Purpose

The purpose of this procedure is to describe all steps involved in the measurement of air-kerma produced from electronic brachytherapy sources using the Lamperti [1-3] standard free-air ionization chamber. The details of the calibration services listed as 46012C (first source), 46013C (each additional source) and 46050S (special proficiency test) are included. The details of the proficiency test service are included in the Appendix C associated with 46050S.

Scope

The calibration of well-type ionization chamber instruments that measure x rays from electronic brachytherapy sources are performed in terms of the physical quantity air kerma in units of gray (Gy) [4,5]. The process for establishing calibration coefficients for well-type ionization chambers is explained in this procedure. Calibrations are performed by comparing the well-type ionization chamber response to air kerma realized by a NIST primary x-ray standard. The NIST calibration coefficients of a well chamber have units of Gy/(A s) normalized to reference conditions of 295.15 K and 101.325 kPa.

Referenced documents

NIST Special Publication 250-58 Calibration of X-ray and Gamma-ray Measuring Instruments NIST Calibration Services (http://www.nist.gov/calibrations) NIST Technical Note 1297 Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results

Records

Electronic files

Definitions

<u>air kerma</u> - the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all electrons liberated by photons in a volume element of air and dm is the mass of air in that volume element. The SI unit of air kerma is the gray (Gy).

<u>beam quality</u> - used to refer to a specific x-ray beam with a characteristic half-value layer and produced by a constant potential kilovoltage.

<u>calibration</u> - the process whereby the response of a dosimeter or measuring instrument is characterized through comparison with an appropriate national standard.

<u>calibration coefficient</u> - the quotient of the air kerma in the absence of the chamber and the charge generated by that radiation in the well-type ionization chamber, expressed in units of Gy/(A s) normalized to reference conditions of 295.15 K and 101.325 kPa.

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<u>electronic brachytherapy source</u> - insertable, miniature, low-energy x-ray tubes for interstitial radiation therapy

<u>exposure</u> - exposure (*X*) is the quotient of dQ by dm, where dQ is the sum of the electrical charges on all the ions of one sign produced in air when all the electrons are completely stopped in air of mass dm. The SI unit of exposure is the coulomb per kilogram (C/kg); the special non-SI unit of exposure, the roentgen (R), is equal to exactly 2.58E-4 C/kg.

<u>half-value layer</u> - (HVL) the thickness of the specified material added as a beam attenuator that reduces the air-kerma rate by one half of the unattenuated-beam air-kerma-rate value.

<u>x-ray unit</u> - system comprised of a high-voltage generator, an x-ray tube and an x-ray controller.

Key words

air kerma; calibration; exposure; free-air chamber; electronic brachytherapy; well- ionization chambers; primary standard; standard; uncertainty estimate; x rays.

Background information and traceability of measurements

The quantity kerma characterizes a beam of photons or neutrons in terms of the energy transferred to any material. For the calibration procedures described in this document, consideration is limited to photon beams in air. A complete description of the determination of air kerma and the traceability of the standards is found in sections 4.1, 6.2 and 6.8 of NIST Special Publication 250-58 [2] and Refs [1,3].

Requirements of instruments to be calibrated

Only well-ionization chambers known to be stable and reproducible are accepted for calibration in this program. Facilities submitting well-ionization chambers for calibration are strongly urged to perform stability checks involving redundant measurements in highly reproducible radiation fields before sending their instruments to NIST, and to repeat those checks after NIST calibration, and again at suitable intervals. The appropriate chamber insert must be provided by the customer. Instruments submitted for calibration, and material submitted for irradiation, must be shipped in reusable containers.

Explanation of calibration service offered

The increased use of limited-lifetime electronic brachytherapy sources which are miniature, low-energy x-ray tubes for clinical applications resulted in the need of a measurement of air-kerma dose from NIST. The type of electronic brachytherapy sources, Axxent S700, used thus far at NIST operates at tube potentials of 50 kV and anode currents of 300 μ A. The millimeter sized anode is shown in Figure 1a revealing the tip detail of a source. Figure 1b shows a typical source in a water-cooling catheter and the high voltage (HV) connector. The calibration service determines the air-kerma rate in terms of Gy/s for each source at 50 cm using the Lamperti free-air ionization chamber [3]. A customer-provided well chamber is used to measure the stability of the source output and serves as a transfer instrument. A NIST-maintained well chamber is also calibrated to provide quality assurance to the process. The

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measurement process results in a NIST calibration coefficient for the well chambers for each source in units of the NIST air-kerma rate (Gy/s) at 50 cm per ampere, Gy/(A s) normalized to 295.15 K (22 °C) and 101.325 kPa (1 atm).

