2 OBJECTIVES

The specific project objectives were to:-

1. Assess whether the current system of approval, which involves assessment of the dosimetry services management, laboratory and quality assurance procedures and the performance of the dosimeter or dosimetry method used every 5 years together with regular performance tests [where applicable] every 18 months, is the most appropriate way to judge the level of accuracy and reliability achieved by dosimetry services. A number of international standards are available relating to personal dosimetry and the use of these within the system might provide a better means of assessing adequate levels of performance.

2. Propose what is acceptable and achievable as “reasonable accuracy” in assessed external and internal doses, and outline approaches as to how the accuracy of dosimetry systems can be determined for different radiation types, radiation qualities dose levels, radionuclide exposures, to ensure that the parameters chosen to establish the accuracy of dose assessment (bias and statistical variation) follow a demonstrably consistent, and transparent method that takes due account of precision and confidence over the required range of doses.
3. Recognising that it is not always possible to provide a reliable assessment of the overall accuracy of assessed internal doses, make proposals on the information on uncertainties that dosimetry services could reasonably be expected to provide in terms of the measured quantities, and that would be adequate for approval purposes.
4. Assess whether the current system of performance tests is the most appropriate way to judge the level of accuracy achieved by dosimetry services and whether the current performance test requirements are fit for purpose.
5. If it is concluded that the current approach should be improved, propose changes (either by reviewing and revising existing performance test criteria and/or replacing with more suitable means of demonstrating accuracy and reliability).
6. Assess whether the current period between reassessments be reconsidered where regular demonstrations of continuing performance are provided by the service.

The assessment of doses from radon and radon daughters, and individual monitoring for external radiation by means other than the issue of personal dosimeters, were not included in this study.

2 TERMS AND DEFINITIONS

In discussing matters of measurement accuracy, and indeed the more general matters of personal dosimetry system approval procedures, it is essential to have a common understanding of the meanings of the terms used. The definitions of the terms used are given in Annex A, and where possible are taken from national and international standards (British Standards Institution, BSI, International Organization for Standardization, ISO, and International Electrotechnical Commission, IEC). In some instances, the definitions of terms are included in the text to aid clarity.

The physical quantity, of which the accuracy and reliability is discussed here, is the measurement quantity. In the case of external radiation this is the personal dose equivalent⁹, $H_p(d)$, where d is the appropriate depth for whole body, skin or the extremities. (A separate measurement of $H_p(3)$ to control equivalent dose to the eye, is not made, in general.) For external radiation, the relationship of $H_p(d)$ to effective dose, skin or extremity equivalent dose is addressed in RADS Part1 and is not considered further here.

In the case of internal radiation, doses cannot be measured directly. The measured quantities are generally amounts of radionuclides in the whole body or in specific organs, radionuclide concentrations in excreta samples such as urine or faeces, or radionuclide concentrations in air. Biokinetic models are used to determine activities in organs of the body as a function of time after an intake from these measured quantities. Dosimetric models are then used to determine the resulting committed equivalent doses to each organ over the 50 years following intake, and the committed effective dose, (ie the "whole body" dose). Because it is not usually possible to provide an assessment of the overall accuracy of assessed internal doses (section 1.2, objective 3), the emphasis in this document is placed on considerations of accuracy of the measured quantities.

3 GENERAL REQUIREMENTS FOR APPROVAL OR ACCREDITATION OF DOSIMETRIC SERVICES, AND ON OVERALL ACCURACY

3.1 APPROVAL, ACCREDITATION AND CERTIFICATION

The purposes of approval are to recognise and verify that an ADS is technically competent; able to generate technically valid results; and has adequate administration, technical and quality systems. If it is considered that certification of all or some aspects of the laboratory management and procedures, including quality assurance, might apply to a personal dosimetry service (but see below), certification alone would not normally be sufficient for approval.

For a service to be approved, HSE requires that it produces a reasonable degree of accuracy in the assessment of dose (or contribution to such assessment); is highly reliable; communicates the results of routine dose assessments to a dosimetry service approved for co-ordination and record keeping (or forwards the results of other work for which it is approved) in a reasonable time; and rapidly communicates to the employer, and subsequently to the ADS (records), the results of dose assessments made in the event of an accident, occurrence, or incident (but see [refs 3 to 8]).

The following definitions are taken from the Ionising Radiations Regulations 1999 (IRR99)¹ and BS EN ISO/IEC 17000:2004¹⁰.

An **approved dosimetry service** (ADS) is a dosimetry service approved by HSE, or by such other persons as may from time to time be specified in writing by the Executive).

Approval is by a certificate in writing (in accordance with such criteria as may from time to time be specified by the Executive for such of the purposes of the IRR99 as are specified in the certificate (see Regulation 35 of the IRR¹). In other words approval is a procedure by which a national authority recognizes the competence of a dosimetry service.

Conformity assessment is the demonstration that specified requirements relating to a product (includes services), process, system, person or body are fulfilled.

A **conformity assessment body** performs conformity assessments.

Attestation is the issue of a statement based on a decision following a review, that fulfilment of specified requirements has been demonstrated

Accreditation is third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Certification is third party attestation related to products, processes, systems or persons. Note that products includes services; certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves to which accreditation is applicable.

A **specified requirement** is a need or expectation that is stated.

From the above definitions, it would seem that since ADS do not, strictly, perform conformity assessments, and since they are not, therefore, conformity assessment bodies, they cannot be

accredited. Initial contacts with the UK Accreditation Service, UKAS, would indicate that they consider that the assessment of conformity of ADS to a standard, BS ISO 17025 for example, is possible. From the above definitions, this would mean certification, not accreditation. This needs to be clarified with UKAS.

The Health and Safety Commission (HSC) has issued a policy statement on the use of conformity assessment to promote health and safety¹¹ which defines accreditation as a process in which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. The policy of HSC is that accreditation has *“the potential to contribute to the development and maintenance of suitable levels of health and safety at work”* and that *“HSC will seek to use conformity assessment for this where it is the appropriate means of achieving this goal.”* However, *“The statement does not apply to HSE assessment of safety cases, or issuing of licenses under a licensing regime, e.g. the licensing of nuclear installations, where the judgment on health and safety covers only the specific situation and uses appropriately defined and selected criteria for the purpose. Nor does it apply to general HSE inspection activity, e.g. where an inspector will consider in broad terms the fulfilment of legislative requirements.”* In the case of approvals- *“Regulatory authorities often required through legislation that products be approved by themselves before they could be used. Typically, these approvals schemes originated in areas of high hazard such as pressure systems, where a succession of incidents led to intensive inspection regimes; or in major utilities with their own specific hazards, like the railways. Often such schemes used conformity assessment techniques (such as testing).”* and *“Where HSC has introduced a direct approval scheme HSC will seek to replace it by independent assessment once an appropriate standards framework and/or bodies competent to assess conformity have developed”*. This would appear a clear indication that where appropriate British standards exist, UKAS should play a rôle in UK approval procedures.

The certification and accreditation criteria developed in international standards constitute broad requirements. To ensure consistent implementation, more detailed guidelines are necessary. These are developed by accreditation bodies through international networks: European co-operation for Accreditation (EA) in Europe (www.european-accreditation.org); International Laboratory Accreditation Co-operation (ILAC) (www.ilac.org) and the International Accreditation Forum (IAF) (www.iaf.nu) globally.

3.2 GENERAL QUALITY ASSURANCE REQUIREMENTS – QUALITY ASSURANCE STANDARDS AND RELEVANT DOCUMENTS

Good measurements, that is measurements of reasonable accuracy and high reliability, require the implementation of quality assurance procedures. Formal quality assurance procedures and quality management systems are basically good practice, but their formal nature introduces rigour and attention to detail which might not otherwise be there, and can also allow tests of conformity to be made. The general HSE guidance⁸ gives an outline of quality assurance procedures. These have many aspects in common with the main quality assurance standard for calibration, test and measurement laboratories, BS EN ISO/IEC 17025:2005¹².

The British, European and international standard ISO/IEC BS replaces ISO/IEC Guide 25 and EN 45001, and contains all the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results. The standard incorporates all relevant parts of BS EN ISO/IEC 9001 such that if a laboratory meets 17025, it will also meet 9001 in respect of those parts relevant to testing and calibration services. More information on this document can be found in section 7.2 and Appendix 3.

The European Commission has issued technical recommendations for monitoring individuals occupationally exposed to external radiation¹³. The quality assurance parts of this document, and also those of the draft ICRU report “Measurement Quality Assurance in Ionizing Radiation

Dosimetry”¹⁴, are in accord with the general BS ISO/IEC 17025 requirements. For more information on these documents and for other relevant documents giving guidance, see Appendix 3.

3.3 ACCURACY – EXTERNAL RADIATION

3.3.1 General

For a measurement, accuracy is the closeness of agreement between the result of a measurement and a true value of a measurand^{15,16}.

The overall accuracy of a measurement of $H_p(d)$ using a given dosimetry method depends on the quality assurance and quality management systems of a given dosimetry service, which determine, amongst other things, the reliability and consistency of the application of the measurement method; and the dosimetric characteristics of the dosimeter/dosimetry system and its suitability for the purpose. Assessment of these components of overall accuracy may be subdivided into four components:-

- (a) the more general laboratory and staff quality assurance, and quality management systems, including software quality assurance, conformity of equipment used, calibration and internal performance tests (see below);
- (b) routine external performance tests of the dosimetric reliability and consistency of the application of the method by an identifiable laboratory (system operator, actual identifiable equipment used, identifiable dosimeter calibration factor, read-out system calibration, environmental conditions for read-out, etc.), periodic inter-comparisons;
- (c) type-testing- the determination of the energy and angle dependence of ($H_p(d)$) response characteristics of the type of dosimeter/dosimetry system used, repeatability and reproducibility, effect of influence quantities, and other factors linked to the measurement method;
- (d) information on the energy and direction characteristics of the radiation field being measured, plus other factors (environmental conditions, dosimeter wear position, etc.).

Component (a) has been considered in section 3.2 above.

External performance tests (component (b) above) serve a different objective to type-tests. As a general principle, performance tests are intended to assess the capability of the dosimetry service/laboratory making the measurements, using a specific dosimetric system, to comply with the specific performance criteria, whereas type-tests are determinations of the dosimetric properties of the method, *i.e.* of the dosimeter/dosimetry system. They are partly a check on quality assurance procedures and laboratory practice, and as such are a check on the consistency of measurement procedures and can be part of what is known as reliability (but see below). Performance tests are of several types^{17,18}. They can be used to obtain a ‘snapshot’ of the overall accuracy of a dosimetry service, as in tests against the ‘trumpet curve’^{19,20} (see below), but may involve attempts to replicate workplace radiation fields²¹. Alternatively, performance tests separately assess components of accuracy as the bias and statistical uncertainty^{22,23}. The performance test used in the USA (see below) assesses bias and standard deviation, but is a hybrid of components (b) and (c) above, with measurements of the performance index for groups of dosimeters irradiated to a range of radiation types, energy and angles of incidence.

The component of accuracy in (c) above is determined by a full type-test of a dosimetry system, which may be carried out to establish conformity with a national or international standard, to ascertain whether a system meets national or international requirements, or as part of an approval procedure (see below). The component of accuracy in component (d) above is determined by workplace field measurements and calculations, and by information from other sources, for example health physicists and equipment suppliers.

A consideration of the acceptable accuracy to be expected of a personal dosimetry system will involve the magnitude of the dose, either for a single issue period or for the annual dose, and may take account of the fact that the quantity measured, $H_p(d)$, differs from the quantities on which regulatory limits are based (the protection quantities). What is considered reasonable accuracy in the assessment of the operational quantity at doses of less than 1 mSv per year may not be acceptable at doses of several mSv per year. Where an assessed dose exceeds a relevant dose limit, part of any investigation should have the aim of reassessing the dose received, taking account of the energy and direction distributions of the radiation field in order to obtain a more accurate assessment of the protection quantity⁴. In most cases, but not all, $H_p(d)$ will provide a good estimate of the effective dose or equivalent dose to skin, eye or extremities^{24,25} for irradiation conditions of uniform broad fields. More generally, personal dosimeters can only be assumed to indicate the dose equivalent received by the regions of the body that are in proximity to these devices.

In ICRP Publication 75 "General Principles for the Radiation Protection of Workers"²⁶, it is stated that : *"In practice, it is usually possible to achieve an accuracy of about 10% at the 95% confidence level for measurements of radiation fields in good laboratory conditions. In the workplace, where the energy spectrum and orientation of the radiation field are generally not well known, the uncertainties in a measurement made with an individual dosimeter will be significantly greater. Non-uniformity and uncertain orientation of the radiation field will introduce errors in the use of standard models. The overall uncertainty at the 95% confidence level in the estimation of effective dose around the relevant dose limit may well be a factor of 1.5 in either direction for photons and may be substantially greater for neutrons of uncertain energy, and for electrons. Greater uncertainties are also inevitable at low levels of effective dose for all qualities of radiation". ICRP further states: " ... the recording level for individual monitoring should be derived from the duration of the monitoring period and an annual effective dose of no lower than 1 mSv ..."* explaining that *"the recording level is useful in defining the low dose requirements of dosimeters; it can be used as the basis for defining performance requirements"*. Recording levels are values of measured quantities above which a result should be recorded. These levels are set by operating management or national authorities. This procedure allows trivial information records to be excluded. The recording level has been interpreted as allowing a 100 % relative uncertainty near a true dose value equal to the recording level^{18,27}.

The ICRP recommendations, applied to the magnitude of the quotient H_m/H_t of the measured dose value, H_m , and the conventional true (*i.e.*, true to the best possible knowledge) value, H_t , can be interpreted as follows for whole body dosimeters to determine $H_p(10)$:

- (i) For a dose value equal to or approaching the annual dose limit, that is 20 mSv, acceptable performance is described by the relation $1.5 \geq H_m/H_t \geq 1/1.5$ at the 95 % confidence level.
- (ii) For a dose value at about the recording level for a monitoring period, the corresponding relation has been taken as $2.0 \geq H_m/H_t \geq 0$. No confidence levels are given. These two criteria have been joined by a smooth curve- the so-called trumpet curve^{19,20}, and applied to routine performance tests in some countries. For and skin, eye and extremity dose determinations, the annual limit is of course higher.

These recommendations of ICRP are generally consistent with the position of ICRU as given in Report 47²⁸ and have become the basis of performance test and type-test criteria (see for example [17]). If applied to the determination of the measurement quantity, the criterion of a

factor of 1.5 on overall accuracy at or near dose limits is reasonable and achievable for body dosimeters for photons and electrons. For determinations of doses from neutrons, or extremity and skin dosimetry for low energy electrons, the 1.5 factor might be replaced by a factor of two. Inter-comparisons carried out under the aegis of both EURADOS²¹ and by IAEA^{29,30} have demonstrated the achievability of these criteria, although it should be noted that they were not met by all the dosimetry systems participating in these intercomparisons.

BS ISO 11929-7:2005³¹ defines so-called “characteristic limits”:

- The **decision threshold** allows a decision to be made for a measurement with a given probability of error as to whether the result of the measurement indicates the presence of the physical effect quantified by the measurand.
- The **detection limit** specifies the minimum true value of the measurand which can be detected with a given probability of error using the measuring procedure in question. This consequently allows a decision to be made as to whether or not a measuring method satisfies certain requirements.
- The **limits of the confidence interval** define an interval which contains the true value of the measurand with a given probability, in the case that the result exceeds the decision threshold.

The difference between using the decision threshold and using the detection limit is that measured values are to be compared with the decision threshold, whereas the detection limit is to be compared with a guideline value.

In personal dosimetry, the detection limit is the dose level such that the reading would be incorrectly reported as background with a stated probability, usually 5 or 2.5%, that is only 5% or 2.5% false negatives. A false negative probability of 5 or 2.5% corresponds to a dose value equal to about 3.3 or 4 standard deviations on background. A suitable detection limit for whole body external radiation dosimeters for photons and electrons would be about 170 μSv . This corresponds to monthly issue and an annual dose of 2 mSv. An achievable detection limit for neutron dosimeters would be several hundred μSv . (see Appendix 1 for more information on this).

3.3.2 Performance tests

There are various national and international standards and recommendations for performance tests, and there are some significant differences among them. A comparative study of the respective requirements can be found in PTB report Dos-27¹⁷. Sometimes the distinction between type testing and performance testing is not clear. In countries with limited access to facilities to carry out type-testing, a kind of approval performance test for the dosimetric services, including a more or less complete type-testing of the dosimeter/dosimetry system is sometimes required by the regulatory authority before authorizing operation. The best method of external performance testing is one which allows the assessment of the performance of the service under actual, or simulated, operational conditions. The service should not give any special treatment to the dosimeters which might lead to unrepresentative results. The best tests of system performance can be investigations of the performance of perhaps several systems simultaneously in the actual workplace³², but here, in most cases, the true value of the measurement quantity is unknown. A similar outcome can be achieved by taking part in inter-comparisons which include simulated workplace fields

Usually, the term ‘performance test’ is taken to mean a routine performance or proficiency test. Such tests have the purpose of determining the reliability of the routine measurement procedure. Performance tests can test consistency (i.e reliability) of measurements, and can also be spot tests of overall accuracy. There are three types of performance/proficiency tests in general use in the EU, the ‘*blind*’ test, the ‘*surprise*’ test and the ‘*announced*’ test. Some information on these types of test is given below, but see [18] for more detail and examples. Depending on the legal and local circumstances, other approaches may be acceptable.

In a *'blind'* test the service is not aware of the tests and cannot use selected dosimeters or special evaluation procedures for the tests. One approach is the invention of a *'dummy customer'* and controlled irradiation of the dosimeters by a control institute. The largest Netherlands and UK services use a dummy customer for in-house quality assurance purposes. Another approach is to issue the same person, identified as someone who gets a non-zero dose, with several (perhaps electronic) dosimeters. In this case the measurement is done in a real radiation field under workplace conditions, but the 'true' value of $H_p(d)$ is unknown.

In a *'surprise'* test the service is aware of the tests but does not know the actual test date in advance. It is possible for the service to use selected dosimeters but not to use special evaluation procedures. The control institute periodically requests (e. g. once a year) a fixed number of dosimeters. The dosimeters are irradiated, and, without prior notice, an official of the verification office submits, in person, the irradiated dosimeters to the service. The official observes the evaluation, which should follow written quality assured procedures, and passes the results back to the control institute. An example of this approach is the procedure in Germany.

In an *'announced'* test, the service is aware of the tests and may not be prevented from using selected dosimeters or taking special care with evaluation procedures. The control institute asks the service to send the dosimeters to it and irradiates them. Then the dosimeters are sent back to the service for evaluation. The HSE performance test and many international (including IAEA) intercomparisons are of this type. The HSE performance test (see below) aims to relate the test results to the expected values for the dosimeter type, taking into account the dosimeter characteristics previously supplied to the approval authority. Accordingly, the ADS can apply corrections to the calibration factor such that the residual bias in the performance test result should be close to zero. Repeated performance tests serve as a measure of the reproducibility of the system.

