PASSIVE CALIBRATION ARTIFACTS FOR SYSTEMS USING IONIZING RADIATION AND RELATED IMAGING SYSTEMS

Passive Calibration Artifacts for Imaging Systems Using Ionizing Radiation

1 Purpose

The purpose of this Procedure is to describe the guidelines for the fabrication, production, and characterization of passive calibration artifacts for systems using ionizing radiation. These systems include but not limited to mammography, x-ray Computed Tomography (CT), Positron Emission Tomography (PET), and x-ray backscatter (XRB) imaging, and imaging systems using non-ionizing radiation such as Magnetic Resonance Imaging (MRI) or Optical Medical Imaging (OMI) including Optical Coherence Tomography (OCT).

2 Scope

This Procedure outlines the requirements for the Standard Operating Procedures (SOPs) that will describe the selection of materials, qualification of certain parts, general assembly instructions, data acquisition, and analysis strategies. This Procedure also describes the Quality System approval process for each SOP. Each SOP will describe the technical requirements specific to a given Standard Reference Material (SRM) or a set of closely related SRMs.

3 Definitions

Subclass of SRMs - a set of closely related SRMs which differ from each other parametrically and are described by a single SOP.

Passive devices – devices that are not sources of radiation, energy, nor contain hazardous materials.

4 Equipment

The SRMs shall be assembled using any appropriate equipment, including purpose-specific fixturing. Measurement traceable to the SI requires the use of specialized, calibrated mechanical or optical instruments. Measurement of the artifacts for use in a system such as a CT requires that such a system be used; however, the system need not be traceable. Each SOP shall specify the equipment required and describe the reason(s) for its selection and use.

5 Safety

The passive calibration artifacts covered by this Procedure shall contain no sources of radiation or other energy, or hazardous materials. All laboratory and machine shop safety procedures shall be followed during assembly and measurement of the artifacts. Operation of devices producing ionizing radiation shall be performed in accordance to the Laboratory Safety Manual [1]. Radiation safety and training services are provided by the NIST Gaithersburg Radiation Safety Division.

6 Procedures

The specific technical procedures shall be outlined in an SOP, which shall discuss the selection of materials, the qualification of certain parts, general assembly instructions, data acquisition, and analysis strategies. The calibration and certification procedures shall be described in the SOP for each subclass of SRM. Typically these will involve performing SI-traceable measurements in a system designed for metrological calibration and demonstrating the device in a system devoted to the application which may not itself be SI traceable. Sampling techniques shall be established in consultation with the Statistical Engineering Division (See NIST QM-I Section 5.7.2.). A random sample of the artifacts may be measured in a non-traceable system to help establish the uncertainty of measurement (see Section 7.2).

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The SOP shall describe:

(1) broad examples of the use and the requirements for the SRM; for example, the SRM may be used in medical CT to determine lengths or densities in the reconstructed CT images and certain tolerances for the physical sizes of the materials and their x-ray attenuation properties with one or more beam qualities;

(2) the physical properties of the SRM and identify the physical quantities that are to be quantified and/or certified, such as lengths, masses, densities, x-ray attenuation, optical properties, etc.;

(3) suitable material or materials for the SRM, including their acquisition, preparation, assembly, and characterization; the requirements for these materials should be specified, such as dimensional and x-ray attenuation tolerances as well as practical instructions for achieving the specifications;

(4) the necessary facilities, equipment, and personnel, including the principal investigator; this should include specialized facilities such as the coordinate measuring instrument, and NIST standard beam qualities, as well as more general facilities such as calibrated mass balances or uncalibrated CT machines;

(5) the measurement of physical quantities, including at least one SI-traceable measurement, and including the homogeneity of the quantities where appropriate; for example, the measurement of basic quantities such as length, mass, density, as well as x-ray attenuation as a function of position;

(6) a measurement model, suitable sampling and measurement method including the sequence of operations for the production process, and a method for evaluating the uncertainty; for example, see section 7.2;

(7) a suitable container and suitable packaging for the SRM and conditions for storage, including consideration of how the container would protect against damage especially in the case of stored liquids; in the case of x-ray materials, suitable packaging may include bubble wrap and shrink wrapped packages that are tough enough to withstand ordinary handling but have a negligible x-ray signature so the materials may be placed in an x-ray beam or CT machine without being removed from the (inner) packaging;

(8) how to conduct the technical review of the SRM artifact and the preparation of its associated SRM certificate; and

(9) record keeping, including from whom the material was acquired, how it was processed to construct the SRM, the measurements of the SRM, the uncertainty analysis, and documentation from the review and approval process. SOPs are submitted to the Division SRM Coordinator who then works in collaboration with the Group Leader for review. At their discretion, the SRM Coordinator and/or Group Leader may request SOP review from technical experts inside or outside the Division. If appropriate, the proposed safety measures shall be reviewed and approved by the NIST Occupational Health and Safety Division and/or NIST Gaithersburg Radiation Safety Division. The Group Leader shall request SOP final approval from the Division Chief.

7 Uncertainty Analysis

7.1 Uncertainty for non-ionizing measurements

The passive calibration artifacts may be measured under the auspices of the Quality Systems of other NIST Divisions. For example, the uncertainties of length measurements performed by the Precision Engineering Division shall be analyzed using the Procedures described in their Quality Manual. The Radiation and Biomolecular Physics Division (RBPD) will develop the uncertainty analysis and describe the methods in the appropriate SOP.

7.2 Statistical Analysis for Lot Sampling

In the event that mechanical or optical probes are not to be applied to each individual unit, nominally identical artifacts may be selected at random using a lot size developed in consultation with the NIST Statistical Engineering Division (SED). The statistical analysis may include performing a non-traceable measurement for every unit and correlating the results of such measurements with SI traceable values for a subset of the units.

8 Records

Records related to a specific SRM are stored by the SRM number and held in the custody of the RBPD co-coordinator for passive calibration artifacts.

9 Filing and Retention

Folders of SRM certificates are maintained in Room 245/C236, a room dedicated to development of these particular SRMs. When the SRM becomes unavailable, a copy of the SRM certificate shall be retained for a period of five years.

The RBPD Quality Manager shall maintain the original and past versions of this RBPD Procedure.

10 References

[1] [NIST] Laboratory Safety Manual, Chapter 8, “Ionizing Radiation Safety,” http://www-i.nist.gov/admin/ohsd/hslsmch8.htm