Design philosophy

The air kerma in units of gray (Gy) or air-kerma rate (Gy/s) is determined at a source to detector distance of 50 cm using the NIST primary standard. After determining the air-kerma rate of the electronic brachytherapy source, the source is then placed in the NIST well chamber for a series of measurements in units of ampere followed by the customer's well chamber. Ionization currents in air-kerma-standardization measurements are produced by the irradiation of a gas in an ionization chamber. The ionization chamber may be a free-air chamber, such as one of the national standard chambers, or a cavity chamber, where the gas is surrounded by the wall material. Ionization chambers, regardless of type, consist of electrodes that are insulated from one another and that are polarized to collect charge produced in the gas. The ions produced in the air by the beam are swept from the chamber volume by the electric field between the electrodes. Included in the measurement of these currents are currents not produced by the radiation of interest, but by background radiation and insulator leakage, referred to as background current.

X-ray range features

The NIST Electronic Brachytherapy Facility is in the Radiation Physics Building 245, Room H116. It was designed with a walk-in shielding enclosure to provide personnel safety during measurements. The leaded-glass shielding maze entrance and leaded-glass walls allow observation of the source and instruments during measurements. Figure 2a is a schematic of the design and Fig. 2b is a photograph of the clear leaded glass walls showing the maze entrance, the radiation area and the operator's control area. Figure 3 shows the essential equipment located inside the leaded glass enclosure. The source is surrounded on three sides by a leaded glass surround which reduces scatter. The cooling pumps for the source catheter, the HV cable, and the well chamber are mounted on a shelf above the source holder, Fig. 4. This positioning was selected since the length of the high voltage connector between the source and the power supply is limited, which is shown in the smaller insert picture in Fig. 4. The source alignment apparatus is also mounted above the source holder. The high-purity germanium detector and the cooling liquid nitrogen Dewar are shown in Fig. 5. The equipment to power, communicate with and control the x-ray sources, Lamperti chamber and well-ionization chamber is located outside the leaded glass shielding enclosure, in the control area of the facility as shown in Figures 6-8 and identified in Table 1. Figure 6 shows the x-ray controller, the HV controller, the power supply for the Lamperti chamber and the data acquisition computer control equipment. Figure 7 shows the barometer, thermometer and the well-chamber electrometer. Figure 8 is the electrometer used for the Lamperti chamber, with details of the back hook-up. All calibration work related to the electronic brachytherapy sources is contained in room 245/H116, as there is sufficient setup area for the storage, preparation and maintenance of the sources.

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Equipment

The Axxent high voltage power supply, the XOFT StellarTech power supply and the XOFT XTC-03 are critical to the production of radiation and have been provided by the manufacturer. The calibration of this equipment will be arranged by the manufacturer and will be documented in the *XOFT Equipment* databook 1053, located in H116. The frequency of the equipment calibration will be determined by the manufacturer unless NIST suspects a voltage change and then the equipment will be returned for inspection and recalibration.

The temperature probes, pressure transducers and electrometers are considered essential support equipment to allow routine calibrations of ionization chambers. The maintenance and calibration of this support equipment follows. All equipment is listed in Table 1 and seen in Figures 3-15.

The temperature sensor in the electronic brachytherapy facility is the Fluke/Hart Scientific 1504A meter with a 5611 thermistor, used to determine the temperature of the air in the calibration area. The thermometer calibration correction is applied internally to the 15004A digital meter at the time of NIST calibration.

A Setra 370 barometer is interfaced through the data-acquisition software to monitor atmospheric pressure. Any necessary correction is applied directly through software as part of the air-kerma calculation.

