



Approval of Dosimetry Services in Ireland – Guidelines for Applicants

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1. Introduction

Dosimetry services providing a service in Ireland in accordance with S.I. 125 of 2000 as amended by S.I. 152 of 2012 must be approved by the Environmental Protection Agency (EPA).

The purpose of approval is to ensure that a dosimetry service is technically competent and can assess doses with a reasonable degree of accuracy. In order to be approved, the dosimetry service must satisfy the criteria in Appendix A. These criteria are based on The European Commission document Radiation Protection No 160 entitled “Technical recommendations for monitoring individuals occupationally exposed to external radiation”, hereafter referred to as RP 160 [EC, 2009]. These recommendations provide a basis for developing consistent and harmonised approval criteria for dosimetry services operating in all Member States and are intended to promote common European standards for such monitoring.

A list of approved dosimetry services (ADS) will be maintained on the EPA website (www.epa.ie).

2. Information to be submitted with applications

A dosimetry service wishing to apply for approval in Ireland must apply in writing to the EPA. The following information should be included with applications:

- i. Full name and address of the dosimetry service and contact details;
- ii. Scope for which approval is being sought;
- iii. Evidence of accreditation to ISO 17025 or approval in accordance with section 2.2;
- iv. Performance data from irradiation tests and intercomparison exercises;
- v. Sample customer reports;
- vi. Statement that the dosimetry service conforms to all of the Approval Criteria;
- vii. Type test data (where appropriate);
- viii. Application Fee.

All applications must be addressed to

Dosimetry Service Approval
Environmental Protection Agency
Office of Radiation Protection and Environmental Monitoring
McCumiskey House
Richview
Clonskeagh Road
Dublin 14
D14 YR62
Ireland

2.1 Scope of approval

The scope of approval should specify each model of dosimeter for which approval is sought. For each model of dosimeter, the following information should be provided:

- i. Dosimeter make and model ID;
- ii. Dosimeter technology (TLD, film, OSL, etc);
- iii. Type of dosimetry (internal, external whole body, external extremity, etc);
- iv. Operational quantity ($H_p(10)$, $H_p(0.07)$, $H_p(3)$);
- v. Radiation type e.g. photons, beta;
- vi. Dose and energy range;
- vii. Limitations or conditions for use.

For convenience, this information should be provided in table format as shown below.

Table 1 Format for scope of approval

Dosimeter Make and Model	Technology / Type of Dosimetry	Operational Quantity	Radiation Type e.g. photons, beta	Dose / Energy Range	Limitations of Use

2.2 Evidence of accreditation

The service shall provide a copy of their certificate and scope of accreditation to ISO 17025 issued by the national body recognised by the European co-operation for Accreditation (EA) as the competent authority to grant such accreditation.

Approval in another EU Member State will be accepted in place of accreditation only where the service operates in a country where accreditation is not widely used for dosimetry services and where the national approval process involves an independent assessment of the service's quality system similar to the accreditation process. Services intending to apply on the basis of approval in another EU Member State should first check with the EPA as to whether approval in that Member State is accepted in lieu of accreditation.

In the case where the application is being made on the basis of approval in another Member State the applicant shall provide documentary evidence issued by the approval body showing:

- i. the type of dosimetry, the dosimeter technology and the dosimeter make/model;
- ii. conditions and limitations of use;
- iii. the period covered by the approval.

In the case of a dosimetry service whose processing is done outside the Irish State, the service's quality management system must cover any part of their operation conducted in Ireland. If, for example, the service (or a third party) runs a depot or distribution centre in Ireland it must demonstrate that these operations are covered by its quality system so that results cannot be adversely affected by that part of the operation.

2.3 Performance Data

The dosimetry service shall provide evidence of participation in recognised laboratory intercomparisons.