Accuracy, in the formalism of BS ISO 5725-1²², can be considered as comprising trueness and precision (see Annex A for definitions and also below). Trueness is the inverse of bias. Trueness/bias is obtained by comparing the measurement result with the accepted reference (conventional true) value. Precision is the inverse of statistical uncertainty, and is normally expressed in terms of standard deviation. It is a term needed because measurements made of presumably identical radiation fields do not yield identical results. The factors involved include (a) the operator, (b) the equipment used, (c) the calibration of equipment, (d) the environment and (e) the elapsed time between measurements. Precision has two conditions – repeatability and reproducibility. Under repeatability conditions, factors such as (a) to (e) are considered to be constant and do not contribute to the variability of the measurement result. Under reproducibility conditions, the factors can vary. Repeatability and reproducibility are the two extremes of precision.

3.3.3 Intercomparisons

In some EU Member States periodic performance testing exercises (intercomparison measurements) are organised for the approved or authorized personal dosimetry services solely to demonstrate that the required standards are being kept over time. The participation in these exercises may be mandatory or voluntary, depending on national regulations. There are different ways to implement such periodic performance tests.

Recent EURADOS and IAEA intercomparisons have included irradiations of dosimeters in simulated workplace fields^{21,29,30} which have broad or mixed energy and angle distributions and/or mixed particle types. ISO standards are being developed for simulated workplace fields for neutrons^{33,34}. EURADOS is proposing that there are regular, periodic EU intercomparisons³⁵. It is proposed that the results of such intercomparisons are published but are anonymous.

3.3.4 Type-tests

Type-testing is the determination of the response characteristics of a dosimeter and/or dosimetry system³⁶. Although sometimes restricted to just the energy and angle dependence of response characteristics of one type of radiation under reference or standard conditions and for the stated range of use, full type-testing includes the effects of all influence quantities which may have a significant effect on the measurement, such as radiation types and/or energies and angles outside the stated range, environmental conditions, *etc.* Type-tests need also to determine the repeatability and reproducibility of the dosimetry system^{22,37}.

Type-tests are frequently carried out to demonstrate conformity against a standard. Although conformity with a standard may not be mandatory prerequisite of approval (it is not in the UK), conformity is often demonstrated by a manufacturer or ADS anyway. A standard may also be used as the basis of the design requirements of a dosimeter and dosimetry system. Type tests may also be carried out against detailed regulatory performance requirements, for example in Germany.

3.3.5 Workplace field characterization

Detailed knowledge of workplace fields (i.e. data on energy and direction distributions, dose rates, worker orientation and occupancy factors, environmental conditions), can be used to assess how well personal dosimeters estimate $H_p(10)$ and $H_p(0.07)$, and contribute to the estimation of the overall uncertainty of measurement (section 3.3.7). Knowledge of workplace fields can also be used to optimize the design of dosimeters; frame the dosimeter performance requirements sensibly; and assist the retrospective interpretation of dosimeter readings if required.

The detailed determination of the energy and direction distributions requires specialized equipment and specialists to use it. Frequently, it is the direction distribution of the field which has the largest influence³⁸. The measurements can be lengthy and therefore expensive. In some instances limited additional information on workplace fields can be sufficient to enable the choice of suitable personal dosimeter. For instance, procedures can be used to identify areas where there is a strong low energy component which may lie below, for example, the threshold of an electronic personal dosimeter. Similarly it is possible to search for radiation incident at unexpected angles, by using lead shielding around a Geiger Müller detector to collimate the response to a few tens of degrees.

Further information of the characterization of workplace fields may be found in a special issue of Radiation Protection Dosimetry “Neutron and photon spectrometry techniques for radiation protection”²⁵, in reports of a EURADOS study³⁹ and a current EC research study, EVIDOS “Evaluation of Individual Dosimetry in Mixed Neutron and Photon Fields”⁴⁰, and in a Contract report to HSE⁴¹.

3.3.6 Field calibrations

Practical considerations may well result in the use of a dosimeter with some deficiencies of response characteristics. Equipment needed for the measurement of the energy and direction distribution of the workplace field is expensive, the analysis time consuming, and the results often difficult to apply to an individual worker. The most effective procedure may be the inter-comparison of the on-phantom readings of specialized devices which give a better determination of $H_p(10)$ and $H_p(0.07)$, but are not generally suitable for routine use, and readings of the preferred practical dosimeter. This is a field calibration^{42,43}. Overnight or over weekend exposures can often be employed to allow the accumulation of sufficient dose well

above the measurement threshold. Multiple dosimeters can be used on the same phantom to mimic rotation of the worker. Using field calibrations, the measurement accuracy can be improved and the overall uncertainty decreased.

3.3.7 Provision of estimates of overall uncertainty

Estimates of the overall uncertainty are needed for any measurement of a physical quantity. The result of any measurement should comprise the name of the quantity, the magnitude of the value, the unit and the uncertainty. For external radiation personal dosimetry estimates of uncertainty are required in the current HSE procedures and in BS EN ISO/IEC 17025:2005¹². It would seem to be acceptable that an estimate of the uncertainty of each individual assessment of $H_p(d)$ is not required, but estimates of uncertainties for ranges of measurement values would be sufficient, together with values of the detection limit (the dose at which one can be 95% confident, say, that the dosimeter reading will be assessed as a dose and not as a background—that is only 5% false negatives) and perhaps also the decision threshold (the dose corresponding to the reading which for a background/unexposed dosimeter has only a 5% probability, say, of being exceeded and therefore being attributed to a dose—5% false positives) (see Appendix 1).

In some cases, it may be possible to obtain an estimate of the uncertainty on an actual individual dosimeter result, or on set of results. The ISO “Guide to the expression of uncertainty in measurement”⁴⁴ (known as the GUM) gives guidance on combining inputs to the total uncertainty. The overall uncertainty of a measurement can be estimated by combining the inputs to the uncertainty assessment from the dosimeter response characteristics with known, or assumed, workplace field characteristics. This can be done by using an analytical method⁴⁵ (with this approach approximations are generally necessary), or using a numerical method^{46,47,48}.

In practice an ADS will not normally have detailed information on the workplace field, which is anyway strictly the preserve of the employer, not of the ADS. Even for the employer, there will normally only be limited knowledge of the workplace field and other factors such as a worker’s pattern of movement, and generalized assumptions, will need to be made leading to an overestimate of the overall uncertainty.

3.4 ACCURACY – INTERNAL RADIATION

3.4.1 General

The evaluation of the overall accuracy of assessed doses resulting from intakes of radionuclides is widely acknowledged to be one of the most difficult problems in radiation protection. The reasons are two-fold: information on the uncertainties of quantities and model parameters used in internal dose calculations is often sparse: and the complexity of the relationship between measured quantities and assessed doses means that a methodology for estimating the uncertainties of assessed doses has yet to be developed. As a result, internal doses are generally reported without confidence intervals.

Because of this lack of information and the current absence of a methodology for the estimation of uncertainties in doses, requirements placed on accuracy in internal doses are less well developed than those specified for external dosimetry. Methods available for the assessment of overall accuracy (cf section 3.3) are also less well developed.

ICRP places no formal requirement on accuracy in assessed internal doses, and provides only limited guidance. In ICRP Publication 78⁴⁹, a simple rule is defined which states that routine

monitoring intervals should be chosen so that intakes should not be underestimated by more than a factor of three due to lack of information on the time of intake. Although sources of uncertainty other than in the time of intake are discussed briefly, no guidance is provided on corresponding accuracy requirements. Consequently, no guidance is provided on accuracy requirements for special monitoring (where the time of intake is usually known). Publication 78 recognises that measurement uncertainties are likely to be the most straightforward to estimate. It advises that systematic uncertainties such as those relating to calibration should be considered, as well as uncertainties due to counting statistics. Publication 78 also recognises that uncertainties in biokinetic models may lead to errors in interpretation of measurements. However, it states that "a good assessment of the uncertainty on the assessment of intake is very difficult to achieve", and so it is recommended that dose assessments should be made on the basis of standard models and default parameter values, with the result being adopted as a nominal value. It is suggested that, depending on the potential health consequences of the exposure, a decision could be made to evaluate the contributions of the various sources of uncertainty with the aim of establishing a realistic confidence interval on the assessed dose.

Since the publication of ICRP Publication 78, research work has been initiated on uncertainties in assessed internal doses^{50, 51,52}, and significant developments can be expected in the near future. At the present time, however, the subject is not well-enough developed to make it feasible to propose requirements on dosimetry services for the routine estimation of overall uncertainties in assessed internal doses.

In general, uncertainties in measured quantities (eg radionuclide activities in the whole body, radionuclide activity concentrations in excreta samples, or air concentrations) are more straightforward to estimate than the overall uncertainty in assessed dose. Dosimetry services demonstrate measurement accuracy by participation in performance tests and in measurement intercomparison exercises. The Requirements for Approval of Dosimetry Services Part 2⁵ require laboratories performing tritium-in-urine measurements to participate in a performance test of these measurements (section 4.2.2). (Services that do not carry out these measurements are not required to participate in any performance testing.) In addition, many laboratories participate voluntarily in intercomparison exercises for both *in vivo* and bioassay (ie urine and faeces) measurements.

3.4.2 *In vivo* measurement intercomparisons

The normal method of carrying out such intercomparisons is to construct a phantom, or set of phantoms, with a radioactive content that is traceable to a national standard. The half-lives and activity of the radionuclides must be chosen so that all should be measurable throughout the schedule of measurements by all participating laboratories. The phantom is then circulated to participating laboratories for measurement. Usually, laboratories are asked to identify the radionuclides in the phantom and their activities. The phantoms may be designed to investigate technical issues such as subject size, e.g. by use of child phantoms; radionuclide distribution, by having a non-uniform but known distribution of one or more radionuclide in the phantom; wound monitoring; or the measurement of low energy photon-emitting radionuclides.

A practical aspect of such intercomparisons is that phantoms needs to be robust and be suitably housed for transportation between laboratories. Some specialised phantoms have been developed for this purpose, such as the St. Petersburg Phantom used in the EC 1995/96 European intercomparison of *in vivo* monitoring systems⁵³.

Table 1 presents descriptions of some recent *in vivo* measurement intercomparisons. Details of some of the more important intercomparisons follow. The EC 1995/96 European intercomparison of *in vivo* monitoring systems involved participation of 44 laboratories in 19 countries, 15 being member states of the EC. It consisted of three parts: measurement of the St.

Petersburg whole body phantom containing four radionuclides including ^{40}K , a voluntary ^{125}I - and ^{131}I -in-thyroid intercomparison in which the participating laboratories prepared their own active phantoms for measurement, and measurement of the ^{40}K content of a human subject travelling with the phantom. Five UK laboratories, including two current Approved Dosimetry Services, participated in this intercomparison.

Two notable series of intercomparisons have been conducted by the IAEA and by the Canadian National Calibration Reference Centre for Bioassay and *In Vivo* Monitoring of the Radiation Protection Bureau (RPB) of Health Canada. The Canadian series of intercomparisons arises from the statutory requirement of Canadian laboratories approved for the assessment of internal dosimetry by direct body measurements to participate in such intercomparisons once every 12 months⁵⁴. IAEA sponsors international intercomparisons of direct measurements of radionuclides in the body as well as of environmental and biological sample assessment and internal dose assessment. Examples include the international intercomparison of the JAERI reference Asian torso phantom⁵⁵. Participation in an IAEA intercomparison is usually by invitation and limited to one laboratory per member state, nominated by the government office contacted by IAEA.

Some intercomparisons are conducted to investigate a scientific question rather than to test the performance of the laboratory. An example is a German intercomparison exercise that investigated how estimates of ^{241}Am in a human skeleton varied when assessed from different measurements of particular bones or regions of the body⁵⁶.

3.4.3 Bioassay measurement intercomparisons

Several series of intercomparisons are conducted in this field, of which the most important is that conducted annually by the Association for the Promotion of Quality Control in Radiotoxicological Bioassay (PROCORAD, <http://www.procorad.org/uk/index.html>). PROCORAD was founded by the Association of French Nuclear Industry Biologists (ABNF), which draws its members from CEA (the French Atomic Energy Commission), COGEMA (Nuclear Fuel Corporation), EDF (Electricité de France) and the French Armed Services. It organises bioassay intercomparisons in order to verify the quality of measurements made by participating laboratories, and to promote good laboratory practice⁵⁷. Although the original participants were exclusively French, participants now include laboratories from 19 countries, and the Scientific Council includes UK membership. Twelve of the 74 participating laboratories are from the UK, and include laboratories at AWE (Aldermaston), BNFL (Springfields), DERA Radiological Protection Services, the Health Protection Agency's Radiation Protection Division (Chilton and Glasgow), Scientifics (Harwell), UKAEA Dounreay, and Westlakes, Cumbria. PROCORAD organises a scientific meeting each year during the Association's General Assembly, which is held alternately in France and abroad. A technical report is published each year in French and in English. IAEA has asked PROCORAD to organise two intercomparisons on its behalf, in 2000 for the measurement of gamma ray emitting radionuclides in urine⁵⁸, and in 2001 for the measurement of actinides in urine.

3.4.4 Dose assessment intercomparisons

Laboratories also participate in dose assessment intercomparisons. Here, monitoring data and exposure information on real or simulated exposure cases are circulated to dosimetry services, who are then required to report their assessment of committed effective doses and/or committed equivalent organ doses based on this information. Great care needs to be taken in presenting information on an exposure case to avoid ambiguity. There is also a degree of artificiality because participating laboratories do not have access to all of the information, knowledge and experience possessed by the service where the case originated. Nevertheless, such exercises

have proved invaluable in promoting good practice and developing common approaches to dose assessment.

Table 2 presents descriptions of some recent dose assessment intercomparisons. Three intercomparisons have been conducted by UK dosimetry services at a national level through the Internal Radiation Dosimetry Group, IRDG^{59,60,61}. Some of the cases created for the second IRDG intercomparison were subsequently used in a Europe-wide intercomparison. Three such intercomparisons have now been conducted, organised by EULEP/EURADOS, although only two were published^{62,63}. The wide range of intakes and doses assessed by participants taking part in the third EULEP/EURADOS intercomparison was one of the impetuses that gave rise to the IDEAS project, which aimed to develop guidelines for internal dose assessment⁶⁴. IAEA has also conducted intercomparisons of internal dose assessments. Most recently, IAEA and the EC-funded IDEAS project have jointly sponsored a dose assessment intercomparison. Unlike previous IAEA intercomparisons, this was organised through a web site and was open to all who wished to participate. Part of the motivation was to test the application of the IDEAS dose assessment guidelines. The final report of the intercomparison should be published in 2006⁶⁵.

3.5 RELIABILITY

Reliability is here taken to mean dependability and consistency. A reliable dosimetry service is one that can be trusted to deliver results of quality acceptable to the customer and in conformity with the relevant requirements, on time and of consistent quality that is of high reproducibility (see BS ISO 5725-1²²). Reliability can, in part, be considered separately from accuracy.

Reliability can only be achieved through the implementation of good quality assurance practices. This can be done by following the general guidance of HSE, or, for example, the guidelines in the ICRU Report¹⁴ or in the EC technical recommendations¹³. The alternative is by conformity to an accepted standard- the most relevant is BS ISO/IEC 17025:2005¹². An important part of establishing and demonstrating reliability is the operation of internal performance tests, such as those of dummy customer type. Confirmation of the ability of a service to produce reproducible results can be obtained by external performance tests and by inter-comparisons^{21,29,30,66}.

The meaning of reliability is not clear in the RADS. In the current RADS Parts 1⁴ and 2⁵, emphasis is given to punctuality (criterion 9). In Part 1, consistency of performance is considered separately (criteria 5 and 6) and includes justification that the dose range and energy response characteristics are adequate for the radiation fields to be measured.

3.6 FREQUENCY OF ASSESSMENT TESTING

UK approval is for an indefinite period, but with re-assessments every 5-7 years. In addition, there are mandatory performance tests every 18 months. This frequency of testing is broadly in line with procedures in other countries. In Germany, for example, there is indefinite approval of a dosimetry system following a thorough type-test/pattern approval, then annual 'surprise' performance tests. In the USA, dosimetry services require re-assessment every 2 years (or 3 years for internal radiations) with extended performance tests and site visits, although there is discretion as to whether the site visit is repeated. For UKAS, accreditation is on a 4 year cycle, with annual surveillance visits.

3.7 STANDARDS AND HARMONIZATION (after Fantuzzi, references [67], [68])

A **standard** is a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their

results, aimed at the achievement of the optimum degree of order in a given context. Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits⁶⁹.

Standardization is the activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context. In particular, the activity consists of the processes of formulating, issuing and implementing standards. Important benefits of standardization are improvement of the suitability of products and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation⁶⁹.

Standards are principally produced to facilitate exchange of goods/services worldwide, and some standards may act, or serve primarily as the basis for contractual agreements. More generally, standards act as guidelines to the performance characteristics which are obtainable or needed. They can assist in the design of dosimeter and dosimetry systems; form the basis for type-test requirements; contribute to guidelines from authoritative bodies for acceptable procedures of dosimetry services and for the results of measurements.

Standards from different standards bodies generally have different purposes. For example IEC standards may be aimed principally at manufacturers or suppliers of electrical and electronic equipment such that if there is conformity with the standard, a purchaser or customer can expect the product to meet specific requirements. ISO standards cover testing, calibration and measurement principles and procedures, such that conformity with the standard should result in consistent results, and also applications and more general performance requirements, such that conformity with the standard should ensure compliance with, for example, internationally accepted practices. Implementation of standards is not always straightforward and harmonization may not always directly result. Furthermore, standards of different standard bodies, and sometimes of the same body, are not always consistent. This is an area to which effort is being directed to improve matters. It is noted that there is an ISO/IEC Radiation Protection Liaison Team.

In the UK, standards are only mandatory if specifically cited in statutes and regulations. This applies to all standards including European Norms (EN). ISO and IEC standards are not necessarily accepted as British Standards. Some IEC standards, after a vote (CENELEC), and based on an international agreement, become EN. EN automatically become BS, but the UK, at the CENELEC stage, can propose changes to the original IEC standard to make it acceptable to become a BS. It may therefore be the case that an IEC standard which was not accepted initially as a BS, becomes an EN, and thus a BS.

Most of the standards applicable to individual monitoring and used in the EU are IEC or ISO standards. These are listed with comments in Annex C. Many are rather old, but there is currently an effort to update these and harmonize them. Examples of the available standards on performance characteristics of personal dosimeters for external radiation are: ISO 1757 on film dosimetry, IEC 61066 on whole body thermoluminescence (TL) dosimetry ((there is a standard being prepared covering other types of passive photon and electron dosimeter, such as OSL), ISO 12794 on extremity TL dosimetry, ISO 21909 on passive neutron dosimeters and IEC 61526 on active personal dosimeters. There are not as many standards available for internal dosimetry. The relevant standards are ISO 12790, on performance criteria for radiobioassay measurements; ISO 11929, on determination of the detection limit and decision threshold for ionizing radiation measurements; and the draft standard ISO 20553, on monitoring of workers occupationally exposed to a risk of internal contamination. Important documents of relevance for internal dosimetry are reports of EURADOS Working Groups and of European Commission funded projects, IDEAS and OMINEX. American Standards (ANSI) can be useful but do not have analogous international or European documents.

