INTERNATIONAL RECOMMENDATION

OIML R 131

Edition 2001 (E)

Polymethylmethacrylate dosimetry systems for ionizing radiation processing of materials and products

Systèmes de dosimétrie à polyméthylméthacrylate pour le traitement par rayonnements ionisants des matériaux et produits

OIML R 131 Edition 2001 (E)

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Contents

Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States.

The two main categories of OIML publications are:

- **International Recommendations (OIML R)**, which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and intended to improve the work of the metrological services.

OIML Draft Recommendations and Documents are developed by technical committees or subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis.

Cooperative agreements are established between OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may apply simultaneously OIML publications and those of other institutions.

International Recommendations and International Documents are published in French (F) and English (E) and are subject to periodic revision.

This publication - reference OIML R 131 edition 2001 - was developed by the OIML Technical Committee TC 15/SC 2 *Instruments for measuring ionizing radiations used in industrial processes*. It was directly sanctioned by the International Conference of Legal Metrology in 2000.

OIML publications may be obtained from the Organization's headquarters:

Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris - France

Telephone: 33 (0)1 48 78 12 82 and 42 85 27 11
Fax: 33 (0)1 42 82 17 27
E-mail: biml@oiml.org
Internet: www.oiml.org

Polymethylmethacrylate dosimetry systems for ionizing radiation processing of materials and products

0 Introduction

0.1 The objective of this Recommendation is to harmonize globally the procedures by which a polymethylmethacrylate (PMMA) dosimetry system (referred to in this Recommendation as a "dosimetry system") is evaluated when subject to law or regulations. It also provides confidence that the dosimetry system can indicate accurate absorbed dose measurements for facilities utilizing radiation processing of materials and products. In addition, the international marketing of dosimetry systems and affected products is facilitated.

0.2 The evaluation of a dosimetry system is carried out by a national responsible body through a process referred to as metrological control which generally includes pattern evaluation and initial and subsequent verification. If successful, pattern evaluation is provided only once to a manufacturer of a specific type of dosimeter. Verification is necessary by a national responsible body or user for each batch or new supply of PMMA dosimeters (hereafter referred to as "dosimeters").

0.3 Pattern evaluation is the primary subject of this Recommendation, which specifies the metrological and technical requirements of the dosimetry system to be evaluated. A manufacturer submits samples of a batch of dosimeters for evaluation and specifies the minimum performance requirements for the measurement instrumentation used for pattern evaluation. The national responsible body will use these dosimeter samples to calibrate the dosimetry system including the measurement instrumentation prior to evaluating other samples of the dosimeters. All calibrations are carried out in a recognized calibration facility.

0.4 The evaluation is conducted according to an overall test procedure, and the results are contained in a test report format, both of which are specified in this Recommendation. After calibration, the national responsible body evaluates the dosimetry system by randomly selecting dosimeters from the same batch used for the calibration and then irradiating these samples in the same or another recognized calibration facility to predetermined absorbed dose values within the absorbed dose working range of the dosimetry system. The dosimetry system and its calibration curve or response function are used to determine the absorbed dose values. An analysis of absorbed dose readings for several dosimeters at a single irradiation dose level provides a determination of the repeatability of the measurement. A comparison of the average absorbed dose values measured using the calibration curve or response function and the absorbed dose values reported by the calibration facility provides the maximum errors of the system.

0.5 The performance requirements for a dosimetry system are the same for verification as for pattern evaluation. This Recommendation indicates three different means of developing documentation that may be acceptable for verification by the national responsible body in which either the manufacturer or the user at the site of application may participate.

1 Scope

1.1 This Recommendation may be applied for PMMA dosimetry systems used to control and supervise any application of ionizing radiation for industrial processing of materials and products. It does not cover, nor does it exclude, the use of other equivalent means of measurement or determination of absorbed dose for such applications.

1.2 This Recommendation is intended to apply specifically to manufacturers of PMMA dosimeters and to national bodies responsible for the metrological control of dosimetry systems. It also contains information of interest to users of PMMA dosimetry systems.

