INTERNATIONAL RECOMMENDATION

OIML R 132

Edition 2001 (E)

Alanine EPR dosimetry systems for ionizing radiation processing of materials and products

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

OIML R 132 Edition 2001 (E)

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Contents

Foreword

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Alanine EPR dosimetry system 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 an alanine Electron Paramagnetic Resonance (EPR) 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 the national responsible body or user for each batch or new supply of alanine 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 either samples of a batch of dosimeters or samples of a batch of dosimeters and an EPR spectrometer for evaluation. In the first case, the national responsible body will use samples of the dosimeters submitted to calibrate the dosimetry system including the EPR spectrometer prior to using that instrument to evaluate other samples of the dosimeters. In the second case, the manufacturer will have calibrated the dosimeters and EPR spectrometer prior to their being presented and will also submit the calibration curve or response function that will serve as the basis for the evaluation. 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 alanine EPR 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 alanine dosimeters, to manufacturers of EPR spectrometers used for dosimetry, and to national bodies responsible for the metrological control of dosimetry systems. It also contains information of interest to users of alanine EPR dosimetry systems.

1.3 The metrological and technical performance requirements of alanine EPR 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 or electrons within the energy range of 0.1 to 28 MeV [1]. Tests of dosimeters according to this Recommendation are specified to be carried out at a reference temperature and humidity within a specified absorbed dose range and absorbed dose rate range.

Note: The following ranges may be covered in radiation processing applications using one or more alanine dosimeters:

- absorbed dose range from 10^0 to 10^5 Gy [1, 2];
- absorbed dose rate up to 10^2 Gy/s for continuous radiation fields and up to 5×10^7 Gy/s for pulsed radiation fields;
- irradiation temperature range from – 60 °C to + 90 °C [3]; and
- humidity range (for encapsulating dosimeters) from 0 to 75 % relative humidity [4].

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 alanine for dosimetry for various irradiation applications are given in references [5] and [6].

3 Terminology

Note: For definitions of terms that are important to metrology other than those in this clause, see reference [7].

3.1 Alanine EPR dosimetry system

System used for determining absorbed dose consisting of alanine dosimeters and an EPR spectrometer.

3.2 Alanine dosimeter

Specified quantity of alanine in a defined physical form in which ionizing radiation produces an identifiable EPR signal that can be related to absorbed dose.

3.3 EPR spectroscopy

Measurement of resonant absorption of electromagnetic energy, resulting from the transition of unpaired electrons between different energy levels, upon application of usually microwave frequency energy to a paramagnetic substance in the presence of a magnetic field.

3.4 EPR spectrum

First derivative of the electron paramagnetic absorption spectrum with respect to the magnetic field.

3.5 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.

3.6 Absorbed dose, *D*

Quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ 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 regulation.

3.16 Manufacturer

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

4 Description of the dosimetry system

4.1 General

4.1.1 The alanine EPR dosimetry system provides a means of determining absorbed dose in materials. Ionizing radiation causes chemical changes to take place in an irradiated alanine dosimeter resulting in the formation of stable free radicals. The EPR spectrometer usually measures the amplitude of the central line in the spectrum from the free radicals in the irradiated dosimeter. The amplitude of this signal is proportional to the absorbed dose.

4.1.2 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 Alanine dosimeter

4.2.1.1 The dosimeter is commonly a pellet, a rod, or a thin film. Either the L or D stereoisomers of α-alanine in appropriate binder or substrate may be used, with L-alanine being the most commonly used. Neither the binder nor the substrate should interfere with the alanine related EPR signal. The dosimeters are usually encapsulated prior to irradiation.

4.2.1.2 The magnitude of the EPR signal from a dosimeter is a function of the mass of its radiation-sensitive material and to the absorbed dose that it receives [1]. Usually the value of the peak-to-peak amplitude rather than the double integral of the central line of the EPR spectrum is used as the response since no simple closed form analytical expression describing the EPR lineshape of the alanine derived radical signal exists.

4.2.1.3 The absorbed dose in the dosimeter is determined by use of a calibration curve or response function that provides a functional relationship between the absorbed dose and the EPR signal amplitude. The absorbed dose shall be traceable to national or international standards.

4.2.2 Measuring the mass of the dosimeter

4.2.2.1 For dosimeters without a binder or substrate, the mass of the radiation-sensitive material may be measured by an analytical balance with mass measurements traceable to national standards. The actual mass of each dosimeter, or the mean value and standard deviation of representative samples of the batch, may be provided by the manufacturer or determined by the user.