The charge measurements for the Lamperti chamber are acquired using a Keithley 6512 electrometer. The charge measurements for the well-ionization chambers are acquired using the PTW Unidose electrometer. Upon initial use, the charge mode of the electrometers is calibrated per the procedures outlined in NIST ID 46011C, for the test of high-quality electrometers. Any necessary electrometer calibration correction factor would be applied as part of the air-kerma calculation for the free-air ionization charge or as part of the well chamber and QA ionization charge calculation. Currently the electrometer calibration uncertainty is entered as a Type B, and no correction factor is applied. The PTW Unidos E electrometer is also used to measure the charge collected in the PTW TN34013 ionization chamber for QA purposes.

Support equipment calibrations

There are no specified intervals for calibration of the critical support equipment because the equipment is calibrated using the "in house" reference standards described below when a concern of reproducibility is identified. Since the QA procedure requires the calibration of the well-ionization chamber, any change in the reproducibility of a single source measurement above 0.2 % may require an investigation into the support equipment used for the calibration. If any of the critical support equipment is found to be out of calibration or damaged, it would be removed, and its condition clearly marked. A calibrated, identical model replacement instrument would be used for calibrations to continue until the repair of the damaged equipment is completed. All new equipment is calibrated against the "in house" reference

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standard and history is created and maintained. The new equipment is checked to verify it meets the specifications of the stated procurement, using the "in house" standards. Any damage and repair to the critical support equipment should be recorded in the *XOFT Equipment* databook 1053, located in H116. All NIST calibration records for the critical support equipment are in a 245/H127. In house calibration records of the barometers and thermometers are maintained in electronic files in the folder named *supportequipqa* located on the group server in the *OBRIEN* folder. The validation records are kept in a file L:\internal\846.02\x-ray*supportequipqa\QMSvalidateH116.xlsx* located on the group server for calibration data, in the x-ray folder.

Temperature indicator calibrations

A Fluke/Hart meter 1504 (SNA95694) with probe model 5610-5 SNA932006 will serve as the "inhouse" temperature reference standard for x and gamma ray calibrations. The meter and probe combination were previously directly calibrated by the NIST to the reference standard and will be calibrated periodically as necessary using the "inhouse" reference standard. Various probe and meter combinations, dedicated for calibration measurements, are periodically directly calibrated at the NIST.

Pressure indicator calibrations

An aneroid barometer, Wallace and Tierman, Model FA 139, Serial Number XX11242, as well as various other laboratory reference barometers are periodically calibrated by the NIST reference standard. Calibrations of individual pressure indicators used in the various x-ray calibration ranges are made by placing the calibrated barometer alongside the instrument to be tested. The instrument readings are compared over a range of pressures. A correction factor is obtained from this data for each pressure indicator, if required. This calibration procedure is conducted periodically, and checks are made when the pressure deviates significantly from the reference value of 101.325 kPa.

Procedures

Administrative procedures

Customers request calibration services in a variety of ways. Typically, a new or first-time customer will establish contact with the Dosimetry Group by email requesting information regarding techniques offered, charges, turnaround time, and shipping information. At this stage, there is generally an opportunity to discuss with the prospective customer the type of service being requested and methods of shipment to reduce the risk of damage. The customer is informed of the administrative procedures for acceptance of the requested work as outlined in the NIST QMI and in the RPD QMII, in accordance with the NIST calibration policy. In addition to completing the NIST payment authorization requirements, the customer must include a detailed description of the calibration request, instrument model and serial numbers, name and telephone number of a technical contact, the official address which will appear on the calibration report, the return shipping instructions including the address, special handling, the specified mail carrier with account number for payment, the value of the equipment and

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instructions for the insurance amount, if any. The customer is directed to the complete instructions and policies for calibrations on the NIST calibration webpage.

The Calibration Order Information form, see Table 2, can be completed by the NIST technical contact as a method to organize the dates and information about the calibration request. The NIST Order number is generated by E-commerce upon the completion of the NIST policy for payment documentation by the customer. A copy of the purchase order, if available, the final copy of the calibration report, the calibration raw data, summary sheets, a copy of the final fee sheet and any documents of correspondence concerning the calibration are maintained in the customer's calibration report folder filed by the unique dosimetry group (DG) number.