1.3 The metrological and technical performance requirements of PMMA dosimetry systems are covered in this Recommendation; however, the selection and routine use of these and other dosimeters for radiation processing applications are discussed in other standards [1, 2]. Performance better than that prescribed in this Recommendation may be achieved.

1.4 This Recommendation applies to dosimeters irradiated by either photons within the energy range from 0.1 MeV to 10 MeV, or electrons within the energy range from 1.0 MeV to 10 MeV. Tests of dosimeters according to this Recommendation are specified to be carried out at a reference temperature and within a specified absorbed dose range and absorbed dose rate range.

Note: The following ranges can be covered using one or more types of PMMA dosimeter:

- absorbed dose range from 10^2 to 10^5 Gy [1, 2];
- absorbed dose rate range from 10^{-2} to 10^7 Gy/s [1, 2];
- irradiation temperature range from – 78 °C to + 50 °C [1, 2].

1.5 Requirements that may be necessary for personnel safety are not covered in this Recommendation; therefore, users should determine that a dosimetry system meets the safety and labeling requirements in accordance with national regulations.

2 Application

2.1 This Recommendation may be applied to any process using ionizing radiation where the desired change in a property or characteristic of a product is related to the absorbed dose in the product.

2.2 National laws or regulations may specify the minimum and maximum absorbed dose for a particular radiation processing application.

2.3 Specific applications of ionizing radiation processing include sterilization of medical devices and products, sterilization of medical waste, and processing of foods and spices for quarantine release, pathogen control, or extension of shelf life. Examples of the use of PMMA dosimeters in various irradiation applications are given in reference [3].

3 Terminology

Note: For definitions of terms that are important to metrology other than those given in this clause, see reference [4].

3.1 PMMA dosimetry system

System used for determining absorbed dose consisting of PMMA dosimeters and associated measurement instrumentation.

3.2 PMMA dosimeter

Piece of specially selected or specially developed PMMA material that exhibits characterizable ionizing radiation-induced changes in specific optical absorbance as a function of absorbed dose, individually encapsulated by the manufacturer in a hermetically sealed pouch. The change in specific absorbance may be related to absorbed dose in the surrounding material.

3.3 Dosimeter batch

Quantity of dosimeters made from a specific mass of material having a uniform composition, fabricated in a single production run under controlled and consistent conditions, and assigned a unique identification code.

3.4 Analysis wavelength, λ

Wavelength used in a spectrophotometer for measuring the optical absorbance of a PMMA dosimeter.

3.5 Specific absorbance, k_λ

Optical absorbance, A_λ, at the analysis wavelength, λ, divided by the dosimeter thickness, t:

$$k_\lambda = A_\lambda / t$$

Note: The thickness, t, is a measure of optical path length.

3.6 Absorbed dose, D

Quotient of $d\bar{e}$ by dm, where $d\bar{e}$ is the incremental mean energy imparted by ionizing radiation to a quantity of matter of mass dm. The unit for absorbed dose is the gray (Gy), where 1 Gy = 1 J/kg.

3.7 Electron equilibrium

Condition that exists in a material under ionizing irradiation whereby the energies, number, and direction of the secondary electrons induced by the radiation are uniform throughout the volume of interest. Thus, for such a volume, the sum of the energies of the secondary electrons entering is equal to the sum of the energies of the secondary electrons leaving that volume.

3.8 Calibration facility

Combination of either a photon or an electron source and associated instrumentation that provides uniform and reproducible absorbed dose, or absorbed dose rates, at specified locations within a specific material. The absorbed dose shall be traceable to national or international standards.

3.9 Calibration curve

Graphical representation of the relationship between dosimeter response and absorbed dose for a given dosimetry system.

3.10 Response function

Mathematical representation of the relationship between dosimeter response and absorbed dose for a given dosimetry system.

3.11 Traceability

Property of the result of a measurement or value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

3.12 Repeatability

Closeness of agreement between the results of successive measurements of the same sample carried out under the same conditions and within a relatively short period of time.

Note: The same conditions would include the same method of measurement, measuring instrument, operator, location, and ambient environmental conditions.

3.13 Maximum permissible errors

Extreme values of an error permitted by specifications, regulations, etc. for a given measuring instrument.

