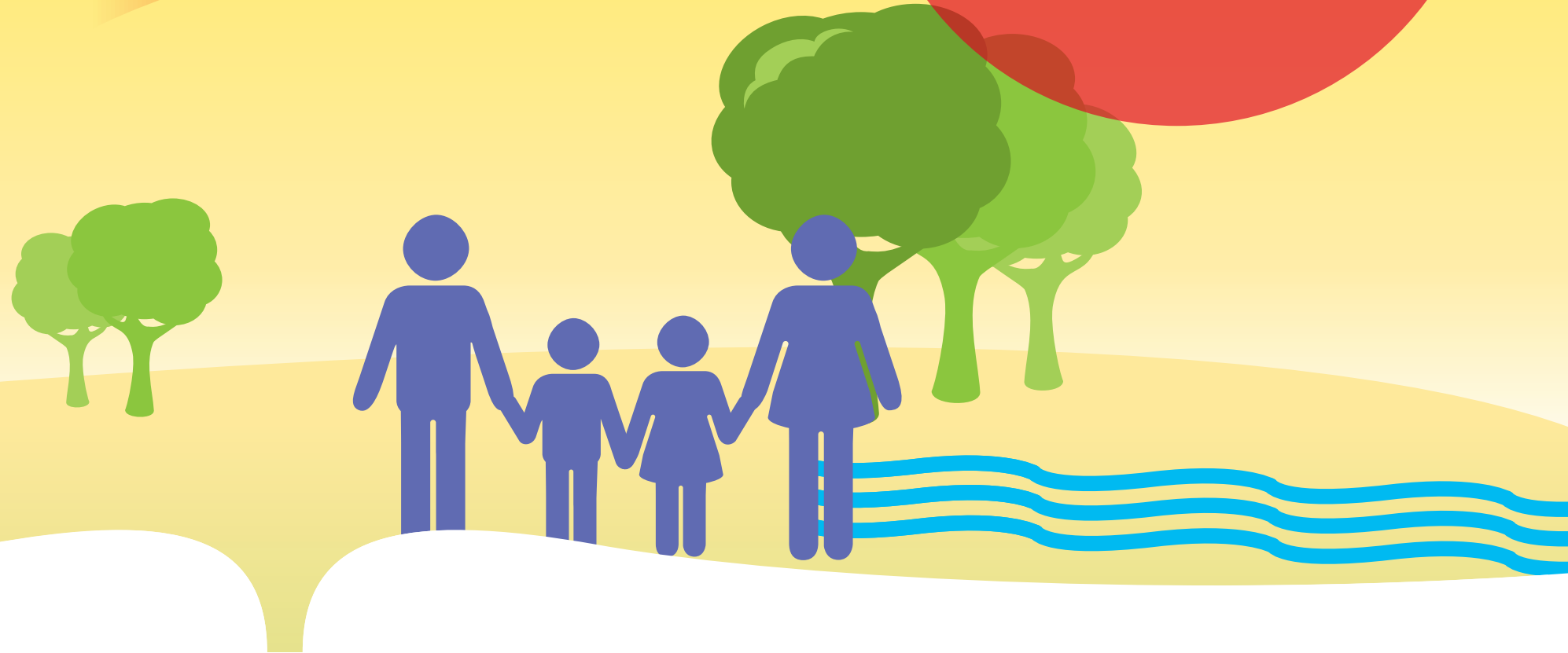




Radiation Protection



● NO 160 — TECHNICAL RECOMMENDATIONS FOR MONITORING INDIVIDUALS OCCUPATIONALLY EXPOSED TO EXTERNAL RADIATION

EUROPEAN COMMISSION

RADIATION PROTECTION NO 160

Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation

Final Report of Contract TREN/07/NUCL/S07.70121

Directorate-General for Energy and Transport
Directorate H — Nuclear Energy
Unit H.4 — Radiation Protection
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The experts having authored this report on behalf of the consortium are:

João Garcia-Alves, ITN (Portugal)
Peter Ambrosi, PTB (Germany)
David Bartlett (UK)
Lorraine Currivan, RPII (Ireland)
Janwillem van Dijk, NRG (the Netherlands)
Elena Fantuzzi, ENEA (Italy)
Vasiliki Kamenopoulou, GAEC (Greece)

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FOREWORD

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Under the terms of the Treaty establishing the European Atomic Energy Community, the Community, amongst other things, establishes uniform safety standards to protect the health of workers and of the general public against the dangers arising from ionizing radiation. The standards are approved by the Council, on a proposal from the Commission, established taking into account the opinion of the Group of Experts referred to in Article 31 of the Treaty. The most recent version of such standards is contained in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

Directive 96/29/Euratom introduces, *inter alia*, principles for the operational protection of workers exposed to ionising radiation, including requirements for the monitoring of individuals exposed to external radiation. The Directive and its requirements have been implemented in all Member States with variations. With the objective to harmonise the technical implementation of these requirements, the Commission provided already in 1975 guidance on individual monitoring of external radiation. The most recent *Technical recommendations for monitoring individuals occupationally exposed to external radiation* were published by the Commission in 1994, as RP 73. The 1994 recommendations were drafted under contract and published after detailed consideration by the Article 31 Group of Experts.

In 2007, the Commission decided to award a contract to update the 1994 recommendations and to prepare new draft technical recommendations for consideration by the Article 31 Group of Experts and by the Commission.

The 2009 *Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation* were drafted under contract and subsequently discussed with various stakeholders. The draft document has been presented to the Article 31 Group of Experts for discussion and approval at their meeting of 9 – 11 June 2009. The Article 31 Group of Experts endorsed the document and recommended it for publication by the Commission.

Augustin Janssens
Head of Radiation Protection Unit

CONTENTS

FOREWORD	3
CONTENTS	5
ABBREVIATION LIST	7
1 PURPOSE AND SCOPE	9
1.1 Purpose	9
1.2 Context	9
1.3 Background.....	11
1.4 Scope	12
1.5 Guide to the document	14
2 FRAMEWORK FOR INDIVIDUAL MONITORING	17
2.1 Introduction.....	17
2.2 Recommendations	18
2.3 Terms	18
2.4 Framework outline.....	19
2.5 Status of individual monitoring in the EU.....	20
2.6 Legislation.....	21
2.7 Standards	22
3 DOSIMETRY CONCEPTS, PROTECTION AND OPERATIONAL QUANTITIES; DETERMINATION OF THE OPERATIONAL QUANTITIES EXPOSURE	25
3.1 Introduction.....	25
3.2 Recommendations	25
3.3 Terms	26
3.4 Dosimetry concepts	27
3.5 Relationships of the protection and operational quantities	29
3.6 Estimation of effective dose and equivalent dose.....	31
3.7 Determination of operational quantities using personal dosimeters	32
4 INDIVIDUAL MONITORING PROCEDURES	35
4.1 Introduction.....	35
4.2 Recommendations for a monitoring programme.....	36
4.3 Terms	38
4.4 Dosimeter requirements and choice of personal dosimeter	39
4.5 Active personal dosimeters	41
4.6 Use of algorithms	41
4.7 Characteristics of workplace fields	42
4.8 Individual monitoring based on workplace monitoring	46
5 ASSESSMENT OF UNCERTAINTIES	49
5.1 Introduction.....	49
5.2 Recommendations	50
5.3 Terms	51
5.4 Measurement model.....	52
5.5 Formulation stage of uncertainty evaluation	52
5.6 Calculation stage of uncertainty evaluation	53
5.7 Thresholds	56
5.8 How realistic is the uncertainty evaluation?	58
5.9 Appraisal of uncertainty evaluation	60
5.10 Reporting of uncertainties.....	60
5.11 An example	60

6	REQUIREMENTS FOR ACCURACY OF DOSE ASSESSMENTS	67
6.1	Introduction.....	67
6.2	Recommendations	68
6.3	Terms	68
6.4	Factors affecting the accuracy of a dose assessment.....	69
6.5	Accuracy of a real measurement.....	70
6.6	Workplace field specific correction factors.....	71
6.7	Background subtraction.....	73
7	CALIBRATION AND TYPE TESTING.....	77
7.1	Introduction.....	77
7.2	Recommendations	77
7.3	Terms	78
7.4	Type testing	80
7.5	Software	81
7.6	Determination of the reference calibration factor N_{ref}	82
7.7	Determination of the individual normalization factor n_i	84
7.8	Other Considerations.....	84
7.9	Use of personal dosimeter as area monitors	85
8	GENERAL CRITERIA FOR APPROVAL OF DOSIMETRY SERVICES.....	87
8.1	Introduction.....	87
8.2	Recommendations for requirements for approval.....	87
8.3	Terms	88
8.4	The approval process	90
8.5	Performance testing.....	90
8.6	Participation in national/international intercomparisons.....	92
9	DOSE REPORTING, RECORD KEEPING AND INFORMATION SYSTEMS	93
9.1	Introduction.....	93
9.2	Recommendations	94
9.3	Terms	94
9.4	Main partners in dose record keeping and the transfer of data	97
9.5	Dose assessment and dose reporting	101
9.6	Dose information systems	103
9.7	NDR links to other data sources and databases.....	104
10	RELIABILITY OF DOSE ASSESSMENT, QUALITY ASSURANCE AND QUALITY CONTROL	107
10.1	Introduction.....	107
10.2	Recommendations	107
10.3	Terms	108
10.4	Implementation of a QA/QC Management System.....	108
10.5	Managing Technical Aspects of a QMS	112
11	BASIS FOR PROCEDURES AND CRITERIA FOR MUTUAL RECOGNITION OF APPROVED DOSIMETRY SERVICES IN EUROPE.....	117
11.1	Introduction.....	117
11.2	Criteria for the harmonization of approval procedures.....	118
11.3	Further considerations of harmonization of approval procedures.....	119
	REFERENCES	121

ABBREVIATION LIST

ADS	Approved Dosimetry Service
AOHS	Approved Occupational Health Service
AP	Antero-Posterior
APD	Active personal dosimeter
BSS	Basic Safety Standards [EU 1996a, IAEA 1996]
CENELEC	European Committee for Electrotechnical Standardization
CLT	Central Limit Theorem
CONRAD	Coordinated Network for Radiation Dosimetry (http://www.eurados.org)
D_{air}	Absorbed dose in air (Gy)
DG TREN	European Commission Directorate General Transport and Energy (http://ec.europa.eu/dgs/energy_transport/)
DIS	Direct Ion Storage dosimeter
D_{T}	Absorbed dose in tissue (Gy)
E	Effective dose (Sv)
EA	European co-operation for Accreditation
EC	European Commission (http://ec.europa.eu/)
EN	European Norm (http://www.cen.eu/)
ESOREX	European Study on Occupational Radiation Exposure
EU	European Union (http://europa.eu/)
EURADOS	European Radiation Dosimetry group (http://www.eurados.org/)
EURADOS WG2	EURADOS Working group on Harmonization of Individual Monitoring in Europe (http://www.eurados.org/)
EURATOM	European Atomic Energy Community (http://ec.europa.eu/euratom/)
EU-Trimer	European Technical Recommendations for Individual Monitoring of External Radiation
EVIDOS	Evaluation of individual dosimetry in mixed neutron and photon radiation fields (http://www.eurados.org)
eV	Electron volt ($1 \text{ eV} = 1.60217646 \times 10^{-19} \text{ joule}$)
GUM	Guide to the expression of Uncertainty in Measurement [JCGM 100] (http://www.bipm.org/utis/common/documents/jcgm/JCGM_100_2008_E.pdf)
GUMF	GUM Framework
Gy	Gray, SI unit of dose (joule per kilogram, J.kg^{-1})
$H'(d)$	Directional dose equivalent at a depth of d mm in tissue (Sv)
$H(d)$	Ambient dose equivalent at a depth of d mm in tissue (Sv)
$H_p(d)$	Personal dose equivalent at a depth of d mm in tissue (Sv)
HPS	Health Physics Society (http://www.hps.org/)
HSE	UK's Health and Safety Executive (http://www.hse.gov.uk/)
H_{T}	Tissue equivalent dose (Sv)
IAEA	International Atomic Energy Agency (http://www.iaea.org/)
ICRP	International Commission on Radiological Protection (http://www.icrp.org/)
ICRU	International Commission on Radiation Units and Measurements (http://www.icru.org/)
IEC	International Electrotechnical Commission (http://www.iec.ch/)
IMS	Individual Monitoring Service
ISO	Iso-directional
ISO	International Organization for Standardization (http://www.iso.org/)
ISOE	Information System on Occupational Exposure (http://www.isoe-network.net/)
JCGM	Joint Committee for Guides in Metrology (http://www.bipm.org/en/committees/jc/jcgm/)

K_{air}	Kerma in air (Gy)
keV	kilo electron volt (1 keV = 10^3 eV)
K_{T}	Kerma in tissue (Gy)
LET	Linear Energy Transfer (keV/ μm)
LLAT	Left Lateral
LPU	Law of Propagation of Uncertainty
MCM	Monte Carlo Method
MeV	mega electron volt (1 MeV = 10^6 eV)
NCRP	National Council on Radiation Protection and Measurement (http://www.ncrponline.org/)
NDR	National Dose Register
NIST	National Institute of Standards and Technology (http://www.nist.gov/)
NMI	National Metrology Institute
NPL	National Physical Laboratory (http://www.npl.co.uk/)
NSO	National Standardization Organization
ORAMED	Optimization of RAdiation protection for MEDical staff (http://www.oramed-fp7.eu/)
OSL	Optically Stimulated Luminescence
OWD	Outside Workers Directive [EU 1990]
PA	Postero-Anterior
PDF	Probability Density Function
PMMA	Polymethylmethacrylate
PTB	Physikalisch-Technische Bundesanstalt (http://www.ptb.de)
$Q(L)$	Quality factor defined as a function of LET, L
QA	Quality assurance
QC	Quality control
QMS	Quality Management System
RBE	Radiobiological Effectiveness
RLAT	Right Lateral
ROT	Rotational
RPE	Radiation Protection Expert
RPL	Radiophotoluminescence
SI	International System of units or Système International d'unités (http://www.bipm.org/en/si/si_brochure/general.html)
SSDL	Secondary Standard Dosimetry Laboratory
SSK	Strahlenschutzkommission (http://www.ssk.de/)
Sv	Sievert, SI unit of dose equivalent ($\text{J}\cdot\text{kg}^{-1}$ with the special name sievert)
TLD	Thermoluminescence Dosimeter
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation (http://www.unscear.org/)
VIM	International Vocabulary of Basic and General Terms in Metrology [JCGM 200] (http://www.bipm.org/utls/common/documents/jcgm/JCGM_200_2008.pdf)
WELMEC	European Cooperation in Legal Metrology (http://www.welmec.org/)
w_{R}	Radiation weighting factor
w_{T}	Tissue weighting factor

1 PURPOSE AND SCOPE

1.1 Purpose

The purpose of the European Commission Technical Recommendations for Monitoring Individuals Occupationally Exposed to Radiation is to provide guidance on those aspects of the implementation of the European Union (EU) Parliament and Council Directives that are directly related to individual monitoring of external radiation, and to encourage harmonization thereof. The Technical Recommendations are primarily aimed at the management and staff of European individual monitoring services. It is considered that the text will also be useful for manufacturers, laboratories supplying type testing services, and for national approval authorities trying to harmonize approval procedures, and perhaps also for Government bodies to harmonize regulations and guidance. Finally other partners in the radiation protection dosimetry framework may find useful information and guidance in these recommendations.

The Technical Recommendations bring together requirements and guidance given in:

- EU Council Directive 96/29/Euratom Basic Safety Standards, hereafter referred to as BSS and EU Council Directive 90/641/Euratom Outside Workers Directive, hereafter referred to as OWD;
- publications on radiation protection of the International Commission on Radiological Protection (ICRP);
- the relevant reports of the International Commission on Radiation Units and Measurements (ICRU);
- various standards and guides on metrology and quality assurance;
- reports, technical documents and safety guides of the International Atomic Energy Agency (IAEA).

The Technical Recommendations aim to present good practice for individual monitoring that follows from these “top-level” documents as a comprehensive and consistent text including guidance and recommendations that will contribute to the harmonization of individual monitoring procedures in Member States.

1.2 Context

In the EU there are a number of Directives of the Council, and of the Parliament and Council, which deal with radiation protection and with other matters which are relevant to individual monitoring practices. The most important Directives relating to the routine monitoring of occupational exposure are the BSS and OWD. Directives have to be implemented in the laws of Member States, normally within 4 years of the enactment of the Directive. However there are differences among Member States in the amount of detail in primary legislation, and the balance of legislation and guidance.

It is obviously desirable, if not always necessary, to have a considerable degree of harmonization of practices in order to have similar standards of health and safety, as well as to facilitate the trade of goods and services. Under Article 33 of the Euratom Treaty, the EC can give recommendations on the provisions made by Member States to comply with the basic safety standards in this field and give recommendations for harmonization.

On matters of basic safety standards, the EC obtains the opinion of a Group of Experts (GoE) established under Article 31 of the Euratom Treaty. Based on this opinion, the Commission may propose new/modified legislation to the Council. The Council will receive guidance from its Atomic Question Group. The Article 31 group of experts prepare for the EC, from time to time, guidance documents and technical recommendations on matters of radiation protection practice.

In line with its aim of assisting in the harmonization of individual monitoring practices, the Technical Recommendations are based on internationally accepted standards and documents of relevance [Fantuzzi 2004, 2007]. Figure 1.1 illustrates the position of the documents and the source organizations within the content of the Technical Recommendations. QA is shown having a central position, with the legislative framework on the left-hand side and the technical documents and standards on the right. If there are matters for which there is no consensus in the supporting literature, and where choices have to be made, the recommendations follow the hierarchy depicted in this scheme.

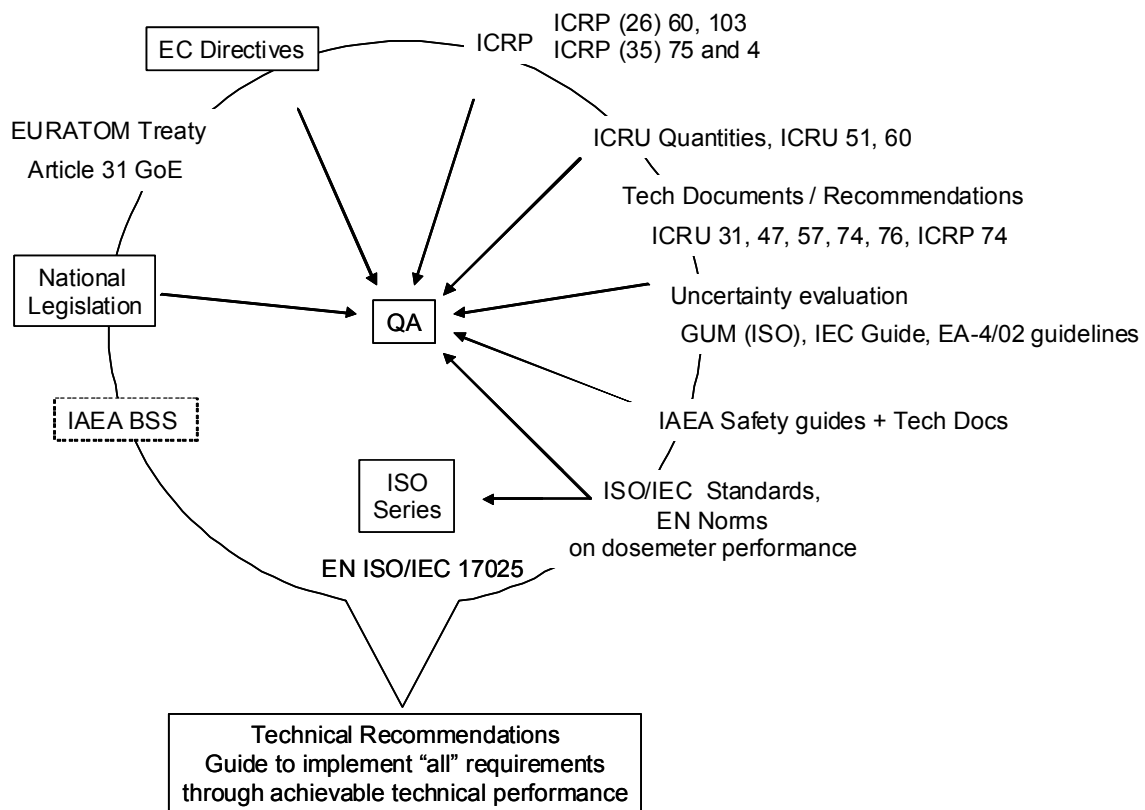


Figure 1.1: Context of European technical recommendations for monitoring individuals exposed to external radiation.

On the left-hand side the BSS and the International Atomic Energy Agency's (IAEA) basic safety standards are both included, as well as the recommendations from the Article 31 Group of Experts. The European Directives are on the higher level as they are legally binding within the EU and have been implemented by legislation at the national level. The IAEA's basic safety standards are included as it is essentially an equivalent document.

The right-hand side shows the main scientific and technical documents issued by the ICRP, ICRU, ISO, IEC, the European Norms (EN), the European co-operation for Accreditation (EA) as well as the IAEA's safety guides and documents. Most of these are listed in a EURADOS publication [Fantuzzi 2004]. The context also includes the knowledge base of the EURADOS Working Group2 on Harmonization in Individual Monitoring in Europe that published reports of studies that were partly funded by the EC [Eurados 2000, Eurados 2004].

Important issues such as measurement quantities and units, expression of uncertainty in measurement and in calibration, dosimeters and dosimetry system requirements, the individual monitoring programme, and their link to QA will be dealt with as shown in this scheme. National legislation in several Member State, and the IAEA's basic safety standards, require the implementation of a QA programme for approval of dosimetry services. The implementation of a quality system conforming to EN ISO/IEC17025:2005 standard [ISO 17025] is a way to demonstrate that the dosimetry service operates a quality system, is technically competent, and capable of generating technically valid results.

1.3 Background

Technical recommendations on individual monitoring of external radiation exposure have been given previously by the EC, the most recent in 1994 [EC 1975, EC 1994a]. The 1994 recommendations were drafted under contract, and published by the EC Directorate General for Environment, Nuclear Safety and Civil Protection and the Directorate General for Science, Research and Development, after detailed consideration by the Article 31 Group of Experts.

The 1994 recommendations replaced the 1975 recommendations at a time when final drafts of the 1990 Recommendations of the ICRP [ICRP 60] were circulating. However, the final versions of the basic safety standards laid down in the BSS were not available until several years later. Therefore, the introduction of the 1994 recommendations quite appropriately ended with the statement: 'These recommendations may have to be revised when the new CEC Directive is published'.

The publication of the BSS generalized the use of the operational quantities, personal dose equivalents $H_p(10)$, $H_p(3)$ and $H_p(0.07)$, ambient dose equivalent, $H^*(10)$ and directional dose equivalent $H'(0.07)$ within the EU. The BSS also emphasized the importance of quality assurance (QA) and quality control (QC) issues. At present, there is increasing pressure for accreditation/certification of dosimetry services, and in particular, demonstration of conformity with EN ISO/IEC 17025:2005 [ISO 17025]. Article 25.1 stipulates that 'Individual monitoring shall be systematic for exposed category A workers. This monitoring shall be based on individual measurements which are established by an approved dosimetric service. ...', but no information is given of preferred methods or approaches as to the procedures for approval.

In addition to the publication and implementation of the BSS, there are other reasons for considering a revision of the recommendations. These reasons include the publication of revised and new international standards in the field of metrology and dosimetry with specific requirements regarding accuracy, performance and the assessment of the uncertainty of measurement.

The 1994 Technical Recommendations, [EC1994a] were written mainly with passive dosimeters in mind, in particular whole body photon thermoluminescence dosimeters (TLD). Specific aspects of the use of passive dosimeters based on other techniques (film, OSL, glass, DIS[®], track etch), extremity dosimeters and dosimeters for measuring in neutron and beta fields were not addressed in detail, and active personal dosimeters were not addressed at all. Active personal dosimeters (APD) have traditionally been used in the context of operational radiation protection taking advantage of an immediate dose reading and an alarm at a pre-set dose and/or dose rate level. Active and passive dosimeters are now frequently used together, the former for its direct reading capability and the latter for regulatory exposure control. The use of APDs is evolving from being work control devices, to fulfilling all the legal aspects of individual monitoring. A number of Member States' authorities are currently preparing national requirements for the approval of personal dosimetry, reporting and recording systems based on these devices. In the UK, APDs are already in use as the dosimeters of record. Guidance to assist in extending the use of APDs is addressed in these Recommendations. The Technical Recommendations give guidance on operational dosimetry (BSS Article 6) as well as legal dosimetry (BSS Article 25).

1.4 Scope

The present Technical Recommendations cover the following topics:

- objectives and aims of individual monitoring for external radiation;
- dosimetry concepts;
- assessment of uncertainty;
- accuracy requirements;
- calibration, type-testing and performance testing;
- approval procedures;
- quality assurance and quality control;
- dose record keeping.

In addition, attention is paid to particular aspects, such as:

- wider energy ranges for the use of personal dosimeters, pulsed fields, and non charged particle equilibrium;
- the use of active personal dosimeters;
- data protection;
- the basis for procedures and criteria for mutual recognition within the EU of approved dosimetry services.

The last point is very important. At present there is a growing need for strengthening harmonization of practices in individual monitoring in Europe, moving in the direction of the mutual recognition of dose assessments performed by approved dosimetry services (ADS). As a consequence of the free movement of workers, different dosimetry services from different Member States may enter dose data into radiation passbooks. This is of concern with regard to entries in the national dose registers of a Member State, because the measured and possibly evaluated dose values may have been submitted by services which are not approved by the authority in that Member State. Different conditions imposed by the authorities for a number of procedures, for example background subtraction, recording levels, and notional doses can have an impact on occupational exposure studies, such as the European Study on Occupational Radiation Exposure (ESOREX). The present Technical Recommendations will contribute to more consistent presentation of data.

Following the publication in 2007 of the ICRP recommendations [ICRP 103], the EC is discussing what changes to the BSS may be necessary and advice concerning these changes is included. It is envisaged that the revised BSS will combine the content of the current BSS [EU 1996a] and with that of the OWD [EU 1990], and that of the directives on medical exposure [EU 1997], high activity sealed sources [EU 2003] and information to the public [EU 1989].

The following issues are not included:

- requirements for emergency response dosimeters (the recommendations refer to normal situations);
- criticality dosimetry;
- retrospective dosimetry;
- radon and cosmic radiation exposure of aircraft crew (but see section 9.4.6.3);
- detailed considerations of the Outside Workers Directive (but see section 9.4.6.5 on passbooks).

It is of particular concern that the recommended procedures for the assessment of measurement uncertainty have proved confusing for many users. Therefore, care has been taken so that this is addressed in a clear way. The procedures to derive estimates of the measurement uncertainty, overall accuracy criteria, and the basis for acceptable uncertainties and characteristic limits will be addressed in detail. The methods recommended follow the guidance of the Joint Committee for Guides on Metrology (JCGM), which has produced the Guide to the Expression of Uncertainty in Measurement (GUM) [ISO GUM; JCGM 100], and the International Vocabulary of Basic and General Terms in Metrology (VIM) [ISO VIM, JCGM 200]. It is noted that Clause 0.4 of the GUM emphasizes the need for uncertainty estimates to provide a coverage interval or level of confidence that corresponds in a realistic way with that required, where in this context realistic means realistic for radiation protection purposes. These Technical Recommendations use the overall accuracy criteria of ICRP and ICRU as the basis, and take into account the guidance of the European cooperation for Accreditation (EA), the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). The accuracy criteria are applied to the range of doses and radiation fields in which a dosimetry system is to be used. There is guidance on type testing requirements and on routine calibrations and in-house performance tests, with recommendations on participating in periodic international intercomparisons. Details are given of approval procedures and of quality management systems.

Although the objectives and fundamental principles of dose record keeping have not changed much over the years, huge developments in information technology, such as easy access to storage media and wider Internet use, have had an impact on dose record, dose data transfer and dose record keeping. The application of EN ISO/IEC 17025:2005 [ISO 17025] on dose registration (for example, archiving of measurement results and traceability) as well as the implications of the EU Directive 95/46/EC [EU 1995] on data protection, is addressed.

Other specific changes/updates include state of the art knowledge on the application of dosimetry, protection and operational quantities in agreement with ICRU and ICRP recommendations and with international standards, and guidance on the following: (i) monitoring procedures in line with the recommendations of ICRP, on the use of workplace monitoring information in order to better estimate E from the measured $H_p(10)$ value; (ii) the use of extremity dosimeters and whole body dosimeters when protective equipment is worn; (iii) assessment of dose to the lens of the eye.

The authorities in the Member States set criteria on the technical performance of approved dosimetry systems. These criteria will in general be derived from those recommended by the ICRP and ICRU, and thus result in a reasonable degree of harmonization throughout the EU. However, their details, in particular when it comes down to exact values, might not always be the same and may vary in relevance from the radiation protection point of view.

Conformity with international standards may not be mandatory but is recommended as being desirable in general, whilst noting that technical standards are more likely to change than radiation protection criteria and guidance. Therefore the Technical Recommendations do not state precise numbers for technical requirements in some cases but refer to the appropriate standards.

Last, but not least, there is a growing need for improving the harmonization of practices in individual monitoring across Europe. Given that there is no specific guidance on harmonized approval requirements of dosimetry services at the present time, the Technical Recommendations give proposals towards achieving this harmonization and the eventual mutual recognition of dose results.

1.5 Guide to the document

The Technical Recommendations can be considered to consist of three parts as shown in Figure 1.2:

- Fundamentals of individual monitoring and its place in radiation protection.
- Metrology of individual monitoring.
- Record keeping and reporting of dose data, quality assurance and control, accreditation and approval.

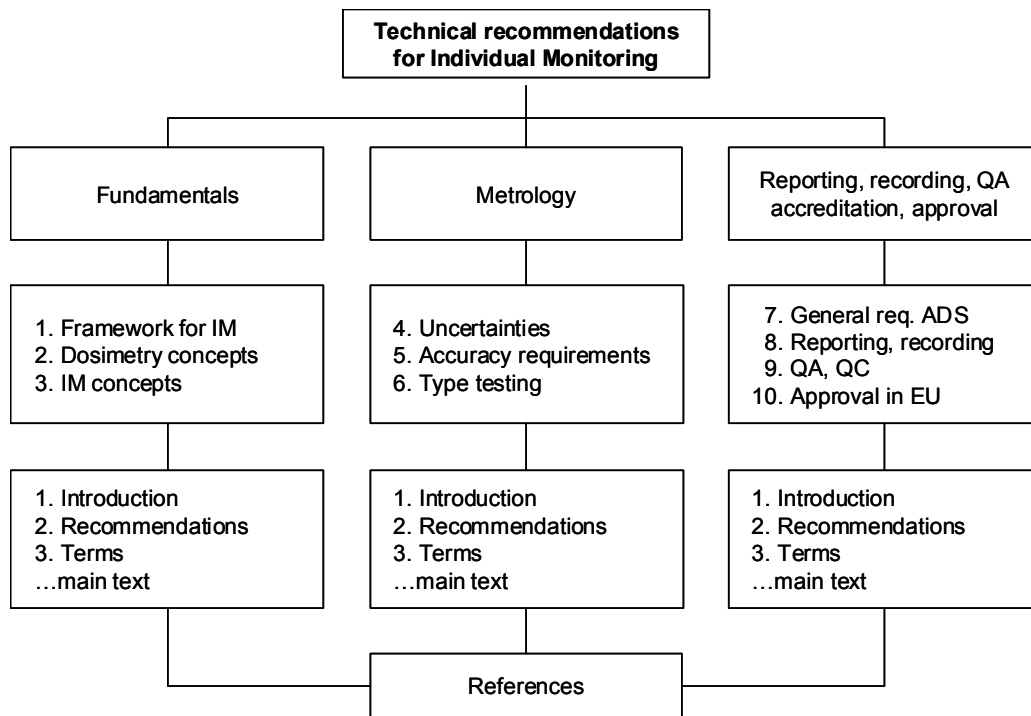


Figure 1.2: Schematic structure of the document.