4.2.2.2 In some cases, the standard deviation in mass of the radiation-sensitive material of the dosimeters may be provided by the manufacturer instead of their actual mass or mean value.

4.2.3 The EPR spectrometer

4.2.3.1 The spectrometer determines the alanine-derived radical concentration in a dosimeter by measurement of the EPR spectrum. Components of the EPR spectrometer should include a stabilized microwave source, attenuators and phase shifters, microwave circulator, reference arm, detection diode assembly, magnet with sweep capability, magnetic field modulation/phase sensitive detector, microwave cavity with reproducible dosimeter positioning device and appropriate read-out display. Reference [6] gives an example of a spectrometer and its basic components.

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

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 to the national responsible body either samples of a batch of alanine dosimeters and an EPR spectrometer or only samples of a batch of dosimeters.
- A calibration curve or response function for the dosimetry system shall be submitted by the manufacturer or determined by the national responsible body and shall be based on an analysis of samples from the same batch of dosimeters. It shall cover the absorbed-dose working range.
- If the EPR spectrometer is not provided by the manufacturer, its performance criteria shall be specified by the dosimeter's manufacturer (see 6.4).
- Procedures for performing calibrations are given in Annex A.

5.2 Maximum permissible errors and repeatability of absorbed dose measurements

5.2.1 At least 10 dosimeters 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 and maximum errors of the absorbed dose shall be determined for dosimeters irradiated under the following reference conditions:

- temperature: 23 °C ± 3 °C or as specified by the manufacturer;
- relative humidity: 50 % ± 10 % or as specified by the manufacturer;

Note: The reference conditions for relative humidity may be achieved by enclosing each dosimeter in a hermetically sealed package.

- calibration facility: irradiation source having the type of radiation and range of absorbed dose rates as specified by the manufacturer.

Note: In reference [7], results show that the expanded uncertainty (for k = 2 or at the 95 % confidence level) in absorbed dose delivered in a calibration facility to the dosimeters 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 mass of the dosimeter should also be clearly indicated on the package.

6.2 If the mass of the radiation-sensitive component of the dosimeter is specified by the manufacturer, then the actual mass of each dosimeter or the mean value and standard deviation of the repeatability of mass 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 For an EPR spectrometer not provided by the manufacturer, the required performance criteria shall be specified by the dosimeter's manufacturer for the instrument to be used in the evaluation as follows:

- the spectrometer shall be capable of the following settings:
  - microwave frequency from 9 to 10 GHz with automatic frequency locking (AFC);
  - corresponding magnetic field at g-factor of 2.0 (at 9.8 GHz this corresponds to 350 mT) with a field scan range of 20 mT about the center field; RF modulation amplitude at 0.1 to 1 mT;
  - microwave power at 0.1 to 10 mW (leveled); and
  - sweep time, time constant, and receiver gain adjustable for optimum analysis over the absorbed dose working range;
- the EPR sensitivity of the spectrometer shall be at least 2×10^{11} spins/mT; and
- the cavity shall have a sample access diameter of at least 1 mm greater than the diameter of the dosimeter to be analyzed.

6.5 The spectrometer used for measuring the EPR signal amplitude of the dosimeter shall be labeled with or include the following information:

- trade (or instrument manufacturer's) name;
- model and serial number;
- instructions for setup, adjustment, use, and maintenance; and
- a record of the service and maintenance dates.

6.6 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, humidity, atmosphere, absorbed dose rate, and the time of measurement after irradiation.

Note: Influence quantities can be significant sources of error in absorbed dose measurements in radiation processing facilities.

7 Practical instructions

Note: This clause provides information for a user to consider prior to selection of 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 EPR spectrometer 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 alanine dosimeters and may also provide test data that demonstrate that these dosimeters meet the performance requirements according to this Recommendation.

8.1.2 The alanine dosimeters shall be evaluated using the EPR spectrometer provided by the manufacturer or an EPR spectrometer that meets the specifications of the manufacturer as indicated in 6.4. In either case, the dosimetry system shall be calibrated according to the requirements of 5.1 and Annex A.

8.1.3 If the EPR spectrometer is provided by the manufacturer, its operating manual shall be reviewed by the national responsible body for completeness and clarity of operating instructions, and the EPR spectrometer shall be inspected visually in conjunction with the manufacturer's specifications to determine whether it complies with the requirements of Clause 6.

