American National Standard for Determination of Uniformity of Solid Gamma-Emitting Flood Sources

Sponsor
National Committee on Radiation Instrumentation, N42

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Abstract: Minimum informational requirements for a Test and Measurement Report for flood sources used with scintillation cameras are provided. It is not intended to specify the means by which such information is obtained although it does place requirements and limitations on the methodology. In addition, it is not intended to cover the use of the source in the determination of the operating characteristics or correction factors for a scintillation camera.
Keywords: flood source, nuclear medicine, quality control, scintillation camera, sealed source, Test and Measurement Report, unit cell, useful region

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Introduction

(This introduction is not part of ANSI N42.27-1999, American National Standard for Determination of Uniformity of Solid Gamma-Emitting Flood Sources.)

This standard is the responsibility of the Accredited Standards Committee N42 on Radiation Instrumentation. Committee N42 delegated the development of this standard to its subcommittee N42.RM. Drafts were reviewed by Committee N42, Subcommittee N42.RM, and other interested parties, and the comments received were utilized in producing the standard as finally approved.

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American National Standard for Determination of Uniformity of Solid Gamma-Emitting Flood Sources

1. Introduction

Nuclear medicine practitioners use solid, uniformly radioactive sources that are several millimeters thick with areas up to 0.25 m^2 (called “flood” sources) to characterize and correct the extrinsic flood field uniformity of scintillation cameras for purposes of both quality assurance and on-line operational corrections. These radioactive sources are intended to produce a uniform radiation field across the camera’s usable field of view. Methods to evaluate camera uniformity are described in NEMA NU 1-1994.[1]

A broad range of flood sources is available in many sizes and configurations from a number of manufacturers. Such diversity suggests the need for a uniform means of reporting calibration data and a common understanding of the parameters reported. This information can permit intercomparison of sources and give practitioners a means to determine whether a particular source is appropriate for a given task.

1.1 Scope

The scope of this standard is limited to commercially-produced, solid radioactive flood sources intended to aid in the determination of the system field uniformity of scintillation cameras used in nuclear medicine.

This standard is intended to provide a set of minimum informational requirements for a Test and Measurement Report for flood sources used with scintillation cameras. It is not intended to specify the means by which such information is obtained, although it does place requirements and limitations on the methodology. In addition, it is not intended to cover the use of the source in the determination of the operating characteristics or correction factors for a scintillation camera.

1.2 Special word usage

The words *shall* or *must* indicate a procedure that is necessary to meet the requirements of this standard. The words *should* or *may* indicate an advisory recommendation that is to be applied when practicable.

[1]Information on references can be found in Clause 2.

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2. References

This standard shall be used in conjunction with the following publications. If the following publications are superseded by an approved revision, the revision shall apply.

ASTM E456-96, Standard Terminology for Relating to Quality and Statistics.[2]

NEMA NU 1-1994, Performance Measurements of Scintillation Cameras.[3]

3. Definitions

For the purposes of this standard, the following terms and definitions apply:

3.1 accuracy: The closeness of agreement between a test result and an accepted reference value. **(**The word "accuracy" is to be understood as it is defined in ASTM E456-96.)

3.2 penumbra: The area over which the sensitivity of the measurement system falls from 90% of its maximum value within the unit cell to 10% of that value.

3.3 statistical terminology: *See:* **accuracy** and **uncertainty**.

3.4 uncertainty: An indication of the variability associated with a measured value that takes into account two major components of error: 1) bias, and 2) the random error attributed to the imprecision of the measurement process. **(**The word "uncertainty" is to be understood as it is defined in ASTM E456-96.)

3.5 uniformity: A quantitative description of the two-dimensional distribution of the photon flux emitted by a radioactive flood source, describing variations in that flux for specified areas.

3.6 unit cell (UC): An area on the source to which a single localized measurement value applies. The UC is the two-dimensional region (in the plane of the measured surface of a source) defined by the response of the measurement system to a point source located in the plane of the source and of the same radioactive composition as the flood source.