Although the Technical Recommendations must be considered a single document, some care has been taken that chapters can to some extent stand on their own. A consequence of this is that some duplication could not be avoided. The chapters are sub-divided into sections of which in most chapters the first three are: 1) Introduction, 2) Recommendations and 3) Terms. The first two sections can more or less be considered a management summary of the chapter. In many cases dosimetry services will have commercially available measurement and data processing systems. In that case the more technical sections of the document will be of use in the appraisal by the services of the claims made by suppliers whereas the industry will need the full details for supplying equipment that conforms to these recommendations.

All references are at the end of the document in a separate chapter. References are indicated in the text between square brackets as [Name year] in case of publications in scientific journals and [Name serial number] in case of standards and reports. In the references list they appear in alphabetical order. Where there is open access to the full text of a document, a web link is given.

2 FRAMEWORK FOR INDIVIDUAL MONITORING

2.1 Introduction

The routine monitoring of the individual exposure of workers constitutes an integral part of any radiation protection programme within the overall scheme for practices as defined in the BSS, [EU 1996a] with prior authorization, and the application of the principles of justification, optimization and dose limitation. The fundamental principles for the operational protection of exposed workers, apprentices and students for practices are laid down in the BSS in Article 17.

These Recommendations are restricted, in the main to routine monitoring. Special monitoring, which is investigative in nature [ICRP 75], is not included. Accident dosimetry is covered in these recommendations in so far as dosimeters used for these purposes are issued by an approved dosimetry service (ADS) as part of a routine monitoring service. Emergency exposure and criticality dosimetry are not covered. Dosimeters issued by an individual monitoring service (IMS) may be used as part of a programme of workplace monitoring. If the results of this programme are applied as part of the assessment of doses to category A workers, the service must be an ADS.

Both the BSS and ICRP recommendations [ICRP 103] provide approaches to minimizing the risk of radiation work by setting out a system of dose limitation, dose constraints, and reference levels. The main principles are:

- Two source-related principles applicable in all exposure situations: **the principle of justification**: any decision that alters the radiation exposure situation should do more good than harm; **the principle of optimization of protection**: the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable (ALARA), taking into account economic and societal factors.
- One individual-related principle applicable in planned exposure situations: **the principle of application of dose limits**: The total dose to any individual from regulated sources in planned exposure situations should not exceed the appropriate limits recommended by the ICRP.

While dosimetry services in Europe do not comply with the same legal or approval requirements, a reasonable degree of harmonization exists in individual monitoring practice. This has been achieved thanks to technical recommendations of the EC, documents such as the recommendations of ICRP, reports of ICRU, and international and national standards. Harmonization has also resulted from the exchange of information through organizations such as EURADOS and the IAEA, and the use of international standards (IEC and ISO) though these are not mandatory.

Concepts and procedures for individual monitoring are considered in Chapter 4.

2.2 Recommendations

Individual monitoring of individuals occupationally exposed to external ionizing radiation should be carried out in order to:

- control occupational exposure and to ensure safe and satisfactory working conditions;
- demonstrate compliance with limits and the application of the principle of 'as low as reasonably achievable, economic and societal factors being taken into account' as part of legislative or regulatory systems;
- inform workers of their radiation exposure; where doses are low this may be for reassurance;
- the controls should be supported by analyses of dose distributions and trends amongst and within groups of workers.

Individual monitoring may also be carried out:

- for epidemiological investigations of effects of radiation, usually retrospective, as part of the surveillance of the operation of facilities;
- to demonstrate that radiation protection principles are being followed: frequently this may be a demonstration that doses are low;
- to safeguard the interests of both employees and employers in the event of compensation claim related to a potentially industrial-related disease.

2.3 Terms

The BSS defines the following terms (given in bold):

Undertaking (BSS): any natural or legal person who carries out the practice or work activities referred to in Article 2 of the BSS and who has legal responsibility under national law for such practices or work activities.

Exposed workers: persons, either self-employed or working for an employer, subject to an exposure incurred at work from practices covered by the BSS and liable to result in doses exceeding one or other of the dose levels equal to the dose limits for members of the public.

Categorization of exposed workers: for the purposes of monitoring and surveillance, a distinction shall be made between two categories of exposed workers: (a) **category A** : those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 3/10 of the dose limits for the lens of the eye, skin and extremities laid down in Article 9 (2); (b) **category B**: those exposed workers who are not classified as exposed category A workers. An **outside worker** is any worker of category A, performing activities of any sort in a controlled area, whether employed temporarily or permanently by an outside undertaking, including trainees, apprentices and students, or whether he provides services as a self-employed worker; The OWD requires Member States to ensure that these workers have the same level of protection as workers employed on a permanent basis by the undertaking.

Approved dosimetry service (ADS): a body responsible for the calibration, reading or interpretation of individual monitoring devices, and/or for the measurement of radioactivity in the human body or in biological samples, and/or for assessment of doses, whose capacity to act in this respect is recognized by the competent authorities. ‘Approved dosimetric service’ is used in the BSS, but ‘approved dosimetry service’ is preferred here. A distinction is made in these Recommendations between an ‘approved dosimetry service’ (ADS) and an ‘**individual monitoring service**’ (IMS) which provides personal dosimeters to users without being approved. In order to recognize the role of an IMS, it has to be considered within the framework of legislation and the network of bodies with whom it is related.

In accordance with the BSS, **individual monitoring** is the assessment of dose to an identified individual and is normally done by **individual measurements** by a device on a person, for which the term **personal dosimetry** is used in these recommendations. Individual monitoring may, in circumstances where measurements on a person are impossible or inadequate, be based on measurements made on other exposed workers or from the results of workplace monitoring and/or calculations.

2.4 Framework outline

A figure showing the major components of the framework for individual monitoring of radiation workers is given below.

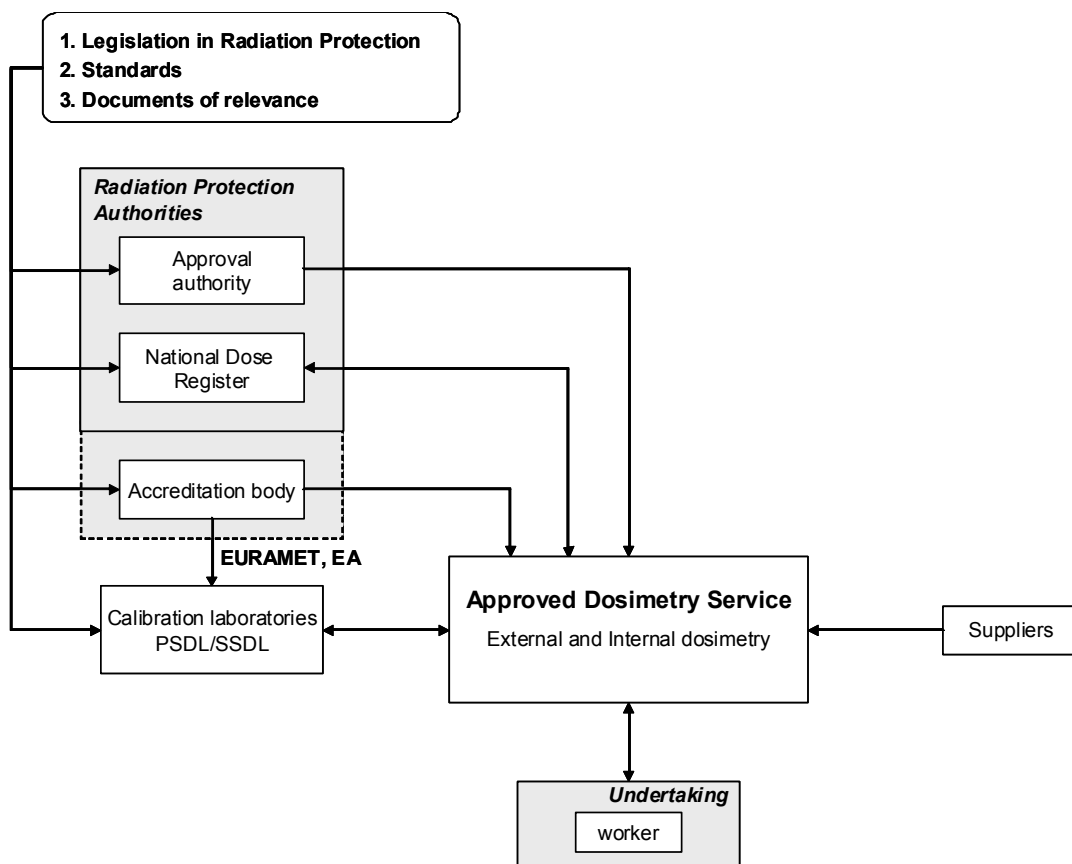


Figure 2.1: Approved Dosimetry Service framework. Adapted from [Fantuzzi 2004].

From the definition given in the BSS, it is normally understood that the purpose of an ADS is to make measurements and, in special cases to contribute to the evaluation of the results, with additional information provided by a customer or a third party. The making of measurements is normally understood to be by the provision of a suitable dosimetry system (see Chapters 3, 4 and 6), appropriately tested and calibrated (see Chapter 7), with quality assurance procedures (see Chapter 10), and approved (see Chapter 8). In all cases, everybody using the data provided by the service should be aware of the uncertainty of the data and/or that the validity of the data applies to specified circumstances (see Chapter 5).

Dosimetry services will interact with different bodies at different levels, for example suppliers and manufacturers, an accreditation body, an approval authority, a body or institution taking care of the national dose register, undertaking/customers both to supply dosimeters and dose reports and to exchange information. IMS and ADS can have different legislation and regulation frameworks in different Member States, for example, different statutory responsibilities. An IMS or ADS may or may not have the responsibility for dose validation after the evaluation of dose results, it could be allowed to correct dose results or not. It may or may not have responsibility for keeping dose records.

Generally, a dosimetry service, ADS or IMS, has the function of delivering the results of “dose measurements”, and any dose assessment or evaluation is the responsibility of the undertaking or of his/her radiation protection expert. This responsibility for dose evaluation is an important, but infrequently mentioned matter in radiation protection practice. In the case of external dosimetry, the person or body responsible for the evaluation and validation of dosimetry results has to get information from the user and not only from the dosimetry service. The service itself cannot validate a dose without information on the specific conditions of use of the dosimeters. If it is supposed to do so by providing, for example, the results to the national dose register, it is acting as a delegate on the basis of an official agreement with the undertaking who is legally responsible for the radiation protection of his/her exposed workers.

The results of individual monitoring may be used for initiating a certain action when a pre-defined dose level, an action or reference level, has been exceeded. The most common forms of action/reference levels of interest in radiation protection programmes are recording levels, reporting levels, investigation levels and intervention levels (see Chapter 9).

2.5 Status of individual monitoring in the EU

The most recent data on occupational radiation exposure in Europe have been collected by the ESOREX (European Study on Occupational Radiation EXposures) project, which was started in 1997 and financed by European Commission DG TREN. The main objectives of ESOREX were to collect information on how individual monitoring is structured in European Member States, how data are recorded and reported, and finally to collect comparable data on personal and collective doses from occupational exposure due to each sector. The project consisted of surveys on radiation monitoring and exposure carried out in 30 European states. It covered a ten-year time series of the calendar years 1995 to 2004. In the latest phase of the project, ESOREX 2005 (lasting from 2004 to 2007) the country reports were updated and dosimetric data for the period of the years 2001 – 2005 were collected.

The numbers of workers who are included in official dose monitoring differs considerably between the European Member States. Some focus only on workers of category A, other countries include also most of the category B workers. In fact, there are not original data available from all countries for all years, and the form of the available data from the different Member States is not still standardized. However data collected are of extreme interest and have allowed statistical evaluation of occupational radiation exposure in different work sectors. Moreover, analysis of different time series of data allowed the evaluation of changes and trends after the BSS implementation.

According to ESOREX data, in 2004 about 1.1 million workers were routinely issued with personal dosimeters in the EU, sub-divided as follows in specific sectors: almost 700 000 in the medicine sector; 115 000 in general industry sectors; 60 000 in the educational and research sector; 170 000 in nuclear sector; about 30 000 occupational exposures from natural sources (excluding aircraft crew). The collective dose has been estimated as 407 manSv with the average doses for workers 0.37 mSv, and 1.21 mSv for those workers with doses higher than 0 mSv.

In addition EURADOS Working Group 2 on “Harmonization of Individual Monitoring in Europe” partly funded by EC Directorate General Research and Development has collected information on IMS and on ADS in Member States. There are major differences between Member States in relation to number of services and approval processes. More detailed statistics are available in two EURADOS WG2 reports [Eurados 2000; Eurados 2004] and two Individual Monitoring Workshop Proceedings [Eurados 2001; Eurados 2007] published as special issues of Radiation Protection Dosimetry by Oxford University Press.

2.6 Legislation

European Union Parliament legislation is in the form of Directives and Regulations. European Directives require Member States to implement their provisions nationally for the benefit of Europe as a whole. Regulations directly implement EU policy in Member States without the need for Member States to enact their own legislation. Directives normally leave Member States with a certain amount of discretion as to the exact methods of implementation (see Chapter 11). As far as radiation protection is concerned, European Directives are issued under the Euratom Treaty [EU 1957]. Under the provisions of the Euratom Treaty, the European Commission acquired the status of a supranational regulatory authority in three areas: radiation protection, supply of nuclear fissile materials and nuclear safeguards. There are a number of Directives of the Council, and of the Parliament and the Council, which deal with radiation protection and with other matters which are relevant to radiation protection practices. The Directives relevant to the monitoring of occupational exposure are listed in Table 2.1.

Table 2.1: European legislative framework

Legislation	Subject	Main issues addressed
Council Directive 96/29/Euratom, 13 th May	Basic Safety Standards	Definitions, principles of justification, optimization and dose limitation, Titles V, VI and VII: Estimates of E and H_T , use of the operational quantities $H_p(d)$, $H^*(10)$ and $H'(0,07,\Omega)$, workers classified in Categories A and B, monitoring by ADS systematic for A, record results, report to worker, undertaking, authorities and Approved Occupational Health Service, as a brief summary.
Council Directive 90/641/Euratom, 4 th Dec.	Operational protection of outside workers exposed to the risk of ionizing radiation during activities in controlled areas	Free movement of workers, permanent and outside workers should receive the same level of protection, issue of radiation passbooks
European Parliament and Council Directive 95/46/EC, 24 th October	On the protection of individuals with regard to the processing of personal data and on the free movement of such data.	Privacy and protection of personal data
European Parliament and Council Directive 96/9/EC, 11 th March	On the legal protection of databases	Data bases
European Parliament and Council Directive 1999/93/EC, 13 th Dec.	Community framework for electronic signatures	Legal effects of electronic signatures
European Parliament and Council Directive 2002/58/EC, 12 th July	Concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)	Privacy and protection of personal data
European Parliament and Council Directive 2006/24/EC, 15 th March	Retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC	Protection of data generated or processed as a consequence of communication by e-mail and internet

2.7 Standards

2.7.1 Role of standards and harmonization

There are several types of publications available on individual monitoring for radiation protection purposes. In addition to European Directives and national legislation which set out

requirements for individual monitoring, there are other publications available, classified [Fantuzzi 2004, 2007] as **standards** and **documents of relevance**. A standard, unlike a textbook or technical publication, does not cover the experience and opinion of just one or a few individuals, but, in principle, is a consensus of the entire scientific and technical community involved. A document of relevance is the outcome of the deliberations and experience of a group of experts or a commission, who, as a result of their competence and experience, can make highly regarded recommendations in the field of interest. ICRP publications and ICRU reports belong to this category, together with reports and guides from international organizations as EC and IAEA.

Standards and documents of relevance, which may be either national or international, are generally not mandatory, and some national framework of legislation and guidance is needed. This legislation and guidance is often based on more than one standard or document of relevance. Detailed lists of significant standards and documents of relevance are given in, for example, [Fantuzzi 2004, 2007] enabling dosimetry service staff, scientists active in dosimetry, national authority's experts to be aware of the state of the art in individual monitoring.

Standards are principally produced to facilitate the exchange of goods/services worldwide, and some standards may act, or may serve primarily as the basis for contractual agreements. In practice, standards generally act as guidelines for 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. Where international and national standards are referred to in national legislation, adherence to their contents is legally binding.

Standards from different standards bodies generally have different purposes. The International Electrotechnical Commission (IEC) prepares and publishes international standards for all electrical, electronic and related technologies. The IEC members are national committees for standardization in these areas, whose delegates come from a large variety of institutions- manufacturers, providers, distributors and vendors, consumers and users, all levels of governmental agencies, professional societies and trade associations. Since 2002, certain IEC standards become European Norms following resolutions of the CENELEC committee CLC/TC 45B '*Radiation Protection Instrumentation*'. These replace any similar standards in Member States and may be made mandatory by some Member States. IEC standards may principally be aimed at manufacturers or suppliers of equipment such that if there is conformity with the standard, a purchaser or customer can expect the product to meet specific requirements.

The International Organization for Standardization (ISO) is a worldwide federation of national standardization organizations (NSO) from more than 140 countries. 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 as a result, harmonization may not follow. Furthermore, standards from 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. However, harmonization of standards themselves and agreement between standards organizations is still needed.

Some aspects of standardization and EU harmonization in radiation metrology are well implemented, for example the participation of metrology laboratories in Euramet, 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, and these requirements are not always based to the same degree on standards or documents of relevance. Nevertheless, many IMSs in the EU are accredited according to EN ISO/IEC17025:2005 [ISO 17025] and this provides a certain uniformity of quality in individual monitoring services in Europe.

2.7.2 Implementation of national and international standards

There are around fifty different standards relevant to individual monitoring, which indicates the complexity and difficulty of understanding and using the appropriate standard in routine work. The main participants in the field of individual monitoring, for example metrologists, radiation protection authorities, individual monitoring services, users, will naturally raise different questions on their relative importance, whether all items mentioned therein are to be fulfilled, and to what extent, and finally if they are compulsory. Guidance on the use of all these documents is needed in order to achieve harmonization of practices and procedures. Discussions of the requirements for standards and details of some existing standards can be found elsewhere [Fantuzzi 2004; Behrens 2008]. Other Chapters in these Recommendations consider relevant international standards.

In some Member States, standards, including European Norms (EN), are only mandatory if specifically cited in the statutes and regulations of that country. The European Parliament and Council Directive 2004/22/EC on measuring instruments [EU 2004], not currently applicable to radiation protection measuring devices, emphasises the desirability of harmonized standards to ease the task of proving conformity with essential requirements laid down in Directives, whilst stating that such standards should retain their status as non-mandatory documents (see Articles 11-13, [EU 2004]).

An 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 conformity testing. Manufacturers and testing laboratories like to work to detailed descriptions and protocols which do not change frequently and are used by other manufacturers and testing facilities, in other words 'standards'. One disadvantage is that a system in use may be fully adequate for the purpose but not meet all parts of the detailed standard. Encouragement on the use of standards – for the realization of radiation fields as well as for the study of measurement devices allowing the characterization of dosimetry systems following well identified procedures – will make the comparison of dosimetry systems' performances and the understanding of reported results easier.

3 DOSIMETRY CONCEPTS, PROTECTION AND OPERATIONAL QUANTITIES; DETERMINATION OF THE OPERATIONAL QUANTITIES EXPOSURE

3.1 Introduction

In the BSS, the requirements for dose assessment and for dose limits are given in terms of the protection quantities, effective dose, equivalent dose to the lens of the eye, equivalent dose to the extremities and equivalent dose to local skin. The protection quantities are difficult to assess and impossible to measure directly. The BSS state that operational quantities for external radiation, personal dose equivalent for personal monitoring, and ambient dose equivalent and directional dose equivalent for area monitoring, are used for individual monitoring for operational protection purposes. The use of the operational quantities as surrogates for the protection quantities is justified by ICRP and ICRU on the basis of the conceptual basis of the quantities and the calculated relationships between the quantities.

3.2 Recommendations

- The operational quantities as defined by ICRU [ICRU 51] should be used as estimates of the protection quantities for doses below the dose limits. For doses near to or exceeding the dose limits, or, in some instances, particular investigation levels, additional information on the radiation characteristics of the workplace and on the response characteristics of the dosimeter should be used to confirm that it is appropriate to use the operational quantities to estimate effective dose, or local skin equivalent dose, or equivalent dose to the eye lens, or to an extremity. This means that:
 - The operational quantity $H_p(10)$ is used for the assessment of effective dose;
 - The operational quantity $H_p(3)$, or in many cases assessments of $H_p(0.07)$ at the head and $H_p(10)$, is used for equivalent dose for lens to the eye;
 - The operational quantity $H_p(0.07)$ for photons and electrons is used for the assessment of equivalent dose to local skin (maximum value of equivalent doses to the skin, averaged over 1 cm^2). For neutrons, the use of dosimeters calibrated in terms of $H_p(10)$ would be appropriate;
 - The equivalent dose to the extremities should be taken as equal to the equivalent dose to local skin on the extremities summed for all components and should normally be assessed in terms of the operational quantity $H_p(0.07)$ for photons and electrons, and $H_p(10)$ for neutrons.
- The determination of the response characteristics for personal dosimeters should be done on appropriate phantoms, normally those defined by ISO [ISO 4037-3; ISO 12794], in terms of the operational quantities, $H_p(d)$ (see Chapter 7).
- The measurement of the operational quantities, $H_p(d)$, for photon and electron radiation fields can normally be accomplished by a simple design of dosimeter with

an approximately tissue-equivalent detector and a tissue-equivalent cover of appropriate thickness.

- The requirements for ADS and requirements for personal dosimeters given in regulations and guidance can vary from Member State to Member State. The statement in the BSS that competent authorities may authorize the use of equivalent methods allows, for example, the use of field-specific correction factors to obtain estimates of the protection quantities, the choice of a depth other than 0.07 mm to estimate equivalent dose to the extremities.

It should be noted that doses approaching or exceeding dose limits should not occur in normal planned exposures, but may occur in accidental exposure or emergency exposure.

3.3 Terms

The quantities used in the dosimetry of ionizing radiation are divided into **fundamental quantities** which are used for the physical description of the radiation field and its interactions with matter [ICRU 60], and quantities in radiation protection dosimetry which includes the **operational quantities** and **protection quantities** [ICRU 51; ICRP 103].

Absorbed dose is a fundamental quantity defined as the mean energy imparted to an element of matter divided by its mass. **Quality factor** is a measure of the biological effectiveness of the type of radiation as measured by its **LET (linear energy transfer)** which is the energy lost by a charged particle along its track, per track length. The dependence of quality factor on LET is given in [ICRP 103]. **Dose equivalent** at a point in tissue is obtained from absorbed dose at the point by multiplying it by the quality factor.

There are two types of **operational quantities**, for area and for personal monitoring. For area monitoring, there are the quantities **ambient dose equivalent**, $H^*(10)$ and **directional dose equivalent**, $H'(0.07)$ which are defined as the dose equivalent at the depths of 10 mm and 0.07 mm in a 30 cm diameter sphere of ICRU 4-element tissue. $H^*(10)$ is the quantity which is related to the protection quantity effective dose, and is generally used for prospective assessment, categorization of work areas, checking shielding configurations etc. It is 'isotropic', that is its value is independent of the direction distribution of the radiation field at the point at which it is defined. $H'(0.07)$ is used for area monitoring to assess doses to skin and other superficial tissues. The quantities for personal monitoring, **personal dose equivalent**, $H_p(10)$, $H_p(3)$ and $H_p(0.07)$ for the assessment of effective dose and equivalent dose to eye lens and local skin, respectively, are defined as the dose equivalent to soft tissue (taken as ICRU 4-element tissue) at depths of 10 mm, 3 mm and 0.07 mm in the body below a specified point on the body. For $H_p(10)$ this is generally taken as the point at which the dosimeter is worn. The quantity is extended to the dose equivalent at these depths in a tissue phantom of the same shape and size as the calibration phantom (see Chapter 7). For a defined angle of incidence, for example, for radiation incident on the tissue slab phantom at 30 degrees, this information would be included as $H_{p,slab}(10, 30^\circ)$. More information on the operational quantities is given in [ICRU 47, 51, 66].

The **protection quantities** are based on the quantity **average absorbed dose** in the volume of a specified organ or tissue from a given radiation type. The effectiveness of a given type of radiation (incident on the body) is specified in terms of its radiation weighting factor [ICRP

103]. Average absorbed dose is multiplied by the **radiation weighting factor** to obtain the **equivalent dose**, H_T , to an organ or tissue for the given radiation type. The quantity used to assess the overall detriment or harm is **effective dose**, E , and is calculated by adding together the equivalent doses of all exposed organs or tissues after multiplying them by tissue weighting factors (given in [ICRP 103]) to take account of the relative effects of radiation on the different organs or tissues. Effective dose will depend on the direction characteristics of the radiation field (the field geometry) and these will normally be specified by the abbreviations AP for antero-posterior; PA for postero-anterior; LLAT and RLAT for lateral irradiation from, respectively the left and right and LAT for the average; ROT and ISO for, respectively, cylindrically and spherically symmetrical fields.

3.4 Dosimetry concepts

The main purpose of individual monitoring is to assess doses to individuals in order to limit or control the incidence of health effects. Most adverse health effects of radiation exposure may be grouped in two general categories: deterministic effects (harmful tissue reactions) due in large part to the killing/ malfunction of cells following high doses; and stochastic effects, i.e., cancer and heritable effects involving either cancer development in exposed individuals owing to mutation of somatic cells or heritable disease in their offspring owing to mutation of reproductive (germ) cells. Consideration is also given to effects on the embryo and foetus, and to diseases other than cancer [ICRP 103]. The dose quantities assessed are the protection quantities effective dose, E , for stochastic effects and equivalent dose, H_T , for skin, eye lens and extremities for deterministic effects. The dose limit for effective dose is such that deterministic effects will not occur for the organs and tissues included in the definition of effective dose. Effective dose includes the tissue weighted equivalent dose to whole skin, whereas deterministic effects are considered for small skin areas.

Absorbed dose at a point in a specified tissue is a physical quantity, whereas the equivalent dose and effective dose include weighting factors that are based on radiobiological findings. Their values are selected from a broad range of radiobiological data (RBE values) by judgment and include simplifications acceptable for application in radiological protection. The weighting factors are mean values representing an average over many individuals of both sexes. This approach is seen to be acceptable for the main purposes of radiological protection.

In order to provide a practical approach for the assessment of effective dose, in particular for occupational exposures to low doses, calculations are made of conversion coefficients from the fundamental quantities, particle fluence, air kerma or absorbed dose to tissue, to equivalent dose and effective dose in anthropomorphic phantoms representing adult humans. ICRP and ICRU have adopted male and female computational phantoms (voxel phantoms) that have been developed from ICRP Reference Man using information on detailed anatomy gained from CT scans of many persons that is both consistent with Reference Man and also realistic [ICRP 103; ICRP 110].

The quantity effective dose provides a value which takes account of the actual exposure situation of a person, but not of his or her individual characteristics - sex, size, weight, age, etc. Effective dose may therefore be described as a "single-valued quantity," which under the same exposure situation provides the same value to all persons considered. It is not,

therefore, a quantity designed for estimating individual risks. More information on the protection quantities is given in the ICRP recommendations section 5 [ICRP 103]. However, the protection quantities are not capable of being directly measured. Because of this, assessments or measurements, supported in many cases by calculations, are made of the operational quantities. How the different types of quantities are related to each other is shown schematically in Figure 3.1.

A distinction has been made between weakly penetrating and strongly penetrating radiation on the basis of whether or not the dose equivalent to a small area of the sensitive layer of skin was greater or less than 10 times effective dose for a given orientation in a uniform, unidirectional radiation field. This concept has sometimes caused confusion in application. It should be understood that measurements of $H_p(0.07)$ and $H'(0.07)$ are used as estimates of the dose to a small area of skin, and will include both weakly penetrating and strongly penetrating radiation [Böhm, 2000; ICRU 66].

It has been demonstrated that following the revision by ICRP of the definitions of the protection quantities which included changes to the $Q(L)$ relationship [ICRP 60], and the change in the evaluated proton stopping powers [ICRU 49], that the operational quantities generally remain a reasonable estimate of the protection quantities [ICRP 74; ICRU 57], and this is still expected to be the case after the changes by ICRP [ICRP 103,110].

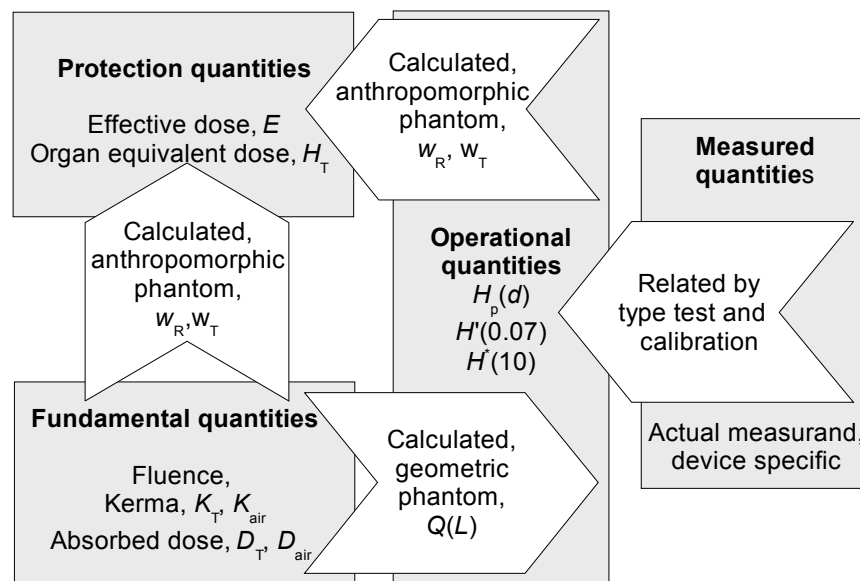


Figure 3.1: Measurement scheme showing relationships of measurement, fundamental, operational and protection quantities in radiation protection.

The dose limit for workers for the extremities, hands, wrists and forearms, feet and ankles, is the same as for skin. For all types of radiation for which exposure of the extremities is of concern, in particular where a field contains a substantial low energy photon or electron component, the skin of the extremities is more likely to become the limiting organ than the extremity itself, and an estimate of equivalent dose to the skin will be a conservative estimate of equivalent dose to the extremities. Thus an extremity dosimeter essentially becomes a skin dosimeter and should be designed to measure $H_p(0.07)$. Over the body as a whole ICRP [ICRP 60] recommend that for stochastic effects the depth of the sensitive layer of the skin

(basal cell layer) be taken to be in the range 0.02 to 0.1 mm; for deterministic effects (tissue reactions), the appropriate depth range for some effects is the same, for others it is 0.3 to 0.5 mm; and that the depth of measurement should be 0.07 mm. However, the sensitive layers over some parts of the extremities are at greater depths, for example, ranging from 0.2 mm to 0.5 mm over the surfaces of the palms of the hands. For this reason it may sometimes be acceptable to assess dose at a greater depth than 0.07 mm. Of course, account should be taken of where the dosimeter is worn, and the use of protective clothing (See section 3.7). For exposure of the extremities to neutrons, $H_p(0.07)$ will also be the appropriate quantity to be determined. However, it will be acceptable that calibrations are carried out using fluence to $H_p(10)$ conversion coefficients, and the dosimeter indication used as the estimate of $H_p(0.07)$ and of extremity dose [ICRU 66].