3.14 Absorbed dose working range

Set of values of absorbed dose for which the error of the dosimetry system is intended to lie within specified limits.

3.15 National responsible body

Organization or agency in a particular country that is responsible for determining whether the dosimetry system meets the performance requirements designated by law or regulations.

3.16 Manufacturer

Producer of the PMMA dosimeter to be evaluated unless the term is otherwise specified.

4 Description of the dosimetry system

4.1 General

4.1.1 The PMMA dosimetry system provides a means of determining absorbed dose in materials. Ionizing radiation causes chemical reactions to take place in exposed PMMA material that create and/or enhance some optical absorption bands. The absorbance within these radiation-induced absorption bands is determined at selected wavelengths. Appropriate wavelengths for analysis for particular dosimetry systems are identified by the manufacturer or in published references.

4.1.2 The dosimetry system is calibrated using absorbed doses traceable to national or international standards. Absorbed dose is usually specified as that which would be received in water. Absorbed dose in other materials may be determined by applying appropriate conversion factors, as discussed in reference [2].

4.2 Major components

4.2.1 PMMA dosimeter

The dosimeter usually has a nominal thickness from 1 mm to 4 mm and is a homogeneous free-standing optically transparent rectangular plaque. The dosimeters are supplied individually packaged in hermetically sealed pouches that protect the PMMA material from possible effects of changes in atmospheric humidity. In use, the dosimeters are irradiated in these sealed pouches. The lower limit of the incident electron energies for which these dosimeters may be used depends on the combined thickness of the dosimeter and its pouch.

Note: A polyester/aluminum-foil/polyethylene laminate is an example of the packaging material that may be used for fabricating pouches.

4.2.1.2 The optical absorbance of the dosimeter at the prescribed analysis wavelength changes when the dosimeter is exposed to ionizing radiation. The optical absorbance of a dosimeter is a function of the thickness of its radiation-sensitive material and of the absorbed dose that it receives.

4.2.1.3 The absorbed dose in the dosimeter is determined by measuring its optical absorbance and its thickness and by using the calibration curve or response function that provides a functional relationship between the absorbed dose and the specific absorbance.

4.2.2 Thickness gauge

The instrument used for measuring the dosimeter thickness is usually a mechanical thickness gauge such as a micrometer or other appropriate instrument.

4.2.3 Instrument for measuring optical absorbance

4.2.3.1 A spectrophotometer is used to determine the absorbance of the dosimeter at the analysis wavelength specified by the manufacturer.

4.2.3.2 Optical components of the spectrophotometer include a light source, a spectral grating monochromator for selecting the wavelength, a holder for reproducible positioning of the dosimeter in the measuring light beam, and a photodetector.

4.2.3.3 The data read-out component may be either analog or digital, and the data may be recorded either manually by an operator or automatically by a data handling system.

4.2.3.4 The usual wavelength and absorbance standards are used to check the instrument; however, it is an advantage if the spectrophotometer has a microprocessor or computer-controlled self-test system designed to check its performance characteristics prior to use.

5 Metrological requirements

Note: This clause provides the performance requirements that the dosimetry system shall meet during pattern evaluation.

5.1 General requirements

- For evaluation, the manufacturer shall provide samples of a batch of PMMA dosimeters to the national responsible body.
- A calibration curve or response function for the dosimetry system shall be determined by the national responsible body based on an analysis of samples from the batch of dosimeters submitted. It shall cover the absorbed dose working range or ranges.
- The performance criteria of the spectrophotometer shall be specified by the manufacturer (see 6.5).
- Procedures for performing calibrations are given in Annex A.

5.2 Maximum permissible errors and repeatability of absorbed dose measurement

5.2.1 At least four dosimeters packaged individually in hermetically sealed pouches shall be irradiated in a calibration facility at each of at least three separate absorbed dose levels within the absorbed dose working range. During pattern evaluation the repeatability of, and maximum errors in, the measured absorbed dose shall be determined for dosimeters irradiated under the following reference conditions:

- temperature: 23 °C ± 3 °C or as specified by the manufacturer;
- calibration facility: irradiation source having the type of radiation and range of absorbed dose rates specified by the manufacturer.