As mentioned above, IEC and ISO have different scopes and their standards have different approaches. The IEC standard on whole body TL dosimeters, for example, covers tests on both the dosimeter and read equipment, including software processing, whereas the ISO standard on TLD for extremity and eyes covers only the dosimeter. IEC standards give criteria to be met for the uncertainties in the assessment of the effect of each important influence quantity. In the recent IEC standards (61066, 61526 and 62387 draft) the criteria for the energy and angle dependence of relative response of a range of 0.71 to 1.67 are based, via criteria on correction factors to the calibration factor, on the ICRP overall acceptable uncertainty of a factor of 1.5 at the 95% confidence level. The standards themselves give no requirement on the overall uncertainty- the standard is put in a form that the uncertainty can be calculated. The combination of uncertainties to determine the expanded uncertainty (ISO Guidance to the expression of uncertainty in measurement (GUM)⁴⁴, prepared in collaboration with BIPM, IEC, IFCC, IUPAC, IUPAP and OIML), should be undertaken by the user and compared with any national requirements. The uncertainties in standards might need to be detector or method related since some detectors and methods can make more accurate measurements and the results of practitioners should reflect this, whereas radiation protection regulations, approval procedures and guidance might sensibly have overall performance requirements that are independent of detector and method.

Some aspects of standardization and EU harmonization in radiation metrology are well implemented, for example the participation of metrology laboratories in EUROMET, and of accreditation bodies in the European co-operation for Accreditation (EA). Dosimetry services in different EU Member States do not have to comply with the same legal or approval requirements. A degree of harmonization existing in individual monitoring practices in Europe has been achieved partly as a result of the implementation of, or at least the awareness of standards, and as a result of international recommendations by ICRP, ICRU and the IAEA. Many dosimetric services are accredited according to BS ISO/IEC 17025 and this provides a certain uniformity of quality in personal dosimetry services in Europe.

However, harmonization of standards themselves is needed, and agreement between standards bodies. Also, it may well be questionable whether standards bodies are the right organizations to publish criteria for performance requirements for approved dosimetry systems. An alternative would be European Commission technical recommendations¹³ as a revised up-dated version, or a set of EURADOS recommendations combining ISO, IEC, IAEA, ICRU and ICRP documents on the basis of best available knowledge and practice.

4 REVIEW OF THE CURRENT APPROVAL PROCEDURES IN THE UK AND ELSEWHERE (Objectives 1 & 6)

4.1 GENERAL

There is a perceived need to know what overall performance characteristics are acceptable or what accuracy is required for different radiation types, radiation qualities, dose levels, radionuclide exposures etc. to ensure that the parameters chosen to establish the accuracy of dose assessment (bias and statistical variation) follow a demonstrably consistent, and transparent method that takes due account of precision (the inverse of the statistical uncertainty) and confidence over the required range of doses. Indeed, a clear statement is needed of what is meant by reasonable accuracy and high reliability. It is recognized that it is not always possible to provide a reliable assessment of the overall accuracy of assessed internal doses. The present system is prone to long delays in the processes of approval and re-assessment of approval of ADSs. More detailed information on the current procedures can be found in the documents cited.

EURADOS has carried out surveys^{70,71} and a workshop⁷² on procedures in Europe. In particular, Fantuzzi and colleagues^{67,68} have summarized accreditation/certification and approval procedures. As of 2004, 12 of 19 EU member states from which dosimetry services replied to a questionnaire, had accredited dosimetry services, and in 9 of these countries accreditation/certification was part of the approval process.

Given below are brief descriptions of the approval procedures in Germany, France and the USA as examples of alternative approaches to that in the UK.

4.2 REVIEW OF THE CURRENT SYSTEM OF APPROVAL IN THE UK

4.2.1 External radiation

General

The HSE process of dosimetry service approval has the basic requirement that the doses are assessed with a “reasonable degree of accuracy”, and HSE has to assess the ability of dosimetry services to continue to attain that level. For external radiation, the additional requirements are that the dosimeter can be shown by type testing and field trials to be suitable and reliable, and have a consistent and adequate performance for the radiation fields and environments in which it will be used. The adequacy of a service to comply with RADS Parts 1 and 2 is largely determined by assessment of the dosimetry services management, laboratory and quality assurance procedures and the performance of the dosimeter or dosimetry method used every 5 years.

Performance testing (see also 3.3.2 above)

For some types of dosimetry, HSE requires that services undertake performance tests prior to initial application for approval and periodically thereafter, currently every 18 months. That not all types are tested is largely due to the difficulty in designing tests for some forms of dosimetry and for deciding on appropriate pass / fail criteria. The performance tests are designed to assess the performance of the service in analysing dosimeters (or biological samples) irradiated to a known level (or containing a known level of activity). Results are banded in A, B, or C

(depending on bias and standard deviation, i.e. accuracy and variability). Band A pass is required for approval (Bands B and C requiring action to be taken by the dosimetry service). A wide variety of dosimetry methods are approved by HSE, but not all of these currently require performance tests.

The two components of accuracy are bias and precision^{15,16,22}. Bias is a measure of the ‘trueness’ of a value obtained. Bias is the difference between the expectation of the test result and the accepted reference value²². In this definition, expectation is meant in the precise statistical sense of expected value or mean of a random variable¹⁵. In the tests of the performance of a dosimetry system and/or the application of a dosimetry method done as part of the UK approval procedures, the results are compared with the values which would be anticipated taking into account the dosimeter/system dosimetric response characteristics. The outcome, which is a measure of systematic uncertainties which are unaccounted for, termed the bias by HSE. This is strictly an incorrect use of the term bias, and should perhaps be termed “residual bias”.

Precision is the closeness of agreement between independent test results obtained under stipulated conditions. Normally the standard deviation is assessed as a measure of the imprecision. Depending on the stipulated conditions, the standard deviation may be a measure of repeatability or reproducibility, or a combination of the two. In the present HSE performance tests, the standard deviation is determined under what are close to repeatability conditions (see 3.3.2) except that for passive dosimeters it is not the same dosimeter that is subject to repeated tests.

The current system uses a ‘banding’ procedure to assess performance, which allows different accuracy criteria at different doses. It is considered that the present approach, apart from the incorrect use of the term bias, is fully acceptable. It tests whether the ADS gets the values it should expect to with acceptable precision. In principle, it could be generalized to all types of service. The tests should be expanded to cover different irradiation conditions and by this means, test whether there are any unanticipated changes to the dosimetric characteristics.

There is a need to explain what the performance test criteria are based on, and whether they are related to an overall accuracy requirement.

Type-testing (see also 3.3.4 above)

Under the present HSE approach, the results of type testing results should be provided unless the dosimeter/dosimetry system is of an established proven design. There are no criteria set for the dosimetric performance characteristics, although reasonable steps are required to be taken to demonstrate conformity with the out-of-date NAMAS information sheets NIS61⁷³ and NIS65⁷⁴.

The advantage of this approach is that it allows flexibility within the over-riding requirement that the dosimeter is fit for the intended use. The disadvantage is the need for a high level of expertise to be maintained to assess dosimeters and systems, and the difficulty of maintaining consistency. It is necessary to have full type test data to have confidence in the use of a dosimeter in other than very well known radiation fields, and to allow an assessment of the accuracy or overall uncertainty of an assessment to be made, or to be able to design or introduce a novel type of dosimeter. This is preferably done in conformity to a standard using standard procedures, standard fields, standard phantom, standard conversion coefficients etc. This approach would allow comparisons to be made of different systems.

Specific comments from Approved Dosimetry Services

The provisional comments listed below are aggregated from responses from a number of external dosimetry ADS:-

- (i) The present approval procedures are broadly acceptable, except for the long delays in assessments and re-assessments.
- (ii) A change to BS ISO/IEC 17025 accreditation/certification might be appropriate, subject to costs, and the availability of companies able to audit. The accreditation/certification could be done jointly with testing and calibration services for some laboratories. The UKAS model of accreditation might solve some problems of the delays with the current procedures.
- (iii) The performance tests work well and do their job of testing whether a service employs the method correctly.
- (iv) There is some support for an extension of performance tests to a wider range of radiation fields, but also some reservations about this, particularly if the UK approach moves towards the US approval process. There is some support for the use of ‘trumpet curves’ for testing.
- (v) The EU recommendations might be the best, but what about the timescale?
- (vi) Independent type-testing might be an option.
- (vii) There should be more emphasis on taking part in national and international inter-comparisons.
- (viii) A round table discussion between ADS and HSE might help to find the way forward.

4.2.2 Internal radiation

Main differences with the approval system for external radiation

The general requirements for approval of dosimetry services and the system of approval as described in Requirements for Approval of Dosimetry Services (RADS) Part 2 are similar to those for external radiation. There are nevertheless some differences in specific requirements, arising from the underlying differences between external and internal dosimetry. Criterion 4 of RADS Part 2 requires that intakes shall be assessed from measurement of radionuclides in the body, measurement of excretion, and/or measurement of exposure by air sampling, and that suitable models should be used to assess effective dose (E_{50}) from the intake. Criterion 5 requires that the dosimetry service shall draw up a suitable strategy for the assessment of dose, which nevertheless allows for expert judgements to be made. Criterion 6 requires that measurements shall use established techniques, or techniques which can be shown to have comparable accuracy, reliability and suitability. Criterion 7 requires dosimetry services to comply with specific requirements relating to the assessment of whole body dose from tritium-in-urine measurements⁷⁵, and guidance on individual monitoring for long-lived radionuclides⁷⁶. Criterion 10 requires either that dose assessment calculations shall use established principles and models, or that assumptions made shall be justified. Guidance related to this criterion states that the service should consider how best to demonstrate the validity of software used for such calculations. With respect to reliability issues, Criterion 9 requires that the dosimetry service shall make adequate arrangements for the timely despatch of sample vessels, etc., and for the availability of suitable counting devices. Guidance related to Criterion 6 states that the service should demonstrate a high degree of reliability in linking measurements uniquely to the person who was subjected to whole body monitoring, provided an excreta sample, or who wore the personal air sampler.

Performance testing

Services that carry out assessments of internal dose from measurements of tritium in urine are required to carry out a performance test based on measurements of tritium concentration in simulated urine samples. The performance test originally used samples of tritiated water, but participating laboratories considered that this was not an adequate test because it did not

simulate the colour quenching effect encountered when real urine samples are measured by liquid scintillation counting. Following work carried out at NRPB, the performance test now includes samples which are intended to simulate urine by the addition of known amounts of tartrazine⁷⁷. A banding system similar to that used for external dosimetry performance tests is used. The performance testing programme is operated by the National Physical Laboratory.

Comments from Approved Dosimetry Services

Organisations that operate Approved Dosimetry Services (ADS) for assessment of internal dose were invited to provide comments on the current system at a meeting held at HPA's Radiation Protection Division in July 2005. Representatives of four ADSs attended. Other interested parties were invited to send written comments. Views expressed were broadly in agreement, and are summarised below.

(a) General views on the approval system

- ADSs are generally content with the current RADS system. Holding an approval from HSE is seen as a "positive business asset".
- The quality of the output of an ADS is controlled by internal quality systems, although RADS provides a useful "backstop".
- The current system lacks flexibility and so does not actively encourage ADS to improve technical performance/measurement systems. Such improvements are driven internally.
- Some organisations felt that HSE inspections were not very effective at confirming that particular procedures and methods are properly implemented, and that response times can sometimes be too long.
- There is a lack of clarity on what is meant by "reliability" in the RADS documents
- In comparison, the United Kingdom Accreditation Service (UKAS) accreditation system is much more effective. For some ADSs, the metrology group is part of the ADS and already maintains UKAS accreditation. For other ADSs, metrology is carried out within a different organisation and may not maintain this accreditation.
- The assessment cycle (5 years) is very long considering the number of changes in practice that typically take place during this period (cf the 1 year cycle for UKAS accreditation)
- The effort involved in gaining and maintaining approval can be excessive. Required effort should be proportionate to the tasks that the ADS needs to fulfil.
- The efficiency of the system would be improved if approvals for external dosimetry, internal dosimetry, extremity dosimetry, etc. were carried out at the same time, rather than at different times in the 5-year cycle as happens at present.

(b) Views on the adequacy of current requirements to provide information on accuracy

- The requirement that ADSs should be able to demonstrate that they produce a "reasonable degree of accuracy in the assessment of dose", as specified in the RADS Part 2, is unclear because "reasonable accuracy" is not quantified. A more precise specification would be useful, but care needs to be taken because it would be easy to create unnecessary difficulties for ADSs.
- Any specified accuracy requirement should take into account the magnitude of potential doses

(c) Views on the current performance test for tritium-in-urine measurements

- The test is simple and easy to perform. It is a valid test for tritium-in-urine measurements. Obtaining a "Band A" result (ie pass) presents no problems.
- However, the test is so narrow in its scope that it can not be considered to be a valid test of the overall performance of an ADS for assessments of internal dose.
- One ADS representative noted that, in devising a performance test, it was often necessary to remove or control many of the sources of variability encountered when making real measurements. Most ADSs thought that the performance test approach is little more than a

bureaucratic exercise, and is of little real value. However, at least one ADS considered that that performance testing was a useful method for assessing laboratory performance.

- Participation in intercomparison exercises was seen to be more useful than participation in performance tests. Intercomparison exercises were seen as encouraging development of skills, and sharing of information between laboratories. Some ADSs consider that the "pass/fail" results of performance tests are to be treated as "commercial-in-confidence", (because a "fail" could have an adverse effect on business) whereas they are content for the measurement results of intercomparison exercises to be published.

4.3 CURRENT SYSTEM FOR APPROVAL IN GERMANY FOR EXTERNAL RADIATION

The German system is in the process of being updated. The present system is much as described in references [18], [19], [78]. The maximum allowable overall systematic uncertainty of a dosimetry system when type-tested is 0.4. This is based on the ICRP Publication 75 factor of 1.5. The dosimetric characteristics of the whole dosimetry system must be approved by PTB. The PTB requirements are specified in a government regulation. An example of the dosimetry system is set up in PTB and tested against detailed PTB requirements for all influence quantities. If the system is not commercially available, or cannot be transported, testing may be carried out partly at the dosimetry laboratory site. System software is also tested. In addition there is an inspection of the dosimetry laboratory and annual performance tests. The performance tests^{18,19,27} are of the 'surprise' type (see 3.3.2). The dosimetry service supplies 12 dosimeters to PTB who irradiate 10 of them to doses for particle type, energy and angle within the stated range. The dosimeters are taken back to the service unannounced and have to be processed according to the quality assurance handbook. Nine out of ten dosimeters have to be within the 'trumpet curve'. The 'trumpet curve' is a fit to the ICRP factor of 1.5 for the response characteristic at the annual dose limits, and an uncertainty of 100% at the recording level, taken as 0.2 mSv.

4.4 CURRENT SYSTEM OF APPROVAL IN FRANCE FOR EXTERNAL RADIATION

In France, laboratories which provide dosimetry services, private or public sector, are obliged to be both accredited and approved. Accreditation/certification (BS ISO/IEC 17025) is done by Comité Français d'Accréditation (COFRAC) (the French equivalent of UKAS). The accreditation/certification by COFRAC is not sufficient to operate as an approved dosimetry service (it only gives the official recognition of the laboratory's ability to perform correctly the dosimetry measurements). After the accreditation/certification assessment, the laboratory needs to get authorization from a section (Direction de la relation du travail (DRT) of the Ministry of Employment, to be recognized as an official laboratory (private or public) able to perform in France.

The authorization granted to a laboratory to make personal dose assessments reflects a concern for the quality of measurement: being certain that monitoring is done correctly. The approval to carry out monitoring of workers is based on a demonstration that the techniques used fulfil a certain number of requirements and that they are used properly (approval of the equipment and the work process). This means in effect that the laboratory must be accredited by COFRAC, must submit its technique for the approval of IRSN, must have participated in an "announced" performance test carried out by IRSN (the dosimeter is irradiated under defined conditions, the laboratory carries out the analysis blind, the result obtained is compared with international standards, either ISO or IEC (depending on the techniques). According to the specifications laid down in these standards, the result obtained by the laboratory must be within +/-30%. IRSN gives either a favourable opinion, a favourable opinion with reservations or an unfavourable opinion, and the DRT gives its approval or not.

4.5 CURRENT SYSTEM OF APPROVAL IN USA FOR EXTERNAL RADIATION

In the USA there are two dosimetry service (processor) assessment programmes: The National Voluntary Laboratory Accreditation Program (NVLAP) (see <http://ts.nist.gov/ts/htdocs/210/214/214.htm>), and the Department of Energy Laboratory Accreditation Program (DOELAP) (a requirement under DOE regulation 10CFR835) (see <http://www.eh.doe.gov/doelap/>). They are both designed to test the proficiency of processors of personal dosimetry and to grant them accreditation after successful passage of a performance test and a site visit by an audit team. The accreditation is granted for a period of two years in both programmes. But as of 2000, the revised HPS/ANSI N13.11 standard “Criteria for Testing Personnel Dosimetry Performance” has been chosen for use by both the DOELAP and NVLAP programs. This standard is now 5 years old, so it is up for revision.

If a processor does not pass all the proficiency tests, or if there are issues uncovered during the site visit, they may be granted provisional accreditation until the deficiencies are fixed and the tests are passed. DOELAP still differs slightly from NVLAP in the respect that the DOE will offer help to the laboratory that has problems passing. They require 100% accreditation, and so this makes sense. NVLAP, on the other hand offers no such help. But, they are willing to make some concessions. For instance, if a processor fails a category in testing, he can quickly re-schedule a re-test and will hopefully pass the second time around. Also, there are some processors who test under both DOELAP and NVLAP because they offer services to both DOE and commercial facilities. In future, they will be allowed to be accredited under either programme and there will be a mutual recognition.

Note that there are also software quality assurance guidance and programmes. Modern dosimetry systems, not just electronic personal dosimeters, depend on the integrity of software.