When instruments arrive for calibration, they are unpacked and inspected for damage. Shipping damage is reported to the NIST shipping department. If an instrument arrives in a state of disrepair that is obvious by visual inspection, the customer would be notified, and the instrument returned without calibration. The instrument would be rejected if the chamber cable is damaged. If the shipping box is visually damaged this should be noted, and the customer consulted.

After the instrument is calibrated, the calibration report is generated. Templates generated in Microsoft Word and Excel are available to simplify this procedure and to ensure consistency in the reporting format. The reports are printed on official NIST letterhead. A sample NIST report is provided in this procedure, Appendix A, with the required elements identified by the corresponding letter in red font. The sample spreadsheet for collecting data is shown in Appendix B.

Upon completion of the requested calibration, the final calibration report is reviewed and initialed by the preparer, the reviewer, the Group Leader and the Division Chief. A scanned electronic copy is provided to the calibration administrator to close the order. A photocopy of the report is maintained in the customer's DG folder located in 245/H127 and the original is sent to the customer within the container of the returned equipment or by mail if requested by the customer. The instrument(s) is then repackaged in the original container, or a more suitable one, for return shipping. A shipping form is prepared by the Group Secretary, or the shipping page of the E-commerce Test Record is printed and attached to the box. The NIST shipping department picks the box up from outside of H127 or the designated collection point.

Laboratory procedures

Procedure for Cleaning and Lubricating the Source

Prior to connecting the source to the HV connector and cooling lines, the source must be cleaned and lubricated. Complete manufacturer's procedures are found in the cabinet with the cleaning supplies in H116, see Fig. 9 for cleaning supplies and general details. In summary, the process involves using alcohol and a lint free tissue to clean the HV connector, paying attention to any dark marks from arcing. After the alcohol has evaporated or air dried then the connector lubricant, MS-383H, should be applied with a swab or lint free tissue, using gloves and taking care not to add any dirt to the connector. If any

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hint of arcing occurred, then the HV connector socket, labeled in Fig. 4, should be inspected and cleaned with alcohol using the swab and/or a lint free tissue.

Procedure for Drying Source

The cooling medium must be removed from the cooling catheter to preserve the life of the source. Complete manufacturer's procedures, using the vacuum pump shown in Fig. 10, are found in the cabinet in 245/H116. Each source must be vacuumed after use. The source should be disconnected from the HV connector and cooling lines. The source is easily connected to the vacuum pump and dried. Select the "1hour" button on the electrical cord of the pump. The pump will automatically stop after one hour.

Procedure for Alignment and Positioning of the Lamperti chamber and the source

Source alignment: As seen in Figures 11 and 12, there are multiple mechanisms for the alignment of the equipment. Figure 11 shows the three alignment control stages for the source. Within the leaded glass surround, the source can be adjusted with the two stages for the horizontal and vertical source position to the lasers which are seen in the large photo in Fig. 12. The power switch for the lasers is mounted under the top of the optical table. Once the laser mounted behind the Lamperti chamber is energized, the alignment to the scale on the "front" of the catheter is possible. This laser is aligned to the center of the FAC and sets the height of the source. The center of the source is visible through the catheter and is used as the alignment point for both the horizontal and vertical positioning. There is a third alignment stage, Fig. 11, which is used to change the angle of the "front" or scale portion of the source relative to the Lamperti chamber. This rotation stage has two etched marks which are to be aligned to the mark at the center of the stage to set the source at 0 degrees, 120 degrees and 240 degrees relative to the front of the Lamperti chamber. The distance of 54 cm between the center of the source and the center of the Lamperti chamber is determined with a measuring tape. Once the laser mounted behind the Lamperti chamber is used to align the source horizontally and vertically, the second laser mounted perpendicular to the other laser can be used to monitor the 2 cm change in distance between the two measurement positions for the inverse square check and the air attenuation measurement. It is also at the same height as the other laser. It should be aligned to the front of the Lamperti aperture and then will align to the black mark, 2 cm behind the aperture on the Lamperti chamber as shown in Fig. 12.