The UC encloses all points at which the sensitivity of the system is equal to or greater than half that of the maximum value measured.

NOTES:
1. For this standard, the area of the UC should be 1 cm^2 or less, but in no case shall it be greater than 6.5 cm^2.
2. This standard may not be construed as to imply any ability to determine the presence of defects smaller than one UC.

3.7 useful region (UR): The region of the source within which all measurements are made and for which all are certified to be correct. All measurements shall be performed and reported for the UR, recognizing that measurement asymmetries are likely to be present at the edge of the source. The source may extend outside the UR, but no claim is made as to uniformity outside of the UR.

[2]ASTM publications are available from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, USA (http://www.astm.org/).

[3]NEMA publications are available from Global Engineering Documents, 15 Inverness Way East, Englewood, Colorado 80112, USA (http://global.ihs.com/).

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4. Procedure requirements

4.1 Test and Measurement Report

Each flood source shall be accompanied by a Test and Measurement Report that shall contain the following information:

- The primary radionuclide and all measurable radioactive impurities (as defined in 4.2) and the amount of radioactivity of each.
- The spatial uniformity of the emitted photon flux in terms of all required parameters described in this standard.
- The method by which these quantities have been measured.
- A summary of the statistical analysis of the data sufficient to determine the bias and imprecision of measurement throughout the analysis of a given source.
- A description of the system constancy procedure as discussed in 4.4.
- A statement that the measurement system is maintained, calibrated, and validated using a validated Standard Operating Procedure (SOP).
- A statement that the source was evaluated using a validated SOP that conforms to the requirements of current good manufacturing practice (cGMP) or equivalent.

4.2 Required reportable parameters

The following parameters shall be reported in the Test and Measurement Report:

- The primary and impurity radionuclide content at the time of calibration shall be reported to an accuracy of ±10% at the 95% confidence level. All radionuclide species present in the source at concentrations greater than 0.05% of the activity of the primary radionuclide shall be listed individually. Total radionuclide impurity concentration shall be reported with an accuracy of ±10% (at the 95% confidence level).
- A calculated estimate of the primary and impurity radionuclide content at a time equal to two half-lives (from the date of manufacture) of the primary radionuclide shall be reported. This shall be in the same form as used in the impurity report described in the previous paragraph. This will report the concentrations of all radionuclides reported in the initial impurity report as well as any other known impurities that are estimated to be present in concentrations greater than 0.05% of the primary radionuclide at the later time.
- The shape and dimensions of the unit cell (UC) in the normal counting geometry, including the width of the penumbra (the area over which the sensitivity of the measurement system falls from 90% of its maximum value within the UC to 10% of that value) shall be reported.
- A complete description of the cluster in terms of size, shape, and distribution within the useful region (UR).

For the entire UR, the following *shall* be reported:

- The number of UC measurements, the mean, and the measured sample standard deviation of the UC count for the entire UR.
- The Maximum Absolute Deviation from the Mean (MADM), defined by the largest sample difference from the mean UC value, expressed as a percentage of the mean UC value.
- The Coefficient of Variation (CV), defined by the standard deviation of the distribution of UC values divided by the mean UC value and expressed as a percentage.

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— The Integral Uniformity (IU), in percent, defined as $100 \times (UC_{max} - UC_{min})/(UC_{max} + UC_{min})$, where UC_{max} represents the largest and UC_{min} the smallest UC measurement acquired over the UR, respectively.

For the entire UR, the following *should* be reported:

— The Differential Uniformity (DU), in percent, defined as $100 \times \Delta UC_{max}/\Delta UC_{sum}$. This parameter is determined by the following method:

1) For each measurement protocol, a cluster of UCs is defined. This cluster consists of a cluster of between 7 and 12 UCs, where the boundary of the cluster is as convex as possible and all UCs within the cluster boundary are included in all calculations. All possible clusters that are completely within the UR are used in the following calculation.
2) Within each cluster, the pair of UCs exhibiting the largest difference in measured count rate is identified (this difference is designated ΔUC_i). When all clusters have been examined, the largest ΔUC_i is selected. This is ΔUC_{max}. ΔUC_{sum} is *simply* the sum of the measured values of the two pixels from which ΔUC_{max} was obtained.