The application for approval should include performance data as follows:

- i. evidence of regular satisfactory participation in national, European or international intercomparisons;
- ii. results of irradiation tests with a satisfactory response of the dosimetry system within the rated ranges of all input quantities as set out in the scope of approval;
- iii. results of intercomparison and irradiation tests must demonstrate compliance with accuracy of measurement of personal dose equivalents criteria set out in the technical criteria;

The EPA may require applicant services to provide dosimeters to it for irradiation and performance testing.

2.4 Sample reports

The service shall provide samples of customer reports and guidance made available to customers.

2.5 Statement of conformance with approval criteria

The following declarations must be provided:

- i. the dosimetry service complies with EPA's approval criteria;
- ii. the service complies with relevant EU guidance and recommendations;
- iii. the reporting time in normal and accident situations shall comply with the response times set out in the technical criteria;
- iv. the service will provide data annually to the National Dose Register (NDR) in a format and manner specified by EPA.

2.6 Type test data

In assessing an application for approval for a dosimetry system which is not of established and proven design, the EPA reserves the right to require the service to provide results of type testing against relevant international standards. For personal dosimeters used to monitor individuals occupationally exposed to external radiation, several international and European standards exist for type testing as set out in Table 2. Such testing shall, where required, be undertaken by an independent laboratory internationally recognised as being competent to undertake such testing. In general, dosimetry systems which are not already in widespread use within the EU will not be considered to be of proven design.

Table 2 Dosimetry Standards

Dosimetry Type	Standard(s)
Extremity TLD	ISO 15382:2015
Whole body passive	IEC 62387:2012
Neutron	ISO 21901-1:2015
Direct reading dosimeters	IEC 61526:2010

2.7 Application fee

The fee for applying for approval is €600. This will be invoiced following receipt of the application. This must be paid in full before a certificate of approval can be issued. A purchase order number to cover this fee should be included with the application.

3. Assessment process

Approval is granted to a dosimetry service following a satisfactory review of the documents submitted with the application to ensure that the criteria specified in Appendix A are met.

The review will be carried out by an Assessment Committee chaired by an EPA Programme Manager and will include a member with expertise in personal dosimetry and an inspector of the EPA's Radiation Protection Regulation Unit. The EPA reserves the right to include one or more external experts in the assessment team. In assessing the applications the assessment team will:

- i. consider whether the type of dosimetry system as set out in the scope of approval is appropriate to its intended purpose;
- ii. consider if the scope of accreditation adequately covers the range of dosimetry systems/devices as set out in the scope of approval;
- iii. consider if the performance data provided adequately demonstrates compliance with RP160;
- iv. consider if the sample reports comply with the requirements set out in the technical criteria;
- v. consider if the declarations given are adequate. The EPA reserves the right to seek evidence to support these declarations;
- vi. in assessing an application for approval for a dosimetry system, which is not of established and proven design, the EPA reserves the right to require the service to provide results of type testing against relevant international standards. In general dosimetry systems, which are not already in widespread use within the EU, will not be considered to be of proven design.

The EPA will not routinely carry out on-site inspections of dosimetry services or systems seeking or holding approval but reserves the right to do so if required. The EPA will rely primarily on accreditation to demonstrate that the service as delivered meets the technical specifications set out in the scope of approval. In assessing the applications the EPA Assessment Committee will consider if the scope of accreditation adequately covers the range of dosimetry systems/ devices as set out in the scope of approval.

Table 3 lists the technical criteria specified in Appendix A and sets out how compliance with each individual criterion must be demonstrated.