Lamperti chamber positioning: Figure 12 has three smaller, inserted photos which show the knobs for the under mounted alignment slides which are used to align the Lamperti chamber for various required measurements. The center photo and the one to the right show the knob in the back of the Lamperti chamber. This knob controls the horizontal positioning of the Lamperti chamber. This alignment slide should never be realigned routinely unless there is a modification to the calibration facility. The knob for the slide used to adjust the distance of the source to the center of the chamber is located to the side of the Lamperti chamber. There are alignment marks, not visible in the photos, on the Lamperti support which are used to establish the various distances from the source, along with a tape measure. The alignment slide, with the knob to the side of the Lamperti chamber is used and the distance verified with the NIST traceable ruler, seen in Fig. 12. The center of the chamber is placed at 54 cm from the source for the air-kerma

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measurements and repositioned to 52 cm from the source, for the inverse square distance dependence of the air kerma rate. The Lamperti chamber is moved closer to the source by 2 cm to measure the scatter conditions of the points of measurements for the air attenuation measurement. Assuming a stable, geometrically centered and well-constructed source, the scatter conditions can be tested using the inverse square distance method over 4 cm, but the routine is to measure when the center of the Lamperti chamber is placed at 54 cm and at 52 cm. The fourth smaller inserted photo in Fig. 12 shows the front aperture of the Lamperti chamber. This tungsten aperture, having a diameter of 0.5 cm, is used for all measurements except the air-attenuation determination.

Lead shields

Figure 13 shows the lead shields that are used during the inverse square distance dependence of the scattered radiation test, angular and air attenuation determination. The air-kerma shield, placed at a nominal 40 cm from the source, has a hole with a diameter of 3.5 cm and does not impact the measurement of air-kerma. It is used to reduce the size of the x-ray beam incident on the Lamperti chamber. It must be removed for the air-attenuation measurements, for which the smaller shield with the hole of diameter 0.3 cm is used. The air-attenuation shield is positioned at 45 cm from the source.

Air-attenuation positioning

The Lamperti chamber tungsten aperture must be removed for the air-attenuation measurement. The airattenuation shield should not be moved during the two measurements required to determine the airattenuation ratio, one when the center of the chamber is at 54 cm and the second when the center of the chamber is at 52 cm from the source. The Lamperti chamber is not moved forward the full air-path length of 4 cm, to 50 cm, because moving that large of a distance disturbs the geometry and poor results are obtained. If the air-attenuation is measured over 2 cm and then calculated for the 4 cm air path, the measured results match the calculated results. The Lamperti chamber was not designed to allow direct measurement of the air-attenuation correction due to the original geometry of the imbedded tungsten aperture. Verification of the calculated value of the air-attenuation correction can be achieved with a simple measurement ratio over the 2 cm path-length. Figure 14 shows diagrams of the various measurement positons of the Lamperti chamber which explain the various positions used for measurements.

Safety for repositioning chamber

When entrance to the radiation area is required for the repositioning of equipment, for example during the inverse square and the air attenuation measurements, the source must be de-energized. Guidance for this is described in step 14 of the XOFT Labview operating procedures on the Xoft control computer. The high voltage, of 3000 volts, remains on the Lamperti chamber during movement of the chamber for the inverse square and the air-attenuation measurements. The voltage is interior to the surface of the Lamperti chamber and there is no risk of electric shock if the interior of the chamber is not touched.

Procedure for using the cooling medium flow pump

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The source should be connected to the cooling medium, located in the hanging intravenous (IV) bag, through the red and blue cooling lines, Fig. 3. Once the tube connections are secure, the red flow clamp should be released prior to energizing the flow pump, Fig. 4. On the pump, the flow needs to be set to **forward** (button down) and the setting is ideally 3. When sufficient flow is achieved, the flow interlock will release, and the source can be safely energized. The flow safety interlock light will illuminate on the Xoft interlock controller, Fig. 6. If the flow decreases such that the source is at risk of overheating, the interlock will switch off and de-energize the source. At the completion of use of the de-energized source, the pump should be de-energized, the red clamp secured, and the tubes disconnected. If the red clamp is not secured fully, or clicked all the way shut, the cooling medium will leak on the table and floor.