4.3 Methodological requirements

4.3.1 General

Uniformity shall be evaluated using a collimated detector or detectors positioned above or below the surface of the flood source so as to derive information from an array of measurements of UCs. The UC shall be completely characterized by its description in the Test and Measurement Report.

4.3.1.1 Configuration

All measurements shall be made with the source in the configuration as it would normally be used.

4.3.1.2 Useful region

The UR of the source shall be defined by the manufacturer by a dimensioned figure. This figure shall define the orientation and position of the UR within the physical area of the source.

4.3.1.3 Unit cell

Individual measurements comprising the evaluation shall be referenced to the UC.

4.3.1.4 Sampling

Measurements shall be taken at a sufficient number of positions of the UC within the UR so that no less than 100% of the UR is measured. Sampling shall be uniform over the UR of the source, with appropriate oversampling to ensure that sensitivity to defects is uniform throughout the UR. For continuous, rotational scanning, the rotational speed of the source must be adjusted with detector radius so that the detector always scans the same total area per unit time.

4.3.2 Uniformity measurement

The measurement system shall have the ability to determine a parameter that is proportional to the local gamma-ray flux (as defined by the UC) from the flood source in the prescribed configuration.

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4.3.3 Required measurement precision

The measurement imprecision for each UC measured, quantified by the coefficient of variation (the standard deviation divided by the mean) of repetitions of the same measurement, shall be no greater than 20% of the integral uniformity. In other words, if the integral uniformity of a particular source (as defined in 4.2) is equal to 5%, then the measurement imprecision must be no greater than 1%.

For counting systems, this means that sufficient counts must be acquired for each UC to ensure this precision. For systems employing count-rate averaging, separate measurements must be made to determine the averaging time constant that will yield a 20% or lower measurement imprecision for the parameter used. A description of these measurements and the results must be provided.

The position of each UC for which a calculation is performed shall be within ±0.1 mm of the stated location.

4.3.4 Dead-time loss

Dead-time losses shall be no greater than 10%. Correction for dead-time losses shall be made either by operating the system timer(s) in “live-time” mode, or by any other generally accepted method that evaluates and corrects for the loss associated with each measurement from each detector. The method for correcting for dead-time losses shall be explicitly described.

4.3.5 Energy resolution

The detector shall be capable of distinguishing the energy of gamma photons so that the full width at half maximum (FWHM) of the primary full-energy peak is no more than 20% of the energy at the maximum value of that peak.

All measurements must be performed using a standard energy window (SEW) for each detector. The SEW should be symmetrical about the primary full-energy peak, with a width that is 1.5 times the FWHM of the primary full-energy peak averaged over all of the detectors being used.

4.3.6 Multidetector systems

Multidetector systems shall be acceptable if the response of each individual detector (prior to the application of correction factors) to a point source of physical dimensions smaller than the UC is within ±10% of the response averaged over all the detectors. This parameter must be monitored at least weekly to determine if detectors have drifted, requiring recalibration and/or physical adjustment.

For multiple detector systems, a detector-specific correction factor shall be applied to each UC measurement. The correction factor may be calculated for each detector by dividing the average of the balance measurements for all detectors by the balance measurement for the detector to which the correction will be applied.

4.4 Constancy of system response

A primary assumption of any radiation measurement methodology, regardless of the region being measured, is the constancy of the detector system response throughout the measurement cycle. System validation must include a procedure by which it can be determined that the system response is stable and independent of position during the measurement of a flood source. Such a procedure might consist of affixing a small source (of the same isotope as the flood being measured) to the detector or detectors, followed by the scanning of a dummy (i.e., nonradioactive) flood disk under otherwise normal conditions. This procedure would reveal mechanical irregularities and systematic errors. A similar procedure for multidetector systems would employ sources affixed to every detector during scanning of the dummy flood disk.