Table 3 Methods of assessing compliance with approval criteria

	Criterion	Method of assessing compliance
A	Scope of approval clearly defined.	Scope of approval
B	General criteria	ISO 17025 or equivalent
C	Dosimetry methods	ISO 17025 or equivalent + scope of approval
D	Quality assurance	ISO 17025 or equivalent
E	System software	ISO 17025 or equivalent
F	Traceability	ISO 17025 or equivalent
G	Irradiation tests	ISO 17025 or equivalent
H	Intercomparison tests	ISO 17025 or equivalent + evidence of satisfactory performance including compliance with accuracy of measurement of personal dose equivalents criteria set out in Appendix A
I	Staff competence	ISO 17025 or equivalent
J	Data handling	ISO 17025 or equivalent
K	Incident preparedness	Statement on response times
L	Reporting	ISO 17025 or equivalent + statement of compliance
M	Implementation of standards	Statement of compliance plus type test results where required
N	Knowledge of relevant Irish legislation	Statement of compliance
O	Supply of data to NDR	Statement of compliance

The Director of the EPA's Office of Radiation Protection and Environmental Monitoring will determine whether or not approval should be granted taking account of the recommendations of the Assessment Committee. Where the dosimetry system is of established and proven design, the EPA will notify an applicant service of the outcome within 3 months of the receipt of a complete application. In all other cases the EPA will notify an applicant of the outcome within 6 months.

3.1 Incomplete application

If the information submitted is incomplete or unsatisfactory, the dosimetry service will be given the opportunity to submit additional information.

3.2 Approval certificate

The certificate of approval specifies the dosimetry system together with details of the type of radiation(s) for which doses are assessed. If any changes are made to the dosimetry system including model of dosimeters used or the type of radiation(s) for which doses are assessed a new application for approval must be submitted.

3.3 Term of approval

Approval will be valid for a 5 year period. However, during this period the dosimetry service must confirm annually, in writing, that they continue to comply with the approval criteria. Before the end of the 5 year period an application for renewal must be made in order to continue to provide the dosimetry service.

3.4 Conditions of approval

Approval is granted with the condition that the dosimetry service must notify the EPA of any significant changes to the dosimetry system, any changes to approval in another country on which the initial application was based, or any changes to the service itself e.g. changes in key staff or location.

Approval is also dependent on satisfactory performance data being submitted at regular intervals as specified by the EPA.

3.5 Failure to receive approval

In the event that an applicant is refused approval they will be notified of this decision by the Director of the EPA's Office of Radiation Protection and Environmental Monitoring and advised of the areas in which they failed to meet the eligibility criteria.

4. Documentation to be provided annually

Approved dosimetry services must provide a declaration that they comply with the approval criteria annually. In the declaration the service must specify the date and organiser of the most recent intercomparison and irradiation tests in which they have participated. Intercomparison and irradiation test results received by the service since the last annual declaration should be provided.

5. Revocation of approval

EPA may revoke in writing any approval given to a dosimetry service. An approval may be revoked if an ADS:

- i. does not conform to the current criteria for approval and fails to provide the EPA with an action plan which is sufficient to enable the deficiencies to be rectified within three months;
- ii. fails to provide evidence of on-going satisfactory performance in intercomparison tests which demonstrate that they continue to meet the relevant approval criteria;
- iii. persistently fails to report dose assessments for which it is approved within the period set out in the approval criteria;
- iv. fails to apply for reassessment of its approval within three months of the expiry of the approval;
- v. fails to provide the required fees for reassessment.

In addition, where a serious complaint has been received, which following investigation by the EPA is upheld, the ADS approval may be revoked. The EPA may also revoke such approval where the ADS fails to cooperate with such an investigation.

6. Re-approval

ADSs must apply for re-approval within 5 years of the date of their first approval. Each application for re-approval must be accompanied by the appropriate fee together with the list of documentation set out in Section 2.

7. Appeals

Applicants who have been refused approval or dosimetry services that have had their approval revoked have the right of appeal to the EPA within four weeks of being notified. In these circumstances the Board of the EPA will appoint a panel of at least two assessors not previously associated with the appellant's original application to investigate the appeal. This Appeals Panel will submit its report to the Board who will decide the outcome of the appeal. The aim of the appeal process is to ensure that the Assessment Committee's assessment has been fair and reasonable and that all complaints against named dosimetry services have been investigated thoroughly. All appeals shall be treated as a matter of urgency.