Procedure for Energizing Source

1. Turn on the water pump, which cools the source, following cooling hook up procedures.

2. Turn on the power switch to the main controller.

3. Verify all interlocks are made on the control area, including a blank source in the well chamber during use of the Lamperti chamber for air-kerma measurements. Voltage will not be applied to the source if the interlocks are not made.

4. Visually verify that no one is in the radiation area.

5. Visually verify that the radiation warning lights both at the control panel and the shielding wall are on.

6. Test the interlock barrier.

7. Reset interlocks.

8. Use control computer to ramp up tube voltage, filament current, and beam current using XOFT Labview procedure.

9. For the inverse square and the air attenuation measurements, entrance into the radiation area is required for repositioning of the Lamperti chamber. The source must be de-energized for safe entrance. This is an option on the computer software.

Procedure for De-energizing Source

1. Use control computer to ramp down x-ray source tube voltage, filament current, and beam current.

2. Turn off the water pump.

3. Secure water-cooling line with clamp to prevent leakage.

Computer procedures and instructions for Labview and XOFT computer applications

Electrometer data acquisition procedures: The application WCCharge.vi collects data on the PTW electrometer, barometer and thermometer when the well ionization chamber or the PTW TN34013 QA chamber is in use. The blue signal cable is switched between the well chamber(s) and the PTW QA chamber to allow measuring the electrical charge produced in either of the two chambers. When the source is in the well chamber the blue signal, cable is connected to the appropriate well chamber. When the source is in the leaded glass surround, for air kerma measurements, made with the Lamperti chamber, the PTW Unidose electrometer is used to measure the charge collected on the PTW QA chamber. The Data Socket Server file must be open on the startup menu on the XOFT control computer for this program to work. The

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WCCharge.vi program allows the user to enter in the number of data points desired to collect and the collection time. Generally, the data is collected every 6 seconds for 5 minutes. The data that are accumulated in rows include columns with the following information: the uncorrected (for temperature or pressure) charge, the collection time, the date, the time stamp, the temperature, the pressure, the calculated temperature and pressure normalization factor, and finally the corrected charge. The output files are saved as ".txt" files and are imported to Excel spreadsheets for analysis. The text files are named using a nomenclature of date, source ID and some counter. The well chamber data is then saved with the Lamperti chamber data on a spreadsheet identified by the source identification number. The PTW QA data is saved on the spreadsheet which contains all measurements per source ID. The PTW QA data is compared for each source in a series of measurements.

The charge measurements for the Lamperti chamber are acquired using a Keithley 6512 electrometer, using the data store option. There is no computer interface for this data collection. The charge data is entered by hand into Excel spreadsheets. The charge is collected, as well as the temperature and pressure, so that the air density and temperature and pressure correction can be applied. The charge is collected at a source to center of the Lamperti chamber distance of 54 cm and at 52 cm so that the inverse square difference can be determined. This agreement is ideally around 1 %; if it is greater than 2 %, then the source needs to be realigned with the lasers. The distance of 52 cm is used because the air attenuation measurement is made at these two distances and the inverse square calculation between these two distances should be determined so that the geometry can be evaluated. The charge is also collected at angles of 0 degrees, 120 degrees and 240 degrees; see Fig. 11 for source rotation details. There are marks on the Lucite source holder which align the source at each position. The leakage electrical charge is determined in the Lamperti chamber at the beginning of the measurement set and the later charge collection measurement sets are adjusted for the leakage. The charge is also determined for the air attenuation determination measurements. See Appendix B for a sample spreadsheet of the data collected. This example shows only a small sample as a guide for the format. In addition to the data for the air kerma, air-attenuation determination, inverse square data and angular measurements, the well chamber and the PTW QA data are also maintained on the sheet identified by the source ID. All data collected is saved in the appropriate files located in the group server in the L:\internal\846.02\xray\calibrationreports\chamberhistory folder. The files are organized and named by model and serial number. Similarly, the data collected using the customer chamber and the associated files and the final calibration or proficiency report is saved in the group server L:\internal\846.02\x*ray*/*calibrationreports*/*proftest*/*xoftPT*. The internal server has routine backups.