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If the system is found to be unstable, the variation with detector position must be reduced to less than 20% of the claimed source uniformity. If the variation is position dependent and reproducible, then position-dependent correction factors may be applied to correct the error. Otherwise, the system must be altered to achieve this constancy level.

A description of this procedure and the results of it must be included in the Test and Measurement Report (as listed in 4.1).

Good practice would suggest the use of this procedure whenever changes in configuration are made, including system modifications, room and source storage modifications, etc. This procedure must be performed whenever revalidation is required.

4.5 Detailed method of measurement

Annex A details methods for measuring source uniformity that are in conformity with this standard. Alternative methodologies (e.g., collimator designs, definition and physical sampling of the UR, etc.) are acceptable in fulfilling the requirements of this standard as long as all requirements specifically stated in the body of the standard are adhered to, and the method used is described in detail in the Test and Measurement Report. Deviations from the method of Annex A should be explained in detail.

5. Precautions and sources of error

5.1 Dependence upon measurement orientation

A determination must be made that measurement of source uniformity performed on one side of a source of a given design is valid for the other side as well. If it is not, the measured side should be clearly marked as such.

5.2 Backscatter and surrounding geometry

Significant systematic error can be introduced into radiation measurement systems from scattered radiation. As flood sources are generally thin and manufactured of relatively low density materials, their contribution to scatter is likely to be small. Attention must be paid, however, to the surrounding structure of the measurement system and to the walls and floors, as scatter from these nearby objects can introduce substantial anomalies into the measurement process. Such interference must be minimized.

5.3 Interference from nearby sources

A potential source of considerable error in a manufacturing environment can be the presence of other gamma or X-ray sources in the vicinity of the measurement system. Care must be taken to ensure that the detector is adequately shielded so that the contribution to the measurement signal due to extraneous sources is insignificant. *The measurement described in 4.5 must include these effects.*

5.4 Calculation error

Care must be taken to evaluate all parameters with sufficient arithmetic accuracy so as to avoid errors during intermediate calculations. Integer calculations shall be avoided in favor of floating-point calculations. Rounding of results shall not be done except at the very final calculation, and then only to the extent supported by the underlying data.

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Annex A

(informative)

Methodological example

This annex describes specific methodologies that may be used to satisfy the requirements of the standard. Other methods may be used as long as all requirements stated in the body of this standard are met.

A.1 Measurement schema

The probe(s) should scan the flood source so that

a) The central axis of the collimator is maintained perpendicular to the surface of the source. The distance from the front face of the collimator to the surface of the source should be no greater than one-eighth of the collimator length. This will provide a penumbra area of approximately 50% of that of the straight projection of the collimator bore.
b) The probe(s) stop for counting at each measurement location.

A.2 Collimator design

The detector or detectors should be collimated with a single-hole, straight-bore collimator of cross-sectional area no greater than 1 cm^2. The collimator should be fabricated from a material having a density no less than that of lead, with a length (from the detector face to the collimator face) that is twice the largest collimator hole diameter. Collimator wall thickness should provide at least five half-value layers for the isotope being evaluated (approximately 1.5 mm Pb for ^{57}Co). Collimator wall thickness should also take into consideration the highest energy radiocontaminant present and should be increased to maintain the contribution of photons from these contaminants to the primary counting window at a level that is below 1% of the total counts in that window.

A.3 Counting equipment

Counting equipment may consist of either a single detector using NaI(Tl) scintillators (or other appropriate type), a single channel analyzer (SCA) and decade counter, or a bank of multiple detector/SCA/counter assemblies. A computer may be used to emulate the analyzer(s) and counter(s). The thickness of the radiation sensitive portion of the detector(s) should be such as to provide at least 70% intrinsic efficiency for the primary photon energy of the flood source.

A.4 Balancing multidetector systems

Individual detectors may be “balanced” by causing the detector bank to scan near the center of the flood source (or one of similar specifications), successively shifting the counting location by one UC along the axis of the detector bank and recounting, so that eventually each detector evaluates the same UC.

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