8. Queries

All queries regarding dosimetry service approval should be sent to

Dosimetry Service Approval
Environmental Protection Agency
Office of Radiation Protection and Environmental Monitoring
McCumiskey House
Richview
Clonskeagh Road
Dublin 14
D14 YR62
Ireland

Tel: +353 1 268 0100
Email: info@epa.ie

9. References

EC, 2009. Radiation Protection No 160, Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation. Luxembourg: European Commission.

Appendix A: Approved Dosimetry Services - Technical Criteria

A. Scope of approval

The scope of approval shall specify the type of dosimetry (internal, external whole body, external extremity, etc), the dosimeter technology (TLD, film, OSL, etc), the dosimeter make and model, energy range, dose rate range and limitations or conditions for use.

B. General

The service shall be able to demonstrate that it has the necessary administration, technical and quality systems to be able to provide and maintain a service which:

- i. produces a reasonable degree of accuracy in the assessment of dose;
- ii. is highly reliable;
- iii. communicates the results of routine dose assessments to the customer within a reasonable time;
- iv. rapidly communicates to the customer the results of dose assessments made in the event of an accident, occurrence or incident.

C. Dosimetry methods

The assessment of individual doses shall be based on:

- i. the issue of individually identifiable personal dosimeters or other devices;
- ii. the processing of those dosimeters or devices;
- iii. the evaluation of the dose recorded by the dosimeters, or of the response of the devices; and
- iv. the assessment of the appropriate dose quantity for the individual for the relevant monitoring period.

The approval system covers only services which undertake all of the above stages.

Identification of dosimeters

The service shall ensure that any dosimeter or other device it uses as part of the dosimetry system is of a readily identifiable type and model and can be shown by type testing and field trials to be suitable and reliable for the environments in which it will be used. Each dosimeter or device shall also be traceable to the individual to whom it is issued and the period of assessment.

Energy/dose ranges

The dose range for which approval is sought must be specified. In general, an appropriate dose range for a dosimeter used in the assessment of effective dose (E) would be 0.1 mSv to ~1 Sv for gamma radiation and 0.2 mSv to at least 50 mSv for neutrons. An approved dosimetry service shall not offer a dose assessment service to a customer if the range of radiation energies likely to be encountered is broader than stated in the certificate of approval.

D. Quality assurance

The service shall implement a quality management system which includes written quality assurance procedures for monitoring its overall performance. The objective of any quality assurance (QA) programme shall be to implement a systematic process which will provide confidence that the results are accurate, conform to the criteria for approval and are retrievable. QA procedures would typically cover such matters as:

- i. organisation and staff;
- ii. accommodation and laboratory equipment;
- iii. test and calibration methods and method validation;
- iv. measurement traceability;
- v. standard of facilities (environment, security, radiation, etc);
- vi. handling of test and calibration items;
- vii. sub-contracting of tests and calibration;
- viii. assuring the quality of test and calibration results;
- ix. reporting the results;
- x. control of records and documents;
- xi. service to customers;
- xii. handling of complaints;
- xiii. internal auditing and dealing with non-compliances and non-conforming work.

E. System software

Dosimetry system software shall be guided by the WELMEC software guide 7.2 (WELMEC, 2015). The guidance requirements prevent any unintended modification of the software and the data.

The service shall take appropriate measures to ensure the confidentiality, integrity, availability and robustness of IT systems used to maintain dosimetry and customer data.

F. Traceability

The calibration of the dosimetry system can be shown to be traceable to national standards and the service shall quantify the uncertainties associated with the calibration.

G. Irradiation tests

Performance tests shall be carried out for a representative number of dosimeters for each of several irradiation conditions to confirm that the overall accuracy is acceptable and the performance of the dosimetry system is as expected.

H. Intercomparison tests

Participation in national and international intercomparison exercises is a useful and necessary part of the performance testing of a service. Approved services shall participate in a recognised independently organised intercomparison test at least once every two years.