5 ACHIEVABLE ACCURACY (Objectives 2 & 3)

5.1 GENERAL

In assessing the accuracy and performance of dosimetry services, there are a number of different terms used, such as decision threshold and decision level, detection limit and minimum detectable amount or dose, uncertainty and confidence level, trueness, accuracy, bias, etc. These are not always used consistently or in accordance with the definitions given in the relevant basic standards. ISO and IEC have not always been consistent with each other. There are a number of basic standards and guides, given below, which should be used as the authoritative sources of terms and definitions (see also Appendix 3). The ICRU report "Measurement quality assurance for ionizing radiation dosimetry"¹⁴ includes most relevant definitions. ISO and IEC are working to produce a consistent set of terms and definitions. The VIM (see below) itself is being revised. The VIM and GUM are produced by ISO jointly with IEC, BIPM, IFCC, IUPAC, IUPAP and OIML. The following is a list of documents giving relevant terms and definitions:-

Vocabulary of metrology Part 1 Basic and general terms (international) (VIM)¹⁶

Vocabulary of metrology Part 3 Guide to the expression of uncertainty in measurement (GUM)⁴⁴

BS ISO 3534 Statistics- Vocabulary and symbols¹⁵

BS ISO 5275 series Accuracy (trueness and precision) of measurement methods and results^{22,23,37}

BS ISO 11929 series Determination of the detection limit and decision threshold for ionizing radiation measurements^{31,79,80}

BS EN ISO/IEC 17000 Conformity assessment – Vocabulary and general principles¹⁰

5.2 EXTERNAL RADIATION

A general discussion of accuracy requirements is in section 3.3.1. Generally, throughout the world, overall accuracy requirements for external photon radiation have been based on, or are broadly consistent with the ICRP²⁶ proposal of a factor of 1.5 at the 95% confidence level and the ICRU proposal²⁸ that for a single measurement, one standard deviation of 30% would be acceptable. The ICRP overall uncertainty requirements are considered to apply to annual doses approaching the dose limits (in practice they are applied to a single dose measurement above a few mSv). A larger uncertainty is normally considered acceptable below an annual dose of 1 mSv.

These ICRP and ICRU proposals have been variously^{13,19,78,81,82,83} applied as limiting the combined uncertainty to about 20%, or having a tolerance level or acceptable range of about 40%. This corresponds to limitations on two components, the bias (or total systemic uncertainty- energy and angle dependence of response etc) and the standard deviation (repeatability and/or reproducibility), of about 15 to 20% and 10 to 15% respectively. For bias, mainly the energy and angle dependence of response, the uncertainty of 15 to 20% can be interpreted as applying to an angle averaged response characteristic¹³; or applied after folding the response characteristics with assumed or known workplace field characteristics^{45,47}; or taken as implying an acceptable range of response of ± 30 to 40%. The total uncertainty of a factor of 1.5 at the 95 % confidence level can also be used to derive criteria for testing separately the many individual contributions to the overall uncertainty⁸⁴.

The accumulated experience for the German photon dosimetry systems²⁷ and more generally the results of recent international intercomparisons^{21,29,30} have indicated that the ICRP factor of

1.5 at 95% confidence can be met in practice. If there are particular non-dosimetric constraints on the design of dosimeter which can be used, one solution is to understand better the workplace field and apply the uncertainty criteria to the actual, restricted, energy and direction distribution, or to apply a field specific calibration factor.

For doses to the extremities from low energy electrons, the overall uncertainty of a factor of 1.5 is achievable for some designs of dosimeter²¹, taking into account the higher dose limits, but there can be difficulties mainly associated with the thickness of the detector and/or covering, in particular to assess $H_p(0.07)$ for low-energy beta emitters.

From considerations of the response characteristics of neutron personal dosimeters in current use⁸⁴ and from the results of recent intercomparisons^{21,29,30}, there are certainly difficulties meeting the factor of 1.5 for doses to the whole body from neutrons. Even with a relaxation of the criterion to a factor 2, it is not possible with any current design of dosimeter to meet the criterion over the full range of neutron energies possibly present in the workplace. However, there are generally only small contributions to total dose for those neutron energies for which there are greatest difficulties. In practice, therefore, a factor of 2 should be achievable for actual workplace fields. The alternative is to use a workplace field specific correction factor. A number of reference simulated workplace fields have been developed to test and calibrate dosimeters^{33,34}.

The overall uncertainty associated with a dose assessment should be evaluated (see section 3.3.7). This can be done by estimating and combining all known inputs to the total uncertainty. This is preferably done with information on workplace field characteristics although this may be outside the remit of the ADS.

5.3 INTERNAL RADIATION

Accuracy requirements on measured quantities (eg radionuclide activities in the whole body, radionuclide activity concentrations in excreta samples, or air concentrations) can not be set on the basis of a consideration of the required accuracy of assessed doses because the two are linked only indirectly. The accuracy of assessed doses is controlled by many other factors, including monitoring intervals or times, assumptions about time(s) of intake, uncertainties in the particle size distribution of the inhaled aerosol, the chemical form of the inhaled material and uncertainties in its lung absorption characteristics, and individual variability in biokinetic behaviour of the radionuclide. Nevertheless, it would be useful and appropriate to set accuracy requirements on measured quantities, corresponding to what should be achievable using “good laboratory practice”.

Separate accuracy requirements would need to be set for *in vivo*, bioassay and air sampling measurements. For *in vivo* measurements, separate accuracy requirements would need to be set for low energy and high energy photon emitters. For bioassay measurements, separate accuracy requirements would need to be set for urine and faecal bioassay measurements, and α , β and γ measurements. For air sampling measurements, separate accuracy requirements would need to be set for static air sampling and personal air sampling measurements. For static air sampling this would require account to be taken of the positioning of samplers in the working environment.

Any accuracy requirement should be set for measured quantities well above the detection limit for the particular measurement. It is proposed that a specification of accuracy could take the form: “*For measurements of activity concentration at least 10 times the detection limit for the counting system being used, the total uncertainty on the final result should be no more than +/- 25%, expressed at the 95% confidence level*”, where the numerical values would depend on the measurement technique, sample type and radionuclide type. Table 3 shows some suggested values.

To meet such a requirement, laboratories would need to perform a formal uncertainty budget for measurements. Guidance is given in a EURACHEM Guide on "Quantifying Uncertainty in Analytical Measurement"⁸⁵. It would be important to ensure that "difficult to achieve" values are only set where this is fully justified. Laboratories should therefore be consulted both on this general approach and on the values that should be specified.

It should be noted that an ISO standard (ISO 12790-1:2001, Performance criteria for radiobioassay) has set numerical criteria for relative bias and repeatability for *in vivo* and bioassay measurements. These criteria are intended to be applied to any measurement of radionuclide amount in the body or radionuclide concentration in excreta samples. However, the requirements are quite generous, and the same numerical criteria are set for all types of measurements. Furthermore, this ISO standard has not been adopted as a British Standard, and so has no formal standing in the UK.

Other requirements could be considered, including:

- (i) a requirement to use radionuclide calibration standards that are traceable to national standards, or if not possible, to international standards. If neither is possible, then activity of a calibration standard should be determined using a method covered by UKAS accreditation/certification.
- (ii) a requirement that uncertainties in measurement should contribute a small fraction of the total uncertainty in assessed dose, as recommended by ICRP in Publication 78⁴⁹. However, it should be noted that such a requirement implies that at least a limited uncertainty analysis for assessed dose is carried out, and so may not be appropriate except for higher doses (see following point).
- (iii) a requirement to perform a limited assessment of uncertainty in assessed dose (taking into account, for example, uncertainties in time of intake, Activity Median Aerodynamic Diameter, and absorption characteristics), for assessed doses above a certain value (eg 1 mSv and 6 mSv). The complexity of such an analysis would depend on assessed dose. This is similar to the approach adopted for the IDEAS guidelines for dose assessment⁶⁴, where a case is assigned to one of a number of levels based on a simple assessment of dose, and the complexity of dose assessment to be carried out then depends on the level.

6 ADEQUACY OF UK PERFORMANCE TEST (Objective 4)

6.1 EXTERNAL RADIATION

The basis of the UK performance test is broadly sound, the tests are useful and are found to be acceptable in application. The test assesses the consistency of application of the dosimetry method and determines the precision of the laboratory's dose assessment procedure. The term 'bias' is used incorrectly in the HSE performance test protocol (see section 4.2.1). In the HSE tests, the determination of 'bias' is a measure of the residual bias, and for repeated performance tests is in effect a determination of reproducibility^{22,23}. The tests compare the measurement results after correction for the known response characteristics of the dosimeter/dosimetry system, with the reference values. The determination of 'standard deviation' is a determination of the repeatability of measurement (but see section 4.2.1).

Some improvements are considered necessary (see 7.3.1).

6.2 INTERNAL RADIATION

The current performance test is an adequate test of proficiency and reliability for measurements of tritium in urine. Because of its limited scope, however, it cannot be considered to be a valid test of the overall performance of an ADS for assessments of internal dose. If the overall scheme of the approval procedure is not to be changed, there is no great need to change the design of this performance test. Nevertheless, the possibility of devising an improved test using real urine samples spiked with known amounts of tritium could be investigated. Additional performance tests could be considered, although it is proposed that a better approach would be to make it a requirement to participate in existing measurement intercomparison exercises such as that operated by PROCORAD (or intercomparison exercises that might be set up to meet HSE's specific needs). This proposal is discussed in section 7.3.1.

7 OPTIONS TO BE CONSIDERED (Objective 5)

7.1 GENERAL

The accuracy of any individual measurement made as part of a routine measurement procedure will depend on all aspects of the service, that is the adequacy of the general quality assurance protocol and the dosimetric characteristics of the dosimeter and/or dosimetry system and its suitability for the purpose. The options for an approval system to assess the continuing competence of a service to provide measurements of reasonable accuracy with high reliability are considered under three headings:-

- (a) the more general laboratory and staff quality assurance, and quality management systems, including software quality assurance, conformity of equipment used, calibration and internal performance tests (see below);
- (b) routine external performance tests of the dosimetric reliability and consistency of the application of the method by an identifiable laboratory (system operator, actual identifiable equipment used, identifiable dosimeter calibration factor, read-out system calibration, environmental conditions for read-out, etc.), and periodic inter-comparisons between systems providing similar services;
- (c) determination of the dosimetric characteristics of the system. For external radiation dosimetry, this is achieved by type-testing- the determination of the energy and angle dependence of ($H_p(d)$) response characteristics of the type of dosimeter/dosimetry system used, repeatability and reproducibility, effect of influence quantities, and other factors linked to the measurement method. For internal dosimetry, this includes the monitoring strategy for the *in vivo*, bioassay or air concentration measurements undertaken, and the models (intake, biokinetic and dosimetric) used to determine internal dose from the measurements made, as well as factors directly related to the determination of the measurement quantity.

7.2 QUALITY ASSURANCE AND QUALITY MANAGEMENT SYSTEMS

7.2.1 OPTION 1: Current approach with improvements

General

Selected requirements of the relevant ISO standards covering quality management systems, quality assurance and laboratory competence could be included or referred to in updated RADS documents. The relevant standards are: - BS EN ISO 9000:2000 (Quality management systems – Fundamentals and vocabulary)⁸⁷, BS EN ISO 9001:2000 (Quality management systems – Requirements)⁸⁸, BS EN ISO 9004:2000 (Quality management systems – Guidelines for performance improvements)⁸⁹, and BS EN ISO/IEC 17025:2005 (General requirements for the competence of testing and calibration laboratories)¹².

ISO 17025 gives all the requirements that testing and calibration laboratories must meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results. It is intended for use by accreditation bodies for testing and calibration services. In practice, "testing and calibration" can be considered to cover the measurement aspects of the work carried out by dosimetry services.

Any laboratory meeting the requirements of ISO 17025 also operates in accordance with ISO 9001 (but see also section 7.2.2).

Topics covered in ISO 17025 under the heading of Management Requirements include:

- responsibilities of, and requirements on, the organisation
- the need for a quality system
- document control
- review of tenders and contracts
- sub-contracting
- purchase of supplies and services
- service to the client
- complaints procedures
- control of non-conforming work
- corrective action after non-conforming work is identified
- preventive action to avoid non-conformances
- control of records
- internal audits
- management reviews

Topics covered under the heading of Technical Requirements include:

- competence of personnel
- requirements on accommodation and the laboratory environment
- measurement methods and method validation
- requirements on equipment
- measurement traceability
- sampling plans, procedures and sample handling
- quality control procedures
- reporting of results

The Requirements for Approval of Dosimetry Services, Parts 1 and 2 (RADS)^{4,5} address the issue of quality management in broad terms. For example, RADS Criterion 1 states that the dosimetry service should be able to demonstrate that it has the necessary staff, expertise, resources and facilities; Criterion 2 states that facilities, staff and general arrangements should meet published requirements; and Criterion 3 states that the dosimetry service should have written quality assurance procedures for monitoring overall performance, including document control and formal approval procedures for documents. More requirements are given in the General Guidance⁸.

However, there seems to be a clear case for adopting the specification of quality management given in ISO 9001, in preference to the material in the current version of RADS. This ISO standard gives a very comprehensive specification for quality management. Furthermore, it has been accepted as both a European and a British Standard, has been adopted widely, and has been generally accepted in industry and commerce.

Similarly, it can be argued that ISO 17025 presents a more comprehensive specification than that contained in RADS of the requirements that a measurement laboratory must meet if it wishes to demonstrate its competence. For internal dosimetry, for example, RADS Part 2 addresses these issues in Criteria 1 - 3 (see above), Criterion 4a (Methods of dosimetry), Criterion 6 (Assessment of intakes), Criterion 8 (Calibration and its uncertainty) and Criteria 19

& 20 (Performance testing). The topic of "Reliability" is addressed in Criterion 9. ISO 17025 does not specifically address reliability as a separate issue, but it is considered in detail throughout the standard, particularly within the Management Requirements section. Specifically, the sections on review of contracts; service to the client; complaints procedures; control of non-conforming work and corrective and preventative action; control of records; and particularly the requirements for internal audits and management reviews, all address different aspects of the reliability issue. There may be some advantage to this, because what is meant by reliability is not made explicit in RADS.

Most, if not all, of the content of ISO 17025 appears to be relevant to the work of dosimetry services. Whether there is a case for selecting particular individual requirements from ISO 17025, rather than making it a requirement to comply with the complete standard, should probably be a matter for dialogue between HSE Inspectors and dosimetry services.

One of the main comments made by dosimetry services regarding the current system of approval was that the period between assessments (5 years) is too long, and that the UKAS accreditation system is much more effective. In the UKAS system, surveillance visits are carried out annually, and generally last no more than one day. Only a fraction of the types of work that the laboratory carries out is examined on each visit, although the laboratory has no prior knowledge of the work that will be examined. Over a period of about five years, most of the types of work carried out by a laboratory are likely to be examined, but complete coverage of the work of the laboratory is not considered necessary. Rather, the findings of a single visit are taken to be representative of the quality of the work of the laboratory. One of the elements of a UKAS surveillance visit is an inspection of the results of internal audits that have been carried out by the laboratory's own staff during the previous year. In general, these audits are expected to cover the full scope of the work of the laboratory, and it is by this mechanism that comprehensive coverage is ensured. A secondary advantage of the annual surveillance visit system is that it facilitates regular contact with the accreditation body. Another important difference between the UKAS and RADS approaches is that a laboratory maintains UKAS accreditation until a decision is made by the accreditation body to withdraw it, usually as a result of major non-compliances. In comparison, RADS requires a formal, comprehensive re-assessment every five years, which places a significant burden on dosimetry services. HSE may wish to consider employing these elements of the UKAS accreditation system in the Approval of Dosimetry Services system.

The main advantage of moving to an improved version of the current approval system, as proposed above, would be that use could be made of material contained in the comprehensive set of ISO standards on quality management and laboratory competence that have been published in recent years. The material contained in the current RADS document that is concerned with quality management and the competence of measurement laboratories could be replaced by a simple requirement to comply with specified elements of these ISO standards, or the complete standards. The need would remain to specify requirements relating to monitoring strategy, assessment of internal dose, and reporting of doses, or at least to provide guidance on these issues. The main disadvantage to using an improved version of the current approach is that HSE would have to apply a similar amount of effort to the approval process as is expended in applying the current system. This could only be avoided if accreditation or certification to these standards were to be made a formal requirement.

Many aspects of the system for approval for the purposes of Regulation 35 of IRR99 (as described in RADS) are similar to the system for approval under regulation 14 of the Radiation (Emergency Preparedness and Public Information) Regulations (REPPIR)². Currently, the two approval systems are operated separately, and involve duplication of effort both by dosimetry services and HSE inspectors. Unifying the two approval systems would result in greater efficiency. Minor differences in the way the results of periodic performance tests are treated would need to be resolved. Specifically, only a Band A result is accepted under REPPIR,

whereas a Band B result is accepted under IRR99 provided that it is followed by an in-service review and a subsequent Band A result). The different fee scales could also be unified.

Furthermore, there are distinct advantages in carrying out approvals for external dosimetry, internal dosimetry, extremity dosimetry, etc. at the same time, rather than at different times as happens at present. Most dosimetry services that seek approval for internal radiations also operate a dosimetry service for external radiations, and there would therefore be significant efficiency savings for both HSE and the services themselves. Furthermore, accreditation/certification of ADS might be able to be combined with accreditation of calibration and testing facilities.

The ICRU is publishing a report entitled “Measurement quality assurance for ionizing radiation dosimetry”¹⁴. The report covers all aspects of quality assurance and quality management, as well as calibration and traceability, and gives definitions of relevant terms and quantities. If ISO 17025 accreditation/certification is not specifically encouraged or required, reference could be made to these ICRU recommendations.

External radiation

There are no particular comments applicable to external to add to those given above.

Internal radiation

There are specific considerations for internal dosimetry. Some of the material considered in RADS is not addressed by ISO 17025, because the ISO standard only considers measurements (or testing and calibration, in its own terminology). Issues relating to the assessment of dose from monitoring measurements (eg whole body measurements, urine or faecal analysis) are therefore outside the scope of the ISO standard. These include the topics covered by Criterion 5 (Monitoring strategy), Criterion 7 (Individual monitoring for long-lived, long retention time radionuclides), Criteria 10 - 12 (Dose assessment) and Criteria 14 - 17 (Reporting). Although strategies for monitoring workers for internal contamination are considered in a draft ISO standard (ISO/FDIS 20553), it is unlikely that the current version of this standard will meet UK needs. This is discussed in section 7.3.1. Therefore, it is clear that a significant amount of material contained in the current Requirements for Approval of Dosimetry Services, Part 2 would need to be carried forward to a revised approval system, even if maximum use were to be made of the requirements presented in ISO 9001 and ISO 17025.

A number of other improvements to the current system can be proposed. The requirements relating to accuracy and uncertainty budgets specified in section 5.3 could be implemented (ie a quantitative specification of required accuracy for different types of *in vivo*, bioassay and air sampling measurements, representing “good laboratory practice”; a requirement to use traceable standards wherever possible; a requirement to perform a limited uncertainty analysis for assessed doses where assessed doses are high enough to justify it). Although ISO 17025 requires the assessment of measurement uncertainties, an additional, quantified requirement on the accuracy of measurements carried out for the purposes of internal dose monitoring could be of benefit.

7.2.2 OPTION 2: Outline UK guidance linked to British, ISO and IEC standards

General

Full certification/accreditation to ISO 17025 could be made a requirement. The main difference from the approach proposed in the previous section is that dosimetry services would be certified/accredited by an external body, against the complete standard(s), releasing HSE

inspectors from the task of approving dosimetry services with respect to quality management and laboratory competence. Accreditation/certification to ISO 17025 would be obtained from the United Kingdom Accreditation Service (UKAS).