Although there is a requirement in the BSS to limit equivalent dose to the lens of the eye, the operational quantity, $H_p(3)$ has not been adopted in all Member States. In many situations, compliance with limits for equivalent dose to the lens of the eye can be ensured by compliance with the limits for $H_p(0.07)$ and $H_p(10)$: there is a small electron energy range from about 1 to 2 MeV for which this is not the case. However, in radiation fields produced by beta sources, there is always a broad energy distribution which will tend to remove this problem. Supported by knowledge of the workplace field, $H_p(3)$ may be estimated from measurements of $H_p(0.07)$ and $H_p(10)$. Alternatively, a simple design of dosimeter can be used, worn on the head, to directly estimate $H_p(3)$, comprising a skin dosimeter with additional covering. There are recommended photon fluence to equivalent dose to the eye lens, and electron fluence to $H'(3)$, conversion coefficients available [ICRU 57; ICRP 74] (for electrons, $H'(3)$ is a good approximation to $H_p(3)$). However, investigations are being made of dose to the eye lens and $H_p(3)$ as measured on a slab phantom as suggested in the ISO standard on TL dosimeters [ISO12794]. International standards do not provide at present conversion coefficients from fluence or kerma to $H_p(3)$ or $H_p(3)$ for standard photon or electron beams useful for calibrating personal dosimeters. There are results published of calculations of photon fluence to $H_p(3)$ conversion coefficients using a suitable head phantom [Ferrari 2005, 2007; Mariotti, 2009]. It is noted that ICRP [ICRP 103] states that there are studies in progress on possibly increased risks from eye lens exposure. Research on eye lens and extremity dosimetry for medical exposure is being carried out in the EC-funded ORAMED project (<http://www.oramed-fp7.eu/>).

In some cases, estimates of personal dose equivalents, or of effective dose and equivalent doses, will need to be based on the results of previous measurements for a worker, on the results of measurements on other workers, or from measurements of workplace fields plus occupancy information.

3.5 Relationships of the protection and operational quantities

For photons, in practical situations, $H_p(10)$ will provide a reasonable estimate of E , although underestimates may occur. $H^*(10)$ will generally overestimate E , and for some energy ranges and field geometries, this overestimate may be large and information on the energy and direction distribution of workplace fields may be necessary in order to apply corrections to measurements.

For neutrons, for some energy ranges and field geometries, either or both of ambient and personal dose equivalent (as approximated by $H_p(10)$ in a 300 x 300 x 150 mm slab of ICRU

4-element tissue) underestimates the protection quantities, and information on the energy and direction distribution of workplace fields is necessary to apply any corrections to measurements that may be needed. An example of the calculational approach to determining the relationships of quantities in neutron workplace fields can be found in [Bartlett, 2002].

These general conclusions as to the relationships of E and $H_p(10)$ are based on the assumption of uniform whole body irradiation, the recommended conversion coefficients in [ICRU 57; ICRP 74] and the correct use of the personal dosimeters.

Ratios of $H_{p,slab}(10,0)$ to $E(AP)$ for monoenergetic photons are shown in Figure 3.2 and for monoenergetic neutrons in Figure 3.3.

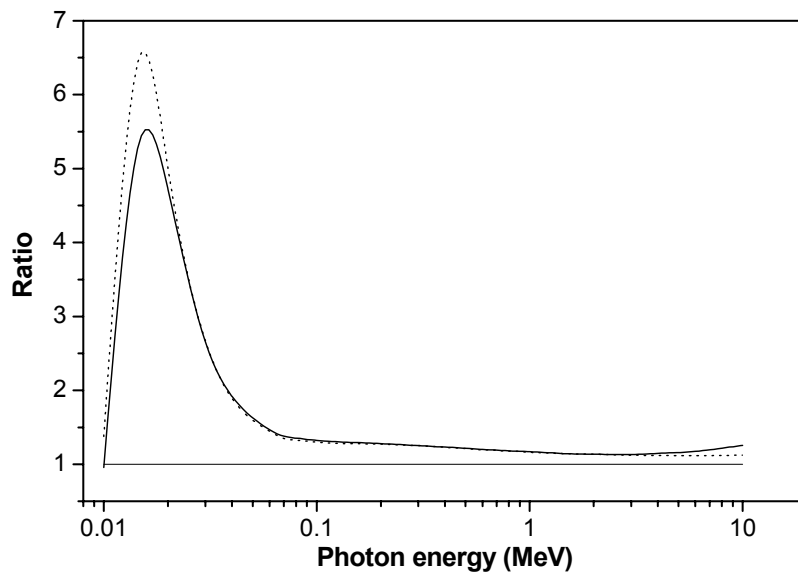


Figure 3.2: Ratios of photon personal dose equivalent, $H_{p,slab}(10, 0)$ [ICRU 57; ICRP 74] to effective dose, $E(AP)$, for [ICRP 60; ICRU 57; ICRP 74] (dotted line) and preliminary results of calculations for [ICRP 103; ICRP 110] (solid line).

Also shown in these Figures are ratios of preliminary values of conversion coefficients calculated using the ICRP/ICRU ‘Adult Reference Computational Phantoms’ [ICRP 110] and the tissue and radiation weighting factors recommended in [ICRP 103]. The differences observed for the ratios for photons are a result of the different phantoms and tissue weighting factors; those for neutrons mainly a result of the change in radiation weighting factors.

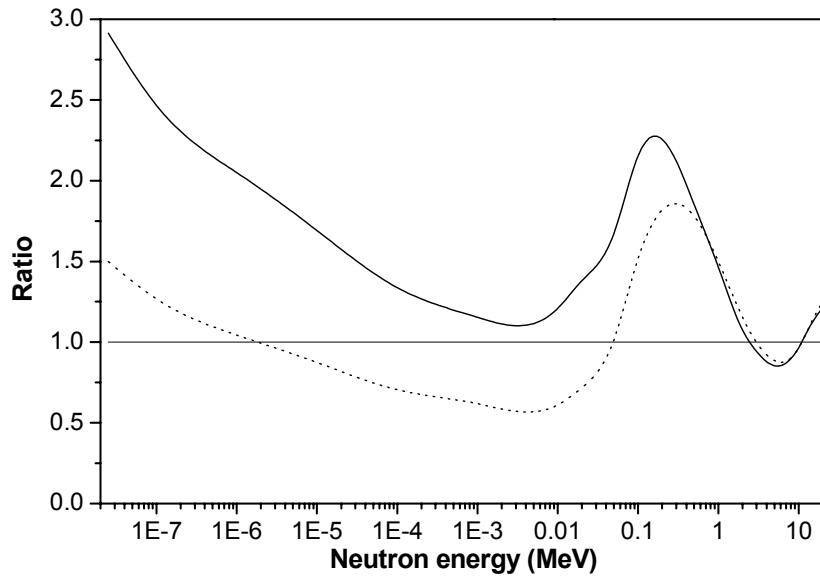


Figure 3.3: Ratios of neutron personal dose equivalent, $H_{p,slab}(10, 0)$ [ICRU 57; ICRP 74] to effective dose, $E(AP)$, for [ICRP 60; ICRU 57; ICRP 74] (dotted line) and preliminary results of calculations for [ICRP 103; ICRP 110] (solid line).

3.6 Estimation of effective dose and equivalent dose

For doses near or above the dose limit, or above a fixed investigation level, it will be necessary to confirm that measurements of the operational quantities provide good estimates of the protection quantities. To do this, information will be needed on whether the field is uniform and its energy and direction distributions, the wearing position of the dosimeter and the dosimeter response characteristics. In some circumstances, it will be necessary to estimate equivalent dose to skin or extremities, or more probably effective dose, from the results of area monitoring plus information on a worker's movements (summarized by the term 'occupancy'). It may well be difficult, or impossible, to obtain data of sufficient quality to estimate effective dose without large uncertainty. To determine effective dose, information is needed on both the energy and direction characteristics of the workplace field(s) and the position and orientation of the personal dosimeter. (See also Section 4.7).

The amount of effort to be devoted to these determinations depends very much on the particular circumstances. In many instances, there will be information on the radiation field from previous measurements or calculations for the exposure situation under consideration, either the actual field or similar. There are compilations of useful field spectrometry data, mainly for neutron fields [Naismith, 1996; NPL, 1997; IAEA 2001]. These data can then be used together with the recommended conversion coefficients for E and $H_p(10)$ and the dosimeter response characteristics to decide whether an estimate of E can be made of sufficient accuracy for the purpose. In other instances, this information can be obtained by computer simulations of the exposure situation, and calculations made of E and the dosimeter indication.

Further information can be found in [Burgess, 1999; Klein, 2002; Eurados 2003; SSK 2006; d'Errico, 2007; Gualdrini, 2007; Schuhmacher, 2007] and the references therein.

3.7 Determination of operational quantities using personal dosimeters

For the assessment of E (whole body dose) by a measurement of $H_p(10)$, it is assumed that the dosimeter is worn on a part of the trunk that is representative of the most highly exposed part. There may, of course, be difficulties in assessing which part of the trunk is the most highly exposed. For fields which are significantly spatially non-uniform, it may be difficult to relate $H_p(10)$ to effective dose, and to relate $H_p(0.07)$ to average dose to skin if this is required as opposed to local skin dose. In some cases, more than one dosimeter may need to be worn for the control of effective dose or dose to skin. There are particular considerations when lead aprons are worn (see below).

Dosimeters are type tested and routinely calibrated in terms of $H_p(10)$ or $H_p(0.07)$ defined in, and calculated for a phantom of ICRU four-element tissue of the same size and shape as that on which the dosimeter is fixed for testing [ISO 4037-3]. This procedure assumes that the energy and angle dependence of response characteristics that are determined when a dosimeter is calibrated in terms of $H_{p,slab}(10)$, are adequately similar to the response characteristics in terms of $H_p(10)$ and $H_p(0.07)$ in the body when the dosimeter is worn. Practical considerations in the design of a reliable, robust operational dosimeter may well result in the use of a dosimeter with some deficiencies of response characteristics. It may then be necessary to calculate or demonstrate the performance of the dosimeter in the workplace fields.

$H_p(10)$ can be estimated for photons and electrons with a single detector whose energy dependence of output signal is acceptably proportional to absorbed dose to tissue for the required energy range, which is then covered with material of thickness corresponding to 10 mm of soft tissue. Such dosimeters should be responsive to radiation backscattered from the body, and able to determine dose equivalent in soft tissue at the defined depth in the body close to the wearing position. An alternative approach, used for some APDs for example, is to design a dosimeter such that the output signal is proportional to $H_p(10)$, adequately independent of energy or angle of incidence, with possibly little, or no contribution from the backscattered field.

Most neutron personal dosimeters to measure neutrons of energies above a few tens of keV, which is generally the energy region making the largest contribution to E (see Section 4.7), are designed using the approach of matching output signal to $H_p(10)$ [see ICRU 66 and references therein]. For neutrons of energies from thermal to a few keV, $H_p(10)$ is approximately proportional to the number of interactions in a $1/v$ detector (where v is the neutron speed) at the surface of the body, either partly shielded from incident thermal neutrons or covered by the equivalent of about 10 mm of tissue-like material. Dosimeters with detectors partly or wholly shielded from incident thermal neutrons are termed 'albedo' dosimeters, and are able, to a lesser or greater extent, to measure neutrons above a few keV which are moderated and backscattered from the body. As well as location on the body, the readings of albedo dosimeters can be very dependent on the separation distance from the body.

In low energy photon and beta radiation fields, $H_p(0.07)$ can only be determined accurately by a thin detector material which has an output signal proportional to absorbed dose to tissue over the energy range of interest, and with a thin covering. There is some scope for optimization of the design.

Some further basic dosimeter design considerations are discussed in Chapter 4.

Where protective clothing for the body is worn, in particular lead aprons, or where there is significant non-uniformity of the radiation field, the correct positioning of the dosimeter(s) will be important and it may be necessary to use more than one dosimeter to obtain an estimate of E or H_T . (See the recommendation in Chapter 4). In the case of double dosimetry, an algorithm is applied to the values of $H_p(10)$ determined with the different dosimeters. The coefficients in the algorithm will depend on whether the below apron dosimeter is on the waist or chest. It may also be adjusted for different irradiation conditions. If only a single dosimeter is used when a lead apron is used, a correction factor derived from experiment or calculation, or a combination, will need to be applied. It is important that this correction factor does not lead to an underestimate of E or too great an overestimate. These matters are discussed further in the report of the EC-funded CONRAD project [Järvinen, 2008] and in ICRP Publication 85 [ICRP 85].

In many cases of measurements in non-uniform fields, such as the handling of low energy beta sources, it will not be possible to place a local skin dosimeter or extremity dosimeter at the most highly exposed part which for many procedures where extremity dosimeters are used is frequently the finger tip. Ring or wrist dosimeters are commonly worn. An experimentally derived correction factor will then be needed to calculate H_T to the finger tip or the extremity [Vanhavere et al., 2008]. See also Section 6.6.

4 INDIVIDUAL MONITORING PROCEDURES

4.1 Introduction

The need for individual monitoring of workers will depend on the radiation conditions in the area concerned and the type of work. For the purposes of monitoring and surveillance of workers, the BSS makes a distinction between two categories of exposed workers, A and B. The categories relate to the likelihood of reaching three tenths of the dose limit and not to the actual exposure incurred in a particular year. In practice, the majority of the annual doses actually incurred by workers in working condition A are lower than three tenths of the dose limits. The dose limits given in the BSS are shown below.

Table 4.1: Dose limits given in the BSS [EU 1996a]

Limiting quantity	Exposed workers (aged over 18)	Apprentices and students (aged between 16 and 18)	Public
Effective dose	100 mSv in a consecutive 5y period, subject to a maximum of 50 mSv on a single year; An annual value may be considered	6 mSv	1 mSv in special cases, a higher value may be authorized in a single year, provided that the average over 5 consecutive years does not exceed 1 mSv/year.
Equivalent dose for the lens of the eye	150 mSv	50 mSv	15 mSv
Equivalent dose for the skin, hands, forearms, feet, ankle	500 mSv	150 mSv	50 mSv

In the BSS it is required that systematic individual monitoring shall be performed for Category A workers. Category B workers need not be issued with personal dosimeters, if sufficient is known from monitoring of the working environment to indicate unambiguously that they belong to this category. In many work situations it is not possible to estimate with sufficient accuracy the doses which people will receive simply by studying their working habits and their working environment. In such situations persons working in these areas should be issued with personal dosimeters, at least for an experimental period, in order to establish that they are not in Category A. The choice of appropriate monitoring programme and the choice of suitable dosimeter are very important.

Although not strictly required, dosimeters are often issued to Category B workers for mainly two reasons: to reassure workers on dose levels and to protect employers against claims for compensation for radiation related diseases. When personal dosimeters are issued to Category B workers, the principles which determine the choice of dosimeter type are the same as they are for Category A workers. The same principles are applied to outside workers [EU 1990].

Visitors should be considered to be individual members of the public. Although monitoring is not required, simple individual monitoring is often advisable. Temporary personnel such as visiting scientists, research fellows, students and contractors who may be engaged in

radiation work must be monitored to at least the same standards as permanent radiation workers.

4.2 Recommendations for a monitoring programme

- Routine individual monitoring of all Category A workers must be carried out by an approved dosimetry service (ADS), and where individual monitoring of category B workers is deemed necessary, it is recommended that this should also be carried out by an ADS.
- The routine individual monitoring by an ADS should normally be by means of personal dosimetry. Where this is not possible, or where retrospective dosimetry has to be made for a worker not wearing a personal dosimeter, the dose assessment by the ADS (in this instance, with the assistance from the undertaking) should be based on area monitoring results together with occupancy data, results for the same worker for previous wear periods, from personal dosimeters of other workers, and, if necessary and where possible, using numerical methods. For high doses alternative measurement techniques may be available.
- The choice of suitable dosimeter should be based on a consideration of the workplace characteristics, including aspects of the workplace other than radiation field properties, and data on dosimeter performance characteristics.
- In its 2007 Recommendations [ICRP 103], ICRP concluded that for the purpose of controlling occupational exposure, there was no reason to distinguish between the two sexes. However, if a female worker has declared (i.e., notified her undertaking) that she is pregnant, additional controls may have to be considered to protect the embryo/fetus [ICRP 84].
- The choice of monitoring period should be related to the exposure situation. If for operational reasons daily monitoring is required, a direct reading dosimeter with sufficient sensitivity should be used in addition to the official dosimeter. Except in situations where people are being exposed at a very non-uniform rate, a monitoring period of between a week and a month is likely to be convenient. Unless exposures are particularly low or uniform, an issue period of more than 1 month is generally undesirable, since the longer the time which has elapsed, the more difficult it becomes to establish the reason for the exposure. An issue period of more than 1 month could be recommended for low exposures because in some cases the dose received may be of the same order of magnitude as the detection threshold. In such cases, an issue period of 3 months may be more appropriate and the result more representative of the actual dose received. Also, for people who may only occasionally receive a dose, that is persons who occasionally enter radiation areas with a low radiation level, a monitoring period of three months may be suitable, if the dosimeter used permits long monitoring periods.
- Direct reading dosimeters, preferably APDs, should be used to monitor the dose received during a particular task. The issue period is therefore usually short, for example one working day or one shift. In recent years developments with this type of dosimeter have resulted in systems suitable for use as the official dosimeter of

record for photon and beta radiation [Ginjaume 2007]. Care should be taken in fields generated by pulsed radiation sources (see [IAEA 2007] and [Clairand et al 2008]).

- For operations of short duration in high radiation fields, special monitoring programmes should be designed, including the use of warning devices. In situations where individual doses could greatly exceed those expected under normal working conditions as a result of unexpected incidents, special attention should be paid to the capabilities of dosimeters and to the application of measurements and calculation methods needed for the assessment of effective dose or organ doses.
- In highly non-uniform radiation fields, additional body and extremity dosimeters should be worn (for example, on the fingers, ankles, knees or head).
- In order to avoid the use of a special additional accident dosimeter, the routine personal dosimeter should be capable of providing information on absorbed doses from photons and electrons up to several Gy. However, it is recognized that certain dosimeters, such as film dosimeters, may not be capable of achieving this at all energies. Wearing a warning dosimeter (bleeper) will usually prevent serious exposures and may help in considerably reducing the dose incurred in the event of an accident. Warning dosimeters need not be very accurate, but should be very reliable, especially in high dose rate fields and in pulsed fields.
- It is particularly important that the routine-use personal dosimeters should perform satisfactorily in minor accidents/unexpected incidents. For most APDs and for incidents such as the exposure to the direct beam of a diagnostic X-ray machine, this is not the case.
- The results of individual monitoring must be made available to the competent authorities, to the undertaking (client/customer), to the exposed worker, and, in the case of Category A workers, to the approved medical practitioner or approved occupational health services. All measured doses should be reported to the undertaking unless specifically requested not to. The further requirements for recording and reporting of results are considered in Chapter 9.
- When reporting the result of a measurement, the uncertainty of the measurement should be estimated and reported. The methods of determining the uncertainty are considered in Chapter 5, and the way of routinely reporting uncertainties considered in Chapter 9.
- Where appropriate, national and international standards on quality assurance and dosimeter system performance should be used, even where not mandatory in national legislation, or approval requirements. More information on this is given in Chapter 10.
- Where possible, dosimetry services (IMS and ADS) should take part in national, European and international intercomparisons.
- The correct positioning of dosimeters is important, and particular care should be paid to the positioning of extremity dosimeters and albedo dosimeters.
- When it is considered that a single dosimeter is adequate for the purpose of monitoring a pregnant worker, for uniform fields the dose measured by the correctly positioned dosimeter should be put equal to the dose to the unborn child.

- Protective equipment should be worn if appropriate, for example gloves, goggles, lead aprons (with/without thyroid shield). When protective equipment is worn, it is essential to correctly position the dosimeter(s).
- When wearing a lead apron, double dosimetry is recommended. The dosimeter above the apron should be worn at the collar level, and the result from this dosimeter can be used, in addition, to estimate equivalent dose to the eye lens. The dosimeter under the apron may be worn at the waist or chest, preferably the chest, but a different algorithm will be needed for the different positions. In situations where it is well established that doses are low, it is acceptable to wear only one dosimeter. To obtain the best estimate of E this should be worn under the apron, although a more sensitive indication of changes in the working environment can be achieved with a dosimeter worn on the collar with the application of a correction factor. This approach is less likely to lead to an underestimate of E . For more information reference should be made to [ICRP 85], [NCRP 122] [Järvinen 2008].

4.3 Terms

Accidental exposure: an exposure of individuals as a result of an accident (BSS). It does not include **emergency exposure:** an exposure of individuals implementing the necessary rapid action to bring help to endangered individuals, prevent exposure of a large number of people or save a valuable installation or goods, whereby one of the dose limits equal to that laid down for exposed workers could be exceeded (applicable to volunteers only). A **radiological accident** is here considered to be an **unexpected incident** which results in actual or potential doses to persons greater than the relevant dose limit. The assessment of doses resulting from accidental exposure or emergency exposure is not considered in these Recommendations. Many routine-use passive personal dosimeters are capable of determining absorbed doses from photons/electrons up to, and in excess of, 10 Gy, and can therefore provide information in the event of a high dose accidental exposure. This may not be true for active personal dosimeters if the exposure is due to pulsed radiation (for example, in medicine), as these dosimeters have problems with high dose rates.

A **minor accident** or **minor unexpected incident** may also result in higher than expected doses, but less than dose limits. An example is the exposure of a nurse in the direct beam of an X-ray facility. As for an accident, routine use passive dosimeters should perform acceptably, but this may not be the case for active personal dosimeters if the radiation is pulsed.

Active personal dosimeter (APD): a personal dosimeter which has powered electronic circuitry, usually battery, with associated software and/or firmware, and normally with visible or audible indication of integrated dose and/or dose rate. A **passive personal dosimeter** does not have powered circuitry or inbuilt software and/or firmware. According to this classification pen dosimeters (electrometers) and discrete ion storage dosimeters (DIS) are passive dosimeters. An **algorithm** is a process or set of instructions which can be represented by a mathematical expression or series of expressions. In individual monitoring, it describes a procedure whereby the output signals from more than one detector are combined to give the indication.

4.4 Dosimeter requirements and choice of personal dosimeter

In practical situations personal dosimeters are required to estimate the quantity of interest with reasonable accuracy for the workplace radiation field, which, in principle, may be distributed over all angles of incidence, and for particle energies up to several MeV, or tens of MeV near high energy medical or research accelerators. In a complicated situation with well shielded sources and multiple scattering it is not possible to predict either the energy or direction distribution of radiation incident at the location of the worker. In principle, a suitable dosimeter for such situations has to be capable of responding within acceptable limits to the full range of particles, possible energies and for all angles of incidence.

The specification of how to assess the dosimetric characteristics and how to present the results of a dosimetry system is invaluable and this is probably best done with reference to published standards. Clear dosimetry 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 [see, for instance, HSE 2005]; assist the approval application and assessment; and make the process more transparent. The characteristics of dosimeters and dosimetry systems should be made available to potential users. However, it should not be mandatory to meet all the requirements of, for example, an ISO or IEC standard. This would lose the flexibility of the over-riding criterion of fitness for purpose. A dosimetry system should be tested against a specified standard, and results given with an explanation of any non-conformity. There should be participation in national and international intercomparisons, and results published. (See the recommendations and discussions in Chapters 8 and 11). Accuracy requirements are discussed in detail in Chapter 6, and type testing in Chapter 7.

In general, the choice of personal dosimeter and dosimetry system by an employer should be made in consultation with a radiation protection expert and, where appropriate, the health physics staff. The technical information on the performance characteristics of the dosimetry service should be provided by the ADS. The consultation should include discussions of the characteristics of the radiation fields in the workplaces (see Section 4.7 below), the most appropriate wear position, issue period etc. The choice of dosimeter for use in a particular set of radiation field parameters may permit, or require, a particular normalization factor to be applied in order to minimize the deviation of the dosimeter relative $H_p(10)$ response of the range of radiation energies and directions to be encountered in the workplace, or to minimize the deviation of the estimation of effective dose. Where an assessed dose received exceeds a relevant dose limit or investigation level, the undertaking may ask the ADS, in conjunction with the radiation protection expert, to take account of information on the wearing position, the response characteristics of the dosimeter, and the characteristics of the workplace field, in any reassessment to provide the best estimate of effective dose.

For routine personal monitoring, the choice of a personal dosimeter will depend not only on the type of radiation but also on the information that is needed in addition to $H_p(d)$. In routine practice, the following types of dosimeter may be used:

- Photon only or photon/electron dosimeters to determine only $H_p(10)$, simple non-discriminating dosimeter. Where only photon radiation is important, it is usually sufficient to measure only $H_p(10)$. A simple dosimeter is adequate in most practical situations. For a wide range of photon energies, TLDs, OSL, radiophotoluminescent (RPL) glass or photographic film dosimeters can be used, provided that they exhibit acceptable energy dependence. In addition, many electronic dosimeters

are available, but consideration needs to be given to the lower threshold of photon energy.

- Photon only or photon/electron dosimeters of the discriminating type giving, in addition to $H_p(10)$, some indication of the effective energy, the presence of other radiation types than photons, for example low energy electrons/betas.
- Photon/electron dosimeters to determine $H_p(0.07)$ and $H_p(10)$. When it is likely that low energy electrons or photons may contribute significantly to the radiation field, dosimeters of this type should be used. These may be TLDs, OSL, RPL, photographic film dosimeters or APDs with two or more elements or films under filters of different materials and thicknesses, or appropriate electronic dosimeters.
- Extremity dosimeters to determine $H_p(0.07)$ for photon/electron radiation. For extremity dosimetry, especially of the hand, a simple single-element TLD should be sufficient if it is placed on the most highly exposed finger and is facing the source. For the best accuracy in measuring low energy beta radiation, an ideal dosimeter would have a thin detector filtered by a thickness of tissue substitute such that the dose at a nominal depth of 0.07 mm can be assessed.
- Neutron dosimeters to determine $H_p(10)$. Simple types of neutron dosimeter cannot provide information over the whole energy range of interest, and therefore extra effort is needed if individual monitoring for neutrons is necessary. However, the neutron $H_p(10)$ contribution is often small compared with the dose limit, with the major contribution from photons. As photons are always present in neutron fields, a photon dosimeter should always be worn with a neutron dosimeter. In some neutron fields, the ratio of neutron to photon dose equivalent has been found to vary by orders of magnitude. Neutron dose equivalents cannot, therefore, usually be derived with sufficient accuracy from photon dose equivalent measurements and assuming a constant ratio. Albedo dosimeters can be used to measure $H_p(10)$ from thermal neutrons and epithermal neutrons (up to a few keV) in a simple design, and with more complex configurations and response characterization and/or field specific correction factors, intermediate and high energy neutrons. Where there is a major contribution from high energy neutrons, other methods, such as solid state track detectors, are usually more suitable: these types of dosimeter can incorporate a capability to measure thermal and epithermal neutrons. A direct reading neutron dosimeter, the superheated emulsion or bubble detector, is very sensitive to neutrons, with a detection capability of a few microsieverts, and is completely insensitive to photons. More information on neutron dosimeters can be found in [ICRU 66].
- Active personal dosimeters, APDs, should be used when it is necessary to control individual exposure on a day to day basis or the radiation field experienced by a worker could increase significantly and unexpectedly (see Section 4.5).

The designs of dosimeters and dosimetry systems have developed along with changes in applications. Tests of photon and electron whole body dosimeters by EURADOS, including irradiations in simulated workplace fields [Eurados 2000] indicated that most current designs have acceptable energy and angle dependences of $H_p(10)$ and $H_p(0.07)$ response characteristics for large regions of the entire range of particle energies likely to be encountered in the workplace. Nevertheless, some unexpected inadequacies of personal dosimeters may be found for particular sets of workplaces [Collison 2005]. This latter report

showed the value of investigating the performance of dosimeters and ADS in the actual workplace.

4.5 Active personal dosimeters

Active personal dosimeters, APDs, can give the worker an instant indication of both accumulated dose and dose rate. Preset visual and audible alarms are also provided, so that these devices can be used simultaneously as an integrating dosimeter and as an alarm dosimeter. APD can be used as supplementary dosimeters to the dosimeter used for routine dosimetry. Often these dosimeters are used for dose control purposes only, and not as replacements for the dosimeter designated by the regulatory authority for record keeping purposes. On the other hand, an APD considered by the regulatory authority to be of a suitable design for use as an approved dosimeter could effectively serve both purposes as currently in the UK (see for example [Weeks 2002]).

Data and information have been presented by EURADOS [Ginjaume 2007] on the current status and availability of APD technology in Europe. Based on these findings it is clear that the energy and directional response characteristics of APD are, in most cases, as good as passive dosimeters, able to measure with acceptable accuracy for continuous fields. A problem, which is presently not solved, is the response of APD to pulsed radiation, see 7.8.4. For the scattered component of pulsed fields, for example in medical applications, the response of some APDs is within specified limits [Clairand et al 2008], but this is not the case in the direct beam for a minor accident/unexpected incident. Therefore, care should be taken when using APDs in workplaces where medical X-ray units or accelerators are operated, particularly if the occurrence of minor accidents/unexpected incidents cannot definitely be ruled out.

4.6 Use of algorithms

Let us consider a dosimeter or dosimetry system that determines one or more of the operational quantities ($H_p(10)$, $H_p(3)$ and $H_p(0.07)$), using one detector (or signal channel) for each quantity. If the dosimetry system meets performance criteria for a given particle type or types for narrow energy distributions or mono-energetic radiation fields, in general, the dosimetry system will be appropriate to all fields of the given particle type or types, for example mixed mono-energetic or wide energy and direction distributions, within the range of energies and angles investigated. The situation is more complicated if a dosimetry system uses the signals from more than one detector to determine the value of one quantity. In such cases a dose calculating algorithm is required to combine the reading from each detector in order to produce a measured dose value. The simplest is the linear combination of the detector readings. Another method uses linear programming [Kragh 1996]. For these two linear methods the situation is almost as simple as for a dosimeter with one detector. A type test with narrow energy distributions covering the anticipated energy range is sufficient to establish whether the dosimeter is appropriate. Algorithms which rely on the ratio of readings from several of the detectors in the dosimeter are more difficult to test, particularly those that use branching algorithms. Strictly, the performance of such dosimeters can only be assumed for the radiation qualities used in the testing process [Kragh 1996]. Performance in workplace fields may be disappointing, as in some cases the algorithm may have been

designed, quite deliberately, to generate good results in established testing programmes rather than to operate well in environments with wide energy and direction distributions. Therefore it is important to test such dosimeters using energy and direction distributions typical of workplace fields.

4.7 Characteristics of workplace fields

One of the precursors to any monitoring programme should include an assessment of the workplace radiation fields, particularly if there is the possibility of significant doses. Knowledge of workplace fields (that is, data on energy and direction distributions, dose rates, worker orientation and occupancy factors, environmental conditions), can be used to select the appropriate types of personal dosimeter and to assess how well dosimeters estimate $H_p(10)$ and $H_p(0.07)$; contribute to the estimation of the overall uncertainty of measurement; allow an assessment to be made of the adequacy of the use of the operational quantities as surrogates for the protection quantities; and where appropriate, allow a better estimate to be made of the protection quantity. 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 characterization of workplace fields may be done by a combination of measurements and calculations, or by measurements alone. Unless necessary, the measurements need not be too elaborate [ICRP 75]. As a minimum, knowledge is needed of the location, type and size of sources, the amount of shielding and scattering material and ambient dose equivalent rates [Donadille, 2007]. Additional characteristics may also include not only the energy and direction distributions of the radiation field, but also the time dependence- in particular whether it is pulsed or not. The determination of energy and direction distributions of workplace fields is not a simple matter, generally requiring sophisticated measurement methods and analysis. Frequently, field characteristics will need to be calculated [Gualdrini 2007]. The fields will usually comprise direct and scattered components resulting in broad energy and direction distributions. In some instances, however, simple procedures can be used to identify areas where there is a strong low energy component which may lie below the threshold of an electronic personal dosimeter, for example. 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. Radiation fields may be significantly spatially non-uniform, leading to non-uniform exposure of the body. It is then difficult to make appropriate assessments of $H_p(10)$ and $H_p(0.07)$, and of effective dose when this is required (see also Section 3.6).