The combined standard uncertainty for measurements of personal dose equivalent at the location of the dosimeter for photons and electrons shall not exceed $\pm 30\%$ (50% for neutrons) over the range of doses for which the system is considered to be suitable, with a combined uncertainty of $\pm 20\%$ or a factor of 1.5 at 95% confidence for doses near dose limits.

If these limits are exceeded the dosimetry service is required to undertake a review and submit a report to the EPA with an action plan showing how the service intends to remedy the deficiency. A dosimetry service may be required to undertake another performance test to confirm that improvement measures introduced have been effective.

I. Staff competence

The service shall ensure that it has the necessary facilities and staff to carry out the measurement and assessment of individual doses. Adequate training programmes shall be available for new staff and refresher/update training for existing staff. Staff shall be free from any internal or external influence which could affect the quality or impartiality of their work. The responsibilities of key personnel shall be clarified to avoid conflicts of interest.

J. Data handling

Procedures shall be in place for the safe and secure handling, storage and back-up of records.

In the event of a data breach of unencrypted records, the dosimetry service shall notify the EPA and affected customers without undue delay.

K. Incident preparedness

The service shall ensure that adequate arrangements are made for the timely despatch of dosimeters or other devices to customers and for the availability of sufficient and suitable dosimeter processing equipment appropriate to the scope of the service. Provision for breakdown of equipment e.g. arrangements with the equipment supplier for routine maintenance, repair or temporary replacement of equipment, must be in place.

When the dosimetry service is notified by a customer of an incident, the service must have in place appropriate arrangements so that dosimeters can be returned, processed and the results made available within 5 working days of despatch of the dosimeter from the customer's premises.

During routine processing, if a dose exceeds any relevant dose limit it shall be reported to the customer as soon as the results are available e.g. by phone or email, and followed up by written confirmation.

L. Reporting

In normal circumstances, every dose result shall be reported to the customer within 14 working days of receipt of the dosimeter. The report shall include the following information:

- i. name and address of the ADS;
- ii. a unique report reference;
- iii. name and address of the customer;
- iv. wearer first name and surname;
- v. wearer unique identification code;
- vi. dosimeter type e.g. TLD, OSL, etc;
- vii. dosimeter identification code;
- viii. issue or wear period for each dosimeter (this shall be clearly defined on the report);
- ix. the position on the body where the dosimeter was worn e.g. trunk, left arm, etc;
- x. $H_p(10)$, $H_p(0.07)$ or $H_p(3)$, as appropriate, recorded on the dosimeter and annual and/or 5-year accumulated dose;
- xi. signature of authorised member of staff;
- xii. a statement of measurement method and uncertainty;
- xiii. the minimum reporting level;
- xiv. the page number and the total number of pages in the report.

Where transit dosimeters are used to estimate the contribution to dose from natural background radiation, arrangements must be put in place to cover situations where the transit dosimeters are not returned for processing.

Operational quantities

The operational quantities for personal monitoring, personal dose equivalent, $H_p(10)$, $H_p(3)$ and $H_p(0.07)$, shall be used as estimates of equivalent dose, H_T and effective dose, E . For photons, in practical situations, $H_p(10)$ will provide a reasonable estimate of E . 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 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. The dosimetry service shall, when requested by the customer, provide additional information on the dose recorded on the dosimeter such as the radiation type and energy.

The operational quantity $H_p(0.07)$ for photons and electrons is used for the assessment of dose equivalent to local skin. For neutrons, the use of dosimeters calibrated in terms of $H_p(10)$ would be appropriate. $H_p(3)$ 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. If a dosimetry service seeks approval for both the assessment of whole body dose (or skin dose) and dose to the eyes, using the same type of dosimeter a case shall be made for such a purpose; and the written instructions to the customer shall cover both uses.