As discussed earlier, the main advantage would be that use could be made of material contained in the comprehensive set of ISO standards on quality management and laboratory competence. An additional advantage would be the reduced effort needed from HSE Inspectors for approvals. However, requiring accreditation or certification to these ISO standards could raise some difficulties, particularly for the smaller internal radiations dosimetry services, who have said that the initial effort to obtain accreditation under ISO 17025, the continuing effort to maintain accreditation/certification, and the financial costs of accreditation/certification could well make the service economically unviable. Annual fees for maintaining accreditation, including annual assessment, could be in the region of £2000 - £5000 for a typical laboratory. In addition, up to 40 man days could be needed annually for maintenance and auditing, depending on the amount of effort already put into internal quality management⁹⁰. Reduction in the number of dosimetry services would presumably be an unwelcome development for HSE.

Any laboratory meeting the requirements of ISO 17025 also operates a quality management system for its testing and calibration activities that meets the *principles* of ISO 9001. In the 1999 version of ISO 17025, it was made clear that laboratories meeting the requirements of ISO 17025 also meet the quality management *requirements* of ISO 9001. However, the 2005 revision of ISO 17025 has introduced new text that is ambiguous on this issue. If Option 2 is to be pursued, it will be important to obtain clarification from UKAS on this issue. This is important because some organisations may already have ISO 9001 certification covering the work of laboratories, and a requirement to obtain ISO 17025 certification could involve duplication of effort.

External radiation

For external radiation, a requirement for conformity to ISO 17025 would appear to be straightforward. Where there are similar quality management systems used, UKAS ISO 17025 certification/accreditation of an ADS could be linked to accreditation of a laboratory's calibration and testing services, with a saving of costs. An ADS could also be certified/accredited to a type-test standard as a further part of the approval procedures (see below), carried out jointly with certification/accreditation to ISO 17025. In all cases, the conformity requirements and the certification/accreditation could be an option within the HSE approval requirements. This would retain the flexibility of the current approach.

Internal radiation

It was noted in the previous section that monitoring strategy, assessment of internal dose, and reporting of doses is not covered by these ISO standards, and that strategies for monitoring workers for internal contamination is considered in a draft ISO standard, ISO/FDIS 20553, *Radiation protection - Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material*. ISO describes the current status of this draft standard as follows: "This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.". However, on the basis of information from the ISO Working Group that has developed this draft standard⁹¹, it appears that it is close to publication. The standard addresses: the purpose of monitoring; workplace and individual monitoring; routine monitoring, including minimum requirements on methods and monitoring intervals; special monitoring; task-related monitoring; recording, documentation and reporting of results; and quality management.

If this International Standard becomes a British Standard, conformity could be made a requirement. However, a number of serious concerns regarding this draft standard were expressed by UK dosimetry services, and the British Standards Institution voted against adoption earlier this year. The main criticisms were that development of such a standard should await the outcome and assimilation of the results of the EC 5th Framework Programme projects OMINEX (Optimisation of Monitoring for Internal Exposure)⁵⁰ and IDEAS (General guidelines for the estimation of committed dose from incorporation monitoring data)⁶⁴ projects, and ICRP recommendations on the interpretation of bioassay data. Furthermore, it was considered that recommendations on routine monitoring methods and intervals were too prescriptive, and could act to limit the capability of dosimetry services to specify monitoring strategies that are appropriate for local conditions. (One of the authors of this report (G Etherington) has recently joined the relevant ISO working group, and there are hopes that the standard could be revised to make it acceptable in the UK when it comes up for review within the next five years).

Thus, even if certification/accreditation to ISO 17025 were to be made a requirement, the need would remain to specify requirements relating to monitoring strategy, assessment of internal dose, and reporting of doses, or at least to provide guidance on these issues. Such requirements or guidance could draw on the results of the EC 5th Framework Programme projects IDEAS and OMINEX^{50,64}, as well as a recent ICRU report on direct determination of radionuclides in the body⁹².

7.2.3 OPTION 3: Outline UK guidance linked to detailed EU guidance (revised EUR14852 technical recommendations)

General

The EUR14852 recommendations are used in several countries in the EU, although they are in need of updating. The recommendations include sections on quality assurance and on management and administration aspects. Harmonization of standards themselves is needed and it may well be questionable whether standards bodies are the right organizations to publish criteria for performance requirements for approved dosimetry systems. An alternative would be to use European Commission technical recommendations¹³, revised and up-dated, combining ISO, IEC, IAEA, ICRU and ICRP documents on the basis of best available knowledge and practice (see section 3.7). The current technical recommendations only consider external radiation, but the recommendations are being reviewed and there are proposals that they be revised. Revised recommendations would include internal radiation. EC technical recommendations could form the basis for EU harmonization and a basic framework for EU acceptability of approval procedures. This could be seen as being a part of the harmonized implementation of EU Council Directives.

7.3 PERFORMANCE TESTS

7.3.1 OPTION 1: Current approach with improvements

General

The current performance tests operate reasonably well and are accepted by the ADS. They are a test of the proficiency of the ADS to carry out measurements according to the dosimetry method that is approved. They are not tests of the dosimetric characteristics of the dosimetry method nor its suitability for the purpose.

External dosimetry

Some improvements are considered necessary.

- (i) The basis for the test criteria should be clearly stated and linked to overall accuracy requirements.
- (ii) The tests should be linked to the appropriate testing standards^{22,23}, and the use of the term 'bias' qualified, perhaps termed "residual bias" or, for a series of performance tests, seen as a measure of the reproducibility of the system (see section 6.1).

In addition, the tests could

- (i) be expanded to cover different irradiation conditions and by this means test whether there are any unanticipated changes to the dosimetric characteristics (see [93]);
- (ii) include unexposed dosimeters, but do not inform service which these are;
- (iii) include a requirement that no more than 5% (that is no more than 1) of the 20 higher dosed dosimeters tested should have a relative responses outside the band width.

Participation in national and international intercomparisons should be strongly encouraged. EURADOS is considering introducing regular, periodic European intercomparisons open to all EU ADS, and is discussing the proposal with the EC. The intercomparisons would be for all types of particle type and would include simulated workplace fields. The results of such intercomparisons should be republished but results of individual ADS are made anonymous.

Internal dosimetry

The possibility of devising an improved tritium-in-urine performance test using real urine samples spiked with known amounts of tritium could be investigated. The current test uses a simulated urine sample, because of concerns about the feasibility of using real urine samples in a multi-laboratory performance test. However, the French PROCORAD Association⁵⁷, which operates an annual international bioassay intercomparison in which UK laboratories take part, offers an intercomparison with a real tritium-in-urine sample. Sample handling methods similar to those used by PROCORAD could no doubt be employed.

Additional performance tests could be considered. Dosimetry services have expressed an interest in a performance test or intercomparison exercise for air samplers (either static or PAS). The feasibility of such a test needs to be investigated, although this is beyond the scope of this project.

An alternative approach to the development of new performance tests is to make it a requirement that services should participate in existing measurement intercomparison exercises (or intercomparison exercises that might be set up to meet HSE's specific needs). Proposals for participation in such intercomparison exercises are presented below.

(a) Proposal for intercomparison exercises for in vivo measurements

From time to time, international intercomparison exercises are organised by, for example, the IAEA and the European Commission. Some of the more important exercises organised during the last 15 years are described in Table 1. Participation in suitable exercises organised by external bodies could be made a requirement of approval. An advantage of this approach is that

HSE would not need to administer exercises, or analyse and evaluate results. However, there are a number of disadvantages. Not all dosimetry services might be invited to participate; this could be a particular problem with IAEA intercomparisons, because IAEA sometimes limits participation to a small number of laboratories in each country. No organisation has a regular *in vivo* intercomparison programme and exercises usually arise as a result of a particular initiative, so suitable exercises might not arise frequently enough. Publication of results can take several years; again, this is a particular problem with IAEA exercises. Perhaps the best way to make use of international intercomparisons would be to make it a requirement to participate whenever possible, and to document the reasons when participation is not possible.

A better approach to that offered by international intercomparisons would be to organise regular UK *in vivo* intercomparison exercises. These could be designed to meet the specific needs of the approval system, and could be performed on a regular basis. HSE could avoid the tasks of devising and administering the exercise programme, and analysing and evaluating results, by commissioning another organisation to carry out these tasks, in effect adopting the approach it has used for the organisation of tritium-in-urine performance testing.

An intercomparison exercise making use of a human subject would avoid the problem that a whole body phantom may not be representative of a human body in terms of radiation transport. However, comparisons could only be made for naturally-occurring ^{40}K in the body unless the subject had received an intake of radioactive material. Administering trace amounts of suitable radionuclides to a volunteer for measurement intercomparison purposes is not acceptable ethically, although such opportunities do arise occasionally as a result of volunteer biokinetics studies or accidental intakes.

Thus, the use of whole or partial body phantoms is likely to be the only feasible way to devise a regular intercomparison programme. In setting up such a programme, the most important decision to be made would be the choice of an appropriate phantom. The whole body phantom that is most commonly used for calibration of laboratory systems is the BOMAB (Bottle Manikin ABsorption) phantom⁹⁴. This consists of a set of bottles that mimic the human body in shape, filled with one or more radionuclides whose activities are known. The BOMAB phantom has several disadvantages, however⁹⁵: decontamination and refilling of the bottles is difficult; different versions of the phantom are required to mimic different body shapes and sizes; positioning of the phantoms is difficult for chair geometries; and the absorption of gamma-radiation by water and body tissue is not identical. Perhaps the most severe problem, given that the phantom would be transported between a number of laboratories, is the fragility of the BOMAB phantom and its susceptibility to leakage.

A possible solution to these problems would be to use solid, homogeneous, modular phantoms. These are built up from identical modules small enough to allow simulation of different body sizes and shapes measured in various geometries (eg, horizontal bed, standing, chair, arc). A phantom constructed using small bottles containing "hydrogel" (a polymerised mixture of acrylamide and 2-hydroxy-ethyl methacrylate) has been developed by the University of Helsinki⁹⁵. Another modular phantom has been developed by the Research Institute for Industrial and Marine Medicine, Mendeleev Institute for Metrology, St. Petersburg, and is available commercially⁹⁶. This consists of a set of "tissue-equivalent" polyethylene blocks of one of two sizes, weighing either 0.88 kg or 0.40 kg. The blocks contain longitudinal holes into which sealed rod sources containing the desired radionuclide(s) can be inserted. These rods contain ion-exchange resin to which a known amount of the radionuclide is bound. The blocks can be assembled in standing, lying, sitting and sitting-bending geometries for each of six human body builds, varying in weight in the range 12 - 110 kg. Photographs of the phantom assembled into the six different body builds, in both standing and sitting positions, can be seen in reference⁹⁶. A "St. Petersburg" phantom of this type was used in the 1995/6 European intercomparison of *in vivo* monitoring systems⁵³, in which a number of UK laboratories participated.

An intercomparison programme might consist of a set of specified measurements to be carried out every (say) 1-2 years. The radionuclides and activities would need to be varied on each occasion, and ideally the body build and distribution of activity in the body would also be varied. This type of programme could be readily established with a phantom of the St. Petersburg type.

As noted above, the phantom is available commercially. The current cost of the phantom is 9000 euro, and the cost of three sets of rod sources, containing ^{137}Cs , ^{60}Co and ^{40}K , is 16,000 euro⁹⁷. Radionuclides and activities differing from those offered in the standard package would presumably be available, but this would need to be negotiated with the Research Institute for Industrial and Marine Medicine.

(b) Proposal for intercomparison exercises for bioassay measurements.

In comparison with *in vivo* measurements, the position with respect to availability of suitable intercomparison exercises for bioassay measurements is much more straightforward. A suitable exercise is organised annually by PROCORAD (Association for the Promotion of Quality Control in Radiotoxicological Analysis). (The organisation and membership of PROCORAD is described in section 3.4.3).

The procedure for participation in the annual exercise is described on the PROCORAD website, <http://www.procorad.org/uk/index.html>. Organisations register in November of each year, samples are despatched to laboratories in February, measurements results returned to PROCORAD in April, results analysed in May and discussed at the annual meeting in June, and proceedings sent to participants in October. The scope of PROCORAD's intercomparison programme can be seen from the programme for the 2005 exercise. This consisted of intercomparisons on 7 separate groups of samples; the samples provided are described briefly below.

- (i) Tritium-in-urine intercomparison: blank urine, urine spiked with tritiated water (1-2 kBq l^{-1}), urine spiked with tritiated water (5-10 kBq l^{-1}), contaminated urine (< 70 kBq l^{-1}), tritiated water (< 70 kBq l^{-1}), contaminated urine resulting from exposure to organically bound tritium (10 - 60 kBq l^{-1})
- (ii) ^{14}C -in-urine intercomparison: blank urine, 3 spiked urine (0.1 - 1 kBq l^{-1} , 1 - 3 kBq l^{-1} , 3 - 10 kBq l^{-1})
- (iii) Sr- and unspecified X/ γ -ray-emitters-in-urine intercomparison: blank urine, 2 spiked urine (< 10 Bq l^{-1})
- (iv) Uranium-in-urine intercomparison: blank urine, 2 contaminated urine (<1.25 Bq l^{-1} , <0.2 Bq l^{-1})
- (v) Actinides-in-urine intercomparison: blank urine, urine spiked with one or more actinides from a predefined list that is provided to the lab., urine spiked with plutonium and americium (< 5 mBq, 5 - 20 mBq)
- (vi) Actinides-in-faecal-ash intercomparison: 3 faecal ash samples, which may be spiked with plutonium or trans-plutonium isotopes, or may be from a real contamination case (< 500 mBq). Uranium and thorium measurements must be carried out.
- (vii) "Surprise" urine intercomparison: Here, a surprise sample is one where the identities of the radionuclides present, as well as their activities, are unknown. ^{40}K must be determined together with unknown radionuclides, and the method described in detail.

The cost of participating in the 2005 intercomparisons is shown in Table 4. Some laboratories do not carry out bioassay measurements for the wide range of radionuclides offered by PROCORAD, and so would not need to participate in all the available intercomparisons. Some laboratories that carry out the full range of bioassay measurements might consider the cost and effort required to participate in all of the available intercomparisons as excessive. Required participation could be limited, on condition that all intercomparisons relevant to the work of a dosimetry service are completed within a specified period (eg three years).

The experience of UK laboratories is that PROCORAD offers a comprehensive, regular and well organised intercomparison programme. A major positive attribute of PROCORAD's programme is that it operates to a well-established schedule (described above), with an annual cycle time. As a result, both laboratories and regulators can be confident that results will be provided by the specified date. Many UK dosimetry service laboratories already participate voluntarily, and so it would seem appropriate to make participation in PROCORAD's programme a formal requirement if bioassay intercomparisons are to be included in the UK's approval system. One possible objection could be that the UK's approval system might become dependent on the support of another EU country (ie France) for the PROCORAD organisation. However, this should not be a major source of concern. PROCORAD can be expected to continue for the foreseeable future, not least because of the dependence of the French approval system on its work. Furthermore, PROCORAD considers that the participation of non-French laboratories is of benefit since the participation of more laboratories increases confidence in the overall outcome of the intercomparison.

The results of both *in vivo* and bioassay intercomparisons could be analysed and processed in a similar way. A requirement could be specified that results of participation in such exercises should be made available to HSE or to an organisation commissioned by HSE to evaluate the proficiency of the laboratory. Results would be assessed by comparing the reported result with the true value and/or the mean of the reported values. Comparison with the true value would be appropriate in the case of *in vivo* phantom measurements or spiked bioassay samples, although comparison with the mean of reported values would also be potentially useful. Comparison with a mean of reported values would be appropriate for bioassay samples collected as a result of real contamination events, since the true value is of course unknown. Criteria to determine whether laboratory proficiency is acceptable could be specified in terms of an acceptable level of bias (ie the difference between the reported result and the true or mean result), or by making use of the "u-test"⁹⁸. This test, which is used by NPL in its environmental radioactivity intercomparison exercises, effectively determines whether the true value falls within a defined confidence interval for the reported value. If the u-test is used, then an additional criterion would need to be placed on the magnitude of the quoted confidence interval, to avoid the possibility that laboratories could obtain satisfactory results by quoting unreasonably large confidence intervals. Acceptable bias or u-values could be determined on the basis of results of previous international *in vivo* intercomparisons, (eg the 1995/6 European intercomparison of *in vivo* monitoring systems⁵¹), or the annual PROCORAD bioassay intercomparisons.

A requirement could be set that laboratories that do not meet these proficiency test criteria should carry out a review with the aim of identifying whether improvements in measurement techniques are needed. This could include a requirement to consult with other laboratories that have obtained satisfactory results. This approach has some similarities to that adopted for the current performance test, but also some important differences. Results would not be classified as either "pass" or "fail". Rather, intercomparison exercises would be used to provide a mechanism by which laboratories producing unsatisfactory results would be facilitated and encouraged to improve their performance.

7.3.2 OPTION 2: Outline UK guidance linked to British, ISO and IEC standards

General

There are no British standards on performance testing applicable to ADS, and only one international standard. There could be advantages in links to standards in that testing might be able to be part of certification/accreditation, and could be linked to a harmonized approach to approval within Europe.

External dosimetry

The only international standard for performance tests is ISO 14146 which has the ‘trumpet curve’ as the test criterion²². This standard was not accepted as a British standard, partly on the basis that this test on overall accuracy was not in accord with the UK approach. Present standards under development by both ISO and IEC do not explicitly include performance tests on dosimetry systems but give requirements for the acceptable limits on the different components of uncertainty. There is an underlying assumption that the overall uncertainty in the assessment of the measurement quantity must be broadly consistent with the ICRP factor 1.5 on the relative response at the 95% confidence level.

Internal dosimetry

Apart from ISO 12790, there are no British, ISO or IEC standards that are relevant to performance testing for internal dosimetry measurements.

7.3.3 OPTION 3: Outline UK guidance linked to detailed EU guidance (revised EUR14852 technical recommendations)

General

The current EC technical recommendations, which apply only to external dosimetry, include both approval performance tests and routine performance tests. The former would be similar to the US approval tests, being carried out to demonstrate that the required standard of dosimetric performance can be achieved, covering a range of radiation energies and angles and doses, and in principle should confirm type test data. The latter should determine bias and precision, should be frequent (monthly is suggested), and should be carried out by the service itself. As noted previously, the EC technical recommendations are being reviewed and may be revised during the next 5 years.

Outline UK guidance might adopt the approach to performance testing developed in the new EC technical recommendations, which could be based on a EU consensus, and could form the basis for harmonized or common EU performance tests.

7.4 DOSIMETRIC CHARACTERISTICS OF THE DOSEMETER/DOSIMETRY SYSTEM

7.4.1 OPTION 1: Current approach with improvements

General

Under the present system, the basic requirement is that the doses are assessed with a “reasonable degree of accuracy”. For external radiation, the additional requirements are that the dosimeter is of a proven design and/or can be shown by type testing and field trials to be suitable and reliable, and have a consistent and adequate performance for the radiation fields and environments in which it will be used. There are no criteria set for the dosimetric

performance characteristics, although reasonable steps are required to be taken to demonstrate conformity with the out-of-date NAMAS information sheets NIS61⁷³ and NIS65⁷⁴.