Note: In reference [5], results show that the expanded uncertainty (for k = 2 or the 95 % confidence level) in absorbed dose delivered in the calibration facility to the dosimeter can be within ± 2 %.

5.2.2 At each irradiated absorbed dose level, the maximum error in measurement shall be the difference between the mean absorbed dose value assigned according to the calibration curve and the corresponding irradiated absorbed dose value provided at each level by the calibration facility. The maximum permissible errors in absorbed dose thereby determined shall be within ± 6 %.

5.2.3 The repeatability of the measured absorbed dose at each irradiated absorbed dose level as expressed in terms of the relative standard deviation shall not be greater than 4 %.

5.2.4 The test procedure for determining repeatability and maximum errors is given in Annex B.

6 Technical requirements

Note: This clause covers information on characteristics and labeling requirements of the dosimeters that shall be provided by the manufacturer to the national responsible body prior to pattern evaluation.

6.1 Dosimeters shall be packaged, and the package shall be marked clearly indicating the product and batch identification. When appropriate, the actual or average thickness should also be clearly indicated on the package.

6.2 If the thickness of the dosimeter is specified by the manufacturer, then the actual thickness of each dosimeter or the mean value and standard deviation of the repeatability of thickness measurements for a specific sample size of a batch shall be provided.

6.3 The manufacturer shall specify the absorbed dose working range of the dosimeter.

6.4 The manufacturer shall make available information about the characteristics of the dosimeters including any known effects on the response of the dosimeters caused by irradiation conditions (influence quantities) such as temperature, absorbed dose rate, and time of measurement after irradiation.

Note: Influence quantities can be sources of significant error in absorbed dose measurements in radiation processing facilities. The response of a PMMA dosimeter material may be affected by the humidity and the atmosphere if it is not contained in a sealed pouch.

6.5 The minimum acceptable performance required for the measurement instrumentation shall be specified by the manufacturer of the dosimeters. The specifications for the spectrophotometer shall include its range and reproducibility for measurement of the wavelength and absorbance. The performance requirements for the thickness gauge shall also be specified.

6.6 Instrument performance shall be tested using certified optical absorbance and wavelength standards, preferably certified reference materials, traceable to national or international standards.

Note: The spectrophotometer may have built-in test filters used in the self-test mode (see 4.2.3.4).

6.7 The spectrophotometer shall be labeled with or include the following information:

- manufacturer's name and trade name;
- model and serial number;
- the instruction manual supplied by the manufacturer; and
- a record of service and maintenance.

7 Practical instructions

Note: This clause provides information for a user to consider prior to selecting a dosimetry system for an application.

7.1 Before using a dosimetry system, all environmental factors related to the specific irradiation

application should be considered. If the irradiation conditions are different from those specified for the dosimetry system, the manufacturer or other relevant sources should be consulted before using the dosimetry system. Reference [2] provides guidance on the choice of dosimetry systems.

7.2 Any necessary precautions or warnings for instrument users shall be indicated explicitly in the operating manual and shall be displayed clearly on the spectrophotometer when applicable as may be required by national regulations.

8 Metrological controls

Note: This clause provides the steps to be followed by the national responsible body in carrying out pattern evaluation of the dosimetry system. Procedures and requirements are also given for verification and routine tests of the dosimetry system. In pattern evaluation, the national responsible body selects dosimeters from the batch used to calibrate the dosimetry system and then irradiates them in a calibration facility to predetermined absorbed dose levels. The absorbed doses determined by the dosimetry system compared with the absorbed doses given at the calibration facility provide data for pattern evaluation.

8.1 Pattern evaluation

8.1.1 The manufacturer shall provide the national responsible body with samples of a batch of PMMA dosimeters and may also provide test data that demonstrate that these dosimeters meet the performance requirements according to this Recommendation.

8.1.2 The PMMA dosimeters shall be evaluated using a spectrophotometer and thickness gauge that meet the specifications indicated in clause 6.

8.1.3 The dosimetry system shall be calibrated according to the requirements of 5.1 and Annex A.

8.1.4 After calibration of the dosimetry system, the national responsible body shall carry out performance tests using the procedure of Annex B to confirm acceptable conformance to the following requirements:

- maximum permissible errors of absorbed dose measurement (5.2.2); and
- repeatability of absorbed dose measurement (5.2.3).