Where reliance is placed on the use of algorithms and correction factors to make an assessment of dose it is important to give a full explanation (by reference to type test data, etc) to show that these are justified in the particular circumstances. Where algorithms are used, the dosimetry service shall state explicitly which particular algorithm will be used and

under what circumstances, in order to avoid ambiguity. The values of any additional factors must also be stated explicitly.

Re-assessment and re-evaluation of doses

The service shall make reasonable arrangements to ensure that doses can be reassessed or re-evaluated up to two years after the receipt of a dosimeter (or other device), which shall include:

- i. sufficient records to link any dose reported to the customer with a particular dosimeter worn, the method of evaluation of the dosimeter and the method of assessment;
- ii. a secure storage facility for the active elements of dosimeters such as film dosimeters; or
- iii. a facility to record and retain the output data retrieved from the dosimeter to assess the original exposure e.g. the glow curve output of TLDs; or
- iv. arrangements for independent diagnostic checks built into the dosimeter reader to ensure that the read-out is normal and where practicable is recorded for future reference; or
- v. other equally effective means of re-evaluation.

The method used may depend on:

- i. a re-examination of the original dosimeter; or
- ii. a re-examination of dosimeter outputs such as glow curves; or
- iii. reliability checks of the output during the read process.

together with a check of stored records relating individuals to the output for individual dosimeters and any special factors used (e.g. quality factors). Where appropriate, the service shall have arrangements for secure storage of exposed films/records to prevent loss e.g. in a fire.

When requested to do so by a customer, the dosimetry service shall update individual dose records.

Guidance made available to customers

The service shall provide advice to customers about the proper handling, storage, issue and use of the dosimeter or other device and any other information necessary to ensure that such dosimeters or devices are used correctly.

The advice to the customer would normally cover matters such as:

- i. any limitations in the scope of approval such as energy restrictions and avoiding exposure to certain fields or environments;
- ii. recommended dosimeter issue and return procedures, including specific arrangements to ensure named persons are unmistakably linked to the dosimeters they wear;
- iii. location on the body where dosimeter should be worn;
- iv. arrangements for dealing with unusual occurrences e.g. late, damaged or lost dosimeters;
- v. storage of dosimeters, including security against tampering and avoiding the risk of inadvertent exposure to ionising radiations;
- vi. security against background radiation and any other environmental condition likely to affect the performance of the dosimeter adversely (this shall include reference to the potential for dosimeters to be passed through security scanning equipment which might affect the dosimeter reading);

- vii. correct assembly of dosimeters e.g. positioning of films/filters etc;
- viii. the warning period provided in active devices before battery failure;
- ix. special features or arrangements e.g. remote reading of dosimeters/devices;
- x. contamination monitoring of dosimeters (where applicable);
- xi. any special arrangements for handling dosimeters (or other devices) in the event of an accident, occurrence or incident;

The service shall provide advice, on request, on the suitability of their service in relation to the needs of the customer.

Unassessed doses

The dosimetry service shall not report a zero dose for components of dose that were not assessed, for example because a dosimeter was lost by the wearer or was not issued for a particular assessment period.

M. Implementation of standards

Dosimetry systems shall be type tested according to the relevant EN/IEC or ISO standard and shall have passed that test. All the radiation fields used must be well characterised and traceable to National Metrology Institutes. Guidance on reference radiation fields for photon, beta and neutron radiation can be found in the ISO standards ISO 4037, ISO 6980 and ISO 8529 series, respectively. As long as the type of dosimeter is unchanged, the type test remains valid.

N. Irish legislation

The dosimetry service must be aware of Irish legislation relating to the dose monitoring of occupationally exposed workers, in particular the Radiological Protection Act, 1991 and the Radiological Protection Act, 1991 (Ionising radiation) Order, 2000.

O. Reporting of results to the National Dose Register

By 30th April each year, a report of all doses measured in the preceding calendar year shall be submitted electronically to the National Dose Register (NDR) in a format and manner specified by the EPA.