There is not much published information on photon and electron workplace fields, but a reasonably large number of published papers on neutron fields. The reason for this is that, in general, there are designs of photon and electron dosimeters available which are able to determine $H_p(10)$ and $H_p(0.07)$ within acceptable limits for the range of energies and directions present in workplaces, whereas this is not the case for neutron fields. For neutron workplace fields it is always necessary to have at least some information on the energy and directions characteristics of workplaces. Nevertheless, it can still be useful to have information on photon and electron workplace fields. Information on workplace fields and methods of measurement can be found, for example, in [Eurados 2003]. Further information is given in [Burgess, 1989; Ambrosi 1996; Burgess 1999]. The Figure below is from [Ambrosi

1996]. A summary of the range of energies in the more usual workplace photon fields is shown in Table 4.2.

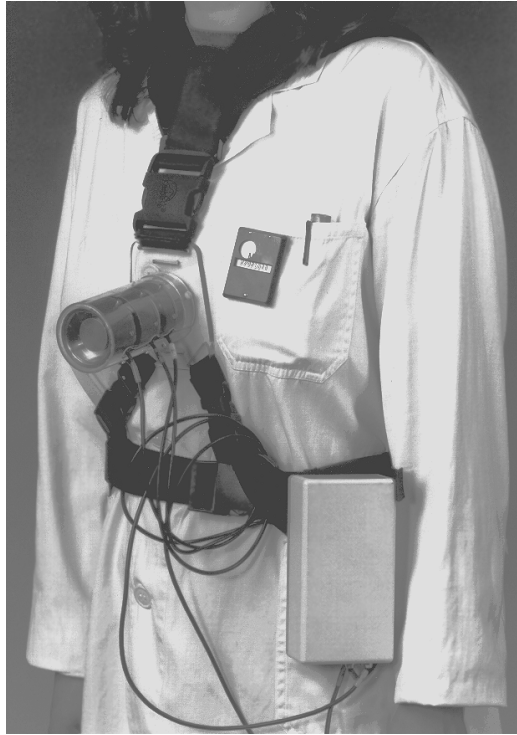


Figure 4.1: PTB device to determine characteristics of photon workplace fields.

Neutron fields in workplaces in the nuclear fuel cycle, in nuclear power generation, and in areas near medical accelerators or where radionuclide sources are used, span energies from thermal to 20 MeV. For workplaces near high energy accelerators and cosmic radiation fields at aircraft altitudes the energies extend up to many GeV. In most workplace fields where any annual doses of significance are received, there is a thermal and epithermal component of neutron fluence, and a fast component. The relative magnitude of the two components varies from fields with a large thermal and epithermal neutron component outside the thick shielding of power reactors ('soft' energy distributions), to almost completely fast neutrons near some reprocessing lines and near unshielded radionuclide sources ('hard' distributions). What is almost universally true, is that there is little dose equivalent between a few keV and 50 keV. However, there is often a significant contribution between 50 keV and 500 keV, and it is the energy region which gives rise to the greatest difficulty in neutron detection and photon discrimination. Table 4.3 shows examples of measured (plus one calculated- the MOX field) neutron energy distributions at various workplaces broadly representative of those in the nuclear industry and source manufacture.

Table 4.2: Examples of energy ranges for some commonly encountered photon and electron workplace fields (after [HSE 2005]).

Field/source		Photon/electron energy ranges	Comments
Radiopharmaceuticals, manufacture and use	Generally only low energy photons and electrons		Very dependent on shielding, probably only concern for dose to extremities, and possibly eye dose
¹⁴⁷ Pm	Electrons plus photons	$E_{\beta,max.}$: 225 keV Photons 20 to 120 keV.	Very dependent on shielding, probably only concern for dose to extremities, and possibly eye dose; possible photon contribution.
Industrial beta thickness gauges, for example, ⁸⁵ Kr	Electrons plus photons	$E_{\beta,max.}$: 687 keV	Very dependent on shielding; note possible bremsstrahlung contribution
⁹⁰ Sr/ ⁹⁰ Y	Electrons plus photons	$E_{\beta,max.}$: 2.274 MeV Photons: 10 to a few 100 keV.	Very dependent on shielding, note probable bremsstrahlung contribution
Contaminated waste	Photons plus secondary electrons	30 to a few hundred keV	Dependent on scatter and shielding
Interventional radiology	Photons plus secondary electrons	20 to 150 keV	Dependent on scatter and shielding
General diagnostic radiology	Photons plus secondary electrons	20 to 150 keV	Dependent on scatter and shielding at location of radiographers
Industrial radiography	Photons plus secondary electrons	50 to 700 keV	Dependent on scatter and shielding
Industrial sterilization facilities	Photons plus secondary electrons	100 keV to 1.3 MeV	Dependent on scatter and shielding
Medical linacs	Photons plus secondary electrons	100 keV to 20 MeV	Dependent on scatter and shielding at location of radiographers
Nuclear fuel cycle	Electrons, photons plus secondary electrons	Electrons from 60 keV to a few MeV plus photons from 17 keV to a few MeV	Large range of energies
Nuclear power reactors	Photons plus secondary electrons	30 keV to 6/7 MeV	Secondary electron equilibrium not always present
Research facilities	Photons plus secondary electrons	100 keV to > 1 GeV.	Very dependent on shielding/secondary particles

There are likely to be particular fields where a correction to the reading of the dosimetry system used, may need to be included for the contribution to total $H_p(10)$ from the component between 5 and 50 keV. The possible poor angle dependence of dosimeters should be paid special attention. It is frequently the case that the broad direction distribution of neutron workplace field and/or the wearer's movements, combined with the angle dependence of response of the dosimeter has the greatest effect on the relative response characteristics [Bartlett 2002].

Table 4.3: $H_p(10, 0^\circ)$ dose fractions within energy bands for various neutron workplace energy distributions (After [HSE 2005]).

Field	Type	Thermal (<0.4eV)	0.4eV to 5keV	5 keV to 50keV	50keV to 100keV	100keV to 300keV	300keV to 20 MeV
²⁴¹ Am-Be	Bare Source	0.00	0.00	0.00	0.00	0.01	0.99
²⁴¹ Am-Be in glove box	Source production	0.04	0.02	0.01	0.02	0.04	0.87
²⁵² Cf in bunker	Source production /use	0.00	0.01	0.00	0.01	0.04	0.94
Trawsfynydd - filter gallery	GCR	0.21	0.07	0.02	0.05	0.17	0.48
Calder Hall – control room	GCR	0.55	0.22	0.03	0.04	0.08	0.08
Ringhals – A	Westinghouse PWR	0.11	0.20	0.06	0.08	0.21	0.34
Fuel Pin Assembly – little shielding	Fuel production	0.01	0.01	0.01	0.01	0.03	0.93
Pu finishing plant – little shielding	Fuel processing	0.01	0.01	0.01	0.02	0.15	0.80
BNFL MOX Site 2 Pos 1	MOX production	0.04	0.02	0.01	0.02	0.07	0.84
CLAB D	Fuel flask	0.03	0.14	0.04	0.07	0.20	0.52

Further information on neutron workplace field are given in two catalogues of measured and calculated energy distributions [IAEA, 2001; Naismith, 1996 and NPL, 1997] and in [Lindborg 1995, and references therein]. 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” [Eurados 2003], and in reports of an EC/EURADOS study, EVIDOS “Evaluation of Individual Dosimetry in Mixed Neutron and Photon Fields” [Schuhmacher 2006, 2007; Vanhavere 2006; Luszik-Bhadra 2007].

For several of the available neutrons dosimeters and dosimetry systems, less than adequate performance was found in both the EURADOS study [Eurados 2000] and in an IAEA inter-comparison [Cruz-Suarez 2007] which included simulated workplace fields. However, it is still considered that a choice of neutron dosimeter should be possible such that regions of inadequate dosimeter response characteristics are in energy regions where there is not a significant contribution to total $H_p(10)$.

Regular periodic Eurados organized international inter-comparisons are being introduced for both photon/electron and neutron dosimetry systems. This programme might contribute significantly to the process of choosing a suitable dosimetry system. The best method, however is to assess the available systems and establish as far as practicable the main characteristics of the workplace fields in which the dosimeter is to be worn, and if at all possible, carry out in-situ tests with available dosimetry services.

4.8 Individual monitoring based on workplace monitoring

Where doses are assessed on the basis of routine workplace monitoring results, that monitoring should be continuous and representative of all working areas within the workplace. The basis for a programme of routine monitoring for external radiation in workplaces should be a comprehensive survey, conducted when any new installation is put into service, or when any substantial changes have been made in an existing installation. The frequency of routine monitoring of the workplace depends on the expected changes in the radiation environment:

- Where no substantial alterations to the protective shielding or to the process conducted in the workplace are expected, routine monitoring should be used only occasionally for checking purposes.
- Where changes of the radiation field in the workplace are expected which are not likely to be rapid or severe, periodical or occasional checks, mainly at pre-established points, will usually give sufficient and timely warning of changing conditions; alternatively, the results of individual monitoring may be used.
- Where radiation fields may increase rapidly and unpredictably to serious levels, a warning system, either located in the workplace and/or worn by workers, will be needed in addition to the personal dosimeters. In these situations, only such a warning system can be relied upon to prevent a large dose in a short working period.

The use of two types of instrument may be necessary for mixed beta–gamma fields in which the relative contributions of beta and gamma to the dose equivalent rate can change substantially as a consequence of minor changes in the work practices. Alternatively, one instrument may be used, provided that it is capable of measuring both $H^*(10)$ and $H'(0.07, \Omega)$.

If appropriately designed and accurately calibrated instruments are used, it may be assumed that a quantity measured in the workplace can, along with appropriate occupancy data, provide the basis for an adequate estimation of the effective dose to a worker or of the equivalent dose in the local skin or extremities. The operational dose quantities $H^*(10)$ and $H'(0.07, \Omega)$ will provide an adequate estimate of effective dose and skin dose. It should be noted that the quantity $H^*(10)$ may significantly overestimate the value of $H_p(10)$, as measured with a dosimeter on an individual, and effective dose, especially if the field is isotropic. This is because instruments for measuring $H^*(10)$ have an isotropic response, whereas this is not the case for the quantities $H_p(10)$ and E (see Sections 2.3 and 7.9).

For situations in which the extremities, the unprotected skin of the body or the eyes may be locally exposed to weakly penetrating radiation, the directional dose equivalent $H'(d, \Omega)$ provides an adequate estimation of the equivalent dose to the worker. For multidirectional fields, the instrument should be rotated in the radiation field and the maximum value of dose indicated by the instrument used in order to prevent underestimation of the skin or eye dose. The operator should be aware of the possible existence of point sources or narrow beams which could give rise to misleading readings.

When calibrating area monitors the detector volume is irradiated uniformly while many operational fields irradiate the detector in a non-uniform manner (for example, close to point sources or narrow beams). These situations need special attention and it may be necessary

to determine a correction factor that can be applied to the instrument readings to give a corrected dose rate. One technique is to use a matrix of point sources to simulate source geometries of interest [Swinth 1988] As a general rule of thumb, the distance between the source and the reference point of the instrument should be equal to or larger than three times the sum of the dimensions of the source and detector in the instrument. Then any corrections can be neglected.

For the purpose of dose assessment and records, realistic estimates of occupancy should be obtained and used as it should not be assumed that a person will be located for the entire working time in that part of the workplace where the dose equivalent rate is highest. Additional information on workplace monitoring can be found in IAEA Safety Guide RS-G-1.3 [IAEA 1999a] and ICRP Publication 75 [ICRP 75].

5 ASSESSMENT OF UNCERTAINTIES

5.1 Introduction

The assessment of uncertainty in measurement is the basis for quantifying the measurement accuracy or metrological quality of measurements or fitness for purpose of a measured quantity value [JCGM 200; ISO VIM]. Measurement accuracy is quantified by an assessment of the uncertainty. The guidance is based on documents and recommendations prepared by three international bodies: the Joint Committee for Guides in Metrology (JCGM), which gives definitions and guidance for metrology in general; the ICRU which gives basic physical quantities and units for ionizing radiation; and the ICRP which defines the radiation protection principles and the role of dosimetry in radiation protection and definitions of the radiation protection quantities.

Guidance on the metrological aspects of dosimetry is found in the documents developed by the JCGM. The two fundamental reference documents are the “International Vocabulary of Basic and General Terms in Metrology (VIM)” [ISO VIM; JCGM 200] and the “Guide to the expression of uncertainty in measurement” [ISO GUM; JCGM 100].

The JCGM have issued or are planning supplements to the GUM that are of relevance for individual monitoring: “Introduction to the expression of uncertainty in measurement” [JCGM 104; ISO 98-1/1] and supplement 1 “Propagation of distributions using a Monte Carlo method” [JCGM 101; ISO GUM.1]. Further guidance in line with the GUM can be found in derived documents [ICRU 76, EA-4/02, NIST 1297, IEC TR62461] and a beginners’ introduction in the NPL Measurement Good Practice Guide No 11 [NPL 2001] and Software Support for Metrology Best Practice Guide No 6 [NPL 2004]. This Chapter gives general guidance and recommends procedures for the evaluation of uncertainties in dose measurements for occupational exposure to external radiation.

An essential aspect of quality assurance in individual monitoring is assessing the quality of the measurement results. In other words to what extent is it reasonable to believe that the reported number is a good estimate of the true dose value. The greater this belief, the confidence or probability that the measured value is within a certain defined range around the true value, or rather that the true value is within a certain range of the observed value, the better the quality of the measurement. A required quality can often be expressed as a combined standard uncertainty or as an expanded uncertainty with a coverage factor of 2, or in a more general probabilistic approach, by a coverage interval, with in general a 95% coverage probability. In the evaluation of the uncertainty, all knowledge of the dosimeter and evaluating system (TLD-readers, densitometers, track counting systems) both from experience and from type testing should be used possibly in combination with information from the client/customer such as local exposure and storage conditions.

The purpose of the guidance and recommendations given here is to promote harmonization in this field such that the results of evaluations of various dosimeters and dosimetry systems result in comparable quantifications of the metrological quality. The responsibility towards the users and authorities of the uncertainty evaluation is with the dosimetry service. However, in practice the actual evaluation may be performed by the manufacturer, type testing laboratory or specialized institute.

5.2 Recommendations

In order to obtain dose data of which the quality is traceable and can be internationally recognized it is recommended that:

- The terms and definitions given in the documents issued by the JCGM should be followed.
- The GUM framework should be followed.
- In the formulation stage:
 - All input/influence quantities that may contribute to the uncertainty should be identified (for example, film density, pm-tube signal, reading or indication of the dosimeter, radiation energy, angle of incidence, calibration sources), and must be considered in the measurement model.
 - All model input/influence quantities should be characterized by a best estimate and either a probability density function (PDF) or a (combined) standard uncertainty. The PDFs can be observed PDFs, or assigned PDFs such as uniform, triangular or Gaussian.
- In the calculation stage:
 - The results from a type test or other characterization of the response of a dosimetry system should be used as inputs to the uncertainty assessment.
 - Other parameters such as standard uncertainty and coverage intervals must be derived from the PDF of the output quantity.
- For doses at or exceeding the radiation protection limits or in some instances specific action levels, information on the irradiation conditions should be used to reduce the measurement uncertainty.
- In the case that the results of an uncertainty evaluation are used for publication, inter-comparison or for assessing conformity to criteria, it is of particular importance that the identification of the input quantities is standardized together with the corresponding rated ranges. The procedures followed in the calculation stage will depend on the algorithms used for the dose calculation for a specific dosimeter or dosimetry system.
- The result of the uncertainty evaluation should be realistic for the application (GUM clause 0.4). Also, many methods for calculating the output PDF or the resulting standard uncertainty involve mathematical or statistical assumptions or approximations. This means that the results must be subjected to an appraisal using a method that is to some extent independent.
- The amount of effort put into the uncertainty should be realistic in view of its purpose in radiation protection.

5.3 Terms

Measurand is the quantity intended to be measured. In individual monitoring, the quantities are personal dose equivalent $H_p(0,07)$, $H_p(3)$ or $H_p(10)$ as estimates for equivalent dose H_T and effective dose E .

Measurement model (or **model**) is a mathematical relation among all quantities known to be involved in a measurement.

Uncertainty (of measurement) is the parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand (GUM 2.2.3 [ISO GUM; JCGM 100], see also notes therein and VIM 2.26 [ISO VIM, JCGM 200]).

Standard (measurement) uncertainty is the uncertainty of the result of a measurement expressed as a standard deviation (GUM 2.3.1 [ISO GUM; JCGM 100], see also VIM 2.30 [ISO VIM, JCGM 200]).

Combined standard (measurement) uncertainty is the standard measurement uncertainty that is obtained using (combining) the individual measurement uncertainties associated with the input quantities in a measurement model (VIM 2.31) [ISO VIM, JCGM 200].

Type A evaluation of standard uncertainty is the evaluation based on statistical analysis of measurement data e.g. averages and standard deviations (GUM 4.2 [ISO GUM; JCGM 100]).

Type B evaluation of standard uncertainty is the evaluation based on other knowledge of the measurement system than statistical analysis of measurement data like that from specifications and certificates or experience (GUM 4.3 [ISO GUM; JCGM 100]).

Decision threshold is a fixed value of the measurand (dose), which if exceeded by the result of an actual measurement, is taken to indicate that a dose has been received, and that the probability that the measurement result would have been produced by some other effect (background) is no more than some given probability (often 5%, corresponding approximately to 1.645 standard deviations on background for a normal distribution). The decision threshold is also known as the critical level.

Detection limit, limit of detection ([ISO VIM; JCGM 200]): measured quantity value, obtained by a given measurement procedure, for which the probability of falsely claiming the absence of a component in a material is β , given a probability α of falsely claiming its presence. It is the smallest true value of the measurand (dose) that ensures a specified probability of being detected by the measurement method. Sometimes this has been called the minimum detectable dose, but this term has sometimes been confused with the decision threshold. The detection limit is the measured value (dose) for which the probability is small that when measured it will give a result that will be wrongly identified as not being a dose. That is, there is only a small probability (often 5%) of giving a result that is less than the decision threshold.

Coverage interval: interval containing the set of true quantity values with a stated probability, based on the information available.

Coverage probability: probability that the set of true quantity values is contained within a specified coverage interval.

The term confidence interval should be avoided as it only relates for measurement models in which all uncertainties are determined by statistical methods (type A evaluation, see GUM 6.2.2 [ISO GUM; JCGM 100]), which is not the case in individual monitoring.

5.4 Measurement model

The evaluation of the uncertainty in a measurement needs a mathematical model of the dosimetry system. This mathematical model, the measurement model, can be given as:

$$Y = f(X_1, X_2, \dots, X_N) = f(\mathbf{X}) \quad (5.1)$$

where the array $\mathbf{X} = X_1, X_2, \dots, X_N$ are the input and influence quantities of the measurement system and Y is the output quantity or measurand, the quantity to be measured for example, $H_p(10)$. The evaluation of the uncertainty in a measurement than consists of two stages: the formulation stage and the calculation stage.

5.5 Formulation stage of uncertainty evaluation

The formulation stage constitutes of:

- Defining the output quantity Y (the measurand, in our case a dose, for example $H_p(10)$).
- Determining the input and influence quantities $\mathbf{X} = X_1, X_2, \dots, X_N$. These are all the quantities that affect the value of the output quantity, in our case the radiation field characteristics (for example dose rate, energy and angle of incidence), dosimeter characteristics (for example sensitivity as a function of radiation energy and angle of incidence, fading), characteristics of the evaluating system (for example developer temperature, densitometer linearity or TLD reader sensitivity) and characteristics of the calibration system. An important input quantity, in particular for the low dose performance of a dosimeter, is the subtraction of the dose due to natural background radiation.
- Developing a model relating the input quantities to the output quantity $Y = f(\mathbf{X})$. In most cases the model is already largely available in the form of the algorithm that is routinely used to calculate the dose from film densities, track numbers or light output using numerous parameters such as calibration and normalization factors or coefficients, fading coefficients, instrumental blank and background dose.
- Assigning a probability density function, PDF, to each of the input quantities X_i . Where the input quantities are mutually dependant a joint PDF must be provided. This assignment is done using all knowledge of the dosimetry system and the measurement conditions.

The assigning of PDFs to some of the input quantities can be based on statistical analysis (the type A evaluation, GUM Clause 2.3 [ISO GUM; JCGM 100]). Examples are the

measurement of film density, the light detection system of a TL-reader and the blank (zero-signal) of the reader system. In TLD where often the sensitivity of the individual detectors is used, the PDF can in principle also be determined by statistical means. In these cases the PDFs are in general Gaussian or can be reasonably well approximated by a Gaussian distribution. In film and track-etch dosimetry, however, an average sensitivity for a whole sheet or batch of sheets is used. Sheets or batches that have sensitivities below or above certain pre-set limits are rejected. Consequently the PDFs that will be found on statistical analysis are at best truncated Gaussians. For many of the other input quantities an educated guess is the best available (the type B evaluation, GUM Clause 2.3). This will in particular apply to the characteristics of the fields to which the dosimeter wearer was exposed but will also to fading parameters such as temperature and time and durations of exposures. In that case, a simple PDF must be assigned where possible helped by the knowledge of experts. Such distributions can for example be the rectangular (uniform) distribution, the trapezoidal or the triangular distribution whereby the rectangular distribution will give the most conservative estimate. If the energy and direction spectral distributions of the workplace field are known in terms of the measurand, than these can, after normalization, be used as PDFs for the energy and angle of incidence input quantities. In this case, however, one is restricted to Monte Carlo methods for the calculation stage.

5.6 Calculation stage of uncertainty evaluation

5.6.1 General

The calculation stage consists of propagating the PDFs of the inputs through the measurement model $Y = f(\mathbf{X})$ into a PDF of the output. From this PDF the following summarizing quantities must be calculated:

- The expectation, the central value of the PDF that is taken as the estimate y of Y for the dose.
- The standard deviation that is taken to be the combined standard uncertainty $u_C(y)$ in the dose.
- A coverage interval that contains Y with a specified probability, the coverage probability which is often taken as 95%.

For the calculation stage essentially two methods are available:

- The GUM framework (GUMF) based on the law of propagation of uncertainties (LPU) and the central limit theorem (CLT) [ISO GUM; JCGM 100].
- Monte Carlo method (MCM, GUM supplement 1 [JCGM 101]).

As mentioned before, the GUM framework is currently the mainstream choice. For complicated and significantly non-linear measurement models the MCM might be a far better route [Cox 2006].

If the model that results from the formulation stage is given by $Y = f(X)$ and the PDFs for each input quantity X_i are given by $g(X_i)$, then the PDF of the output quantity is given by the convolution integral of all $g(X_i)$ (eq. 3.1 in [NPL 2004]). In general there is no solution of this integral in closed form. Consequently approximate solutions or numerical methods must be used. The most commonly chosen solution path is using the law of propagation of

uncertainties, LPU, together with the central limit theorem, CLT. This method is discussed below as the GUM framework method, GUMF. The other is based on numerical methods for solving the integral. The method of choice is in this case statistical sampling using Monte Carlo methods (MCM) as standard, faster converging, methods for numerical integration cannot reliably be applied.

5.6.2 GUM framework method

The framework for uncertainty evaluation is given by the GUM [ISO GUM; JCGM 100]. In this guide the main building blocks are given in general terms. The main focus in the GUM is on calculation methods that depend on the law of propagation of uncertainties, LPU, and the central limit theorem, CLT, which is the method used, usually unknowingly, by a majority of laboratories. The PDFs of the input quantities are assumed to be, e.g., Gaussian, rectangular or triangular and described by the expectation x_i of X_i and the standard uncertainty $u(x_i)$. The sensitivity of the measurand Y to small changes in the input and influence quantities X_1, X_2, \dots, X_N is calculated by taking the partial derivatives:

$$c_i = \frac{\partial Y}{\partial X_i} \quad (5.2)$$

The standard uncertainty in $u(y)$ follows then from the standard uncertainties $u(x_i)$ and these sensitivity coefficients c_i (the LPU):

$$u(y) = \sqrt{[c_1 u(x_1)]^2 + [c_2 u(x_2)]^2 + \dots + [c_N u(x_N)]^2} \quad (5.3)$$

If input or influence quantities are not independent then corrections have to be introduced of the form:

$$2c_{ij} u(x_i, x_j) \quad (5.4)$$

Where

$$c_{ij} = \frac{\partial y}{\partial x_i} \frac{\partial y}{\partial x_j} \quad (5.5)$$

and $u(x_i, x_j)$ is the covariance of x_i and x_j .

In dosimetry systems the calibration of the detector, either individually or based on, for example, sheet averages, will be done with the same evaluation instruments as the evaluation of the used dosimeters. Thus the input quantities calibration factor and dosimeter signal will be dependent. In general the contribution to the combined uncertainty of the evaluating system is rather small and ignoring the co-variances will not have a major impact but it is a strong argument for validating the GUMF approach for a dosimetry system.

If the uncertainty in X_i is evaluated by statistical means and the PDF is assumed to be Gaussian, then $u(x_i)$ has the numerical value of the standard deviation of x_i otherwise the PDF is in many cases assumed to be rectangular with a range $-a$ to $+a$ symmetrical about the best estimate x_i . The standard deviation as it directly follows from its definition is then:

$$u(x_i)_{\text{rect}} = \frac{a}{\sqrt{3}} \quad (5.6)$$

An overview of input and influence quantities and associated PDFs and standard uncertainties can be found for example in the IEC Technical Report on uncertainties [IEC/TR 62461]).

If the measurement model (eq. 5.1) is entirely multiplicative and all input quantities independent:

$$Y = f(\mathbf{X}) = X_1 X_2 \dots X_N \quad (5.7)$$

then eq. 5.4 simplifies to:

$$u(y) = Y \cdot \sqrt{u_R(x_1)^2 + u_R(x_2)^2 + \dots + u_R(x_N)^2} \quad (5.8)$$

where $u_R(x_i) = u(x_i)/x_i$ is the relative standard uncertainty of x_i . Except for the subtraction of the instrument blank and the contribution of the natural background, the measurement model of a passive dosimetry system will in general be a multiplicative model. For active dosimetry systems further additive influence quantities like electromagnetic disturbances or shock may occur.

Equations 5.3 and 5.8 are based on the central limit theorem which, loosely formulated, states that if a sufficient number of symmetrical distributions is combined then the resulting distribution will be Gaussian. For the calculation of the decision threshold, detection limit and coverage interval, the effective degrees of freedom must be known. They can be approximated using the Welch-Satterthwaite formula (Annex G [ISO GUM; JCGM 100]). Often, however, it will suffice to state that using a coverage factor $k = 2$ will result in a coverage interval $y \pm k \cdot u(y)$ with approximately 95% coverage probability. Care must be taken when interpreting such coverage intervals because when the dose value y approaches its uncertainty $u(y)$, the lower bound of the coverage interval will become negative. When in that case a detailed analysis is required, Bayesian based methods must be used [Weise 2006].

5.6.3 Monte Carlo methods

The Monte Carlo method, MCM, uses statistical sampling from the PDFs of the input quantities to evaluate the convolution integral of the PDFs. The general scheme for a MCM calculation is outlined in Table 5.1 [ISO GUM.1; JCGM 101; NPL 2006].

Table 5.1: Steps in the Monte Carlo Method.

1	Generate a random sample $x_{i,r}$ from the PDF of each X_i , $i = 1, \dots, N$
2	Calculate y_r using eq. (5.1)*
3	Repeat steps 1 and 2 M times
4	Calculate the average value y using eq (5.9)
5	Calculate the standard deviation $u(y)$ (eq. 5.10) see note 1 in clause 7.6 in GUM Suppl 1 [ISO 2007b]
6	Take y as the estimate for Y and the standard deviation as the standard uncertainty $u(y)$ associated with y .

(*) In case of a Bayesian evaluation y_r is rejected if $y_r < 0$ [Elster 2007].

Step 2 can take the form of calculating the raw signal from the system, e.g. TLD-reader, from the samples $x_{1,r}..x_{N,r}$ and then use the routine algorithms for evaluating a dose from the raw signal to obtain y_r .

$$y = \frac{1}{M} \sum_{r=1}^M y_r \quad (5.9)$$

$$u(y) = \sqrt{\frac{1}{M-1} \sum_{r=1}^M (y_r - y)^2} \quad (5.10)$$

In general a value of M between 10.000 and 1.000.000 will suffice for a standard uncertainty in 2 or 3 significant digits [van Dijk 2006]. A prerequisite for the method is the availability of random number generators for each of the PDFs. These are, however, available in most programming languages (notably open source numerical libraries) and statistical packages. If the PDF is only available as experimental data points like in the case of the energy distribution of the dose and the energy response of the dosimeter then random number generators for arbitrary distributions are available [Press 2007, van Dijk 2006]. These generators are all based on generating random numbers from the uniform distribution: supplement 1 to the GUM gives guidance on the generators to use [ISO GUM.1; JCGM 101; NPL 2006]. From the dataset $y_r, r = 1,..,M$, it is straight forward to calculate a coverage interval (GUM Supplement 1 Clause 7.7) as shown in Table 5.2.

Table 5.2: Steps in calculating coverage intervals.

<ol style="list-style-type: none"> 1 Sort y_r in non descending order. 2 Assign to each y_r in the sorted order a probability p_r using eq. (5.11). 3 For a 95% coverage interval find the range $p_- ... p_+$ such that $p_+ - p_- = 0.95$. 4 The corresponding y values constitute the coverage interval.

$$p_r = \frac{r - \frac{1}{2}}{M} \quad (5.11)$$

As only values that have a physical meaning are obtained in step 2 in Table 5.2, the resulting coverage intervals contain only physical relevant data and will coincide with that found using a Bayesian approach [Elster 2007].

5.7 Thresholds

Thresholds are meant to indicate the lowest measured or true dose value for which the dosimetry system is believed to give a reliable value. Generally, two thresholds are of relevance in individual monitoring, the definitions of which are given in the Table 5.3 [ISO 11929].

Table 5.3: Definitions of two thresholds where α and β are the probabilities of errors of the first and second kind respectively.

Decision threshold (Critical Value):	$y^*, \alpha = 0.05$ $P(Y > y^* Y = 0) \leq \alpha$	(5.12)
Detection limit (Minimum Detectable Value):	$y^\#, \beta = 0.05$ $P(Y \leq y^\# Y = y^\#) = \beta$	(5.13)

Other terms and symbols in common use are for y^* critical level L_C and for $y^\#$ minimum detectable value L_D [IAEA 2004]. Essentially, the decision threshold is the value at the upper level of what is likely to be background, the detection limit is the value of dose for which there is only a small probability of confusion with background (Figure 5.1). 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. On the other hand, 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 difference in application is that measured values are to be compared with the decision threshold, whereas the detection limit of a measuring system is to be compared with a guideline value.

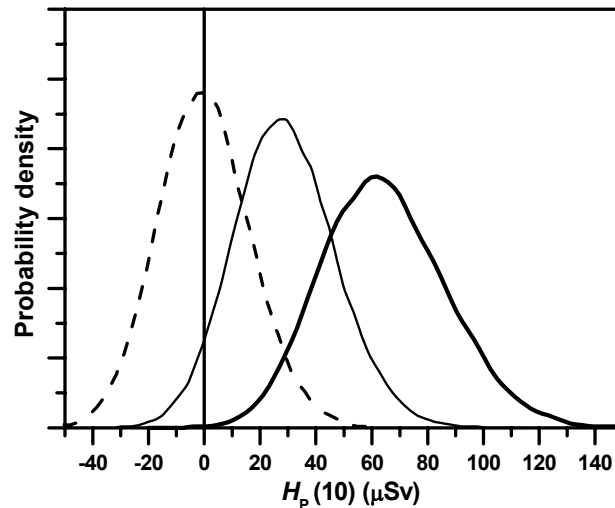


Figure 5.1: The probability density function at the level of the natural background (dashed), at the level of the decision threshold y^* (thin solid) and the detection limit $y^\#$ (thick solid).