Clear dosimetric requirements are useful for manufacturers and services designing new or modifying current dosimeters and dosimetry systems; enable comparability of systems and aid choice and assessment of suitability; assist the approval application and assessment; and make the process more transparent. However a mandatory requirement to meet, for example, an ISO or IEC standard, would lose the flexibility of the present system with its over-riding criterion of fitness for purpose. Improvement to the present system might involve reference to specific BS, ISO and IEC standards, but with no mandatory requirement for complete conformity to the standard, only that the dosimetry system is tested against a specified standard, and results given with an explanation of any non-conformity.

External dosimetry

It would be very useful to be able to compare and assess different systems. Some clearer specification of how to assess the dosimetric characteristics and present the results would be valuable. This is probably best done with reference to published standards. As stated previously, participation in national and international intercomparisons should be encouraged, and results published.

International standards have been, and are being based on the ICRP Publication 75 factor of 1.5 at the 95% confidence for individual monitoring. This accuracy requirement is similar to that of ICRU for instrumentation. Although the ICRP requirement is for the protection quantity, E, the requirement is usually considered to apply to the assessment of the quantity being measured- $H_p(10)$ or $H_p(0.07)$. See section 3.3.1.

An example of the application of the use of ICRP factor of 1.5 in standards is the IEC standard on dosimetric performance requirements for TL dosimetry systems (IEC61066 ed2 2005)⁹⁹. The factor of 1.5 corresponds to a range of relative response from 0.67 to 1.5. This is interpreted as a range of about $\pm 40\%$ about a mean of 1.085. This is then applied to the calibration (correction) factor (the reciprocal of the response characteristic) as a range from 0.6 to 1.4.

Internal dosimetry

Participation in dose assessment intercomparisons could be made a requirement. UK dosimetry services, working within the framework of the Internal Radiation Dosimetry Group (IRDG), have in fact been active in setting up and promoting such exercises, and most dosimetry services already participate voluntarily. It would there seem appropriate to make participation a formal requirement. Participation in European intercomparison exercises (sponsored by the EC, EURADOS or IAEA) could be required whenever these take place. In the absence of such an exercise after a specified period of time, it could be made a requirement that dosimetry services should jointly organise a UK exercise (perhaps through the IRDG). A requirement could be specified that results of participation in such exercises should be made available to HSE, and that a review should be carried out if results fall outside specified limits. Similar comments to those made in section 7.3.2 on the analysis and processing of results from such intercomparisons also apply here. Caution would need to be exercised to avoid drawing over-simplified conclusions from the results of dose assessment intercomparisons. It often has to be recognised that there may be no single “correct answer” for internal doses that are assessed on the basis of limited monitoring data and information on exposure conditions and material characteristics that is often inadequate for dosimetry purposes.

7.4.2 OPTION 2: Outline UK guidance linked to British, ISO and IEC standards

General

See 7.4.1 above.

External dosimetry

There are a number of international standards in this field, either published or in draft, (not all have been found acceptable in the UK). One advantage of using detailed standards is that the criteria are known to all and can be used as the basis for the design of systems as well as for compliance testing. A disadvantage is that a system in use may be fully adequate for the purpose but not meet the detailed standard. It is noted that in the present RADS, conformity to the NAMAS NIS 61 and 65 'standards' is expected. This implies that a link to standards may be considered desirable.

The relevant international standards are the following (some detailed comments are given in Appendix 3):-

ISO 1757:1996, *Personal photographic doseimeters*;

BS ISO 12794:2000, *Nuclear energy — Radiation protection — Individual thermoluminescence doseimeters for extremities and eyes*;

ISO 21909:2005, *Radiation Protection-Passive personal neutron doseimeters-Performance and test requirements*;

IEC 61066 Ed. 2.0 2005, *Thermoluminescence dosimetry systems for personal and environmental monitoring* (see also first edition IEC 1066);

IEC 61526 Ed.2 2004, *H_p(10) and H_p(0.07) direct reading personal dose equivalent meters and monitors*;

IEC 62387 Ed 1.0 in draft, *Passive, non-thermoluminescence, dosimetry systems for personal and environmental monitoring*..

Test laboratories like to work to detailed descriptions and protocols which do not change frequently and are used by other test houses, in other words standards. If it is decided to have outline UK guidance linked to standards, in particular if this is mandatory and with the possibility of a requirement of certification/accreditation, it is essential that the standards are good standards and that there is effort from the UK towards this end.

Internal dosimetry

As noted in section 7.2.2, while strategies for monitoring workers for internal contamination are considered in a draft ISO standard (ISO/FDIS 20553), it is unlikely that the current version of this standard will meet UK needs. There are no relevant British, ISO or IEC standards addressing the issue of internal dose assessment. However, the EC 5th Framework Programme project IDEAS⁶⁴ has developed proposed guidelines for the assessment of internal doses. Most UK dosimetry services that are approved for the assessment of internal doses have contributed to this project. As a minimum requirement, services could be required to consider the applicability of these guidelines when assessing doses for individual cases. Note that ICRP is developing a Guidance Document on this topic that will incorporate the main features of the advice developed by the IDEAS project.

7.4.3 OPTION 3: Outline UK guidance linked to detailed EU guidance (revised EUR14852 technical recommendations)

General

See 7.3.3.

In the current EC technical recommendations, the energy and angle dependence of response requirement is that the relative response averaged over the angles 0°, 20°, 40° and 60° for each energy, should be (approximately) within the range 0.6 to 1.4 at the 95% confidence limit. If outline UK guidance were to adopt in principle a link to detailed EC recommendations on dosimetric performance requirements, it would be essential to ensure that the UK position was represented in the discussions leading to the preparation of these recommendations. The development and application of revised EC technical recommendations could be seen as being a part of the harmonized implementation of EU Council Directives

8 SUMMARY AND CONCLUSIONS

The report gives the project background and objectives and includes a consideration of general requirements for approval, certification or accreditation of dosimetry services; British and international standards, and other documents of relevance; and harmonization within the EU.

The report considers what is a reasonable degree of accuracy and how best to assess the ability of dosimetry services to continue to attain that level. The overall accuracy of the assessment of dose by a given dosimetry method depends on the dosimetric characteristics of the method used and its suitability for the purpose; and the quality assurance and quality management systems of a given dosimetry service, which determine, amongst other things, the reliability and consistency of the application of the measurement method.

Suitability for purpose, which involves information of the energy and direction characteristics of the radiation field being measured, plus other factors (environmental conditions, dosimeter wear position, etc.), is not addressed in this report. The remaining components of overall accuracy which are addressed are:-

- (a) the more general laboratory and staff quality assurance, and quality management systems, including software quality assurance, conformity of equipment used, calibration and internal performance tests (see below);
- (b) routine external performance tests of the dosimetric reliability and consistency of the application of the method by an identifiable laboratory (system operator, actual identifiable equipment used, identifiable dosimeter calibration factor, read-out system calibration, environmental conditions for read-out, etc.), and periodic inter-comparisons between systems providing similar services;
- (c) determination of the dosimetric characteristics of the system. For external radiation dosimetry, this is achieved by type-testing- the determination of the energy and angle dependence of ($H_p(d)$) response characteristics of the type of dosimeter/dosimetry system used, repeatability and reproducibility, effect of influence quantities, and other factors linked to the measurement method. For internal dosimetry, this includes the monitoring strategy for the *in vivo*, bioassay or air concentration measurements undertaken, and the models (intake, biokinetic and dosimetric) used to determine internal dose from the measurements made, as well as factors directly related to the determination of the measurement quantity.

The present system of approval is reviewed with comments from currently approved dosimetry services taken into account. The adequacy of the present performance test is assessed. Current procedures are satisfactory. Clearly, though, some improvements are possible. More frequent, but shorter, re-assessments might be better, and with little delay, perhaps using the UKAS accreditation system as a model. In general, a move towards a more standard-based system is indicated, in particular for quality assurance aspects. Improvements are suggested for performance tests, and also for more transparent type-test requirements. The advantage of the current system has been the flexibility of approach linked to radiation protection and dosimetry expertise at HSE. However consideration has to be given to the continuing availability of resources.

For both external and internal dose assessment, and where appropriate for each of the three aspects of overall accuracy ((a), (b) and (c) above), three options are considered: present system with improvements; more general version of present system, linked to detailed standards on quality assurance and dosimetric requirements; more general version of present system, linked to detailed EC guidance.

For external radiation, the recommendations of ICRP are generally consistent with the position of ICRU as given in Report 47²⁸ and have become the basis of performance test and type-test

criteria (see for example [17]). If applied to the determination of the measurement quantity, the criterion of a factor of 1.5 on overall accuracy at or near dose limits is reasonable and achievable for body dosimeters for photons and electrons. For determinations of doses from neutrons, or extremity and skin dosimetry for low energy electrons, the 1.5 factor might be replaced by a factor of two. Inter-comparisons carried out under the aegis of both EURADOS²¹ and by IAEA^{29,30} have demonstrated the achievability of these criteria, but it should be noted that they were not met by all the dosimetry systems participating in these intercomparisons.

The detection limit is the dose level such that the reading would be incorrectly reported as background with a stated probability, usually 5%, that is only 5% false negatives. A false negative probability of 5% corresponds to a dose value equal to about 3.3 standard deviations on background. A suitable detection limit for whole body external radiation dosimeters for photons and electrons would be about 170 μSv . This corresponds to monthly issue and an annual dose of 2 mSv. An achievable detection limit for neutron dosimeters would be several hundred μSv . (see Appendix 1 for more information on this).

The overall uncertainty associated with a dose assessment for a personal dosimeter measurement should be evaluated (see section 3.3.7). This can be done by estimating and combining all known inputs to the total uncertainty, preferably including workplace field characteristics. This can be done by using an analytical method⁴⁵, or using a numerical method^{46,47,48}. In practice there is limited knowledge of the workplace field and other factors such as a worker's pattern of movement, and generalized assumptions will be needed leading to an overestimate of the overall uncertainty.

For internal dose assessment, the evaluation of the overall accuracy of assessed doses resulting from intakes of radionuclides is widely acknowledged to be a difficult problem. Although research work is progressing on this topic, the subject is not well-enough developed to make it feasible to propose requirements on dosimetry services for the routine estimation of overall uncertainties on assessed doses. On the other hand, the accuracy of measured quantities (eg radionuclide activities in the whole body, radionuclide activity concentrations in excreta samples, or air concentrations) are more straightforward to estimate. In the current approval system for internal radiations, the only direct measure of measurement accuracy is provided by the performance test for tritium-in-urine measurements. While this test is adequate in itself, it cannot be considered to be a valid test of the overall performance of a dosimetry service for assessments of internal dose. Participation in *in vivo* measurement and bioassay measurement intercomparisons is considered to be a preferred approach by the authors of this report. As well as providing information that can be used to evaluate a laboratory's performance, intercomparisons also provide a mechanism by which laboratories producing unsatisfactory results would be facilitated and encouraged to improve their performance.

For dosimetry services seeking approval, clear benefits would arise from a move towards adopting ISO 17025 for the requirements that a measurement laboratory must meet if it wishes to demonstrate that it operates a quality system, is technically competent, and is able to generate technically valid results. Some or all of the requirements of this standard could be adopted in a revised approval system, and this approach could be considered to be preparatory to introducing a system where certification/accreditation to ISO 17025 is a formal requirement. For internal dosimetry, the requirements of ISO 17025 could be supplemented by additional, quantified requirements on the accuracy of different types of *in vivo*, bioassay and air sampling measurements. However, until acceptable international standards are developed for the design of internal dose monitoring programmes and the assessment of internal dose, the need will remain to specify requirements relating to monitoring strategy, assessment of internal dose, and reporting of doses, or at least to provide guidance on these issues.

The conclusion of the authors is that the present system should be improved and some detailed recommendations are given.

Consideration of the legal dimension- compensation claims or litigation, are outside the scope of this study.

9 RECOMMENDATIONS

- (a) It is recommended that the three parts of the approval procedure are clearly distinguished. These are (i) establishing the competence of the laboratory to provide reliably technically competent results; (ii) establishing that the dosimetric performance characteristics of the dosimeter and dosimetry system meet stated criteria; (iii) periodically checking the consistency of performance.
- (b) The RADS and REPPIR approval processes should be unified. This would be advantageous for both external and internal dosimetry system approval. Furthermore, there are distinct advantages in carrying out approvals for external dosimetry whole body photon, internal dosimetry, extremity dosimetry, etc. at the same time, rather than at different times as happens at present. Most dosimetry services that seek approval for internal radiations also operate a dosimetry service for external radiations, and there could therefore be significant efficiency savings for both HSE and the services themselves. It is recommended that the option be given of combining or co-ordinating the approval of several services
- (c) On occasions, there are long delays in assessments and reassessments of services under the present procedures. This could be improved by a change to a UKAS-type procedure with annual inspections or surveillance visits covering only parts of the service operating procedures rather than the current 5-yearly reassessment, or a change to UKAS certification/accreditation (see (d) below).
- (d) It is recommended that in respect of (a)(i) above, the approval system should move towards requiring conformity to British and international standards of quality assurance, specifically BS EN ISO/IEC 17025:2005, with certification/accreditation undertaken by UKAS. The changes will need to take place over a period of time to allow dosimetry services to adapt to revised approval procedures and it will probably be necessary that, at least initially, ISO 17025 certification/accreditation would not be mandatory, there would be the option to obtain certification/accreditation, and this would form part of the approval procedure. It may be necessary that for 5 to 10 years, the option is retained of following the present procedure system. It might be anticipated that the number of ADS choosing to do so would rapidly decrease. Further consultations with interested parties are to take place. It is noted that the present HSE procedures give guidance on necessary quality assurance and quality management practice which is similar in many respects to the ISO 17025 requirements.
- (e) For **external radiation**, the recommendations of ICRP are generally consistent with the position of ICRU as given in Report 47 and have become the basis of performance test and type-test criteria. If applied to the determination of the measurement quantity at doses below dose limits where the use of the operational quantities is justified, the criterion of a factor of 1.5 on overall accuracy proposed by ICRP for the protection quantity at or near the dose limit is reasonable and achievable for body dosimeters for photons and electrons. For determinations of doses from neutrons, or extremity and skin dosimetry for low energy electrons, the 1.5 factor might be replaced by a factor of two.
- (f) The overall uncertainty associated with a dose assessment should be evaluated by estimating and combining all known inputs to the total uncertainty. It may be possible in some situations to include the characteristics of the workplace.
- (g) The participation in national and international intercomparisons should be encouraged. The results of such intercomparisons should be published but the results of individual ADS should be made anonymous.
- (h) There should be a suitable detection limit proposed for the different dosimetry methods. The detection limit is the dose level such that the reading would be incorrectly reported as background with a stated probability, usually 5%. That is only 5% false negatives would be expected. A false negative probability of 5%

corresponds to a dose value equal to about 3.3 standard deviations on background. A suitable detection limit for whole body external radiation dosimeters for photons and electrons would be about 170 μSv . This corresponds to monthly issue and an annual dose of 2 mSv. An achievable detection limit for neutron dosimeters would be several hundred μSv . (see Appendix 1 for more information on this).

- (i) For **external radiation**, it is recommended that in respect of (a)(ii) above, the approval system should move towards dosimetric requirements linked with either British, European or international standards, or with detailed EC guidance. It is difficult to judge at the present time which of these alternatives would be more appropriate to the UK situation, or, indeed, feasible. There are many discussions at both the European and international level in this area at the moment. The explicit requirement to conform to a standard or to meet detailed EC guidance would also not be mandatory, at least initially. The option would exist to continue to use the present system, that is for the employer to demonstrate that a given dosimetry system was fit for the purpose, with specific workplace field information for example. Conformity to stated standards would be the default condition. It is noted that in the RADs, conformity to the NAMAS NIS 61 and 65 'standards' is expected.
- (j) Performance test protocols should be linked to standards for the statistics of testing, in particular to BS ISO 5725:1994. In particular the use of the term 'bias' should be corrected, or at least qualified. Perhaps the term "residual bias" could be used. For external radiation specific improvements to routine performance tests are recommended.
- (k) For **internal radiation**, it is recommended that dosimetry services should participate in vivo measurement and bioassay measurement intercomparisons, rather than an extension or improvement of the current performance test. A suitable programme of regular in vivo intercomparisons would need to be developed, and a possible approach has been proposed. A suitable programme of bioassay intercomparisons already exists, (ie the PROCORAD intercomparison programme). Participation in dose assessment intercomparisons could also be made a requirement. In addition to the adoption of the requirements on measurement laboratories specified in ISO 17025, quantified requirements on the accuracy of different types of in vivo, bioassay and air sampling measurements could be introduced; a possible approach has been discussed.

The changes should be seen as the evolution of current system.