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 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), except that 5 dosimeters may be used instead of 10 dosimeters at each absorbed dose level tested.

8.2.2 Initial verification and, if necessary, subsequent verification, of a batch of alanine 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 using 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 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 EPR spectrometer used. The calibration should also reflect the specific irradiation conditions of an application.

8.3.3 Tests of the performance of the dosimeter to exposures at the extremes of environmental conditions of humidity and temperature and of the extremes of the 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 specific dosimeters 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 EPR spectrometer; and
- identification of major components replaced in the EPR spectrometer.

References

[1] ISO 15566:1998(E), “Practice for use of the Alanine-EPR 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] Nagy, V.; Puhl, J.M.; Desrosiers, M.F. - “Advancements in Accuracy of the Alanine Dosimetry System. Part 2. The Influence of the Irradiation Temperature”. Radiat. Phys. Chem., 57, 1-9 (2000).

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

[8] Maier, D. and Schmalbein, D. - “A Dedicated EPR Analyzer for Dosimetry”, Applied radiation and Isotopes, Vol. 44, (1993) p. 345.

[9] Humphreys, J.C.; Puhl, J. M.; Seltzer, S. M.; McLaughlin, W.L.; Desrosiers, M.F.; Nagy, V.Y.; Benson, D.L.; 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 five dosimeters to be irradiated at each desired absorbed dose level. Use at least five absorbed dose levels per decade of the absorbed dose 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 or by placing it in a numbered envelope or sealed capsule.

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

A.3 Check the dosimeter for defects such as damaged edges. Discard any dosimeters with imperfections, since the defects might affect the readings.

A.4 Check and adjust the EPR spectrometer according to the instructions given by the instrument's manufacturer in its operating manual. (See also 6.4.)

A.5 If necessary, encapsulate each dosimeter in a hermetically sealed package in order to provide controlled environmental conditions during irradiation.

A.6 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 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.7 Measure and record the post-irradiation EPR signal amplitude, *A*, of each dosimeter using the same instrumentation as in A.4.

Note: The post-irradiation time of measurement may be specified by the manufacturer. For measurements at low absorbed dose levels, a background EPR signal amplitude should be determined on the basis of reading samples from the batch of dosimeters used. This background signal may, if required, be subtracted from the EPR signal amplitude of each irradiated dosimeter.

A.8 If appropriate, measure and record the mass of the radiation sensitive material of each dosimeter, or record the individual or mean value of mass provided by the manufacturer. Mass measurements shall be traceable to national standards.

A.9 Calculate the response of each dosimeter, that is, the EPR signal amplitude per unit mass.

A.10 Generate a calibration curve or a response function. Use an analytical form (for example, linear, polynomial, or exponential) that fits the measured data using 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.11 Examine the resulting calibration curve or response function for goodness of fit.

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

A.12 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.13 The resulting dosimetry system calibration curve or response function applies only for the batch of dosimeters and the EPR spectrometer 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, including repair of the EPR spectrometer that may affect the calibration.

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 at three absorbed dose levels within the absorbed dose working range of the dosimeter.

B.2 Following the procedures in A.2 through A.5, prepare a set of ten dosimeters for each of the three required dose levels by selecting randomly 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 in 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 Measure the response of each dosimeter following the procedures in A.7 through A.9 and using the same EPR spectrometer and the data handling system either supplied or specified by the manufacturer.

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

(Mandatory)

This *Test report format* presents, in a standardized way, the results of the various tests and examinations to which a pattern (or type) of an alanine EPR 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 alanine EPR 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

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.....

.....

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 alanine dosimeter (pattern) tested

Name of manufacturer: .....

Product name: .....

Product number: .....

Batch number: .....

C.6 Identification of the EPR spectrometer 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: .....

.....

.....

Instrument operating parameters:

Microwave frequency: .....

Microwave power: .....

Magnetic field sweep range: .....

Magnetic field sweep time: .....

Modulation frequency: .....

Modulation amplitude: .....

Receiver gain: ..... offset: .....

Receiver time constant: .....

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
Relative humidity surrounding the dosimeter: ..... %
Atmosphere surrounding the dosimeter: .....

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

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

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

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

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

C.7.3 Maximum errors and repeatability of measured absorbed dose

Absorbed dose levels (values) →	1	2	3
Measurements ↓			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
$\bar{D}$			
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

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

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: .....

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