For simple systems where the PDF of the measurand is (to a good approximation) Gaussian, the thresholds can be given as:

$$y^* = t_{1-\alpha, \nu} u(0) \quad (5.14)$$

where $t_{1-\alpha, \nu}$ is the value of the Student t-distribution for ν degrees of freedom and $u_{C,0}$ the combined standard uncertainty in the dose at zero dose.

$$y^\# = y^* + z_{1-\beta} u(y^\#) \quad (5.15)$$

where $z_{1-\beta}$ is the standard normal variate. Approximations with $\alpha = \beta = 5\%$ that can serve as a rule of thumb are $y^* \approx 1.7u(0)$ and $y^\# \approx 3.3u(0)$. They assume that the blank indication (zero dose indication) and the subtracted natural background (see Section 6.7) are well known and that $u(y)$ is more or less constant in the interval $y = 0$ to $y = y^\#$.

In Figure 5.1 the area below the dashed curve to the right of the vertical at $y = y^*$ and that below the thick solid curve to the left of that line are both 5% of the total areas below the curves. The PDF's are obtained by applying the Monte Carlo Method to a realistic system and are not exactly Gaussian but slightly skewed. Also the distributions get wider at increasing y , together making that the thick solid and dashed curves do not intersect at $y = y^*$ as is often the case in examples in the literature.

This evaluation of the characteristic limits ignores the fact that the calculated values of the lower bounds of the coverage intervals will in general be negative. As negative occupational doses have no physical meaning, the prior knowledge that the PDF of y must be zero for all $y < 0$, $f(y | y < 0) = 0$, must be introduced in the evaluation using Bayesian statistics. The Bayesian evaluation of the coverage intervals and characteristic limits is defined in ISO 11929 and can be calculated from $u(y)$ using the formula in Chapter 7 of the standard [ISO 11929]. It must be expected that the Bayesian values for y^* and $y^\#$ are between 5% and 10% higher than the conventional ones.

Eq. 5.15 and its Bayesian counterpart (eq. 22 in [ISO 11929]) are implicit equations in that the right hand side also contains $y^\#$. This means that it must be solved by interpolation of tabulated values of y and $u(y)$ or by an iterative method.

5.8 How realistic is the uncertainty evaluation?

The best judgment on the uncertainty evaluation would be the comparison of the distributions of dose values routinely measured with a given dosimeter with the best estimates of distributions of those dose values. For individual dosimetry this is not possible as best estimates of the distributions of dose values are not normally available. A reasonable approach is to use the results of performance tests, see 8.5. This is shown in the Figures 5.2 for photon whole-body dosimeters and 5.3 for neutron whole-body dosimeters.

The performance tests for photon dosimeters cover the whole rated range of radiation energy, angle of radiation incidence and dose without any prior knowledge to the participants. The results indicate that the requirements given in Chapter 6 of a combined standard uncertainty of 30% for photons, and by IEC 62387-1 [IEC 62387-1] are quite achievable and the distributions of the results of dosimeters participating in the performance tests are only slightly better than the minimum requirements for the uncertainties.

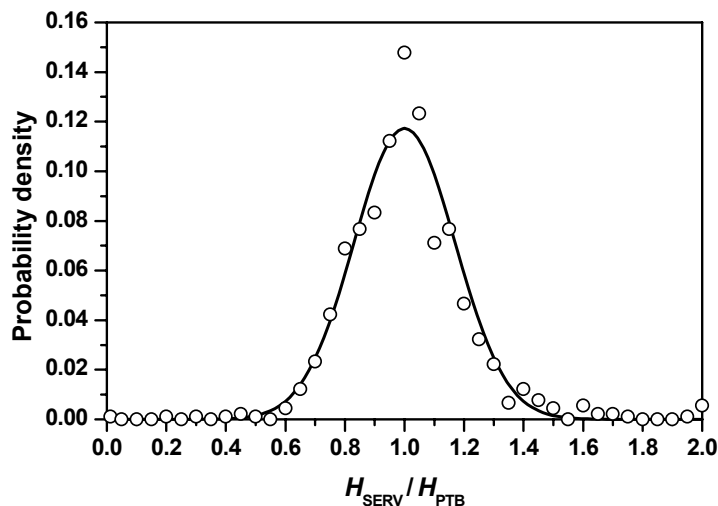


Figure 5.2: Comparison of the results of the German annual performance tests for photon whole-body dosimeters of the years 2001 to 2006 (circles, derived from 900 values) with the minimum requirements of IEC 62387-1 and uncertainty calculation according to Annex B of IEC/TR 62461 (solid curve) leading to a relative uncertainty of $u_{\text{rel}} = 17\%$.

The performance tests for the German neutron dosimeters, which are all of the albedo type, also cover the whole rated range of dose and angle of radiation incidence without any prior knowledge to the participants, but the participants get some information on the neutron energy. The requirement in Chapter 6 for neutrons is for a combined standard uncertainty of 50% or less. As there is no EN or IEC requirement available for passive neutron dosimeters, which is suitable for the uncertainty calculation, the requirements of EN 61526 [IEC 62526], which is written for active neutron dosimeters, were used for the determination of an uncertainty value. The results indicate that the dosimeters perform better than the requirements given by EN 61526 [IEC 61526], but this might be due to the prior information given on the energy.

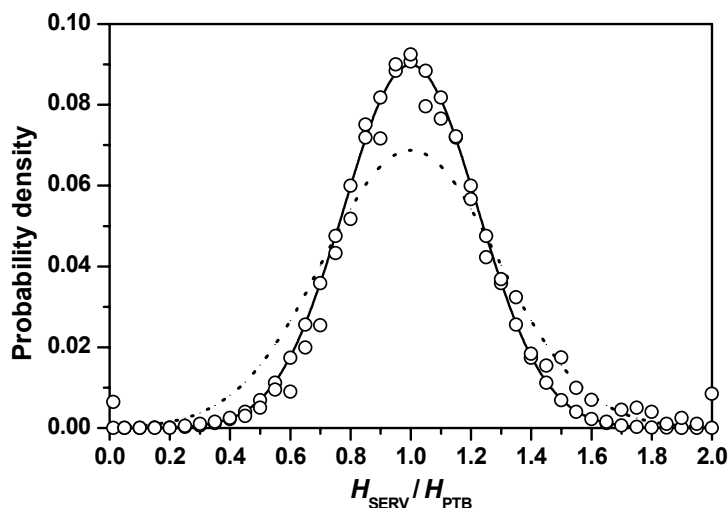


Figure 5.3: Comparison of the results of German annual performance tests for neutron whole-body dosimeters of the years 1998 to 2007 (circles, derived from 2011 values) with the requirements of EN 61526 and uncertainty calculation according to Annex B of IEC/TR 62461. The minimum requirements lead to a relative uncertainty of $u_{\text{rel}} = 29\%$ (dotted curve), the best fit is a relative uncertainty of $u_{\text{rel}} = 22\%$ (solid curve).

5.9 Appraisal of uncertainty evaluation

In the previous sections it was mentioned on several occasions that approximations are used. These fall in two categories: a) neglecting the impact of certain input or influence quantities of which experimental evidence or expert judgement tells it is safe to do so (notably very often co-variances that result from quantities being interdependent) and b) approximations in the mathematical evaluation like assuming linearity of the model over a sufficient range of X values. The GUMF method makes extensive use of approximations and it is therefore important to validate the evaluation based on the GUMF by Monte Carlo calculations [JCGM 101, NPL 2006].

Data mining in the results of routine monitoring and QA/QC program results [van Dijk 1998] and careful analysis of the results of national and international inter-comparisons, in particular if various datasets over several inter-comparisons are available, can add to the appreciation of the method of uncertainty evaluation including a qualitative judgment on the relevance of the evaluation of characteristic limits. For further discussion see also Section 6.5.

5.10 Reporting of uncertainties

In order to conform to the requirements in the quality assurance standard EN ISO/IEC 17025:2005, the uncertainty in measurement should be reported. In routine monitoring this requirement can be fulfilled by including in the directions for use, the detection limit and the relative standard uncertainty for doses that could sum to an annual dose approaching dose limits, for example by stating what the relative standard uncertainty is for a 1 mSv measurement. Uncertainties are in general not reported to more than two significant digits. As reporting doses in more detail than the standard uncertainty allows is from a metrological point of view not too meaningful, the doses of systems with a standard uncertainty in low doses of less than 0.1 mSv can be reported in multiples of 0.01 mSv and with a higher standard uncertainty in steps of 0.1 mSv. Regulations may deviate from this metrological argument.

5.11 An example

5.11.1 Example dosimeter

For illustrating the various technical evaluations in this Chapter an imaginary thermoluminescence dosimeter is used. It consists of a standard magnesium titanium doped lithium fluoride detector (LiF:Mg,Ti, MTS® or TLD100®) covered with a 1 mm thick aluminium filter. The dosimeter is presumed to have been type-tested for $H_p(10)$ for photon energies between 20 keV and 2000 keV at angles, α , between 0° and 75°. A summary of the results are given in Table 5.4. The responses are normalized such that the response at normal incidence and 1250 keV is unity.

Table 5.4: Response with respect to $H_p(10)$ for an imaginary dosimeter with a LiF:Mg,Ti detector and a 1 mm aluminium filter.

E (keV)	α	0°	15°	30°	45°	60°	75°
20		1.01	0.99	0.97	0.92	0.82	0.52
30		1.17	1.17	1.17	1.19	1.22	1.30
40		1.14	1.15	1.16	1.18	1.26	1.50
60		1.03	1.04	1.04	1.08	1.15	1.42
80		0.97	0.97	0.99	1.01	1.10	1.34
100		0.95	0.95	0.96	0.99	1.07	1.34
...	
1250		1.00	1.00	1.00	1.01	1.04	1.12
1500		1.00	1.00	1.00	1.01	1.04	1.12
2000		1.00	1.00	1.00	1.01	1.04	1.11

The irradiations and evaluations are assumed to be done in triplicate from which follows a combined standard deviation of 0.05 ($u_{R,E,\phi}$). For the sake of simplicity this is here taken to be the same for all table entries. This combined uncertainty comprises all sources of uncertainty including that in the calibration of the sources.

5.11.2 Example routine dose assessment procedure

The imaginary dosimetry service has a sufficiently large pool of reference dosimeters that are selected for having detectors with closely similar sensitivity. This sensitivity is set to 1.00 and has a standard deviation of 0.02 ($u_{f_{Ref}}$). All routine dosimeters were irradiated in a homogeneous field together with a sufficient number of reference dosimeters. The ratio between the response of a dosimeter and the average response of the simultaneously irradiated reference dosimeters is the detector normalization factor (also called element correction coefficient or ecc).

$$f_{TLD} = \frac{x - z}{\eta - z} \quad (5.16)$$

Where x is the reader signal from the detector, z the reader blank signal and η the average net signal from the detectors of the reference dosimeters.

Every day the service determines the sensitivity of the readers by reading 5 irradiated reference dosimeters. The irradiations are done with a source of which the dose rate is traceable to the primary standard. The reader sensitivity f_{Ref} is the quotient of average net signal of the used reference dosimeters and the dose. The average of third re-readings is used as the reader blank indication, z .

$$f_{Ref} = \frac{\overline{x - z}}{H_p(10)_{Ref}} \quad (5.17)$$

Where $\overline{x - z}$ is the average of the net signals from the exposed reference dosimeters and $H_p(10)_{Ref}$ the reference dose in μSv .

5.11.3 Measurement model

Using the above description including eq. 5.16 and 5.17, the dose of an issued dosimeter is calculated to be:

$$y_{\text{gross}} = \frac{x - z}{f_{\text{Ref}} f_{\text{TLD}} f_{E,\alpha}} \quad (5.18)$$

where $f_{E,\alpha}$ is the correction for the energy and angle dependent response. For monochromatic radiation the values for the example dosimeter $f_{E,\alpha}$ can be found in Table 5.4. In the absence of knowledge of the field to which the user was exposed $f_{E,\alpha}$ is usually taken to be 1.0. The dose due to the natural background in terms of $H_p(10)$ is calculated using a national average dose rate \dot{H}_{Bg} of $2 \mu\text{Sv d}^{-1}$. With t days between consecutive readings this gives a net occupational dose of:

$$y = y_{\text{gross}} - t \dot{H}_{\text{Bg}} \quad (5.19)$$

For the sake of simplicity all possible corrections like fading correction and corrections for the not ideal energy and angle response, including that for the natural background radiation, are assumed to be unity in the example calculations. The Table 5.5 summarizes the input quantities of the simplified measurement model with example values and uncertainties.

Eq. 5.19 is the relation the service uses for calculating the dose to be reported. In general this relation will not satisfy the assumptions needed for the validity of the law of propagation of uncertainties (LPU) as discussed in 5.6.2. In equation 5.19 several parameters that contribute significantly to the uncertainty appear in the denominator which means that the second order terms of the Taylor series on which the LPU is based, will not vanish. If the standard uncertainty of a parameter in the measurement equation is not small compared to the ratio of the first and second derivative, then the LPU gives no reliable results. After a variable transformation $K_i = 1/f_i$ this problem is in general solved resulting in:

$$y = K_{\text{Ref}} K_{\text{TLD}} K_{E,\alpha} (x - z) - t \dot{H}_{\text{Bg}} \quad (5.20)$$

From eq 5.20 the sensitivity coefficients in the LPU are easily calculated as the partial derivatives of the output quantity and the input quantities giving for the standard uncertainty in the dose y :

$$u_y = \sqrt{c_{K_{\text{Ref}}}^2 u_{K_{\text{Ref}}}^2 + c_{K_{\text{TLD}}}^2 u_{K_{\text{TLD}}}^2 + c_{K_{E,\alpha}}^2 u_{K_{E,\alpha}}^2 + c_x^2 u_x^2 + c_z^2 u_z^2 + c_{\dot{H}_{\text{Bg}}}^2 u_{\dot{H}_{\text{Bg}}}^2 + c_t^2 u_t^2} \quad (5.21)$$

In order to calculate the decision threshold and detection limit with $\alpha = \beta = 5\%$ the limits of the 90% coverage interval must be calculated at zero dose and, by interpolation, at the level of the detection limit itself. The boundaries of the coverage interval are given by:

$$y^< = y + t(v_{\text{eff}}, 0.05) u(y) \quad y^> = y + t(v_{\text{eff}}, 0.95) u(y) \quad (5.22)$$

where $y^<$ and $y^>$ are the lower and upper value of the coverage interval and $t(v_{\text{eff}}, 0.05)$ and $t(v_{\text{eff}}, 0.95)$ are respectively the 5% and 95% quantiles of the Student t-distribution for v_{eff} effective degrees of freedom. The effective degrees of freedom must be approximated by the Welch-Satterthwaite formula (GUM eq. G2b and G3 [ISO GUM; JCGM 100]) using the standard uncertainties in the input quantities and their degrees of freedom. The decision

threshold, y^* , is the value of $y^>$ for a zero dose ($y = 0$). The detection limit, $y^\#$, is the value of y for which $y^<$ is equal to the decision threshold. This value can be approximated by an iterative procedure or simply by interpolation from tabulated values, e.g. between 60 and 70 μSv in Table 5.6.

Table 5.5: Quantities and their value, uncertainty and effective degrees of freedom, ν_{eff} , as used in the examples.

Quantity	Unit	Expected value	Uncertainty	Distribution	ν_{eff} ⁸⁾
Z	1 (counts)	110	5% of 110 = 5.5	Normal ¹⁾	4
X	1 (counts)		2%	Normal ¹⁾	100
$f_{E,\alpha}$	1	1.01 ²⁾	$0.5(1.50-0.52) / 3 = 0.16$	Normal ³⁾	G.3
f_{TLD}	1	1	$0.5(1.1-0.9) / \sqrt{6} = 0.041$	Triangular ⁴⁾	100
f_{Ref}	μSv^{-1}	20	2% of 20 = 0.4	Normal ⁵⁾	4
t	d	50	$0.5*(51-49) / \sqrt{3} = 0.57$	Uniform ⁶⁾	G.3
$H_{\text{Bg}}^{\&}$	$\mu\text{Sv d}^{-1}$	2.00	0.3	Normal	100
$K_{E,\alpha}$	1	1.29 ²⁾	$0.5(0.52^{-1}-1.50^{-1}) / 3 = 0.21$	Normal ⁷⁾	
K_{TLD}	1	1	$0.5(0.9^{-1}-1.1^{-1}) / \sqrt{6} = 0.041$	Triangular ⁷⁾	
K_{Ref}	1	1/20	2% of $20^{-1} = 0.001$	Normal ⁷⁾	

- 1) In TLD-readers that work in photon counting mode z and x actually will have a Poisson distribution and f_{Ref} a gamma distribution but the count results will in general be large enough to allow approximating by the normal distribution.
- 2) The GUM requires the expected value to be in the centre of the distribution. The resulting bias has no effect on the outcome of the uncertainty evaluation for the associated uncertainty. But it affects the value of the sensitivity coefficients c in eq. 5.21 and thus the combined standard uncertainty $u(y)$.
- 3) Assuming a normal distribution the standard uncertainty in $f_{E,\alpha}$ is approximately the difference between the highest and lowest value in table 5.4 divided by 6.0 [IEC TR 62461]. Taking a normal distribution gives preference to the middle energies in the table and normal incidence.
- 4) For f_{TLD} a triangular distribution is used to reflect the fact that detectors with a too low or too high response will in general be rejected for routine use as a measure of quality assurance. The standard deviation is the half range divided by $\sqrt{6}$ [IEC TR 62461].
- 5) The uncertainty in f_{Ref} includes the uncertainty in the dose rate of the calibration sources.
- 6) In general the readout moments will be stored in the databases in terms of dates which will introduce a discretization error of 1 or 2 days. The standard error is the half range divided by $\sqrt{3}$ [IEC TR 62461].
- 7) These parameters refer to the variable transformation necessary to improve the validity of the LPU (see equation 5.20). Assuming the same distributions for K_i as for f_i means essentially that different assumptions are made on the distribution of the physical parameters. As these are best guesses anyway this will not impair the validity of the LPU approximations for the standard uncertainty (see also note 2 and [IEC TR 62461]).
- 8) G.3 refers to GUM eq. G.3, 100 means based on a large number of observations and 4 means based on the average of 5 daily measurements during reader calibration.

5.11.4 Numerical example GUM framework

The data from Table 5.5 entered into the above equations results in the combined standard uncertainties, the effective degrees of freedom and the borders of the 90% coverage interval as shown in Table 5.6. The standard uncertainty at low occupational doses is mainly caused

by the uncertainty in the subtraction of a national average background. As this is supposed to be based on an extensive survey, the effective degrees of freedom for low dose values is rather high which makes that for deriving the decision threshold and detection limit the t -values for infinite degrees of freedom can be used in comparable situations thereby avoiding the cumbersome evaluation of the Welch-Satterthwaite calculations.

Table 5.6: Combined standard uncertainties as a function of net dose given the parameters in Table 5.5 and using eqs. (5.21) and (5.22), together with the parameters needed for the calculation of decision threshold and detection limit.

y (μSv)	$u(y)$ (μSv)	ν_{eff}	$t(\nu_{\text{eff}}, 0.95)$	$y^<$ (μSv)	$y^>$ (μSv)
0	22.5	64	1.67	-37.6	37.6
90	35.2	33	1.69	30.5	150
100	36.7	32	1.69	37.9	162
1000	184	23	1.71	684	1316

5.11.5 Bayesian evaluation.

The Table 5.6 shows that the lower bound of the coverage interval becomes negative. This starts at below approximately 30 μSv . Negative dose values, however, have no physical meaning. The prior knowledge that the probability of a true occupational dose of less than 0 is zero, $P(y | y < 0) = 0$, can be introduced by applying Bayesian statistics [Weise 2007]. Using the eq. 29 through 34 in the standard ISO 11929 [ISO 11929] the data in Table 5.6 can be corrected for the prior knowledge $y \geq 0$. The results are given in Table 5.7 and the combined data from Table 5.6 and 5.7 are shown in Figure 5.4.

Table 5.7: Combined standard uncertainties as a function of net dose given the parameters in Table 5.5 and using eqs (5.21) and (5.22), together with the parameters needed for the calculation of decision threshold and detection limit using the Bayesian analysis of ISO 11929.

y (μSv)	\hat{y} (μSv)	$u(\hat{y})$ (μSv)	$y^<$ (μSv)	$y^>$ (μSv)
0	18.0	13.6	1.4	44.1
90	90.5	34.5	33.8	147
100	100	36.2	40.7	160
1000	1000	185	696	1303

5.11.6 Monte Carlo method

The same input data have been used in an MCM calculation according to GUM Supplement 1 [JCGM 101; ISO GUM.1, Elster 2007]. Also an MCM calculation was done using the inputs from Table 5.5 except that, as in line 2 of the table, not with a Gaussian distribution for the responses in Table 5.4, but with a uniform dose versus log energy distribution:

$$P(E) = \frac{1}{\ln(E_1/E_0)E} \quad (5.23)$$

This model distribution gives results that are almost identical with those using a weighted average of workplace fields [van Dijk 2007]. The Table 5.8 compares the results of various evaluation methods: The conventional GUMF framework and, using Bayesian statistics, the GUMF, MCM and MCM with the uniform $H_p(10)$ versus $\log(E)$ distribution over the rated range from $E_0 = 20$ to $E_1 = 2000$ keV.

Table 5.8: Comparison of characteristics of the LiF:MgTi example dosimeter for a conventional GUMF evaluation, a Bayesian GUMF evaluation according to ISO 11929, a Bayesian MCM evaluation using the same inputs as for GUMF and one using a uniform $H_p(10)$ versus $\log(E)$ distribution.

	GUMF	GUMF Bayesian	MCM Bayesian	Uniform $H_p(10)$ - $\log(E)$ Bayesian
u_y at $H_p(10) = 0$ (μSv)	22.5	13.6	13.6	14.1
Decision threshold (μSv)	37.6	44.1	33.9	34.5
Detection limit (μSv)	99.6	105	69.3	63.6
Rel. std uncertainty at 1 mSv	18.5%	18.5%	17.9%	11.0%

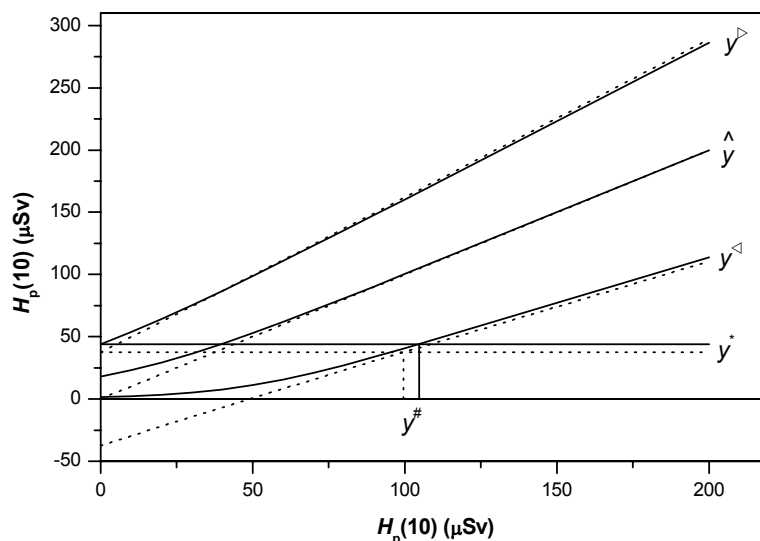


Figure 5.4: Uncertainty evaluation of example dosimeter. From top to bottom the curves show the upper limit of the 90% coverage interval, the expected value and the lower bound of the coverage interval. The dotted lines show the results of the GUMF evaluation and the solid line gives corresponding values for the Bayesian evaluation. The intersection of the upper bound with the vertical axis shows the decision threshold y^* . The intersection of the horizontal line at the level of y^* and the lower bound of the coverage interval shows the detection limit $y^\#$ (compare with fig 2 in ISO 11929).

5.11.7 Conclusions

The table shows that, depending on the choices made, the results differ, be it not dramatically. This takes into account that in uncertainty analysis only the first or first and

second digit have a meaning (here more digits are shown only for comparison reasons). This implies, however, that if far reaching decisions are to be made on the basis of an uncertainty analysis, i.e. as criterion for approval, all details of the testing and evaluation procedures must be precisely described. This also might need to involve far more sophisticated statistical analysis [Brunzendorf 2007]. The differences between the columns 3 and 4 of Table 5.8 may be due to the fact that the MCM method automatically takes care of correlation between parameters whereas the GUMF in its usual form does not. The lower value for the detection limit and the relative standard uncertainty of a dose of 1 mSv in the right most column can be seen as an indication that an evaluation only based on the lowest and highest values in Table 5.4 can result in a clear over estimation when compared with an MCM method that uses all values in the table and makes a realistic assumption on the dose/energy distribution.

6 REQUIREMENTS FOR ACCURACY OF DOSE ASSESSMENTS

6.1 Introduction

For doses below dose limits, or in some instances below specific action levels, E and H_T , are assessed in terms of the operational quantities (see Chapter 3). As stated by ICRU, 'Personal dosimeters will, at best, only register the dose equivalents received by regions of the body that are in proximity to these devices', and there is obviously the possibility of a significant source of uncertainty in the assessment of E and H_T in going to these quantities from the operational quantities. ICRP in Publications 60 and 75 recommends 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." These statements strictly apply to the assessment of E and H_T , but for doses below limits can be applied to the operational quantities.

ICRU makes recommendations on the acceptable levels for total uncertainty in Reports 47 and 66 [ICRU 47, ICRU 66] (these recommendations have been recently confirmed) which are broadly consistent with the ICRP statements. ICRU recommends for single measurements of the operational quantities that "...in most cases, an overall uncertainty of one standard deviation of 30% should be acceptable." "The error of instruments may substantially exceed this limit at some radiation energies and for certain angles of incidence, but conform to it when they occur in a radiation field with a broad energy spectrum and broad angular distribution."

It must be recognized that there may need to be different requirements on accuracy for (a) a measurement of the operational quantity at the location of the dosimeter in the workplace (or perhaps in a performance test or inter-comparison in simulated workplace fields); (b) a measurement of a protection quantity in the workplace, for example an estimate of equivalent dose to the finger tips from a measurement of $H_p(0.07)$ several cm away; (c) an assessment of annual dose approaching dose limits.

The recommendations given below apply to (a) which relates to the requirement on a measurement by an ADS of the operational quantity, except at, or near, dose limits, where the recommendation applies to the assessment of the protection quantities. In the latter case, the ADS alone will not be in a position to carry out the assessment which is likely to require detailed information on the conditions in which the dosimeter and worker were irradiated (see remarks about evaluation of dose results in Chapter 2).

6.2 Recommendations

- For a measurement of the operational quantity $H_p(10)$ for a single field component for a quantity value equal to or greater than 1 mSv (annual dose limit for E for members of the public) in proportion to the wear period, the combined standard uncertainty should be less than 30% for photon/electron workplace fields and less than 50% for neutron fields.
- For a measurement of the operational quantity $H_p(3)$ for a single field component for a quantity value equal to or greater than 15 mSv (annual dose limit for H_T for eye lens for members of the public) in proportion to the wear period, the combined standard uncertainty should be less than 30%.
- For a measurement of the operational quantity $H_p(0.07)$ for a single field component for a quantity value equal to or greater than 50 mSv (annual dose limit for H_T for local skin or extremities for members of the public) in proportion to the wear period, the combined standard uncertainty should be less than 30%.
- The combined standard uncertainty for values of assessed annual dose values at or near the dose limit should not exceed 20 %, or in a more general probabilistic approach the 95% confidence interval should not exceed 0.67 to 1.5, after all corrections have been made. This applies to values of effective dose, equivalent dose to a small area of skin, equivalent dose to eye lens or extremities, summed for all components. The expanded uncertainty (coverage factor of 2) of 40 % is close to the 95% confidence interval of 0.67 to 1.5 (factor 1.5) given by ICRP. The uncertainty in the assessment of the protection quantity at or near the dose limit includes any uncertainty determined by type B evaluation (systematic uncertainty) in the application of a model, which incorporates data on dosimeter and irradiation conditions, to go from the measured quantity to effective dose or equivalent dose [ICRP 75].

Where the external radiation field has both a photon plus electron component and a neutron component, the overall uncertainty is derived from the uncertainties for the two assessments/measurements. If, as is usually the case, the photon plus electron component is the larger, and the combined standard uncertainty for this assessment/measurement is less than 30%, a combined standard uncertainty of greater than 30% can be accommodated for the neutron component, and still meet the criterion for the uncertainty on the total dose. If the field is overwhelmingly dominated by the neutron component, additional information and possibly a field-specific correction, may need to be applied in order to meet the overall accuracy criterion. Any contributions from intakes of radiation must be included. For these contributions, the combined uncertainties may be substantially greater than 30%.

6.3 Terms

Accuracy: There are two approaches to what is meant by the concept accuracy (see ISO/IEC Guide 99 VIM 3e, [ISO VIM, JCGM 200]). In the classical approach, measurement accuracy/accuracy of a measurement is defined as the closeness of agreement between a measured quantity value and a true quantity value of the measurand. In the uncertainty approach, the concept is defined as the closeness of agreement between measured quantity

values that are being attributed to the measurand. The concept of measurement accuracy is not given a numerical value, but a measurement is said to be more accurate when it offers a smaller measurement error. Methods of measuring measurement accuracy are found in ISO 5725 [ISO 5725]; the definitions of statistical terms in ISO 3534 [ISO 3534]. Uncertainty is considered in Chapter 5.

Trueness is the closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value. Measurement trueness is inversely related to only systematic measurement error. The term ‘measurement trueness’ should not be used for ‘measurement accuracy’ and vice versa.

Bias is the systematic measurement error or its estimate, with respect to a reference quantity value. Trueness is the inverse of bias. The term bias is normally used rather than trueness.

Precision is the closeness of agreement between indications obtained by replicate measurements on the same or similar objects under specified conditions. Precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement. 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. Under **reproducibility conditions**, one or more of factors such as (a) to (e) are varied, with replicate measurements made on the same or similar objects.

Error is the difference between measured quantity value and reference quantity value. Measurement error should not be confused with production error or mistake.

Indication: quantity value provided by a measuring instrument or measuring system [JCGM 200; ISO VIM]. It should be noted that an indication may not be in terms of the same quantity as being measured, the measurand $H_p(d)$.

Background (blank) indication: indication from a phenomenon, body or substance similar to the one under investigation, but for which a quantity of interest is supposed not to be present, or is not contributing to the indication [JCGM 200; ISO VIM]. For a dosimetry system the background indication has the components intrinsic detector background and readout system background. Another term used for this quantity is **zero dose indication**.

Natural (radiation) background is understood to be that part of the ionizing radiation induced indication which is not produced by the radiation field which is a result of the practice or activity to which a radiation worker is exposed in the course of his work.

6.4 Factors affecting the accuracy of a dose assessment

The uncertainty of a dose assessment can be reduced by using knowledge of the workplace field(s), and/or the bias reduced by applying correction/normalization factors.

For doses to the extremities from low energy electrons, the combined standard uncertainty of 30% is achievable for some designs of dosimeter, 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 use and from the results of intercomparisons, there are certainly difficulties meeting 30% combined standard uncertainty for doses to the whole body from neutrons. Even with a relaxation of the criterion to 50%, 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 combined standard uncertainty of 50% should be achievable for single measurements in actual workplace fields. The use of a workplace field specific correction factor should enable an overall uncertainty for the assessment of annual effective dose within the limit of a factor of 1.5 to be achieved. A number of reference simulated workplace fields have been developed to test and calibrate dosimeters. See section 6.6.

The combination of uncertainties to determine the combined standard uncertainty and the expanded uncertainty [ISO GUM; JCGM 100], should be undertaken by the user and compared with any national requirements. The uncertainties in some 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.

In many cases, unrealistic values of the decision threshold and detection limit for routine dosimetry systems will be obtained if they are derived from measurement results for (optimized) calibration of the system. To obtain values which are applicable to routine use, realistic calibration factors/coefficients must be applied together with consideration of the more important influence quantities (see Chapters 5 & 7).