Table 1. A selection of international *In Vivo* Measurement Intercomparisons

Measurement	Radio-nuclides	Organiser	Date	No. of Labs	Comment	Results	Reference
Measurement of BOMAB phantom (4 year old child)	K-40, Y-88, Cs-137	Canadian National Calibration Reference Centre for In Vivo Monitoring, US DoE	1993	35 labs using 43 detection systems	Highlighted subject size dependence of measurements. 2 UK labs took part		G. H. Kramer et al. (1999)
12 human subjects	K-40, Cs-137, Cs-134, I-125	KFKI Budapest, GSF Frankfurt, IAEA, Ostereichisches Forschungszentrum, Seibersdorf	1994	4	Contamination from Chernobyl	Standard deviations of measured activities were all within 10%	E Werner, et al. (1995)
St Petersburg Phantom, human subject, labs. own neck/thyroid phantom	Phantom: Cs-137, Cr-60, Co-57 and K-40 Person: K-40, Thyroid: I-125, I131	BfS Neuherberg, funded by EC	1996	Phantom: 44 Person: 40 I-125: 9 I-131: 17	St Petersburg Phantom is robust and suitable for intercomparisons. 5 UK labs (2 ADS) took part	Standard deviation of K-40 (phantom and person) and Cs-137 was $\pm 20\%$, Co-60: 26% and Co-57 27%	M Thieme et al. (1998)
JAERI phantom	Actinides	IAEA, Japan Atomic Energy Research Institute (JAERI)	1996-98	9	Conducted to assess differences in calibrations arising from Western vs Asian stature		IAEA (2003)
Skull	Am-241	BfS	1998	5	Measurements used to determine activity in skeleton	Measurements in range 2300 – 5450Bq	W Ruhm, et al. (1998)
BRMD BOMAB phantoms ⁵ : PFB, PF-Acc,	Zn-65, Cs-137, Co-60, Co-57, Fe-59	The Canadian National Calibration Reference Centre for In Vivo	2002	10	Conducted annually in Canada as a regulatory requirement.	All labs consistent with regulatory requirements: Bias	G. Kramer (2002)

Measurement	Radio-nuclides	Organiser	Date	No. of Labs	Comment	Results	Reference
PM5A, PME, PM-Acc, PMG		Monitoring				50% to –25% for activities more than 5 times MDA	
BOMAB phantoms: PFB, PF-Acc, PFC, PME, PM-Acc1, PMF	Na-22, Cs-137, Cs-134, Co-60, Co-57	The Canadian National Calibration Reference Centre for In Vivo Monitoring	2003	10	The following are tested: size dependency, radionuclide identification, counting accuracy, location dependence, effect of an interferent.	Precision (repeat measurements) < 40%	G. Kramer (2003)

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Table 2. A selection of international internal dose assessment intercomparisons

Monitoring measurements	Exposure to	Organiser	Date	No. of Labs.	Comment	Results	Reference
Urine data sets from 17 individuals, and post-mortem analysis data	Plutonium	PNL, US Trans-uranium Registry, USA	1986	6	Comparison of assessments of systemic uptake of Pu	Good agreement for urine assessments, within a factor of 2 of the value. Wider variation in the ratio of urine to autopsy estimates (0.9 to 21.7)	R L Kathren et al. (1987)
Urine data	Plutonium (4 cases)	UK Internal Radiation Dosimetry Group (IRDG)	1989	6	Intercomparison of methods used for the assessments of systemic burdens of plutonium	The exercise, using realistic data, showed no major differences between the labs, with an overall standard deviation for all cases of 44%.	D Ramsden, et al. (1990)
Urine, Faeces, PAS, In Vivo	A: Tritium: 4 Cases B: Uranium C: Cobalt-60 D: Plutonium	IRDG	1991	6	Cases were devised to be as realistic as possible using real data sets	Results similar to earlier study. Main sources of variation: use of different models and parameter values; treatment of data (statistical weighting, less than limit of detection etc.)	D Ramsden et al. (1992)
Urine, Faeces, PAS, In Vivo	A) Sr-90, Cs-137 B) P-32 C) Pu wound D) Pu/Am nitrate E) Pu-239	EURADOS, CEC	1991	9		The standard deviation of results was of the order of $\pm 30\%$. However, some results were revised after initial discussions.	J. A. B. Gibson et al. (1992)
Urine, Faeces, PAS, In Vivo	A) Tritium B) Sr-90/Y-90	EULEP/ EURADOS	1999	50	The large spread of results reported was	Geometric standard deviations for intake varied from 1.32 to	H. Doerfel et al. (2000)

Monitoring measurements	Exposure to	Organiser	Date	No. of Labs.	Comment	Results	Reference
	C) I-125 D) Cs-137 E) Enhanced intake of NORM F) Pu-239 G) Pu exposure reconstruction				due in part to the transition at that time from ICRP 30 to ICRP 60 recommendations and use of new models.	5.64, and for E(50) from 1.61 to 2.8, the higher values applying predominantly to the Pu cases.	
Wound monitoring, Whole body, urine, faecal	A) Wound/ inhalation of Pu/Am B) Cs-137 C) Tritiated water D) Uranium E) Am oxide F) Pu/Am oxide	IRDG	2000	4	All labs used IMBA and the revised ICRP 60 dosimetry for their analysis. E) Ca-DTPA was given.	79% of the results for E(50) are within $\pm 40\%$ of the mean value.	J Speed et al. (2003)
Urine, Faeces, PAS, In-Vivo	A) HTO B) Sr-90 & Cs-137 C) Co-60 D) I-131 E) U (enriched) F) Pu/Am	IAEA/EC IDEAS	2002 - 2005	~ 60	Test of the IDEAS / IAEA Guidelines for internal dose assessments.	Not yet published	H Doerfel et al. (2006)

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Table 3. Suggested accuracy requirements for *in vivo*, bioassay and air sampling measurements

Monitoring method	Measurement / sample type	Radionuclide type	X	Y(%)
<i>In vivo</i>	Whole body	High energy gamma-emitters	10	±20
	Lung	Low energy photon-emitters	10	+100/-50
Bioassay	Urine	α-emitters	10	±25
		β-emitters	10	±25
	Faeces	γ-emitters	10	±20
		α-emitters	10	±25
		β-emitters	10	±25
		γ-emitters	10	±30
Air sampling	Personal air sampler	α-emitters	10	?
		α-emitters	?	?
	Static air sampler	β-emitters	?	?
		γ-emitters	?	?

Note: "Radionuclide type" indicates whether the measurement is of α, β or photon emissions

Table 4. PROCORAD intercomparison exercise costs in 2005

Number of intercomparisons	Cost (euros, ex VAT)
1	600
2	1200
3	1800
4	2300
5,6,7	2500

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APPENDIX 1 TERMS AND DEFINITIONS

(note that where several standards are referred to, the current accepted definition is contained in the latest standard, earlier standards are given for additional information on the definition)

accreditation: third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks
BS EN ISO/IEC 17000:2004

accreditation body; authoritative body that performs accreditation

NOTE

The authority of an accreditation body is generally derived from government

accuracy of a measurement: closeness of the agreement between the result of a measurement and the true value of the measurand

NOTES

1 “Accuracy” is a qualitative concept.

2 The term **precision** should not be used for “accuracy”.

BS/ISO 3534-1:1993; BS ISO 5725-1:1994; VIM1995; GUM 1995

approved dosimetry service/approval: an approved dosimetry service, ADS, is a dosimetry service approved by HSE, or by such other persons as may from time to time be specified in writing by the Executive); approval is by a certificate in writing (in accordance with such criteria as may from time to time be specified by the Executive for such of the purposes of the IRR as are specified in the certificate (see Regulation 35 of the IRR¹). In other words approval is a procedure by which a national authority recognizes the competence of a dosimetry service.

approval: permission for a product (including a service) or process to be marketed or used for stated purposes or under stated conditions

NOTES

1 Approval can be based on fulfilment of specified requirements or completion of specified procedures.

BS EN ISO/IEC 17000:2004

attestation: issue of a statement based on a decision following review, that fulfilment of specified requirements has been demonstrated

NOTES

2 The resulting statement referred to in this International Standard as a “statement of conformity”, conveys the assurance that the specified requirements have been fulfilled. Such an assurance does not, of itself, afford contractual or other legal guarantees.

BS EN ISO/IEC 17000:2004

bias: the difference between the expectation of the test result and an accepted reference value : the systematic error of a measurement

BS/ISO 3534-1:1993; BS ISO 5725-1:1994; VIM1995; GUM 1995

certification: third part attestation related to products (including services), processes, systems or persons

NOTES

1 Certification of a management system is sometimes also called registration

2 Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.

BS EN ISO/IEC 17000:2004

characteristic limits: The decision threshold allows a decision to be made for a measurement with a given probability of error as to whether the result of the measurement indicates the presence of the physical effect quantified by the measurand.

The detection limit specifies the minimum true value of the measurand which can be detected with a given probability of error using the measuring procedure in question. This consequently allows a decision to be made as to whether or not a measuring method satisfies certain requirements.

The limits of the confidence interval define an interval which contains the true value of the measurand with a given probability, in the case that the result exceeds the decision threshold.

BS ISO 11929-7:2005

confidence limits: values which define a confidence interval to be specified for the measurand in question which, if the result exceeds the decision threshold, includes the true value of the measurand with the given probability $(1-\gamma)$.

BS ISO 11929-7:2005

conformity assessment: demonstration that specified requirements relating to a product (includes services), process, system, person or body are fulfilled

NOTES

- 1 The subject field of conformity assessment includes activities such as testing, inspection and certification, as well as the accreditation of conformity assessment bodies.
- 2 The expression “object of conformity assessment” or “object” is used to encompass any particular material, product, installation, process, system, person or body to which conformity assessment is applied. A service is covered by the definition of a product of conformity assessment.

BS EN ISO/IEC 17000:2004

conformity assessment body: body that performs conformity assessments

NOTE

- 1 An accreditation body is not a conformity assessment body

BS EN ISO/IEC 17000:2004

decision quantity: random variable for the decision whether or not the physical effect to be measured is present

BS ISO 11929-7:2005

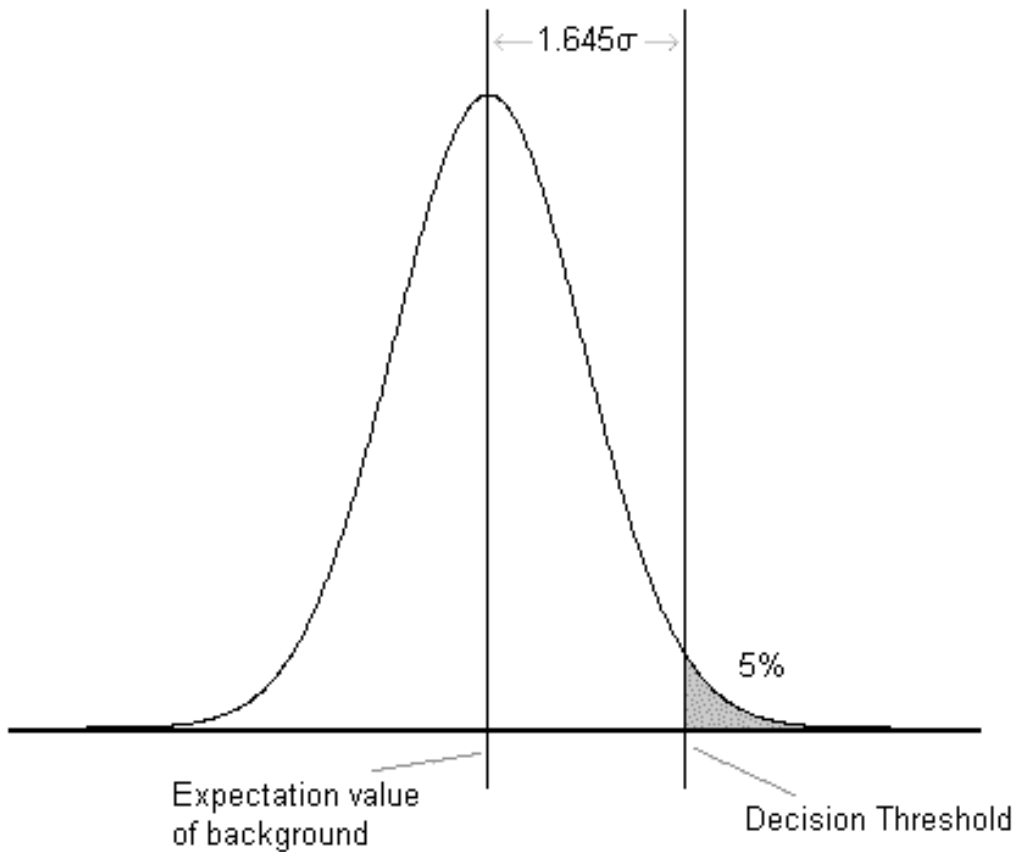
decision threshold: fixed value of the decision quantity by which, when exceeded by the result of an actual measurement of a measurand quantifying a physical effect, one decides that the physical effect is present

NOTE

The decision threshold is the critical value of a statistical test to decide between the hypothesis that the physical effect is not present and the alternative hypothesis that it is present. When the critical value is exceeded by the result of an actual measurement, this is taken to indicate that the (null) hypothesis should be rejected. The statistical test will be designed such that the probability of wrongly rejecting the (null) hypothesis (error of the first kind) shall be at most equal to a value α .

BS ISO 11929-7:2005

[α is fixed prior to the measurement. The error of the first kind corresponds to the wrong decision that there is a sample contribution. Readings above the detection threshold are not considered part of the background distribution. A simple example is given below for a Gaussian distribution of background and $\alpha = 5\%$]



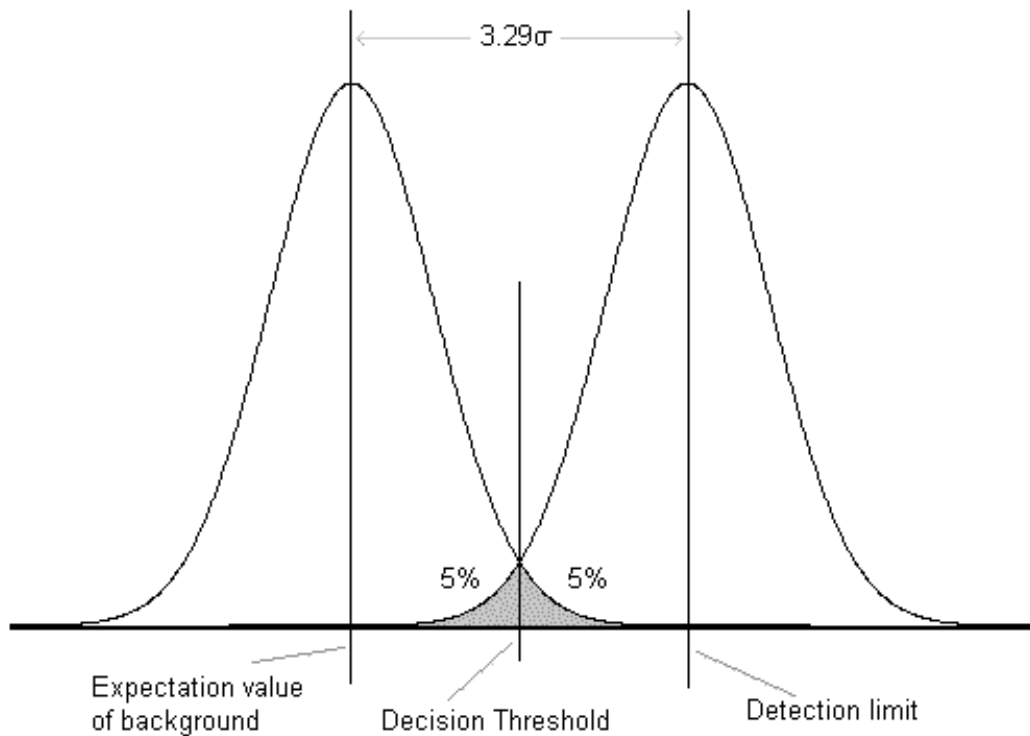
detection limit: smallest true value of the measurand which is detectable by the measuring method

NOTES

- 1 The detection limit is the smallest true value of the measurand which is associated with the statistical test and hypotheses according to the definition of decision threshold by the following characteristics: if in reality the true value is equal to or exceeds the detection limit, the probability of wrongly not rejecting the (null) hypothesis (error of the second kind) will at most be equal to a given value β .
- 2 The difference between using the decision threshold and using the detection limit is that measured values are to be compared with the decision threshold, whereas the detection limit is to be compared with the guideline value.

BS EN ISO/IEC 11929-7:2005

[The value β is fixed prior to the measurement, and corresponds to the wrong decision that there is not a sample contribution. The detection limit can be defined as the dose that is distinguishable from background with a stated probability, usually 95 or 97.5%. An simple example is given below with the background and measurand distributions of the same, Gaussian, form, and both α and $\beta = 5\%$].



expectation: (of a random variable or of a probability distribution); **expected value; mean:**

(1) For a discrete random variable X taking the values x_i with the probabilities p_i , the expectation, if it exists, is

$$\mu = E(X) = \sum p_i x_i$$

the sum being extended over all the values x_i which can be taken by X .

(2) For a continuous random variable X having the probability density function $f(x)$, the expectation, is

$$\mu_x = E(X) = \int x f(x) dx$$

the sum being extended over all the interval(s) of variation of X .

BS ISO 3534-1:1993; GUM 1995

measurand: particular quantity subject to measurement

NOTE

1 The specification of a measurand may require statements about quantities such as time, temperature and pressure.

BS/ISO 3534-1:1993; BS ISO 5725-1:1994; VIM1995; GUM 1995

Precision: the closeness of agreement between independent test results obtained under stipulated conditions.

NOTES

1 Precision depends only on the distribution of random errors and does not relate to the true value or the specified value.

2 The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.

3 “Independent test results” means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme stipulated conditions.

Precision is inverse of statistical uncertainty. It is a term needed because measurements made of presumably identical radiation fields do not yield identical results. The factors involved include (a) operator, (b) equipment used, (c) calibration of equipment, (d) environment, (e) elapsed time between measurements. Precision has two conditions – repeatability and reproducibility. Under repeatability conditions, factors such as (a) to (e) are considered to be constant and do not contribute to the variability of the measurement result. Repeatability and reproducibility are the two extremes of precision. Precision is normally expressed in terms of standard deviation.

BS/ISO 3534-1:1993; BS ISO 5725-1:1994

Repeatability (of results of measurements): closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement

NOTES

1 These conditions are called repeatability conditions.

2 Repeatability conditions include:

- the same measurement procedure
- the same observer
- the same measuring instrument, used under the same conditions
- the same location
- repetition over a short period of time.

3 Repeatability may be expressed quantitatively in terms of the dispersion characteristics of the results.

BS/ISO 3534-1:1993; BS ISO 5725-1:1994; VIM1995; GUM 1995

Reproducibility (of results of measurements): closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement

NOTES

1 A valid statement of reproducibility requires specification of the conditions changed.

2 The changed conditions may include:

- principle of measurement
- method of measurement
- observer
- measuring instrument
- reference standard
- location
- conditions of use
- time

3 Reproducibility may be expressed quantitatively in terms of the dispersion characteristics of the results.

4 Results are usually understood to be corrected results.

BS/ISO 3534-1:1993; BS ISO 5725-1:1994; VIM1995; GUM 1995

Specified requirement: need or expectation that is stated.

NOTES

1 Specified requirements may be stated in normative documents such as regulations, standards, and technical specifications.

BS EN ISO/IEC 17000:2004

Standard: document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context; NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

ISO/IEC Guide 2:1996

Standardization: activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context; NOTE 1 In particular, the activity consists of the processes of formulating, issuing and implementing standards; NOTE 2 Important benefits of standardization are improvement of the suitability of products and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation.

ISO/IEC Guide 2:1996

Trueness: the closeness of agreement between the average which would ensue from an infinite number of quantity values obtained under specified measurement conditions and the true value of the measurand.

NOTES

1 Trueness is usually expressed in terms of bias.

BS/ISO 3534-1:1993; BS/ISO 5275-1:1994; VIM draft revision

Uncertainty of measurement: parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

NOTES

1 The parameter may be, for example, a standard deviation (or a given multiple of it), or a half-width of an interval having a stated level of confidence.

2 Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

3 It is understood that the result of a measurement is the best estimate of the value of a measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

BS/ISO 3534-1:1993; VIM1995; GUM 1995

APPENDIX 2 INTERNATIONAL BODIES

(after Fantuzzi, references 67 & 68)

- *The International Commission on Radiological Protection (ICRP)*, founded in 1928, is an advisory body which according to its constitution, provides recommendations considering the fundamental principles and quantitative bases upon which appropriate radiation protection measures can be established, while leaving to the various national protection bodies the responsibility of formulating the specific advice, codes of practice, or regulations that are best suited to the needs of their individual countries. Although ICRP has no formal power to impose its proposals on anyone, in fact legislation in most countries adheres closely to ICRP recommendations.