Note: Instead of carrying out the calibration and these tests, the national responsible body may consider accepting test data submitted by the manufacturer that demonstrate acceptable conformance.

8.1.5 The results of tests of a dosimetry system carried out at pattern evaluation shall contain, as a minimum, the items of information according to the format provided in Annex C. A specific test report form may be developed according to national preference. The manufacturer shall be provided with specific comments about any test failures.

8.2 Initial and subsequent verification

8.2.1 The performance requirements for verification at either the site of the manufacturer or the site of application shall be the same as for pattern evaluation (8.1.4).

8.2.2 Initial verification and, if necessary, subsequent verification of a batch of PMMA dosimeters may be carried out on the basis of information provided by the manufacturer or the user. Such information should document the necessary performance tests (8.1.4) at each of at least three absorbed dose levels covering the working range of the intended application of the dosimeters. The documentation reviewed for verification may be developed using samples of a batch of dosimeters by use of one of the following methods:

(a) by carrying out with sample sets a calibration of a dosimetry system and verifying that the data obtained for the calibration curve or response function meet the necessary repeatability requirements;

(b) by using a calibrated dosimetry system to analyze sample sets irradiated in a calibration facility and comparing the measured absorbed doses with those reported for the sets by the calibration facility; or

(c) by using a calibrated dosimetry system to analyze sample sets irradiated in the user's facility along with transfer standard dosimeters

whereby the measured absorbed doses are compared with those values reported for the transfer dosimeters as determined by a recognized calibration facility.

The procedures of Annexes A and B should be used as appropriate in developing the documentation that meets the requirements of 8.1.4.

Note: Verification may be carried out by the user utilizing a calibration method that is a part of the user's quality assurance procedures.

8.2.3 The test report format in Annex C may be modified appropriately to report the results of tests for verification.

8.2.4 The period of validity for initial verification carried out according to 8.2.2 shall be one year unless documented data provided by the manufacturer support a different period of validity. The period of validity for subsequent verification shall be one year.

8.3 Routine tests by the user

8.3.1 The national responsible body may refer users to appropriate methods for using dosimetry systems for specific industrial applications. Some measurement methods may be appropriate for use as quality control of the response of the dosimeter system during radiation processing.

8.3.2 The user shall develop a calibration curve or response function for each specific batch of dosimeters and each spectrophotometer used. The calibration should also reflect the specific irradiation conditions of the application.

8.3.3 Tests of the performance of the dosimeter to exposures at the extremes of environmental conditions of temperature and at the extremes of absorbed dose rates shall be carried out when required for specific applications.

Note: Data provided by the manufacturer or in relevant publications on the environmental effects for a specific dosimeter may be used instead of testing. In some cases, the data provided by the manufacturer on a specific batch of dosimeters may be more current and appropriate than information on environmental effects found in publications.

8.3.4 A chronological written record for each dosimetry system shall be maintained for a period according to national requirements and shall contain at least the following information:

- results of calibrations;
- results of all routine tests;
- extent of maintenance and repair of the readout instrumentation; and
- identification of major components replaced in the readout instrumentation.

References

[1] ISO 15558:1998(E) "Practice for use of a polymethylmethacrylate dosimetry system", International Organization for Standardization, Geneva, Switzerland.

[2] ISO 15556:1998(E) "Guide for selection and calibration of dosimetry systems for radiation processing", International Organization for Standardization, Geneva, Switzerland.

[3] McLaughlin, W.L.; Boyd, A.W.; Chadwick, K.H.; McDonald, J.C. and Miller, A. - "Dosimetry for Radiation Processing" (Textbook), Taylor and Francis (publishers), London, New York, Philadelphia, 1989.

[4] International Vocabulary of Basic and General Terms in Metrology (VIM), BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, 1993 Edition (ISO).

[5] Humphreys, J.C; Puhl, J.M.; Seltzer, S.M.; McLaughlin, W.L.; Desrosiers, M.F.; Nagy, V.Y.; Benson, D.L. and Walker, M.L. - "Radiation Processing Dosimetry Calibration Services: Manual of Calibration Procedures," NIST Special Publication 250-45, National Institute of Standards and Technology (1998).