6.5 Accuracy of a real measurement

A distinction should be recognized between the accuracy of a measurement with a dosimeter under laboratory condition, in a well-known radiation field, and a measurement in the workplace (see, for example, [van Dijk 2007; Ambrosi 2006; van Dijk 2006]). Further, the accuracy of any individual measurement made as part of a routine measurement procedure will depend on all aspects of the service, which are 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 acceptable accuracy with high reliability can be considered under four 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;
- b) routine external performance tests of the dosimetry 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. This is achieved by type-testing (the determination of the energy and angle dependence of the $H_p(d)$ 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.).

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.

The combining of the sources of uncertainty included in (c) and (d) have been considered in detail in publications by Ambrosi and van Dijk [Ambrosi 2006, van Dijk 2006, 2007] and previously by a number of other authors, for example: Christensen, publication of the Health Physics Society, Hirning [Christensen 1994; HPS 1993, Hirning 1998]. Ambrosi and van Dijk adopt different approaches, but essentially both use all available information on the dosimetric characteristics of the dosimeter and dosimetry system and of the workplace in which the dosimeter is worn (see Chapter 5). Practical investigation of the performance of dosimeters in the workplace has also been carried out. Examples are the EC-supported EVIDOS project for neutron workplace fields, which included measurements of the neutron energy and direction distributions and attempts at direct determinations of $H_p(10)$ [Schuhmacher, 2006], and the investigations of the relative performances of a number of photon/electron dosimeters in the workplace at a nuclear submarine dockyard [Collison, 2005].

In practice an ADS will not normally have detailed information on the workplace field, which is anyway strictly the preserve of the undertaking, not of the ADS. Even for the undertaking, 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. In depth analysis of a dosimeter's performance will not usually be required.

6.6 Workplace field specific correction factors

Practical considerations may well result in the use of a dosimeter with some deficiencies of response characteristics. In such instances, correction factors may need to be evaluated and can be applied to improve the accuracy of dose assessment [see for example Lindborg 2007]. More generally, the accuracy of a measurement can often be improved by the application of a field-specific correction factor, or normalization factor. This can be determined by carrying out in-field calibrations or by using information of the workplace field characteristics combined with the dosimeter energy and angle characteristics.

The detailed determination of the energy and direction distributions requires specialized equipment and specialists to use it [Eurados 2003]. Frequently, it is the direction distribution of the field which has the largest influence [Bartlett 2002; Burgess 1989; Ambrosi 2001]. The measurements can be time consuming and therefore expensive. In some instances limited additional information on workplace fields can be sufficient to enable the choice of suitable personal dosimeter. There is more information on workplace field characterization and characteristics in Section 4.7.

Field-specific correction factors can be determined by the "calibration" of a dosimeter in the actual workplace radiation field of interest, in particular for albedo neutron dosimeters, but also for track dosimeters [ICRU 66], or using simulated workplace reference fields [Chartier 1997; Lacoste 2007; ISO 12789, ISO 12789-2]. Independent measurements of energy and direction distributions, or calculations, are necessary to assure that simulated workplace fields are reasonable approximations to the actual workplace fields of interest. In actual workplace fields, measurements or calculations are made of the energy and direction distributions and calculations made of $H_p(10)$ (rate). Such a procedure would yield a "field-specific correction factor", k_f , and the final measured value of the dose equivalent, M_{field} , in this field would thus be determined by

$$M_{\text{field}} = k_f \times M_{\text{corr}} \quad (6.1)$$

For M_{corr} see equation (7.5).

As the 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, an alternative method can be used. The readings of the routine-use dosimeter can be compared with 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. 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.

The response characteristics of a dosimetry system and knowledge of the workplace fields in which the dosimeter is to be worn can be used as the basis for the choice of either a field correction factor [Lindborg 2007] or an appropriate normalization factor (or integral dosimeter calibration coefficient) [Gilvin, 1987] in order to minimize the possible bias of a single measurement or the average bias, and thus to obtain more accurate results on average. The latter approach can involve folding the dosimeter response characteristics with the energy and direction distributions of workplaces, preferably after applying occupancy factors or weighting for the component of dose equivalent received.

In particular instances of poor/non-ideal wearing position of a dosimeter, which cannot be improved, for example a finger ring dosimeter for low energy beta radiation which are used in handling radiopharmaceuticals where the maximum dose is at the finger tips. In such cases, field calibrations with special dosimeters can be performed. The special dosimeters are worn at the finger tips and the routine dosimeters are worn as usual. From the ratio of these measured values a "field-specific beta correction factor", k_β can be determined and the final measured value of the dose equivalent, M_{field} , in this beta field would thus be determined by $M_{\text{field}} = k_\beta \times M_{\text{corr}}$. A typical value of k_β for radiosynoviorthesis is of the order of 3 if the

detector of the fingering is oriented towards the source, i.e. worn on the inner side of the hand.

Implementing these approaches can involve considerable effort and expense. It is clear, however, that the effect of the differences between the calibration field and the workplace field on the detector response, should not be ignored. Once a field-specific correction factor has been determined for a particular instrument in a particular working environment, it is important to perform simple checks to assure that the field has not changed very much. It is particularly important at a research laboratory, where the field may change as experiments are changed. This is of special importance for dosimeters for which the field-specific correction factor exhibits a large dependence on such changes. This may mean that a restriction should be put on the use of field-specific correction factors, or on the range of numerical value used.

The determination of field-specific correction factors is the responsibility of the employer but should be carried out in consultation with the ADS, using information supplied by the ADS on the dosimeter characteristics. The system normalization factors based on the workplaces in which the dosimeter is to be used are applied by the ADS but with workplace field information supplied by the employer.

6.7 Background subtraction

The **dosimeter indication**, G , will, after subtraction of the zero dose indication (background or blank indication), and after the application of correction factors (see below), the instrument constant, c_{inst} , and the calibration function, N_H , give the gross dose, M_o (more formally known as the **measured quantity value** or **measured value**). The gross dose, M_o , will, in general, include a contribution from the natural (radiation) background, M_{nat} , in addition to any dose from the worker's occupational radiation field, M_{occup} . The measurement model for a dose measurement is given below (equation 6.2) (see Chapter 5). The zero dose indication and the natural background dose need to be subtracted, and estimates of the associated uncertainties included in the overall uncertainty assessment following the procedures given in Chapter 5.

$$M_o = N_H(E, \alpha) \cdot c_{inst} \cdot G_{corr} \quad (6.2)$$

with

$$G_{corr} = k_n \cdot \prod_{f=1}^q k_f \cdot \left(G - \sum_{s=1}^p G_s \right) \quad (6.3)$$

where the correction factor k_n is for non-linear response, the p correction summands, G_s , for the influence quantities of type s (which cause additive changes) and the q correction factors, k_f , for the influence quantities of type F (which cause multiplicative changes). Many of the correction summands, G_s , are only of importance for APDs, for example a correction for the influence of electromagnetic fields. For passive dosimeters, only those correction summands related to the zero dose indication are of importance, and in this case the sum $\sum_{s=1}^p G_s$ is called the zero dose indication.

$$M_{occup} = M_o - M_{nat} \quad (6.4)$$

The above equations, 6.2 to 6.4, are in all respects equivalent to equations 5.18 to 5.20 in Chapter 5, and can also be expressed in terms of a response function $R(E,\alpha)$ (see Chapter 7) thus:

$$M_o = \frac{G_{\text{corr}}}{R(E,\alpha)} \quad (6.5)$$

The zero dose indication (background or blank indication) of a dosimetry system, $\sum_{s=1}^p G_s$, in the above measurement model, comprises the readout system background plus the detector intrinsic background. The readout system background can be either determined separately or can often be combined with the intrinsic detector background. The determination of the intrinsic detector background and readout system background is straightforward for reusable passive detectors.

Intrinsic detector backgrounds can be determined for individual detectors or for batches. In the latter case the uncertainty contribution to a single result will be larger, in general, but this effect will be lessened for the aggregate of a number of dose assessments for a worker issued with a different dosimeter for each wear period. For batch intrinsic background determination, care must be paid to the sampling procedure. In both approaches, the determination should be repeated at the same frequency as the determination of individual or batch calibration factors/coefficients (normalization/sensitivity factors/coefficients (see Chapter 7). For a TLD, a typical frequency would be every 10 readouts or every two years, whichever comes first.

For non-reusable passive detectors, there is more emphasis on the choice of sampling procedure. A particular case is that of PADC neutron detectors which can have a high and over-dispersed intrinsic background for which the mean value and standard deviation may correspond to several tens of μSv . Each sheet of material must be assessed using a background sample of about 10% and even for such a large sample, the uncertainty in the standard deviation of the mean, based on data from the UK Health Protection Agency, can be as great as a factor of 2 (Tanner in [Harvey 1998]). For non-reusable detectors in general, the best procedure is to take random samples for calibration and background determination at the time of dosimeter issue.

The methods of natural background subtraction are to use either an average value based on customer geographic spread (usually a national average) or specific customer or location values. In Europe, the cosmic radiation photon and directly ionizing component is about 300 μSv per year. The terrestrial photon natural background ranges upwards from about 300 μSv per year, with considerable geographic variation (thus the total ranges upwards from about 600 μSv) [UNSCEAR 2000]. Nevertheless, for monthly issue, the use of a geographic spread average background between readouts, although adding to the total uncertainty of dose assessment, will for many services still enable the recommended accuracy requirement to be met. For example, where for whole body photon/electron dosimeters, the difference between a local and the geographic spread average natural background radiation dose is no greater than about 100 μSv per year, it would seem to be acceptable to simply use the average value. The value of 100 μSv is 10 % of the lower limit of 1 mSv for which the recommended uncertainty bound is 30%.

Obviously for those instances where a dosimetry service supplies customers in areas where the terrestrial natural background is significantly greater than, or less than (an extreme case is in submarines) the national average, the local natural background dose rate will need be taken into account. Local background variation can be taken into account by the use of control dosimeters which are supplied by an ADS to a customer, and stored at the location where workers' dosimeters are kept when not being used. In some cases, subtraction of transit doses may be done. For dosimeters issued to customers in Europe but issued and processed in the USA, natural background radiation transit doses (return trip) for an electron/photon dosimeter may be about 30 to 50 μSv .

The contribution to photon/electron dosimeters of a few tens of μSv from the dosimeter wearer's incorporated ^{40}K can be neglected, as can, in general, the neutron cosmic radiation background. This is about 100 μSv per year, but about half is from neutrons of energy greater than 20 MeV, measured with a lower response by many detectors. A method to determine the natural background distribution is described [Stadtmann, 2007] and a method to estimate the uncertainty resulting from the variability of the natural background by [van Dijk, 1996], both methods using an analysis of the results for issued dosimeters. These methods are based on the assumption that the majority of issued dosimeters are only exposed to natural background radiation. Mean values and standard deviations can then be derived from an examination of the relationships of dose and number of days of exposure using regression analysis.

The considerations discussed above also apply in principle to APDs. For APDs which are issued on a shift basis, it may be the normal practice to neglect the natural background contribution. Some devices may allow a value for the natural background subtraction to be programmed in. This obviously could lead to problems where the programmed value is location-specific, and the APD is moved elsewhere.

7 CALIBRATION AND TYPE TESTING

7.1 Introduction

The term 'calibration' has been used in a number of different ways which have not been entirely consistent. In these recommendations, the definition in the VIM (ISO/IEC Guide 99) [ISO VIM; JCGM 200]) is followed. This definition of calibration covers a number of the procedures included in a type test. In the first step, a series of calibration factors (or calibration coefficients, see below) or responses may be determined for a set of reference conditions, usually a set of radiation energies and angles, to establish a matrix of calibration factors/coefficients or responses, or a calibration/response function. The second step, when used, applies these data to obtain the value of the desired quantity from the instrument indication.

The term 'type test' can also have a range of meanings, but this is not a cause for misunderstanding, as it is common practice to mention the publication on which the type test is based, for example, 'type test according to EN 61526:2007' or 'type test according to IEC 62387-1, Ed.1:2007' or 'type test according to PTB-requirements' in Germany. By giving statements such as these, no misinterpretation is possible.

7.2 Recommendations

- It is preferable, but not mandatory, that dosimetry systems are type tested according to the relevant EN/IEC or ISO standard and should have passed that test. Failure of any part of the test should be clearly detailed and reasons for the failure considered.
- Every type of dosimeter issued by an ADS or IMS should be fully tested and the results of these tests made available to users and potential users. Fully tested means the determination of the dosimetric performance characteristics, including detection limit; tests of influence quantities; tests of the reliability of the complete system, including system software.
- For a fully tested dosimeter or dosimetry system, a reference calibration (determination of a single calibration factor or calibration coefficient for one set of reference conditions) is sufficient to ensure absolute dose measurements traceable to national dose standards.
- The reference calibration of the dosimetry system should be repeated at regular intervals, for example every two years. There should be more frequent periodic checks on the dosimetric performance of the dosimetry system which may be carried out using non-reference fields using a fixed procedure.
- In addition to the type test every dosimeter should have a traceable individual normalization/calibration factor.
- For reusable dosimeters, the individual normalization/calibration factor should be checked periodically and adjusted if necessary. There should be additional quality assurance procedures, for instance a visual inspection (see Chapter 10).

- Facilities for internal periodic calibrations should be owned by the dosimetry service while, the other test facilities can be either owned or hired as appropriate.
- A final version of the software should be available before the type test begins. The manufacturer should be aware that any change in the software may invalidate the type test.
- Dosimetry system software should follow the WELMEC software guide 7.2, [WELMEC 2008].

7.3 Terms

Calibration [ISO VIM; JCGM 200]: operation that, under specified conditions, in a first step establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

NOTE 1: A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases it may consist of an additive or multiplicative correction of the indication with associated uncertainty.

NOTE 2: Calibration should not be confused with adjustment of a measuring system, often mistakenly called 'self-calibration', nor with verification of calibration.

NOTE 3: Often, the first step alone in the above definition is perceived as being calibration.

The **calibration factor**, N_{fact} , is a dimensionless factor by which the corrected indication or reading of the instrument is multiplied to obtain the **measured quantity value**. In the calibration procedure, the calibration factor is determined by the equation:

$$N_{\text{fact}} = \frac{H_0}{G_{H_{\text{corr}}}}, \quad (7.1)$$

where H_0 is the **conventional quantity value** (the best estimate of dose equivalent of the reference radiation field) and $G_{H_{\text{corr}}}$ is the **corrected indication** or reading of the instrument given in units of the quantity to be measured. The corrected indication is the **instrument indication**, G , corrected for effects such as intrinsic background and non-linearity (see section 6.7).

If the indication or reading of the device is not expressed in terms of the quantity to be measured, then the corrected instrument indication, G_{corr} , has to be converted to the same units as the measurand by applying an **instrument constant**, c_{inst} , before the calibration factor is applied. Equation (7.1) becomes

$$N_{\text{fact}} = \frac{H_0}{G_{\text{corr}} \times c_{\text{inst}}}. \quad (7.2)$$

The value of c_{inst} will have dimensions, for example, millisievert per coulomb (measured by the TLD reader) or per observed track density. The instrument constant, c_{inst} , and the

calibration factor, N_{fact} , need not be identified separately but can be applied together as the **calibration coefficient**, N_{coeff} , that has dimensions.

$$N_{\text{coeff}} = N_{\text{fact}} \times c_{\text{inst}} = \frac{H_0}{G_{\text{corr}}} \quad (7.3)$$

The calibration coefficient, N_{coeff} , is the factor used to multiply the corrected dosimeter indication (when not expressed in terms of the quantity to be measured), G_{corr} , to obtain the value of the quantity being measured.

Substituting M for H_0 , in equations 7.2 and 7.3 (in case of a measurement instead of a calibration) gives the measured quantity value for the measuring instrument under reference conditions. Reference conditions are those defined conditions under which the calibration is performed and valid. In the case of non-reference conditions, these can be considered by an additional correction factor, k , leading to

$$M = G_{\text{corr}} \times N_{\text{coeff}} \times k \quad \text{or} \quad (7.4)$$

$$M = G_{\text{corr}} \times c_{\text{inst}} \times N_{\text{fact}} \times k \quad (7.5)$$

For most routine measurements the correction factor, k , is set to unity. This setting allows an uncertainty of measurement which can be taken directly from the results of the type test. For some instances this factor is generally set to a field specific value to consider deficiencies of the instrument or of the measurement process, resulting in an improvement of the accuracy of the dose assessment, see section 6.6. In special cases, e.g. in an accident, this factor can be determined from the workplace conditions to reduce the uncertainty of the measurement under consideration.

The **response**, r , is the quotient of the corrected (direct) dosimeter indication, G_{corr} , by the conventional quantity value, H_0 , determined under the given conditions

$$r = \frac{G_{\text{corr}}}{H_0} \quad (7.6)$$

Thus, any value of the response needs the specification of the kind of value and the kind of quantity, e.g., response of the corrected direct indication, G_{corr} , to the personal dose equivalent, $H_p(10)$, see (7.7).

$$r_{H_p(10)} = \frac{G_{\text{corr}}}{H_p(10)} \quad (7.7)$$

Depending on the kind of quantity value, the response may have a dimension or be dimensionless.

If the radiation field is a single specified reference radiation field, for example ^{137}Cs or $^{241}\text{Am-Be}$, and the dose equivalent value and all other influence quantities have the specified reference values, then the term calibration may be used in the restricted sense of determining a single calibration factor for a single set of reference conditions. This is the case, for example, in the IEC standard for passive dosimeters [IEC 62387-1]. This restricted definition not only fixes the values of the non dosimetric influence quantities, but also includes fixed values of dose and dose rate. In the national standards of some Member States, for example Germany, this restricted definition of the calibration factor is extended to be the definition of calibration itself. The single calibration factor may then be combined with a number of correction factors (a matrix of correction factors or a correction function) to be

applied in specific conditions of use. The combination of a single calibration factor and a matrix of correction factors is equivalent to a matrix of calibration factors. To avoid any misunderstandings, the term '**reference calibration**' is used for this restricted use of the term calibration and the factor might be termed the '**reference calibration factor**', N_{ref} .

Type testing and reference calibration of dosimetry systems/dosemeters are closely interlinked. The result of a type test is the detailed description of all the properties of a given type of dosimeter. This includes the dependence of the response on particle energy, on angle of radiation incidence, on temperature and so on. Such a procedure only makes sense if the type is fixed by a manufacturer (a dosimetry service can also be a manufacturer) as then the properties determined in the type test are valid for all dosimeters of a given type produced by the manufacturer. A reference calibration without a prior type test can be misleading, as the calibration certificate can be misinterpreted as a certificate that the dosimeter can be used at a given workplace. Such a judgement can only be done using the results of a type test performed according to well defined procedures, thus giving comparable results, e. g. based on standards.

In routine dosimetry, two types of reference calibration are important. The first type is the reference calibration in reference radiation fields, which are traceable to National Metrology Institutes (NMI), the aim of which is to obtain an absolute reference calibration factor or absolute reference calibration coefficient for the dosimetry system. All dosimetry systems should have periodic laboratory reference calibrations, typically at intervals of about one to two years, or as required by the regulations. It will be necessary to confirm the stability of the dosimetric performance of the dosimetry system at more frequent intervals. The second type is an **internal calibration** to normalize the response of all the dosimeters or detectors to a reference value which is given by a fixed procedure, for example using an internal 'calibration source' of a TLD reader. This allows for the variations in sensitivity of TL detectors within a batch, or the variation with time of a single detector, for example. This procedure determines an **individual normalization factor**, or individual calibration factor. Periodic repeated internal calibrations are of particular importance for passive (solid state) personal dosimeters to adjust the normalization /calibration factors for changes due to repeated use, or to confirm that their performance has not changed. A suggested frequency is every 10 uses or every 2 years, whichever occurs first.

7.4 Type testing

To carry out type tests is the responsibility of the manufacturer. All the radiation fields used must be well characterized and traceable to NMIs. There are a number of ISO standards giving guidance to establish such reference radiation fields for photon, beta and neutron radiation. These are the ISO 4037 series for photon radiation, the ISO 6980 series for beta radiation and the ISO 8529 series for neutron radiation. For neutron workplace fields the ISO12789 series gives guidance. For details see References. In addition, further equipment which may be needed to test environmental influence quantities, mechanical effects, electromagnetic fields, etc. is required. All these are not required at the dosimetry service site, it is sufficient if they are available at the testing laboratory assigned by the manufacturer. As long as the type of a dosimeter is unchanged, the type test remains valid.

The measurement quantity for personal dosimeters is the personal dose equivalent, $H_p(10)$, and/or $H_p(0.07)$ and in rare cases $H_p(3)$ BSS [EU 96].

For personal dosimeters to monitor individuals occupationally exposed to external radiation several international and European standards exist for type testing them. For active personal dosimeters IEC/EN 61526 "*Radiation protection instrumentation – Measurement of personal dose equivalents $H_p(10)$ and $H_p(0.07)$ for X, gamma, neutron and beta radiations – Direct reading personal dose equivalent meters and monitors*" [IEC 61526] covers all types of radiation, photon, beta and neutron. For passive dosimeters IEC 62387-1 "*Radiation protection instrumentation – Passive integrating dosimetry systems for environmental and personal monitoring – Part 1: General characteristics and performance requirements*" [IEC 62387-1] covers photon and beta radiation. These two standards are adjusted to each other so that type test results are comparable irrespective of the type of detector, active or passive. As a result of a type test according to these standards rated ranges of use for all influence quantities are determined. Comparing these rated ranges with those required for a given workplace, the suitability of the dosimeter can be judged. For thermoluminescent extremity personal dosimeters the standard ISO 12794:2000 "*Nuclear energy – Radiation protection – Individual thermoluminescence dosimeters for extremities and eyes*" [ISO 12794] is available and for passive individual neutron dosimeters there is the standard ISO 21909:2005 "*Passive personal neutron dosimeters – Performance and test requirements*" [ISO 21909]. Unfortunately these last two standards are not harmonized with the above mentioned standards, so that the type test results are not comparable. For the neutron standard this problem exists even between different types of dosimeters using different types of passive detectors.

7.5 Software

In modern instruments the software has become of increasing importance for the generation of the measured value. Therefore, the final version of the software should be available at the beginning of the type test, as a great part of the software test is indirectly covered by the metrological test. The manufacturer should be aware of the fact that any change of the software may question the validity of the type test.

Dosimetry system software should be guided by the WELMEC software guide 7.2, [WELMEC 2008]. The guidance requirements prevent any unintended modification of the software and the data. This is achieved if the requirements for active, direct reading instruments are based on those given by the guide for instruments with embedded software in a 'built-for-purpose measuring instrument', and for passive instruments on those given for 'systems suitable also for other purposes in addition to the purposes for which it is intended' (Type U, the system includes, for example, a PC). The risk class should be B (low/middle level) or C (middle level).

It is recommended to separate the software into two parts. One part contains all the functions necessary to evaluate, store and display the indicated values. This part is the "data relevant part". The other parts of the software, the "non data relevant part", contain for example value, date and time of a maximum of the indication. The data relevant part has well defined functions (software interface) that are used to communicate with the non data relevant software parts. This technical concept of software separation has the advantage, that the "non data relevant part" may be modified without influencing the "data relevant part". The

concept of software separation is state of the art in software engineering. This is of special importance for passive dosimetry systems, as they require lot additional management software, which, in case of software separation, does not influence the dosimetric properties of the dosimetry system.

In Table 7.1 examples of the type test and software requirements are given for some of the mentioned standards, see Behrens and Ambrosi [Behrens 2008].

7.6 Determination of the reference calibration factor N_{ref}

To determine the reference calibration factor, N_{ref} , the radiation field used must be well characterized, as for type tests. For the periodic determination of the reference calibration factor of the dosimetry system in most cases radioactive sources are sufficient, for example a ^{137}Cs or ^{60}Co source for photon radiation, a $^{90}\text{Sr}/^{90}\text{Y}$ source for beta radiation and/or a ^{252}Cf source for neutron radiation. These fields must have traceability to a NMI.

For a dosimetry service, it is sufficient to have only a reproducible and stable source to normalize the response of all dosimeters (badges) to a reference value, which is to perform the internal reference normalization. The required (bi) annual determination of the reference calibration factor of the dosimetry system can be provided by another laboratory.

The measurement quantity should be the personal dose equivalent, $H_p(10)$ and/or $H_p(0.07)$ and in rare cases $H_p(3)$, as given in the BSS. All details of the required procedure are given in the relevant ISO standards. There is only one variation which has sometimes been used and that is the reference point of the detector assembly for calibration and type test purposes. In deviating from the procedure detailed in the current ISO standards, the front surface of the required phantom has been used as the reference point of the detector assembly comprising the dosimeter (or parts thereof) and the phantom, and this is now recommended. Discussions are underway to change the ISO standards accordingly.

Table 7.1: Comparison of some requirements given by international standards for photon dosimeters.

(Influence) quantity	passive dosimetry systems			direct reading dosimeters
	ISO 1757	ISO 12794	IEC 62387-1	IEC 61526
Type of detector and type of dosimeter	film, whole body	TLD, extremity	all passive; TLD, whole body	all active, whole body
Radiation energy ¹	$0.65 \leq \text{response} \leq 1.35$	$0,5 \leq \text{response} \leq 1.5$	any energy and angle: $0.71 \leq \text{response} \leq 1.67$	any energy and angle: $0.71 \leq \text{response} \leq 1.67$
Angle of incidence ¹	at two energies: $0.7 \leq \text{response} \leq 1.3$	at one energy: $0.85 \leq \text{response} \leq 1.15$		
Linearity	0.2 mSv to 1 Sv: check only at limits ²	1 mSv to 1 Sv: $0.9 \leq \text{response} \leq 1.1$	0.1 mSv to 1 Sv: $0.91 \leq \text{response} \leq 1.11$	4 orders of magnitude: $0.85 \leq \text{response} \leq 1.15$
Coefficient of variation	optical dens.: 2% to 5% homogeneity of filters: 2%	reproducibility: 10% batch homogeneity: 15%	from 15% to 5% at higher dose values	from 15% to 5% at higher dose values
Environmental conditions and others	temperature up to +50°C: $0.8 \leq \text{response} \leq 1.2$ humidity up to 90%: $0.9 \leq \text{response} \leq 1.1$ fading: $0.9 \leq \text{response} \leq 1.1$	temperature up to +40°C and humidity up to 90%: $0.9 \leq \text{response} \leq 1.1$ light exposure: $0.9 \leq \text{response} \leq 1.1$	temp.: -10°C to +40°C, humidity 40% to 90%, fading, light, reader stability and power supply combined: $0.83 \leq \text{response} \leq 1.25$	temp. -10°C to +40°C: $0.85 \leq \text{response} \leq 1.15$ humidity 40% to 90%: $0.9 \leq \text{response} \leq 1.1$ power supply: $0.9 \leq \text{response} \leq 1.1$ atmospheric pressure: $0.9 \leq \text{response} \leq 1.1$ dose rate for dose meas.: $0.8 \leq \text{response} \leq 1.2$
Additivity ³	no requirement	no requirement	$0.91 \leq \text{response} \leq 1.11$	$0.9 \leq \text{response} \leq 1.1$
Electromagnetic compatibility	no requirements	no requirements	IEC 61000-6-2 deviation ⁴ limited	IEC 61000-6-2 deviation ⁴ limited
Mechanics	no requirements	no requirements	IEC 60068-2-32 deviation ⁴ limited	IEC 60068-2-32 deviation ⁴ limited
Software	no requirements	no requirements	WELMEC Guide 7.2 ⁵	no requirements

¹ Values valid for photon radiation including X-rays and gamma rays with energies of at least up to those of ⁶⁰Co (1.25 MeV).

² Requirements are specified for optical density, not for dose values.

³ Additivity of measured values for different irradiation conditions. It is important for the type test being valid for workplace fields.

⁴ Deviation is an additional indication which is due to the influence quantity, e.g. to additional or lost pulses as a result of EMC.

⁵ A guide to software requirements from the European Corporation in Legal Metrology, recommended for application all over Europe.

7.7 Determination of the individual normalization factor n_i

As mentioned above, a typical passive dosimeter of a dosimetry service consists of many similar dosimeters (badges), each equipped with detectors like film, TLD, OSL, or RPL glass, which require an individual reference normalization in regular intervals. Prior to the reference normalization a 'visual inspection' should be performed to give assurance of the unchanged mechanical conditions of the detectors. The reference normalization is done under specified (reference) conditions, for example to allow for the variations in sensitivity of a TL detector. This determination of the individual normalization factor is of internal nature of the service and should be performed under simplified conditions. These simplified conditions could even include other type of radiation, for example ^{137}Cs photon radiation for the TLD detector of a neutron albedo dosimeter, and irradiation free in air instead of on the phantom. Some simple checks of the reader should be performed every day, for example using irradiated detectors.

These procedures are normally described by an individual normalization factor n_i , where i indicates the identification number of the detector. Thus the reference calibration factor N_{ref} becomes a product of the reference calibration factor $N_{\text{ref},0}$ of a reference detector (or mean value of a batch) and the individual normalization factor n_i :

$$N_{\text{ref}} = n_i \times N_{\text{ref},0} \quad (7.8)$$

In the ideal case, the value of n_i is unity, in reality it scatters around 1.0 by, say, ± 0.3 . Details of the procedure depend on the manufacturer's or ADS's decision. It is for example possible to determine $N_{\text{ref},0}$ by using a special batch of detectors reserved only for this purpose, or to build groups of detectors, which differ in sensitivity by a given amount, for instance 5%, instead of using a special value for each detector.

In the case of single use detectors, for example all photographic film detectors and some types of extremity detectors and track-etch neutron detectors, batch calibrations have to be performed. This requires attention to sampling statistics and estimation of the uncertainty component, and to quality control procedures. The latter are discussed in more detail in Chapter 10.

7.8 Other Considerations

7.8.1 Specific matters to be considered

In the following some special points are discussed which require special attention when using dosimeters and of course also when type testing them. Some points are only valid for some kind of radiation or application, others only for some kinds of dosimeters. Workplace field-specific corrections are discussed in Chapter 6.

7.8.2 High energy photon radiation

In an increasing number of workplaces the maximum energy of the photon radiation fields is much higher than the mean energy of the gamma radiation of ^{60}Co of $\bar{E} = 1250$ keV which is the highest gamma energy of radionuclides given for calibration purposes in the ISO 4037 series. For the measurement in such high energy fields the type test shall be extended to the

high energy photon radiation fields given in ISO 4037. The field with the maximum photon energy is produced by the reaction $^{16}\text{O}(n,p)^{16}\text{N}$ and has a mean energy of $\bar{E} = 6.61$ MeV. For higher energies, there are currently no reference fields specified. Many dosimeters exhibit an over-response up to a factor of about 2 in high energy photon fields owing to the use of high-Z filter materials.

It should be noted that for calibrations the use of a layer of 25mm PMMA in front of the dosimeters for the calibration in high energy photon radiation is mandatory, in order to establish secondary charged particle equilibrium at the dosimeter position, the condition for which the ICRU/ICRP conversion coefficients are applicable, see section 7.8.3.

7.8.3 Secondary charged particle equilibrium

For measurements of $H_p(10)$ in photon fields with components above about 2 MeV, but also for $H_p(0.07)$ in photon fields with components above about 60 keV, there are contributions to $H_p(10)$ and $H_p(0.07)$ from both photons and secondary electrons. Tests to determine the photon response characteristics are performed with full secondary charged particle equilibrium, conditions for which the published conversion coefficients are applicable. In the standard ISO 4037-3 [ISO 4037-3] the required thicknesses for the different reference fields and measuring quantities are given for PMMA as build-up material. In workplace fields, this charged particle equilibrium will not always exist. Ideally, dosimeters should respond correctly to both the photon and electron field components and where possible should be tested to establish whether this is so.