- *The International Commission on Radiation Units and Measurements (ICRU)*, established in 1925, has its principal objective the development of internationally acceptable recommendations regarding: quantities and units of radiation and radioactivity. ICRU reports are helpful, practical, and authoritative recommendations on all types of radiation measurement problems in all applications (e.g. health and radiation physics and industry). ICRU utilizes the freely volunteered services of physicians, scientists and engineers who participate in its program through service on the Commission or on working groups engaged in the development of guidance and recommendation.

- *The International Organization for Standardization (ISO)* is a worldwide federation of national standardisation bodies from more than 140 countries, one from each country, ISO standards are developed according to three phases: the *agreement phase* on the need of a standard, the *consensus-building phase* adding detailed specifications and preparation of committee drafts (CD) and eventually the *approval phase* of the DIS (Draft International Standard) in compliance to strict approval criteria (i.e. two-thirds of participating ISO members and 75% voting members).

- *The International Electrotechnical Commission (IEC)* is the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies. The IEC members are National Committees for Standardization, whose delegates come from a large variety of institutions, i.e. manufacturers, providers, distributors and vendors, consumers and users, all levels of governmental agencies, professional societies and trade associations. Adoption of IEC standards for radiation protection by any country was entirely voluntary until 2002. Then, a task force (i.e. CLC/BTTF 111-3) was set out and according to its resolutions certain standards should become European Norms, which is then mandatory for all member states. In 2004 such a decision is in the final stage for the standards IEC!60846 and IEC!61005; for IEC!61526 the decision has passed the first stage.

- *International Atomic Energy Agency, IAEA*, can provide standards, guides or reports for IAEA Member States. The IAEA Occupational Protection Programme has the specific objective to promote and assist in establishing an internationally harmonised approach for optimising occupational radiation protection through developing safety standards. Guidance to IAEA Member States is provided through the hierarchical Safety Standards series: Fundamentals, Requirements and Guides. Moreover, IAEA policy for the implementation of standards is based also on additional publications (i.e. documents of relevance) like Safety Report Series, Technical Report Series and Technical documents (IAEA-TECDOCS). Publication of documents follows a procedure, the higher position in hierarchy the stricter the procedure is, except for the IAEA-TECDOCS which are not edited and might not conform to high quality standards of IAEA publications.

APPENDIX 3 STANDARDS AND DOCUMENTS OF RELEVANCE

3.1 ISO AND IEC STANDARDS FOR PERFORMANCE REQUIREMENTS (ACCURACY AND/OR ENERGY AND ANGLE DEPENDENCE OF RESPONSE) OF PERSONAL DOSEMETERS AND/OR DOSIMETRY SYSTEMS

((draft in blue) with comments as appropriate(in red))

ISO 1757:1996, *Personal photographic dosimeters*

ISO 12790-1:2001, *Radiation protection — Performance criteria for radiobioassay — Part 1: General principles*

ISO 12790-2:2003, *Radiation protection — Performance criteria for radiobioassay — Part 2: Rationale and specific applications*

BS ISO 12794:2000, *Nuclear energy — Radiation protection — Individual thermoluminescence dosimeters for extremities and eyes*

Revision requested.

Current version has requirements for energy dependence of response (photons and electrons) of $\pm 50\%$, plus angle dependence of response (photons only) of $\pm 15\%$, plus other requirements for influence quantities and batch homogeneity, reproducibility, linearity etc.

ISO 14146:2000, *Radiation protection — Criteria and performance limits for the periodic evaluation of processors of personal dosimeters for X and gamma radiation*

Revision requested.

Not accepted as BS. Gives overall performance requirements of 'trumpet curve' (German standard based on factor of 1.5 opening out to $\pm 100\%$ at low doses) for test radiation qualities and angles of incidence within stated ranges of dosimeter/dosimetry system, and the majority should be similar to workplace fields.

ISO/DIS 20553, *Radiation protection- Monitoring of workers occupationally exposed to internal contamination with radioactive material.*

Out for vote and comment. Many UK comments (q.v.).

ISO 21909:2005, *Radiation Protection-Passive personal neutron dosimeters-Performance and test requirements*

Previously many UK comments, but published in spite of these.

The scope of this standard is to provide performance and test requirements for determining the acceptability of personal dosimeters to be used for the measurement of personal dose equivalent $H_p(10)$ for neutrons ranging in energy from thermal to 20 MeV. There are separate performance requirements for different types of dosimeter- nuclear emulsion, etched track, thermoluminescent albedo, superheated emulsions (bubbles) and direct ion storage. Detailed specification of test to determine energy and angle dependence of response and effect of influence quantities. Could be basis for BS but only after revision.

IEC 61066 Ed. 2.0 2005, *Thermoluminescence dosimetry systems for personal and environmental monitoring* (see also first edition IEC 1066)

Published but a number of comments had still to be addressed.

Gives detailed performance tests on accuracy of complete system. Requirements for the energy and angle dependence of response are based on ICRP factor of 1.5 but note the requirement that reciprocal of relative response, rather than response, is required to be within $\pm 40\%$. Other additional criteria for tests of effects of influence quantities.

Subject to detailed revision, could form basis of BS.

IEC 61526 Ed.2 2005, $H_p(10)$ and $H_p(0.07)$ direct reading personal dose equivalent meters and monitors (see first edition:1998; also replaces IEC 61283:1995, IEC 61323:1995, IEC 61525:1996)

This is moving towards becoming a European (CENELEC) standard. IEC 61526 was not considered by BSI to be acceptable as a BS, but if it becomes a European standard it will automatically become a BS. Similar to 61066 in scope, but not always consistent.

IEC 61577-1 Ed 2.0, *Radiation protection instrumentation- Radon and radon decay product measuring instruments- Part 1: general principles*

Out for vote.

IEC 61582 Ed. 1 2004, *Radiation protection instrumentation- in vivo counters : classification, general requirements and test procedures for portable, transportable and installed equipment*

IEC 62387 CD Ed 1.0, *Passive, non-thermoluminescence, dosimetry systems for personal and environmental monitoring.*

Recent committee draft- covers non-TL dosimeters, otherwise very similar to 61066. Detailed UK comments.

3.2 STANDARDS FOR CALIBRATION OF PERSONAL DOSEMETERS AND/OR DOSIMETRY SYSTEMS

((draft in blue) with comments as appropriate (in red))

BS ISO 4037-1:1996, *X and gamma reference radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of photon energy — Part 1: Radiation characteristics and production methods.*

BS ISO 4037-2:1997, *X and gamma reference radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of photon energy — Part 2: Dosimetry for radiation protection over the energy ranges 8 keV to 1,3 MeV and 4 to 9MeV*

BS ISO 4037-3:1999, *X and gamma reference radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of photon energy — Part 3: Calibration of area and personal dosimeters and the measurement of their response as a function of energy and angle of incidence*

To be revised- some initiatives from BSI NCE/02

BS ISO 4037-4:2004, *X and gamma reference radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of photon energy — Part 4: Calibration of area and personal dosimeters in low energy X reference radiation fields*

BS ISO 6980:1996, *Reference beta-particle radiation for calibrating dosimeters and dose rate meters and for determining their response as a function of beta-radiation energy*

ISO/DIS 6980-1, *Nuclear energy-Reference beta-particle radiation — Part 1: Production methods*

Out for vote

BS ISO 6980-2:2004, *Nuclear energy-Reference beta-particle radiation — Part 2: Calibration fundamentals of radiation protection devices related to the basic quantities characterizing the radiation field.*

ISO/DIS 6980-3, *Nuclear energy-Reference beta-particle radiation — Part 3: Calibration of area and personal dosimeters- and the determination of their response as a function of beta radiation energy and angle of incidence.*

Out for vote. Many UK comments. Not acceptable as BS as it stands.

BS ISO 8529-1:2001, *Reference neutron radiations — Part 1: Characteristics and methods of production*

BS ISO 8529-2:2000, *Reference neutron radiations — Part 2: Calibration fundamentals of radiation protection devices related to the basic quantities characterizing the radiation field*

Revision requested- needs to be updated, also some inconsistencies.

BS ISO 8529-3:2001, *Reference neutron radiations — Part 3: Calibration of area and personal dosimeters and determination of response as a function of energy and angle of incidence*

Revision requested

BS ISO 12789: 2000, *Reference Neutron Radiations: Characteristics and Methods of Production of Simulated Workplace Neutron Fields*

Revision requested (to become 12789-1)- needs to be updated and made consistent with 12789-2 and 8529 series.

ISO/DIS 12789-2 *Reference Neutron Radiations radiations — Part 2: Calibration fundamentals related to the basic quantities characterizing simulated workplace neutron fields.*

Out for vote.

IEC 61577-4 Ed 1.0, *Radiation protection instrumentation- Radon and radon decay product measuring instruments- Part 4: equipment for the production of reference atmospheres containing radon isotopes and their decay products (STAR)*

This is a committee draft circulated for comment. Many comments.

3.3 OTHER RELEVANT STANDARDS

BS ISO:1993, VIM — *International Vocabulary of Basic and General Terms in Metrology.*

Revision is in draft

BS ISO:1995 GUM — *Guide to the Expression of Uncertainty in Measurement*

BS ISO GUM Suppl.1 (DGUIDE 99998) — *Guide to the Expression of Uncertainty in Measurement(GUM)—Supplement !: Numerical methods for the propagation of distributions*

BS ISO 31-10:1992, *Quantities and units — Part 10: Nuclear reactions and ionizing radiations*

BS ISO 1000:1992, *Specification for SI units and recommendations for the use of their multiples and of certain other units*

ISO 3534-1:1993, *Statistics—Vocabulary and symbols—Part 1: Probability and general statistical terms*

Definitions of all the important statistics terms, but note some are modified in later standards such as the VIM and the GUM.

BS ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results- Part 1: General principles and definitions.*

BS ISO 5725-2:1994, *Accuracy (trueness and precision) of measurement methods and results- Part 2: Basic methods for the determination of repeatability and reproducibility of a standard measurement method.*

BS ISO 5725-4:1994, *Accuracy (trueness and precision) of measurement methods and results- Part 4: Basic methods for the determination of the trueness of a standard measurement method.*

BS ISO 5725-6:1994, *Accuracy (trueness and precision) of measurement methods and results- Part 6: Use in practice of accuracy values.*

BS ISO 11929-1:2000, *Determination of the detection limit and decision threshold for ionizing radiation measurements -- Part 1: Fundamentals and application to counting measurements without the influence of sample treatment*

BS ISO 11929-2:2000, *Determination of the detection limit and decision threshold for ionizing radiation measurements -- Part 2: Fundamentals and application to counting measurements with the influence of sample treatment*

BS ISO 11929-3:2000, *Determination of the detection limit and decision threshold for ionizing radiation measurements -- Part 3: Fundamentals and application to counting measurements by high resolution gamma spectrometry, without the influence of sample treatment*

BS ISO 11929-5, *Determination of the detection limit and decision threshold for ionizing radiation measurements – Part 5: Fundamentals and application to measurements of filters during the accumulation of radioactive material.*

ISO/FDIS 11929-7, *Determination of the detection limit and decision threshold for ionizing radiation measurements -- Part 7: Fundamentals and general applications*

ISO/FDIS 11929-8, *Determination of the detection limit and decision threshold for ionizing radiation measurements -- Part 8: Fundamentals and application to the unfolding of spectrometric measurements without the influence of sample treatment*

BS ISO 9000:2000, *Quality management systems – fundamentals and vocabulary, international organization for standardization*

BS ISO 9001:2000, *Quality management systems – requirements.*

BS ISO 9002:2000, *Quality systems – model for quality assurance in production installation and servicing.*

BS ISO 9004:2000, *Quality systems – guidelines for performance improvement.*

ISO 9001 [13] and ISO 9004 [G20] form a consistent pair of standards on quality management. ISO 9001 addresses the quality assurance of the product, and is the standard against which organisations can be accredited. ISO 9004 consists of guidance and recommendations, and is not intended for accreditation purposes. It uses a broader perspective of quality management to give guidance on performance improvement, and considers the effectiveness and efficiency of a quality management system and the performance of the organisation as a whole

The two standards cover the following topics:

- The Quality Management System (principles, managing systems, documentation (including statements of policy, objectives, the quality manual, etc.) and document control)
- Management Responsibility (establishing: communication, quality policy, quality objectives, management reviews, availability of resources; needs and expectations of the

customer and other interested parties; quality planning; definition by management of responsibility and authority)

- Resource Management (people: competence, training; infrastructure; work environment; information; suppliers and partnerships; natural resources; financial resources)
- Product Realisation (managing processes; process inputs, outputs, review; verification, validation; monitoring, inspection, testing, records; customer information (eg market research, contract requirements; benchmarking, statutory requirements); design and development planning, processes (input and output), review; verification (ie does the product do what was intended?), validation (does the product meet the requirements of the intended use?); purchasing; production and service operations; control of measuring and monitoring devices)
- Measurement, Analysis and Improvement (measurement of performance; internal audit; measurement and monitoring of processes and product; customer satisfaction; control of non-conformity; improvement and corrective action)
- Guidelines for Self Assessment

BS ISO International Guide 25:1990, *General requirements for the competence of testing and calibration and testing laboratories.*

BS EN ISO/IEC 17000:2004, *Conformity assessment- Vocabulary and general principles.*

BS EN ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories.*

ADD NOTES

ISO 17025 gives all the requirements that testing and calibration laboratories must meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results. It is intended for use by accreditation bodies for testing and calibration services. In practice, "testing and calibration" may be considered to cover the measurement aspect of the work carried out by dosimetry services. Any laboratory meeting the requirements of ISO 17025 also meets the requirements of ISO 9001, by definition. Topics covered under the heading of Management Requirements include: responsibilities of, and requirements on, the organisation; the need for a quality system; document control; review of tenders and contracts; sub-contracting; purchase of supplies and services; service to the client; complaints procedures; control of non-conforming work; corrective action after non-conforming work is identified; preventive action to avoid non-conformances; control of records; internal audits; and management reviews. Topics covered under the heading of Technical Requirements include: competence of personnel; requirements on accommodation and the laboratory environment; measurement methods and method validation; requirements on equipment; measurement traceability; sampling plans, procedures and sample handling; quality control procedures; and reporting of results.

BS ISO 10012:2003, *Measurement management systems – requirements for measurements processes and measuring equipment.*

3.4 RELEVANT ICRU REPORTS

ICRU Report 39:1985, *Determination of Dose Equivalents Resulting from External Radiation Sources*

ICRU Report 43:1988, *Determination of Dose Equivalents Resulting from External Radiation Sources*

ICRU Report 47:1992, *Measurements of Dose Equivalents from External Photon and Electron Radiations- Part 2*

(which states, *inter alia*, that instrumental errors will not be the major component of the overall uncertainty in practical radiation protection measurements, and a total uncertainty in the measurement of the operational quantity of one standard deviation of 30% should be acceptable)

ICRU Report 51:1993, *Quantities and Units in Radiation Protection Dosimetry*

ICRU Report 56:1997, *Dosimetry of External Beta Rays for Radiation Protection*

ICRU Report 57:1997, *Conversion Coefficients for Use in Radiological Protection against External Radiation*

ICRU Report 60:1998, *Fundamental Quantities and Units for Ionizing Radiation*

ICRU Report 66:2001, *Determination of Operational Dose Equivalent Quantities for Neutrons*

ICRU Report 69:2003, *Direct Determination of the Body Content of Radionuclides*

[ICRU Report \(draft\) *Measurement Quality Assurance in Ionizing Radiation Dosimetry*](#)

3.5 RELEVANT ICRP PUBLICATIONS

ICRP Publication 65, *Protection Against Rn-222 at home and at work* (Oxford:Pergamon Press) (1994).

ICRP Publication 66, *Human Respiratory Tract Model for Radiological Protection*, (Oxford:Pergamon Press) 1994).

ICRP Publication 67, *Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 2* (Oxford:Pergamon Press) (1994).

ICRP Publication 68, *Dose Coefficients for Intakes of Radionuclides by Workers Replacement of ICRP Publication 61*, (Oxford:Pergamon Press) 1994).

ICRP Publication 69, *Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 3*, (Oxford:Pergamon Press) (1995).

ICRP Publication 70, *Basic Anatomical and Physiological Data for Use in Radiological Protection: the Skeleton*, (Oxford:Pergamon Press) (1995).

ICRP Publication 71, *Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 4. Inhalation Dose Coefficients* (Oxford:Pergamon Press) (1996).

ICRP Publication 72, *Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 5. Compilation of Ingestion and Inhalation Dose Coefficients*. (Oxford:Pergamon Press) (1996).

ICRP Publication 74, *Coefficients for Use in Radiological Protection against External Radiation*, (Oxford:Pergamon Press) (1996)

ICRP Publication 75, *General Principles for the Radiation Protection of Workers*. (Oxford:Pergamon Press) (1997)

ICRP Publication 78, *Individual Monitoring for Internal Exposures of Workers*. (Replacement of ICRP Publication 54), (Oxford:Pergamon Press) (1998)

ICRP Publication 89, *Basic Anatomical and Physiological Data for Use in Radiological Protection: Reference values*. (2003)

3.6 RELEVANT IAEA DOCUMENTS

SS-114 IAEA *Direct Methods for Measuring Radionuclides in the human body*; (1996).

SRS-18 IAEA Safety Reports Series No. 18, *Indirect Methods for Assessing Intakes of Radionuclides Causing Occupational Exposure*, 2000.

TECDOC-1334 IAEA-TECDOC-1334 *Intercalibration of in vivo counting systems using an Asian phantom*, (2003).

ISRS Draft IAEA Safety Reports Series, *Methods for Assessing Occupational Radiation Doses due to Intakes of Radionuclides* DRAFT Version (October 2003).

SS-50 IAEA, *Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations*, Safety Series No. 50-C/SG-Q, IAEA, Vienna (1996).

SRS -16 IAEA Safety Report Series n° 16, *Calibration of Radiation Protection Monitoring Instruments*, (2000).

SS – 120 IAEA Safety Series n° 120 *Radiation Protection and the Safety of Radiation Sources*; (1996).

SRS -5 IAEA, ILO, WHO, Safety Reports Series No.5, *Health Surveillance of Persons Occupationally Exposed to Ionizing Radiation: Guidance for Occupational Physicians*, (1998).

SRS -18 IAEA, *Indirect methods for assessing intakes of radionuclides causing occupational exposure*, *Safety Report Series No.18*,(2000).

SR –Draft IAEA, *Safety Report on Assessment of radiation doses from intakes of radionuclides by workers*, Safety Report (in preparation); (2003).

Working Material IAEA, *Quality Management Systems for Technical Services in Radiation Safety*, Vienna (2003).

3.7 OTHER RELEVANT INTERNATIONAL DOCUMENTS

EUR 73 European Commission: *Technical recommendations for monitoring individuals occupationally exposed to external radiation*. EUR 14852 EN, (1994).

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[ANSI/HPS N13.30 Performance criteria for radiobioassay](#). American National Standards Institute and Health Physics Society (1996).

[ANSI/HPS N13.42 Internal dosimetry for mixed fission activation products](#). American National Standards Institute and Health Physics Society (1997).

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