Annex A

Calibration procedure for the dosimetry system

(Mandatory)

A.1 Select randomly from a single batch a set of at least four dosimeters encapsulated individually in hermetically sealed pouches to be irradiated at each desired absorbed dose level. Use at least five absorbed dose levels per decade of the absorbed dose working range, with a minimum of five absorbed dose levels if that range is less than one decade. Specify the absorbed dose in terms of absorbed dose in water, or in another material appropriate for the specific application.

A.2 Identify each dosimeter by writing a number on the dosimeter label or by placing it in a numbered envelope.

Note: Improper handling of the dosimeter may affect its analysis. Follow the manufacturer's guidelines for handling the dosimeter.

A.3 Irradiate the dosimeters in a calibration facility under reference conditions as specified in 5.2.1. Photon irradiations shall be carried out under conditions of electron equilibrium.

Note: The definition of electron equilibrium is given in 3.7. For example, in determining the absorbed dose in water for a ^{60}Co irradiation, electron equilibrium can be achieved by surrounding the dosimeters with 3 mm to 5 mm thick solid polystyrene or an equivalent polymeric material. The surrounding material forms an approximate "cavity" and should be thick enough to absorb any secondary electrons generated by the radiation source outside that material before reaching the "cavity".

A.4 Measure and record the post-irradiation absorbance, A_8, of each dosimeter.

A.5 Measure and record the thickness, t, of each dosimeter, or record the individual or mean value of thickness provided by the manufacturer. Gauge blocks or other standards used to calibrate the thickness measuring instruments shall be traceable to national standards.

A.6 Calculate the response of each dosimeter, that is, the specific absorbance, k_λ (see 3.5).

A.7 Generate a calibration curve or a response function. Use an analytical form (for example: linear, polynomial or exponential) that fits the measured data, using suitable standard curve fitting techniques.

Note: Linear fitting is normally appropriate only for narrow dose ranges. Polynomial fitting is commonly used; when used, it is important to choose the lowest order polynomial that will provide a good fit (the order equals the highest value of exponent in the equation).

A.8 Examine the resulting calibration curve or response function for goodness of fit.

Note: Standard statistical procedures may be used for eliminating outliers and testing goodness of fit.

A.9 Repeat this calibration procedure if any value deviates significantly from the determined curve and if discarding that value would result in not having sufficient data to define the curve.

A.10 The resulting dosimetry system calibration curve or response function applies only for the batch of dosimeters and the specific spectrophotometer used in the calibration procedure. A new calibration shall be carried out if a change is made in the batch of dosimeters or any component of the dosimetry system that may affect the calibration including repair of the spectrophotometer.

Annex B

Test procedure

(Mandatory)

B.1 The objective of this test is to evaluate the repeatability and maximum errors for absorbed dose determined by the dosimetry system for at least three absorbed dose levels within the absorbed dose working range of the dosimeter.

B.2 Following the procedure in A.2, prepare a set of at least four dosimeters for each of the selected required dose levels by randomly selecting dosimeters from the same batch from which samples were selected to calibrate the dosimetry system.

B.3 Irradiate the sets of dosimeters in a calibration facility to at least three absorbed dose levels including the low, middle and high regions of the absorbed dose working range specified by the manufacturer.

Note: The calibration facility does not have to be the same facility used to calibrate the dosimetry system; however, it should meet the requirements of 5.2.1.

B.4 Following the procedures in A.4 through A.6, measure the response of each dosimeter with the same spectrophotometer used to calibrate the dosimetry system (see A.4).

B.5 Assign an absorbed dose value, D, corresponding to each measured response using the calibration curve or response function for the dosimetry system.

B.6 Determine the mean absorbed dose, $\bar{D}$, and the relative standard deviation, σ_r, for each absorbed dose level using the following equations:

$$\bar{D} = \frac{\Sigma D_i}{n}$$

$$\sigma = \left[\frac{\Sigma (D_i - \bar{D})^2}{n - 1} \right]^{\frac{1}{2}}$$

$$\sigma_r = \frac{\sigma}{\bar{D}} \times 100\ \%$$

where:

D_i is an individual absorbed dose value, and

$\bar{D}$ is the average absorbed dose of a number (n) of dosimeters at the absorbed dose level.