7.8.4 Pulsed radiation

Nearly all radiation fields in X-ray diagnostic and in accelerator-based therapy are pulsed. For passive dosimeters this should not cause an increased measurement uncertainty unless the dose range is exceeded. For electronic direct reading dosimeters this is totally different, especially for those using pulse counting. Unfortunately, both the amount of influence on the measured value and the method of type testing the performance of direct reading dosimeters in such fields have not yet been established. Clairand and co-workers [Clairand et al., 2008] performed measurements in a simulated scattered radiation field representative of interventional radiology. These measurements indicate, that several, but not all, APDs are capable of measuring correctly in this type of field. Initial measurements in direct radiation fields used for X-rays of the thorax to simulate an (minor) accident, where a person is irradiated by the direct beam, show for a frequently used electronic personal dosimeter an indication that can be as low as 20 % of the true dose [M. Borowski, 2008]. This seems to be due to the high dose rate that can occur in the radiation field pulse (up to about 100 Gy/h) and the short duration of the radiation field pulse (less than 100ms down to a few milliseconds). One possible reason is pile-ups of the counting pulses, another is the fact that the radiation field pulses are much shorter than measurement cycle of the instrument. If the instrument corrects for example, for dead-time effects, it assumes a constant dose rate during a measurement cycle. As this is not the case for pulsed radiation, the correction is not sufficient.

7.9 Use of personal dosimeter as area monitors

The use of personal dosimeters as area dosimeters is in principle not possible as the measurement quantities are different. The dose equivalent quantity for personal monitoring

at the depth of 10 mm, is defined for phantom-present conditions, and also the conversion coefficient from air kerma free in air to $H_p(10)$, $h_{p,K}(10,E,\alpha)$, has a strong dependence of on the angle α of radiation incidence, especially at low energies, E . The dose equivalent quantity for area monitoring at the depth of 10 mm, $H^*(10)$, is defined free in air, and the conversion coefficient from air kerma free in air to $H^*(10)$, $h_K^*(10,E)$ has no dependence on the angle α of radiation incidence. Nevertheless such use is common practice in some Member States.

An example is the use of a personal dosimeter, mounted on a wall in a controlled area, to demonstrate compliance with the dose limits for such controlled areas. The wall will serve as replacement of the person or phantom. If the photon energy is higher than 50 keV the additional uncertainty due to the angular dependence of the conversion coefficient, $h_{p,K}(10,E,\alpha)$, will not exceed 70 % for angles up to 60°.

Such use should at least be accompanied by a careful consideration of the associated additional uncertainty. The results of a type test in terms of $H^*(10)$ can be used to estimate this uncertainty.

8 GENERAL CRITERIA FOR APPROVAL OF DOSIMETRY SERVICES

8.1 Introduction

The BSS requires that 'individual monitoring shall be systematic for exposed category A workers (...) based on individual measurements which are established by an approved dosimetry service'. Each Member State needs to make arrangements to recognise the capacity of an approved dosimetry service, which is defined as: 'a body responsible for the calibration, reading or interpretation of individual monitoring devices, and/or for the measurement of radioactivity in the human body or in biological samples, and/or for assessment of doses, whose capacity to act in this respect is recognised by the competent authorities'. The implementation of the BSS has led to the use of the same dose quantities, either protection or operational.

The purpose of approval (by the Member States' authority) is to recognize and verify that an approved dosimetry service is technically competent; able to generate technically valid results; and has adequate administration, technical and quality systems. For a service to be approved, it is a general requirement 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 the employer and/or the NDR in a reasonable time; rapidly communicates to the employer, and subsequently to the authorities, the results of dose assessments made in the event of an accident, occurrence, or incident.

At present, approval of dosimetry services in different EU Member States is not harmonized. The assurance of the quality of measurements and evaluations of individual monitoring is covered by different recommendations and publications to meet the criterion of recognition by the competent authorities in the different Member States. However, some similarities can be found. Eurados WG2 has gathered information on approval procedures and these have been published [Ambrosi, 2000] [Fantuzzi, 2001].

8.2 Recommendations for requirements for approval

- For dosimetry services seeking approval: clear benefits would arise from a move towards adopting EN ISO/IEC17025:2005 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.
- Awareness and documentation of dosimetry methods: This includes the preparation of internal documents or reports which describe in detail the whole dosimetry system, covering both organizational structure and technical methods. These approval documents should include the "Scope of Approval". A service should state to what use its system can be put, and this is reflected in its approval certificate.
- Quality Assurance, QA, programme: An ADS should implement a quality management system based on "process oriented" documents and proper corresponding protocols to check the stability, reproducibility and correctness of all processes. The QA process must extend to the procedures for the design,

specification and testing of all materials and equipment. The implementation of a QA programme improves an awareness of methods and procedures. There should be a quality manager with well defined responsibilities. There should be a mechanism for customer feedback.

- System software: In principle, this should have been tested, preferably with conformity demonstrated with national and international standards, although this may be difficult in practice. If full testing is not possible, at least a validation exercise demonstrating the intended functionality should be performed and documented.
- Traceability to NMI, SSDL: The dosimetry methods should demonstrate traceability to national standards. An ADS should be able to provide, on request, calibration certificates which show traceability to an appropriate calibration laboratory for the dosimeters used.
- Irradiation tests (blind tests): Routine performance tests should be performed at the ADS to show that calibration and traceability is maintained and the whole dosimetry system provides reliable dose results in routine use. A typical example is the case of a dummy customer (i.e. blind test) by using dosimeters properly irradiated but unknown to the ADS staff. Comparison of results with irradiation and resulting data can show the reliability of the whole system.
- Intercomparison tests: ADS should be encouraged to participate, where possible, in national or international inter-comparison tests.
- Staff competence: The quality of a service is determined largely by the quality of its staff, and therefore close attention must be paid to staff recruitment, training and management.
- Data handling: There should be compliance with national legislation and conformity to national and international standards.
- Accident preparedness: A service should be able to report within specified required times an unexpected dose or a high dose according to requirements either chosen by the customer or national accident plan programme.
- Reporting uncertainties: A service should give clear directions as to the conditions of use of the service, including values of uncertainties for the rated ranges of doses.
- Implementation of standards: Where applicable, an ADS should conform to national and international standards.
- Agreement with these recommendations: Where applicable, an ADS should follow national and international guidance and recommendations.

8.3 Terms

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

Accreditation body: authoritative body that performs accreditation.

NOTE: The authority of an accreditation body is generally derived from government.

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

NOTE: Approval can be based on fulfilment of specified requirements or completion of specified procedures [EN ISO/IEC 17000:2004].

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

NOTE: 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 [EN ISO/IEC 17000:2004].

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 [ISO/IEC 17000:2004].

It is important to point out that approval does not demonstrate conformity with any standard, but that the service satisfies the requirements of the national approval body. In fact approval is determined by national procedures which may, or may not, implement requirements stated in international or national standards. Where approval is based on accreditation or certification, there will be further requirements such as laboratory inspections, periodic external audits and participation in independent intercomparisons.

In some Member States, EN ISO/IEC17025:2005 [ISO 17025] or other quality standards are included in national approval requirements, whilst technical performance requirements included in specific national protocols for the dosimetry system have been based on ISO, IEC standards and the EUR 14852 Technical Recommendations [EU1994a]. Evaluation of dosimetry systems or dosimeters is done either through a complete type test performed by a standards laboratory or through the examination of results and all technical information given by the service itself. In the latter case, a performance test is often carried out before approval is granted. It must be stressed, however, that it is the dosimetry service which is approved and not just the dosimetry system.

In some Member State a national dose register is established and regularly maintained and updated. Therefore requirements maybe set for dose record keeping but these are not usually detailed in the approval procedure. Moreover, in many Member States national authorities may request information about management of data and record keeping. There may be a separate approval procedure for the provision of co-ordination and record keeping services. There is a lack of international standards or recommendations on this subject.

In all countries, the approval body is a national authority related to a government ministry or to the nuclear safety body. In most Member States, there are approval procedures in place for photon dosimetry, but procedures for beta and neutron dosimetry test are less well

established. The renewal of approval, whose frequency can be periodically every 2 or more years, can be based on evaluations of the technical and management documentation, irradiation tests, and on-site inspection of the service laboratories, separately, perhaps with different periodicity, or all three steps together.

8.4 The approval process

An approval process will usually contain the following elements: (a) establishing the competence of the laboratory to provide reliably technically competent results; (b) establishing that the dosimetric performance characteristics of the dosimeter and dosimetry system meet stated criteria; (c) periodically review the consistency of performance. The steps, generally included in the approval process can be summarized as follows:

- Documentation: A report containing information about the dosimetry system is examined by the authority with responsibility for approval. An example of technical documentation typically requested is type test results, dosimetry procedures, calibration traceability, management, organisation, personnel, equipment, quality assurance control and procedures.
- Quality system: Quality system certification or accreditation according to either ISO9000 series or EN ISO/IEC17025:2005 [ISO 9000, 17025] or a similar level of application of procedures (see also [ICRU 76]).
- Traceability to national standards: The dosimetry of the system should have certified traceability to the appropriate national standard and the use of the ICRP and ICRU recommended conversion coefficients for the operational quantities.
- Irradiation performance test: Irradiation performance test at unknown doses in unknown conditions (but see section 8.5).
- Inspection of the laboratory: On-site assessment by dosimetry experts who evaluate such areas as staff (including training), equipment, facilities, calibration and dosimetry procedures in accordance with what is stated in the approval documentation.

In most Member States, approval is periodically confirmed through a checking process. For this purpose, periodic performance testing exercises are organized for the ADS to enable it to demonstrate that the required capacity is being maintained. Participation in the exercises if not mandatory should be strongly recommended.

8.5 Performance testing

This section is concerned with external performance tests: tests which are not carried out by the ADS as part of its internal system checks. Routine external performance tests are aimed at checking the dosimetry 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.) This requires careful consideration of the dose range, the type and the energy of the radiations to be measured, the uncertainty of the dose estimations, and the measurement

process including traceability and calibration. The results obtained by the service being tested should meet specific performance criteria, with reference to a standard where applicable.

External performance tests 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 dosimetry system, to meet specific performance criteria; whereas type-tests are determinations of the dosimetric characteristics of the dosimeter/dosimetry system. Performance tests 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 Chapter 10).

Performance tests are of several types. They can be used to obtain a 'snapshot' of the overall accuracy of a dosimetry service, and may involve attempts to replicate workplace radiation fields. Alternatively, performance tests may separately assess components of accuracy as the bias and statistical uncertainty. Sometimes the distinction between type testing and performance testing is not entirely clear. In countries with limited access to facilities to carry out type-testing, a kind of approval performance test for the dosimetry 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, or perhaps a comparison of several services, under actual, or simulated, operational conditions. Of course, in the actual workplace, in most cases, the true value of the measurement quantity will be unknown. The service should not give any special treatment to the dosimeters which might lead to unrepresentative results.

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. 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 an independent '*dummy customer*' and irradiation of the dosimeters under controlled conditions independent from the ADS. Most services use a dummy customer for in-house quality assurance purposes.

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

dosemeters are sent back to the service for evaluation. Many international (including IAEA) inter-comparisons are of this type.

In some Member States the results of performance tests and of intercomparisons are displayed using the so-called 'trumpet curves' originally proposed by [Böhm 1990] and included in Radiation protection — Criteria and performance limits for the periodic evaluation of processors of personal dosimeters for X and gamma radiation, ISO 14146 [ISO 14146]. A performance test organised by EURADOS WG2 in 1999 used both a range of 0.67 to 1.5 and the trumpet curve [Bordy 2000].

In the future, it might be desirable to use the combined standard uncertainty of 30 % (50% for neutrons) over the range of doses for which the system is considered to be suitable, with a combined uncertainty of 20% at or near dose limits or the factor of 1.5 at 95% as an alternative.

8.6 Participation in national/international intercomparisons

An intercomparison exercise among dosimetry services can be seen as an announced performance test. Generally the results of such intercomparisons are published but anonymized. In many Member States participation in national and international intercomparisons, though not mandatory is strongly recommended as results can be used to support an application for approval or accreditation.

Periodic intercomparison exercises within the EU would be a first step towards awareness of performance of dosimetry services. This would stimulate services to investigate and improve their dosimetry systems in order to achieve successful results in the tests.

9 DOSE REPORTING, RECORD KEEPING AND INFORMATION SYSTEMS

9.1 Introduction

Dose record keeping is the making and keeping of personal dose records for radiation workers. It is an essential part of the process of monitoring the exposure of individuals to radiation and shares many of the same objectives (see Chapters 2 and 3). The purpose of record keeping, the nature and scope of the records that are kept, the extent of record keeping systems and the information provided are influenced by national requirements. Apart from demonstrating (the degree of) compliance with legal regulations (dose limits), record keeping may also be used for several additional needs and uses, such as:

- to demonstrate the effectiveness of ALARA;
- to provide data for analysis of dose distribution;
- to evaluate trends in exposure (possibly as a function of work practices or radiation sources), necessary information for the evaluation of a radiation protection system;
- to develop effective monitoring procedures and programmes;
- to provide data for medical and/or legal purposes;
- to provide data for epidemiological and research studies.

In principle dose record keeping is compulsory for workers in category A working conditions, though in view of the objectives described above, it is often considered useful to also keep records of doses received by workers in category B conditions. If the authorities require individual measurements for workers in Category B, these should be carried out by an ADS. It is crucial that doses are attributed to the correct individuals. In the BSS the requirement is that for Category A workers records should be kept until the individual has or would have attained 75 years of age, and not less than 30 years from the termination of the work involving exposure. In some countries an ADS (not necessarily the same ADS that assesses the doses) may maintain the dose records on behalf of the undertaking.

Increased computer, internet and database use have largely contributed to enhance the level of organization and storage of dose related records. Traditionally ADS reported the dose value as a result of a measurement by printing a report on paper sent to the customer by ordinary mail. Now, reports can be sent via the internet and some active personal dosimeters (APD) are also capable of transmitting the measured dose quantity to a central processing unit using infrared technology.

In some Member States countries dose records are considered sensitive and classified information and should be made available to a restricted number of persons, namely the undertaking, the authorities, the worker and the approved occupational health service. The circulation of dose records as well as other personal information (for example, identity card and passport data) must comply with personal data protection regulations. Handling and storage of classified information as well as the protection of the circulating data are important unavoidable issues.

As well as the documents mentioned in Chapters 1 and 2 there are also a number of Directives concerning the processing and privacy of personal data [EU 1995], on the legal protection of databases [EU 1996b], framework for electronic signatures [EU 1999], the

electronic circulation and privacy of personal data [EU 2002], as well as the retention and electronic communication of data [EU 2006]. Most, if not all, Member States, have implemented legislation on the use, dissemination and access to personal data. In some countries, the periodically evaluated dose values are also considered as classified and confidential information and are treated with the same precautions as other medical data. Moreover, the competence of an ADS complying with EN ISO/IEC 17025 extends to cover all features of data handling, dose reporting and keeping, in agreement with the requirements from the radiation protection authorities and law in general.

9.2 Recommendations

It is recommended that:

- Approval procedures for dosimetry services in relation to dose reporting should: a) state the dose information needed on the report, e.g. dose in measurement period, annual and/or 5-year accumulated dose; b) state detection limits of the dosimetry system; c) detail background subtraction methods; d) state the destination of the dose report; e) give details about the storage of monitoring records and reported dose values; f) state monitoring and reporting periods.
- Every Member State should create and maintain a national dose register where the dose values received by workers (as a minimum those in Category A) monitored in the country are kept for time intervals longer than the worker's working life and the life-time of the undertaking. In conformity with ISO/IEC 17025, all reported doses should be stored for an appropriate period.
- The national dose register (NDR) should: a) store dose values reported by an approved dosimetry service or by an undertaking, for example, in the case where aircraft crew dose evaluations are performed by airline companies or as results of investigation of occurrences; b) perform statistical analysis of data to characterize occupational exposure in the country; c) define work activities (for example, nuclear, medicine, industry, or natural); d) regularly publish occupational exposure reports; e) provide and/or issue radiation passbooks.
- In respect of security of dose records: a) databases with personal classified information should be registered; b) access to premises, files, archives, computers, servers, etc where personal information is handled and stored should be restricted; c) access to the classified information should be allowed only for radiation protection purposes; d) circulating information, particularly when using IT networks should be secure; e) there should be back-up procedures and equivalent security for copies; f) there should be similar security in use of active personal dosimeters and associated software.

9.3 Terms

The terms used herein, and the definitions given below, are taken from the current Directives and from ICRP recommendations. In the revised BSS which are in preparation, there are likely to be changes made to the definitions of some these terms.

Approved occupational health service: (AOHS) a body or bodies to which may be assigned responsibility for the radiation protection of exposed workers and/or medical surveillance of category A workers. Its capacity to act in that respect is recognized by competent authorities (BSS).

Undertaking (BSS): any natural or legal person who carries out the practice or work activities referred to in Article 2 of the BSS and who has legal responsibility under national law for such practices or work activities.

Outside undertaking (OWD): any natural or legal person, other than the undertaking including members of his staff, performing an activity of any sort in a controlled area.

Exposed worker (BSS): a person either self-employed or working for an employer who is subject to an exposure incurred at work and liable to result in doses exceeding one or other of the dose levels equal to the dose limits for members of the public.

Outside worker (OWD): any worker of category A (...) performing activities of any sort in a controlled area, whether employed temporarily or permanently by an outside undertaking, including trainees, apprentices and students (...) or whether he provides services as a self-employed worker.

Levels, as defined by ICRP Publication 75 [ICRP 75]: generally, a **reference level** is a predetermined value for any of the quantities that may be encountered in radiation protection programmes which will require a certain course of action to be taken in the event that the value of a quantity exceeds (or is predicted to exceed) this pre-defined level. A reference level is not a limit in itself and the action associated to it may range from just recording the value to intervention.

Recording level: a level above which all measured doses should be recorded [ICRP 75]. ICRP recommended that 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 (the dose limit for the members of the public) or an annual equivalent dose of about 10% of the relevant dose limit. As a consequence, any reading that is smaller than the recording level may be discarded and treated as zero in assessing the annual dose equivalent for the purpose of radiation protection. ICRP also states that little use is made of recording levels in individual monitoring for external exposure, because the measured dose is usually entered directly as a measure of the effective dose. The detection limit should then be used as the recording level and with results below that level being deemed to be zero.

In Figure 9.1 the definition suggested by ICRP for recording level as well as the actions undertaken are represented.

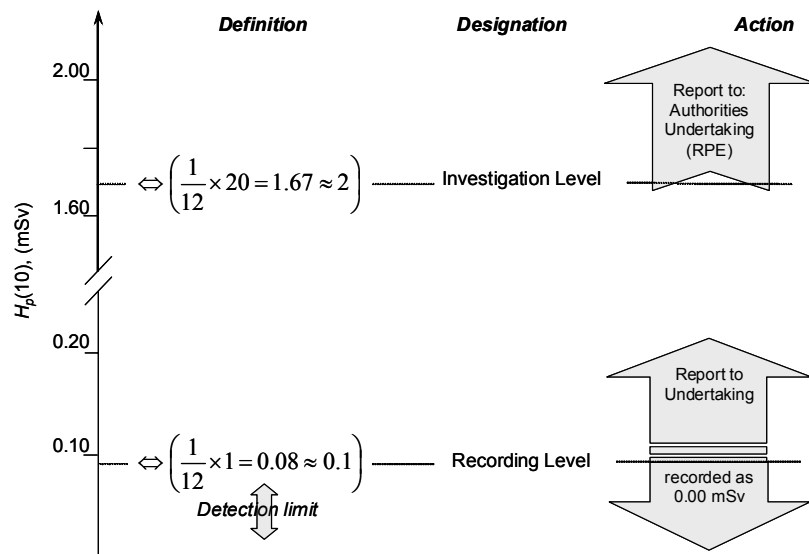


Figure 9.1: Dose reference levels for dose reporting and interpretation of the results. (In this figure undertaking was taken as an abbreviation of undertaking)

Investigation level: levels above which the cause or the implications of the result should be examined [ICRP 75]. They should initiate a review of the protection arrangements and address how a particular value above the investigation level was received.

Reporting level: a level below which it may not be necessary to issue a particular report but to wait until the next summary. **Action level** or any other level defined by the radiation protection authorities calling for a specified action.

The annual effective dose limit corresponding to the monitoring period is also shown in Figure 9.1. A worker who systematically receives a dose value around this figure will most certainly exceed the annual dose limit.

National Dose Register (NDR): a national repository for dose records.

Qualified Expert (term used in the BSS) or **Radiation Protection Expert (RPE):** Persons having the knowledge and training needed to carry out physical, technical or radiochemical tests enabling doses to be assessed, and to give advice in order to ensure effective protection of individuals and the correct operation of protective equipment, whose capacity to act as a qualified expert is recognized by the competent authorities. A qualified expert may be assigned the technical responsibility for the tasks of radiation protection of workers and members of the public. The RPE may not be employed by the undertaking and may act as an outside advisor.

Notional Dose: an estimated dose based on an investigation by an undertaking in conjunction with the RPE, or by the authorities, in circumstances where the routine assessment of dose is not possible, for example, where a dosimeter is lost or destroyed.

Radiation passbook: A document that facilitates the circulation of workers in different countries and contains radiation protection information for example the worker's identification, medical classification and the results of monitoring (dose values received).

9.4 Main partners in dose record keeping and the transfer of data

9.4.1 The main partners

In Figure 9.2 the main partners involved in individual monitoring are identified, as well as the flow of records between them in normal circumstances. High dose evaluations procedures will be dealt with in section 9.5.3 (Figure 9.4).

The main partners are represented by the sharp edged boxes and the national regulations and guidelines are represented by the round edged boxes.

9.4.2 Radiation protection authorities and regulations

The role and obligations of Member States and their radiation protection authorities toward individual monitoring issues have already been stated in Chapters 2 to 4 and 8. The characterization of the work and related tasks performed at the facility in terms of radiation fields, field of activity, practices and professions of the workers is also important, particularly when analysing task related exposures (see Figure 9.3).

9.4.3 The undertaking

The undertaking is responsible for assessing doses from exposures incurred on his site, to permanent and outside workers and should arrange for individual records where the dose results of each worker are stored (section 9.6.2). In some countries an ADS (not necessarily the same ADS who assesses the doses) maintains the dose records on behalf of the undertaking, but more generally the ADS only has to store the assessed records for a short period of time as agreed with the authorities.

The AOHS and the RPE are included in the undertaking box but in a dashed one meaning they may not be hired nor employed by the undertaking but considered as advisors and/or consultants whenever necessary. The dashed line in Figure 9.2 represents the situations where the undertaking (or the RPE on his behalf) reports doses to the NDR, for instance, dose values attributed to a worker based on doses received by others performing the same tasks, dose corrections or estimations based on workplace measurements modified with occupancy factors and dose values assessed in the case where a lead apron was worn, as a result of an investigation relating to a high dose report (section 9.5.3).

9.4.4 The worker

The worker is responsible for correctly using the dosimeter provided. The worker should be aware of the dose results received in relation to the work he has performed, particularly if monitored by two different ADS, for example when a person works at more than one location and may get dose results from different ADS. There could be a role for the NDR in these circumstances for communicating dose results to the individual.

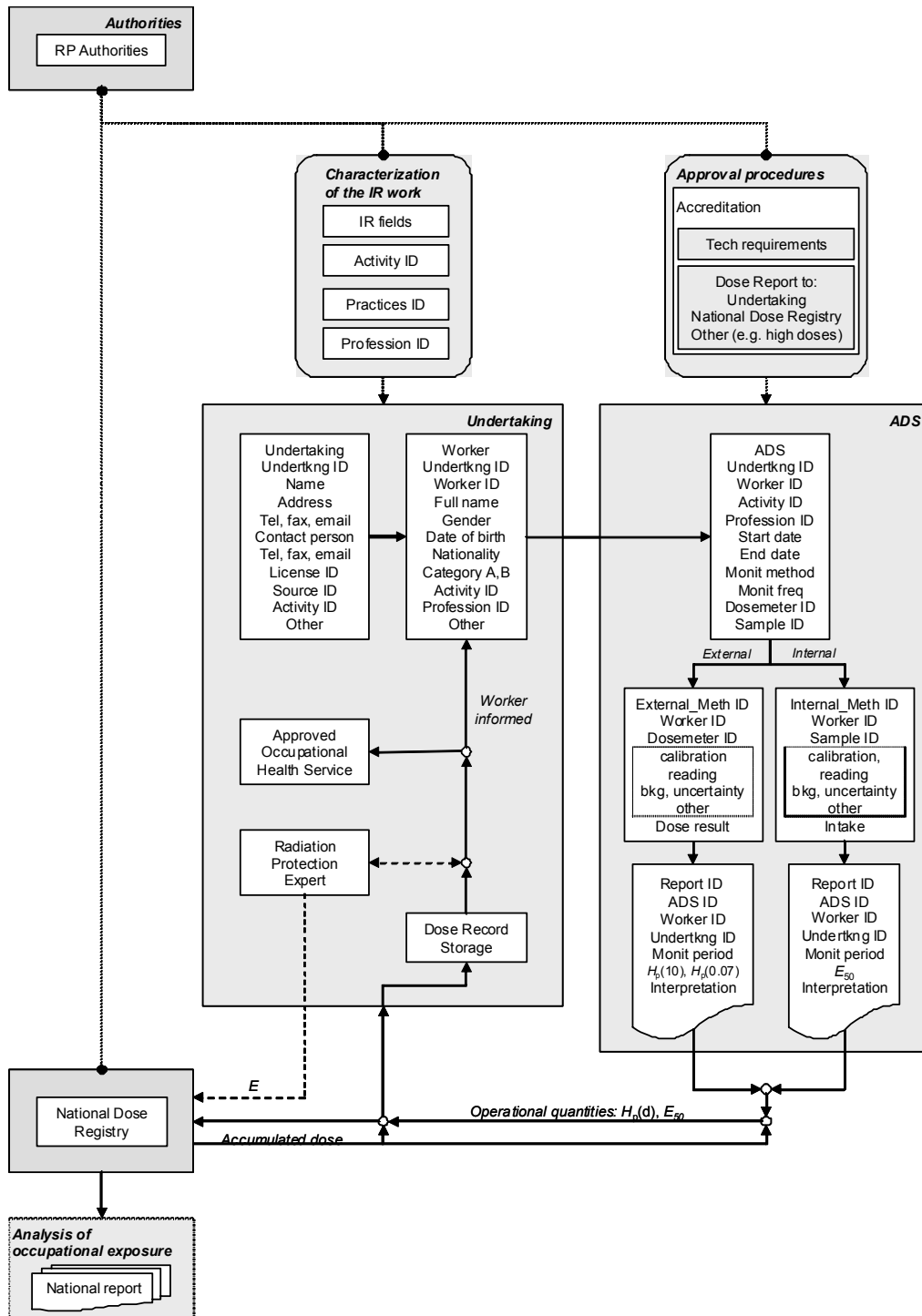


Figure 9.2: General picture of the flow of records between the main partners in individual monitoring (in normal circumstances).

9.4.5 Approved Dosimetry Service

As a minimum the ADS holds information on the employer, the worker and a unique dosimeter identifier.

Raw data from monitoring for example, integrated charge in the case of TLD and other parameters in the measurement model, should be stored for an agreed period of time so that if necessary a dose value can be reconstructed. The developed film (or the TL glow curve) may also be considered as a proof of the reading process.

The information generated should be unambiguously associated with a dosimeter and monitoring period which in turn is uniquely linked to a worker.

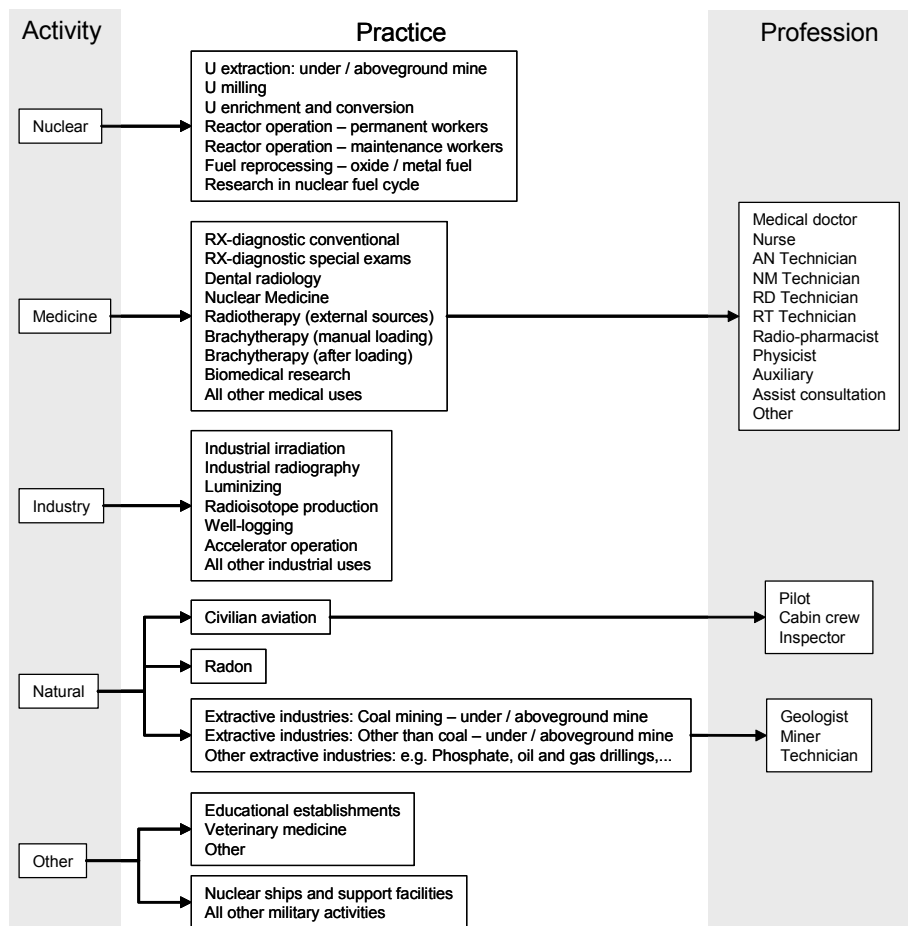


Figure 9.3: Example of a structure designed to provide information on the exposure received by fields of activity (increased detail from left to right).

9.4.6 National Dose Register

9.4.6.1 General aspects

National dose registers are part of the radiation protection authorities and are responsible for the collection and maintenance of dose records provided by the ADS and in some cases, by undertakings.

The national dose register should be able to communicate information either to the ADS or to the undertaking, see Figure 9.2. The information stored at the national dose register should allow follow up of the doses received by a person during his working life and a time interval

after the termination of work. Long-term storage of dose records at a national dose register is also a way to prevent the loss of individual dose data in case the undertaking ceased its activities in the country. The national dose register should perform regular analyses of the dose data collected in order to characterize national occupational exposure and may also share information with other databases (see section 9.7).

9.4.6.2 Quantities stored at the National Dose Register

In the national dose register the effective dose must be recorded in order to be compared to the (annual) dose limit. The effective dose will refer to all possible exposure pathways. For external dose assessment $H_p(10)$ is normally stored as the surrogate for effective dose.

9.4.6.3 Aircraft crew

Article 42 of the BSS [EU 1996a] includes the exposure to elevated levels of cosmic radiation of aircraft crew as occupational exposure. For aircraft crew liable to be subject to an annual exposure of more than 1 mSv, airline companies should assess the exposure of the aircraft crew concerned, take the assessment into consideration when organizing working schedules aiming at the reduction of doses of highly exposed crew, inform aircraft crew of the associated risks, and apply article 10 of the BSS to female crew member.

Owing to the complexity of the radiation fields at aircraft flight altitudes the estimation of the exposure is based on the results provided by computer codes. The results obtained using such codes should be validated. Further information of the assessment of doses to aircraft crew may be found in [EC 2004].

9.4.6.4 Emergency dosimetry

These Technical Recommendations do not specifically cover emergency dosimetry but where dose assessments have been made the assessed value of dose along with the personal data should be entered in the NDR following the event. Provision should be made to identify these special circumstances.

9.4.6.5 Outside workers and radiation passbook

The OWD [EU 1990] clearly states Member States must ensure that outside workers are afforded the same level of protection as that of workers employed on a permanent basis. To this end a radiation passbook should be issued which includes the identification of the outside worker and detailed information before and after the start of any activity, for example, medical classification of the worker and results of the worker's individual exposure monitoring. For practical reasons the radiation passbook should be in English and the Member States' language.

The employer is responsible for keeping and updating the radiation passbook and must make provisions to provide appropriate individual monitoring to the outside workers.

9.4.6.6 Notional Doses

Notional doses, in keeping with the recommendations of section 4.2 may have been added to the dose record prior to it being sent to the NDR. In some Member States the assessment of notional doses is the task of the NDR.

9.4.7 Security of the circulating information

The flow of records referred to in Figure 9.2, can happen in a number of ways by hard copy or use of electronic media. In general these records are personal information and special procedures are applicable as they are protected by law.

There should also be provisions for the destruction of paper-work (or other media) that contains confidential information that may no longer be necessary, useful or where their respective retention period has expired.

The software used for circulation and handling of data should be protected against intentional and unintentional modifications. It may be considered that the low level of software conformity recommended in the WELMEC Guide [WELMEC, 2005] may be adequate for this activity.

9.5 Dose assessment and dose reporting

9.5.1 Dosimeter assignment

Assigning dosimeters to a worker is establishing a unique link between the worker, dosimeter and in many cases the facility where it will be used. Dosimeter issue files should contain all the relevant information needed to proceed to monitoring. A monitored worker record is uniquely identified using both the worker's ID number and the undertaking ID code. This may provide information related to the facility, category of worker and type of work performed. Both the facility and the worker's records can be linked using a common code. In Figure 9.3 the minimum fields of activity considered for applications of ionizing radiation are listed on the left hand side with increasing detail to the right hand side.

Passive dosimeters are regularly sent by the ADS by mail. At the end of the monitoring period the dosimeters return to the ADS for readout, dose evaluation and dose reporting.

Since the late 1990, active personal dosimeters are increasingly used, for instance at Nuclear Power Plants (NPP) in the UK, gradually replacing passive personal dosimeters, giving some advantages, including for dose record purposes [Clarke 2001, Weeks 2002, Zodiates 2004]. At NPP there are very strict procedures for the entrance and exit of workers from specific areas including a more complete assignment of dosimeters to workers. In principle, APD are assigned from a pool of dosimeters available at the workstation, supplied, regularly calibrated and checked by an ADS. The method also relies on an information technology (IT) system shared by the undertaking and the ADS that assigns an APD at the access gate to a person who will be performing a specific task. When leaving the area the APD reading will be assessed, validated and stored on the person's file. The users should receive special training on the use of such devices, should be made aware of the need to properly use them. Other special precautions include operating procedures, arrangements

for computer support and maintenance of the hardware, as well as provisions for the storage and retrieval of dose data.

Unlike NPP, hospitals or industrial premises do not have such strict procedures for the access to specific areas. There is no actual control on who is entering an area, if the worker is wearing the correct dosimeter and when leaving the area, if the dosimeter is read, the result validated and inserted into the database to the correct user's file. Although at NPP the use of currently available active devices seems to satisfy requirements, in other fields, such as medical and general industrial applications of ionizing radiation, much still remains to be done.

9.5.2 Dose assessment

The aim of the measurement performed at the ADS is the periodic determination of the operational quantities $H_p(d)$. If the dose measured in the monitoring period is lower than the investigation level, the procedure represented in Figure 9.2 is followed.

However, if the dose exceeds the investigation level, the process in Figure 9.4 is followed. The appraisal of the situation by the RPE should include feed-back from the worker, and corrections based on the knowledge of the radiation field distribution, characteristics of dosimeter (energy and angle dependence), the results of workplace monitoring if available and occupancy factors, etc (Chapter 4).

9.5.3 Dose report

9.5.3.1 Content of the dose report

Every dose result should be reported. The report may be divided into three main areas, dedicated to:

- Clear identification of the ADS, undertaking, monitoring period and report title;
- List of monitored workers mentioning: name, dosimeter number, dose values measured in the period $H_p(10)$ and $H_p(0.07)$, and the accumulated dose (annual and/or 5-year accumulated dose) expressed on both quantities;
- Interpretation of the result taking into consideration the measured dose, the accumulated dose to date and their relation to the dose limits, and/or reference levels, as defined by the national authority.

The report should be signed by the person responsible at the ADS.

9.5.3.2 Communication of the uncertainty

ISO/IEC 17025 states that the uncertainty of the measurement should be evaluated and reported, but does not clearly suggest how, allowing freedom as to the way it should be communicated. An obvious solution would be to include the uncertainty of the dose results in the dose report. The employer should be made aware of the way in which the measurements and the uncertainty are calculated (see Chapter 5). As an alternative, the ADS may produce a leaflet or, report where specific information relating to the measurement procedure and their characteristics (limitations) including the uncertainty, are shown.

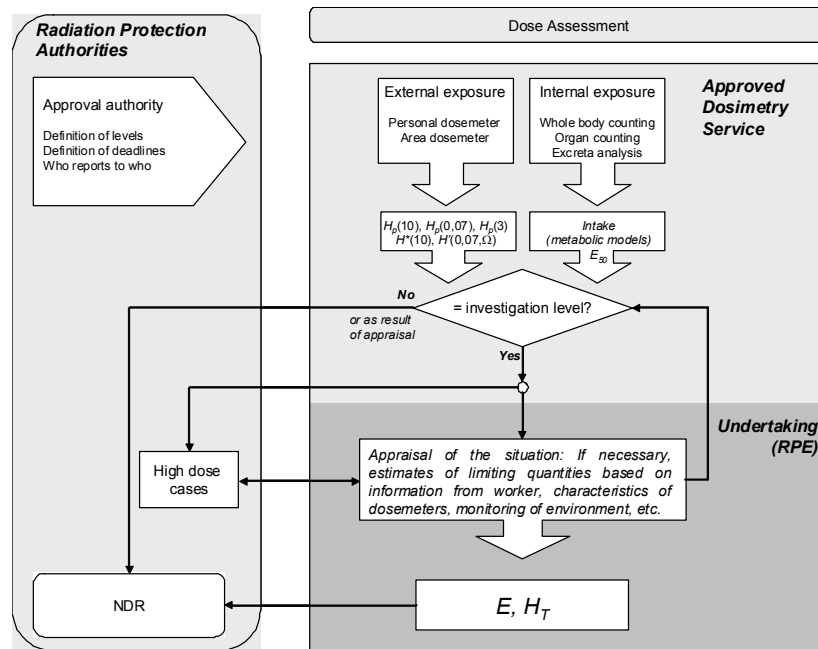


Figure 9.4: Dose assessment and reporting in high dose situations.

9.5.4 Dose recording

Procedures should be in place for the safe handling, storage and back-up of records. Although electronic systems allow the storage of large amounts of data, only relevant records should be kept, maintained and stored for a period of time compatible with the requirements of the radiation protection authorities. The radiation protection authorities should define the retention periods. Once the periods have expired, the corresponding records should be destroyed.

9.6 Dose information systems

In general, it is required by law that databases used for the handling of personal and classified information should be registered and the access of the worker to his personal data should be ensured.

Databases in use at ADS are generally developed in order to meet the needs of each monitoring method and at the same time to give an answer to most of the administrative features necessary to keep the service running, for example, allocation of dosimeters, visualization of readouts, the production of mailing lists, dosimeter labels, etc. Their main purpose is to enable the ADS-user full access to the data related to the undertakings, monitored workers and measured doses. Every monitoring period, the databases are updated with the upload of dose measurements produced in each of the reading sessions. As the most recent dose values are inserted, the accumulated annual dose is also updated. The structure of the database for dose record storage at the ADS can be briefly taken from Figure 9.2.

The database for use at the undertaking site is developed to enable access to the data related to the monitored workers, access to controlled areas, tasks attributed to the worker,

doses received in each monitoring period, results from monitoring of the workplace and of the environment, appraisal of occurrences, results from the investigation of occurrences, register of reports sent to radiation protection bodies, amongst other information. If the worker is monitored for external and internal exposures, the results may be provided by two different ADS and this should be considered in the organization of the individual dose files. In this case, the sum of the contributions from external and internal dose assessments should be compared with the annual dose limits. As addressed in previous sections, in some countries the stored data is considered classified and confidential information and may require special precautions.

9.7 NDR links to other data sources and databases

9.7.1 Links

NDR may periodically share information with international organizations concerned with the characterization of occupational exposure such as ISOE, ESOREX and UNSCEAR. The sharing of dose results to perform occupational exposure studies reveals the need for harmonized procedures for generating, storing and reporting results. Different dose measurement methods may be used, however background dose subtraction methods should be considered, as well as the use of detection limits instead of recording levels. The use of notional doses, that is, a dose value on a record that does not correspond to an actual dose received by a worker, should also be avoided.

On the other hand, the characterization of ionizing radiation work using a structure to provide information on the exposure received by fields of activity, for example, as suggested in Figure 9.3 (with increased detail, if practices and professions are also considered) allows an easier classification of workers into occupational categories.

9.7.2 ISOE

The Information System on Occupational Exposure (ISOE,) provides a forum for radiation protection experts from utilities and national regulatory authorities to discuss, promote and co-ordinate international co-operative undertakings for the radiological protection of workers at NPP (www.isoe-network.net). ISOE is jointly sponsored by the Organization for Economic Co-operation and Development, Nuclear Energy Agency (OECD, NEA) and the International Atomic Energy Agency.

The objective of the ISOE Programme is to provide participants with broad and regularly updated information on methods to improve the radiological protection of workers at nuclear power plants, as well as a mechanism for sharing information on these issues, including analysis of the occupational exposure data, as a contribution to the optimization of radiation protection.

9.7.3 ESOREX

The European Study on Occupational Radiation EXposures (ESOREX project) provides a survey within the European Union Member States, Iceland, Norway and Switzerland with the objective to provide the European Commission and the national competent radiation protection authorities with reliable information on how personal radiation monitoring, reporting and recording of dosimetric results is structured in European countries.

9.7.4 UNSCEAR

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) periodically performs a survey of occupational radiation exposures from both man-made and natural sources with data collected from countries all over the world (www.unscear.org). The objective of the survey is to assess long-term trends in occupational radiation exposures, identifying the main contributors to these exposures and the distributions of exposures within various work categories.

10 RELIABILITY OF DOSE ASSESSMENT, QUALITY ASSURANCE AND QUALITY CONTROL

10.1 Introduction

Good measurements, by which is meant 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 rigor and attention to detail which might not otherwise be there, and can also allow tests of conformity to be made. The recommendations given here are an outline for establishing and implementing a quality management system (QMS). A detailed description of implementing standards within an IMS is given by Fantuzzi et al. [Fantuzzi 2004]. See also [ICRU 76]. This outline has many aspects in common with the main quality assurance standard for calibration, test and measurement laboratories, EN ISO/IEC17025:2005 [ISO 17025] and contains all the requirements that testing and calibration laboratories should meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results.

If a laboratory meets the requirements of EN ISO/IEC17025:2005 it will also be operating a quality management system for its testing and calibration activities that is in accordance with ISO 9001[ISO 9001], since the first one deals with accreditation (includes measurements) whereas the latter only with certification.

10.2 Recommendations

When establishing a QMS attention should be paid to the following matters:

- Top management commitment is vital if the system is to be introduced successfully.
- Look at the system that is currently in place: EN ISO/IEC17025:2005 will allow the principles that work to be kept, while refining those that do not.
- Ensure there are good internal communication channels and processes within the dosimetry service. Clearly lay out a well communicated plan of activities and timescales. Make sure everybody understands them and their role in achieving success.
- Involve all the staff in the implementation of the QMS and the processes that comprise the dosimetry service.
- Give some thought to process interaction. It is important that staff within the dosimetry service do not work in isolation but work as a team for the benefit of the customers and the dosimetry service.
- Do not ignore the impact that introducing a QMS will have on the customers and suppliers. Communicate with them to gain insight as to how they view the service and how they feel improvements could be made.

10.3 Terms

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 [ISO/IEC 17000:2004].

Conformity assessment body: body that performs conformity assessments.

NOTE: An accreditation body is not a conformity assessment body [ISO/IEC 17000:2004].

Quality assurance can be defined as those planned and systematic actions necessary to provide adequate confidence that a structure, system, procedure, or component will perform satisfactorily and comply with agreed upon standards [ISO 2003].

Quality management system consists of a set of interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective way. A management system should be established, implemented, assessed and continually improved. It should be aligned with the goals of the organization and should contribute to their achievement [IAEA 2006]. **Quality control** consists of the set of operations intended to maintain or improve quality [ICRU 76].

10.4 Implementation of a QA/QC Management System

10.4.1 Key elements

National regulations may require that dosimetry services which carry out external dose assessment be accredited to a relevant standard. Such accreditation programmes will include specifications of the QA and QC measures to be implemented. Details of the QA system management, organization and administration may be related to national legislation and may depend on the nature of the service.

By establishing a QMS, the implementation of standards can be achieved more easily. Amongst the many benefits which can be gained, a QMS helps organizations to improve customer satisfaction levels, internal efficiency and employee involvement. A QMS can be established in different ways and should best suit the dosimetry service. To establish the QMS, a good knowledge of the business and processes of that specific dosimetry service will be needed. Hence, for example, outside quality consultants alone may not be able to develop a practical QMS.

The key elements are:

- establishing the quality management system;
- using the quality management system;
- reviewing whether the results are satisfactory;
- improving the quality management system.

10.4.2 Basic topics for QMS

In EN ISO/IEC17025:2005 topics covered under the heading of management requirements include:

- responsibilities of, and requirements on, the organization;
- the need for a quality system;
- document control;
- review of tenders and contracts;
- sub-contracting of tests and calibration;
- purchase of supplies and services;
- service to the customer;
- complaints;
- control of non-conforming testing and/or calibration work;
- improvement;
- corrective action;
- preventive action;
- control of records;
- technical records;
- internal audits;
- management reviews.

In technical requirements, topics covered include:

- staff;
- accommodation and the laboratory environment;
- test and calibration methods and method validation;
- equipment;
- measurement traceability;
- sampling plans;
- handling of test and calibration items;
- assuring the quality of test and calibration results;
- reporting the results.

Most, if not all, of the content of EN ISO/IEC17025:2005 is relevant to the work of dosimetry services. Whether there is a case for selecting particular requirements from ISO/IEC 17025,

rather than making it a requirement to comply with the complete standard, should probably be a matter for dialogue between national approval authorities and dosimetry services.

One advantage of following the route of EN ISO/IEC17025:2005 accreditation is the effectiveness of frequent, annual, surveillance visits which generally last no more than one day. The laboratory is assessed for conformity to the standard. Both the quality management system operational within the organisation and the technical competence of the laboratory to perform the tests are assessed. The essential requirements which should be fulfilled are:

- a documented quality management system and quality manual;
- an organized functional structure with clearly defined technical and quality responsibilities impartiality, integrity and independence;
- technically competent personnel;
- calibrated equipment;
- traceable measurement;
- uncertainty of measurement for all tests and/or calibrations;
- participation in and achievement of satisfactory results in proficiency testing or inter-laboratory comparison schemes applicable to the applied scope of accreditation;
- technically valid procedures.

Although not all types of work that the laboratory carries out is examined on each visit, over a period of about five years, most 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. Surveillance visits will include 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.

10.4.3 Establishing the QMS

Establishing a QMS is covered in Clause 4 of EN ISO/IEC17025:2005 and requires the identification of the processes, their success criteria, the inter-relationship between processes and the system for checking on results. Appropriate process identification is key to a practical system and the key is to start with two processes (management and technical). Then decide if sub-processes are necessary rather than working from the “bottom up”.

Each process should have an “owner” and the owner is responsible for the activities that relate to the success criteria of the process.

A quality manual is required and a number of documents and records. The documentation should be kept to a minimum. Besides the quality manual, the following areas require a documented procedure:

- document control;

- records control;
- internal audits;
- non-conforming product;
- corrective action;
- preventive action.

Additional procedures may be required if, without them, the processes might end up having variable or unpredictable results like those that can be caused by inexperienced staff, complicated parameters or other risks. The QMS is, in essence, a means of minimizing business risks.

Records are required to show that the requirements (established through the procedures) have been met.

The Quality Policy is the area where the owners or managers of the dosimetry service establish the fundamental direction of the QMS. Of particular importance in the area is a recognition of customer expectations and a system should be in place to ensure customer satisfaction.

Resources should be put in place to provide human, technological and environmental resources. These will include computers, processing equipment, processing areas, offices as well as trained staff. The QMS requires that each dosimetry service establish a way of demonstrating that their staff is competent.

10.4.4 Using the QMS

Having established the QMS, it should be used to see that it works in the way it was intended. It will be necessary to use the procedures, forms, equipment, instructions in the way that it was planned.

10.4.5 Reviewing whether the results are satisfactory

The results of QMS should be reviewed at appropriate intervals. When the system is new the intervals will be short but can be longer once the QMS becomes mature. The reporting of results against the process success criteria should be regular and be used by management to ensure that everything is working as it should be. The recording of information should be such that problems are detected promptly. It is expected that dosimetry services have some problems or “challenges” but a successful dosimetry service will identify these at an early stage and deal with them in an effective manner.

Reviewing perceived customer satisfaction is a key metric that has to be reviewed. It is recognized that the handling of complaints may not be enough as customers may just move their business elsewhere.

One of the key elements of the review is the management review. This procedure reviews whether the QMS is working and whether the results meet the dosimetry service objectives and whether the process criteria have been met.

10.4.6 Improving the QMS

Improvement is often another name for dealing with the challenges of the dosimetry service. These challenges may be actual issues (such as being late with a delivery) or be about “near

misses” (such as almost forgetting to make a delivery). Within a QMS these are called corrective actions and preventive actions respectively. Corrective actions must be recorded as they often involve customer complaints. Other examples are issues with suppliers or issues that have arisen with the processes (non-conforming work). It is recommended that preventive actions are handled in a similar way.

10.5 Managing Technical Aspects of a QMS

Along with establishing and maintaining a QMS the following technical aspects should also be taken into account:

10.5.1 Staff

One important requirement for approval is trained and independent staff. Management should ensure that the number of staff involved is sufficient to accomplish all the processes and that they are competent to assure that the processes are carried out properly. The main categories of staff that work at a dosimetry service are technicians and physicists. Both can be involved in administrative, methodology and software related tasks. Staff performing calibrations, dose assessments and other special tasks have to be appropriately qualified through a combination of education, training and experience. Personnel should be free from any internal or external influence, which could affect the quality or impartiality of their work at the service. The responsibilities of key personnel should be clarified to avoid conflicts of interest. Adequate training on radiation protection, dosimetry and calibration work should be provided. New staff should be given ‘on-the-job’ training along with appropriate supervision. Physicists are usually involved in research and development tasks, understanding the complexity of dosimetry concepts and implementing improvements to the system (for example, new dosimeter design and optimization of methods).

The EN ISO/IEC17025:2005 standard also intends to clarify task/procedure assignment, so that it is possible to establish ‘responsibility levels’ for each task of a process. Most critical equipment and procedures should only be undertaken by appointed personnel.

10.5.2 Accommodation and the laboratory environment

The dosimetry service should ensure that appropriate conditions for staff, equipment and procedures are attained. It would be desirable to have specific areas for different activities. The dosimetry service premises should be installed in a low background radiation area, dust free and temperature controlled environment.

The detectors should be kept in reproducible conditions of temperature, humidity, lighting, background radiation, etc. as these may influence the measurements, e.g. response to fading, aging, self-irradiation dose, residual dose evaluation, etc. Environmental reference conditions (ambient temperature, relative humidity, light intensity, etc.) are also mentioned in the standards in relation to the performance tests.

A preventive maintenance programme should be instituted to minimize the chance that equipment will fail at a critical time, such as in an emergency. Activities that are not directly related to the performance of dosimetry service operations should be separated to avoid unnecessary interference.

A stable power supply is needed so that the voltage and AC frequency remain within the specifications of the equipment in use. Stray electric and magnetic fields should be minimized to avoid affecting equipment and dosimeters.

10.5.3 Test and calibration methods and method validation

The EN ISO/IEC17025:2005 specifies that the laboratory should use appropriate methods and procedures for all tests and calibrations. These should be carried out in accordance with the requirements set out by the national authorities, and in keeping with the appropriate standards, see Chapter 7 and [Fantuzzi 2004]. The dosimetry service may also introduce procedures and methods for its own use as a result of research and development carried out and validated by qualified personnel. The estimation of the uncertainty of the measurement is addressed in Chapter 5.

10.5.4 Equipment

The dosimetry service should be equipped with the necessary items of equipment to carry out its task. Staff should be trained to use the equipment with manuals and instructions being readily available. Maintenance records should be kept for all pieces of equipment in use. The equipment should be identified and labeled to indicate for example, the status of calibration, calibration date, maintenance date, etc. A record should be kept of software versions used for testing, calibrating and sampling and respective updates should be kept for example, for dosimeter reading, processing and storage, databases, etc.

10.5.5 Measurement traceability

The dosimetry system should be designed and operated so that calibration and measurements are traceable to the quantities required. The BSS [EU 1996a], states that the relevant operational quantities for individual monitoring of external radiation are personal dose equivalent $H_p(10)$, $H_p(0.07)$ and $H_p(3)$. Traceable calibrations/irradiations, together with reliable estimated uncertainties are provided by NMI or accredited standard dosimetry laboratories. Typically, the calibration procedures and data used in these standard dosimetry laboratories follow the ISO standards for calibration of radiation protection instruments [ISO 4037] (see also Chapter 7). Traceable calibration, that is those carried out by a standards laboratory, should be performed at regular intervals as part of the quality system.

Reproducibility of the calibration can be controlled by verification of the calibration. The verification can be done under simplified conditions. For example, the verification is done using dosimeters irradiated free-in-air, instead of on a phantom, with a ^{137}Cs source. The correction factor for these simplified conditions must be determined individually for each type of dosimeter. It is between 1.00 (for dosimeters insensitive to backscattered radiation) and 1.07 (the backscatter factor of the phantom for measuring quantity $H_p(10)$ for dosimeters fully sensitive to backscattered radiation).

When a dosimetry service makes use of its own radioactive source for these type of verifications, care must be taken not only for the calibration of the source output, but also for the consistency of the local practice (phantoms, beam geometry, conversion coefficients air kerma/dose equivalents, radiation scatter, etc.) with the procedures of the calibration standards mentioned above. The metrological traceability of calibration cannot be achieved through verification, but it can be used for QC purposes to verify the reproducibility of calibration. The verification of calibration can follow for example a QA-procedure, where the action limits for the stability/reproducibility of the calibration factors are stated, based on the expertise and experience of the laboratory and existing international guidance.

10.5.6 Sampling plans

The dosimetry service should have a sampling plan and procedures for sampling, like procedure for receiving new dosimeter batches. As a kind of example, the acceptance procedure for the new TL pellets according to which parameters like repeatability should be checked.

10.5.7 Handling of test and calibration items

The dosimetry service should have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of the items. This should include provisions necessary to protect the integrity of the item and to protect the interests of the dosimetry service and its customers.

10.5.8 Assuring the quality of test and calibration results

An important aspect of any quality system is the identification of critical parameters that contribute to quality and may change with age and use. This could be an essential part of internal QC and QA procedures of a quality system. Monitoring of the most important parameters will ensure the performance of the procedure remains within accepted and predefined limits and that measures are taken when the action limits are exceeded.

The data obtained over long periods may be used to feed QC charts [Dutt 1994], where acceptance, action and rejection levels have been considered. In this way, trends can be observed and corrected, if necessary.

The overall performance of the service should be periodically checked. Participation in national and international comparison exercises is a useful test of the performance. The performance of the service for routine measurements is assessed under normal workplace conditions, provided that the service does not give any special treatment to its dosimeters. Three possible methods for comparison exercises are the blind test, the surprise test and the announced test have already been described in Chapter 8.

10.5.9 Reporting the results

Reports should be compatible with national regulations and standards. The report should provide to the customer an interpretation of the measured doses, including a warning when the possibility of exceeding dose limits exists. The uncertainty of measurement should be quoted, particularly if the recorded dose is high and the uncertainty affects compliance with limits (see sections 5.10 and 9.5.3.2).

The dose report is issued and sent to the customer and, in some countries, to the National Dose Register in the frequency and format required by the authorities.

EN ISO/IEC17025:2005 details the information that should appear in a report, for external radiation, as well as containing dosimetry service and customer details, the dose report should also mention the monitoring period, the dosimeter number, the identification of the wearer, the dose measured in the period, accumulated dose to date, identified causes for no dose evaluation (dosimeter not returned, damaged, etc) and interpretation of the result concerning compliance to the applicable limits.

According to the BSS [EU 1996a] and OWD [EU 1990], each Member State shall facilitate the exchange, amongst competent authorities or approved dosimetry services, of all relevant

information on the doses received by a Category A worker. This implies common approval criteria when employing such a person as an occupationally exposed worker. As a result, record keeping may form an essential part of the dosimetry service work. The purpose of dose record keeping, the nature and scope of the records that are kept, the extent of record keeping systems and the information provided are all influenced by national requirements.

Dose record keeping and other information systems should fulfill the requirements for good practices of data management. The main principles relating to data quality are that data are processed confidentially, collected for specified purposes, adequate in relation to the purposes for which they are collected and kept up to date.

11 BASIS FOR PROCEDURES AND CRITERIA FOR MUTUAL RECOGNITION OF APPROVED DOSIMETRY SERVICES IN EUROPE

11.1 Introduction

As stated in Chapter 8, the purpose of approval (by the Member States' authority) is to recognize and verify that an approved dosimetry service is technically competent; able to generate technically valid results; and has adequate administration, technical and quality systems. For a service to be approved, it is a general requirement 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 the employer and/or the NDR in a reasonable time; rapidly communicates to the employer, and subsequently to the authorities, the results of dose assessments made in the event of an accident, occurrence, or incident.

The current Technical Recommendations [EC 1994a] are used in several Member States as the basis for technical requirements for approval, together with national and international standards. It is anticipated that the revised Technical Recommendations will be similarly used, and should therefore contribute to the harmonization of approval procedures within the EU.

Member States' have freedom as to how directives are implemented into national laws, and this, together with, and probably linked to, differences in legal systems, can result in differences in approval procedures. Member States may require that an undertaking operating under its laws must use an approved dosimetry service covered by its legislation, and meet the specific approval requirements administered by its approval authority. The relationships of approved dosimetry services with the relevant government bodies, approval authority, the customer/employer requiring the service for his employees, the national dose registry, accreditation body, are likely to be different in each country.

In these Recommendations, the framework for individual monitoring was described in Chapter 2, and the general criteria to be met for approval of approved dosimetry services were recommended in Chapter 8. These criteria correspond to the achievement of quality and competence on all following issues: dosimeter design and performance, traceability of calibration, uncertainty evaluation and management organization. These common criteria will make it easier to compare and to recognize the technical competence of services operating in different Member States, and allow Member States where approval procedures are not yet in place, to implement a national procedure for this purpose.

The eventual goal is that within the EU the result of a measurement by an approved dosimetry service approved in one Member State for a dosimeter worn by a citizen of another Member State will be accepted by the authorities of the citizen's Member State. This may mean, but not necessarily, that the approved dosimetry service is recognized in the citizen's Member State as if it were approved. It may still be necessary, as now, for an approved dosimetry service to apply for and be granted approval by the approval authority of

a Member State in order to act for an undertaking or to monitor a citizen coming under its legislation.

In this Chapter, further criteria for approval are recommended, which if met, would be a significant step towards this goal.

11.2 Criteria for the harmonization of approval procedures

In the following table, the main general (minimum) criteria, taken from Chapter 8, are listed together with the additional criteria recommended.

Table 11.1: General criteria (Chapter 8) and additional criteria for approval

Issue to be demonstrated	General (minimum) criteria (Chapter 8)	Additional criteria (attainable in a reasonable time frame)
Satisfactory/suitable dosimetric characteristics	Type test against current international standard(s), including software. All data, including the rated ranges for each input quantity, graphs, combined standard uncertainty reported together with the laboratory at which the test has been performed	Type test to demonstrate full conformity, including software, with current international standard(s), or with European Council and Parliament requirements if these are introduced. All data, including the rated ranges for each input quantity, graphs, combined standard uncertainty reported together with the laboratory at which the test has been performed
Traceability	To a NMI or secondary standard laboratory	
Quality management system	In accordance with EN/ISO/IEC17025	Accredited according to EN/ISO/IEC17025
Accuracy of measurement of personal dose equivalents	Combined standard uncertainty for measurement of personal dose equivalents at the location of the dosimeter for photons and electrons of $\pm 30\%$ for doses greater than 1 mSv for $H_p(10)$ and 50 mSv for $H_p(0.07)$, and $\pm 20\%$ or factor of 1.5 at 95% confidence, for doses equal to dose limits, in both cases <i>pro rata</i> for wear period. Combined standard uncertainty for measurement of personal dose equivalents for neutrons of $\pm 50\%$ for doses greater than 1 mSv for $H_p(10)$ and 50 mSv for $H_p(0.07)$ (using dosimeters calibrated in terms of $H_p(10)$), <i>pro rata</i> for wear period.	
Performance test for approval	'Announced test' (see Chapter 8) with the satisfactory response of the dosimetry system within the rated ranges of all input quantities.	'Surprise test' (see Chapter 8) with the satisfactory response of the dosimetry system within the rated ranges of all input quantities.
Periodic performance test	For a small number of dosimeters for each of several irradiation conditions every 3 years	
Intercomparisons	Take part in national, European and international intercomparisons	
Internal audit	Every year	
External audit	Audit by approval authority condition for approval	Audit according to accreditation requirements.
Inspection	Condition for approval + repeated at least every 3 years	Condition for approval +repeated on a 'surprise' basis
Annual confirmation by the service	Annual declaration that everything is in accordance with approval requirements and annual report on operations	

11.3 Further considerations of harmonization of approval procedures

Approval procedures for photon external dosimetry are well established in most Member States, although with differences. Low energy electron/beta radiation and neutron dosimetry frequently receive less consideration - in the case of whole body beta irradiation the contribution to effective dose is unlikely to be significant. Low energy electron/beta radiation extremity dosimetry assessed in terms of $H_p(0.07)$ needs more attention.

In the case of neutron dosimetry: (i) irradiation facilities are not as readily available as for photons in all Member States, not allowing easy dosimetry performance investigations at reasonable cost; (ii) for most routinely used neutron dosimeters the dosimetry requirements met by photon dosimeters are not so easily achievable, and therefore less stringent criteria are necessary.

It would be advisable that the irradiation conditions for external performance tests are not just standard laboratory conditions at only one energy as this actually shows only mis-calibration/normalization of the dosimetry system and not weak points of the dosimeter design and/or algorithm which may apply field-specific correction factors determined for the specific type test fields. However, as irradiation tests are not cheap and in some countries not so easily available, a good compromise would be a protocol where each year a particular irradiation condition is checked together with the calibration/normalization of the system.

Given the fact that periodic external performance tests are desirable, the choice of their frequency is not a trivial matter. They cannot be performed too often owing to cost constraints. However, it is important that they take place regularly, so that services are stimulated to attain and then maintain their level of quality as high as at the time for approval, knowing that they will be checked regularly.

In-house quality assurance and quality control are recognized and recommended as key elements to the successful running of a dosimetry service, and a QA programme are essential for compliance with national and international requirements: conformity with EN ISO/IEC17025:2005 will allow harmonization in this field.

Routine performance tests carried out by the service itself are to confirm that the overall accuracy is acceptable and/or the performance of the dosimetry system is as expected. They should be frequent (monthly is suggested).

Harmonization through the implementation of standards could be achieved if the competent authority or another legal body of Member State set out requirements for approval based on international standards and/or international recommendations.

In the EU, national accreditation bodies sign the Mutual Recognition Agreement. This would imply that an approved dosimetry service accredited in one of these countries would also be accredited in any other signing countries. This is not the case for approval.

It is recommended that for approval individual monitoring services should follow the recommendations on accuracy, type-testing, dose record keeping and reliability given in these Technical Recommendations.

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