Note: Standard statistical procedures may be used for eliminating outliers.

B.7 The maximum errors of $\bar{D}$ and the value of σ_r at each absorbed dose level shall meet the requirements of 5.2.2 and 5.2.3, respectively.

Application no.: ..... Date: .....

Annex C

Test report format

This *Test report format* presents, in a standardized way, the results of the various tests and examinations to which a pattern (or type) of a polymethylmethacrylate dosimetry system for ionizing radiation processing of materials and products shall be submitted when being considered for approval. These tests are listed in Annex B to this Recommendation.

In the case of the application of this Recommendation:

- to the *OIML Certificate System for Measuring Instruments*, **use of this *Test report format* is mandatory**.
- in national regulations (and in other cases), **use of this *Test report format* is informative**. However, in this case:
  - it is **strongly recommended** that all metrology services or laboratories evaluating patterns (or types) of polymethylmethacrylate dosimetry systems for ionizing radiation processing of materials according to national regulations based on this Recommendation should use this *Test report format* directly, or after translation into a language other than English or French;
  - it is **even more strongly recommended** that this *Test report format* is used directly in English or French, or in both languages, whenever test results may be transmitted by the country performing these tests to the approval authorities of another country, for example under bi- or multi-lateral cooperation agreements.

A test report intended for use in the OIML Certificate System and for other purposes shall include the following information:

Report No. .....

OIML Recommendation No. ..... Edition (year) .....

C.1 Name and address of the testing laboratory(ies)

.....

.....

.....

.....

C.2 Location at which tests were performed, if other than indicated in C.1

.....

.....

.....

.....

C.3 Name and address of the dosimeter manufacturer

.....

.....

.....

C.4 Name and address of applicant, if other than the dosimeter manufacturer

.....

.....

.....

C.5 Identification of the PMMA dosimeter (pattern) tested

Name of manufacturer: .....

Product name: .....

Product number: .....

Batch number: .....

C.6 Identification of the spectrophotometer used in testing

Trade (or instrument manufacturer's) name: .....

Model number: .....

Serial number: .....

Review the operating manual including instructions for set up, calibration and use and provide a subjective opinion on the clarity of the instructions with comments, if appropriate:

☐ Acceptable ☐ Deficient

Comments: .....

.....

.....

Manufacturer's specifications: Wavelength range: .....

Absorbance range: .....

Reproducibility: .....

Comments: .....

.....

.....

C.7 Summary of the results of the pattern evaluation tests carried out

C.7.1 Reference conditions of testing

Absorbed dose rate (Gy/s in water) .....
Ambient temperature of irradiation volume..... °C

If not hermetically sealed packages then:
Relative humidity surrounding the dosimeter ..... %
Atmospheric gases surrounding the dosimeter .....

Comments: .....
.....
.....

C.7.2 Identification of the calibration curve or response function of the dosimetry system

Absorbed dose working range: .....
Analysis wavelength: .....
Date and location of calibration: .....

Comments: .....
.....
.....

C.7.3 Maximum errors and repeatability of measured absorbed dose

Absorbed dose levels (values) →	1	2	3
Measurements ↓			
1			
2			
3			
4			
$\bar{D}$			
σ_r			

Maximum error (difference in the mean absorbed dose determined by the calibration curve or response function and that provided by the calibration facility) for each absorbed dose level:

1 ..... 2 ..... 3 .....

☐ Pass ☐ Fail with respect to maximum permissible errors.

Comments: .....
.....
.....

Repeatability for absorbed dose levels:

1 ..... 2 ..... 3 .....

☐ Pass ☐ Fail

Comments: .....
.....
.....

C.8 Brief statement of conclusions that indicate whether or not the tested dosimeters or dosimetry system meets the requirements of this Recommendation

.....
.....
.....
.....

C.9 Person(s) responsible for the testing

Signature(s) and title(s)

....
....
....
....

Date: .....

Notes

Notes

Printed in France

GRANDE IMPRIMERIE DE TROYES