HPGe spectrometer

1. Open the Canberra software found on the desktop computer in H116.

2. Select Gamma Acquisition and Analysis in Startup.

3. Select file, open DATAsource, select detector, DET1USB, open, clear, preset 100 then start. Only use the SAVEAS when saving files.

4. On Exit, NEVER save changes. One spectrum is typically saved for each angle used. The output files are saved as ".cnf" files. The files are named using a nomenclature of date, angle and counter, for example 219901 means February 19, 90-degree position and the first file created.

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XOFT Labview operating procedures on the Xoft control computer

1. Secure source in the appropriate measurement position, either in the well chamber or the airkerma position, which is in the leaded glass enclosure.

2. Follow the procedures for cooling and energizing the source.

3. Open the Labview application named EXPERT, which is located on the desktop in the upper right corner.

4. Open the datasocket server on the desktop in the upper right corner.

5. Once the Expert icon is clicked then the Manufacturing Test Fixture application opens to the MTF Logon window.

6. Enter Username: Expert and Password: XOFTexpert not case sensitive, then log on

7. Then numerous Manufacturing Test Fixture Administrator windows will open. The EXIT and TEST button should be selected on most.

8. Select YES for the zero electrometer; the PTW will take about 1 minute to zero

9. STOP at the MTF V&V Test C Setup and select MTFV&V test C setup MM10 hrs

10. Verify that the interlocks are all illuminated to left of screen and on the control box.

11. On final window select Test Type: select V&Vtest C

12. Enter Tube ID.

13. Toggle between Set ID and type for Test and Run Test to energize source.

14. If entrance to the radiation area is required for repositioning of equipment, for example during the inverse square and the air attenuation measurements, the source must be de-energized or ramped down for safe entrance. This is accomplished by selecting Abort Test. The selection will allow voltage to be removed from the source and a safe entrance, without exiting the entire Labview program. Once the repositioning is complete then repeat step 13.

15. If the source is being de-energized and no additional source will be used and the software is being exited then the Abort Test button should be selected twice and the Exit option should be selected.

Procedure for charge collection in a well chamber

1. Connect the blue tri-axial signal lead to the correct well chamber and the Unidose electrometer.

2. Connect a prepared source to the cooling tubes and HV connector. Insert in the well chamber.

3. If the well chamber in use is NOT the NIST QA (A080851) well chamber then verify that the safety interlock is made for the NIST QA well chamber. This means place a voided source in the NIST QA well chamber.

- 4. Follow procedures for using the cooling medium flow pump.
- 5. Follow procedures for energizing the source.
- 6. Run the application WCCharge.vi as directed in the electrometer data acquisition procedures.

7. Use the average charge collection to determine the NIST calibration coefficient in units of Gy/(A s) normalized to reference conditions of 295.15 K and 101.325 kPa.

Environmental parameters procedures

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WELL-IONIZATION CHAMBER	CALIBRATION WITH ELECTRONIC BRACHYT	HERAPY SOURCES

During all calibrations, the laboratory temperature must be maintained between $22^{\circ}C \pm 2^{\circ}C$ and stable to $\pm 0.1 \,^{\circ}C$ for typical measurement sets of 10 minutes. If the temperature is unstable during a typical measurement set, calibrations should be postponed. The laboratory humidity should be maintained between 20 % and 50 % relative humidity. Since the pressure is monitored and the charge data is normalized to pressure it is good laboratory practice to postpone data collection and calibration work during sudden changes in pressure due to storms or weather fronts. If the pressure reading is stable during the calibration collection time, the measurements can continue. The pressure should be monitored and the influence on the normalization factor should be considered.

Uncertainty Analysis

The method of uncertainty assessment follows the NIST policy of expressing uncertainty, as outlined in the NIST Technical Note 1297 [6]. Conventional statistical estimates are given as standard deviations of the mean, and are designated as "Type A", which can be considered objective estimates based on statistical analysis. All other uncertainty estimates, which are designated "Type B," are subjective estimates, based on extensive experience and scientific judgment. The "Type B" uncertainties are estimated to correspond approximately to one standard deviation. The Type A and Type B estimates are combined per the usual rule for combining standard deviations, by taking the square root of the sum of the squares, the quadratic sum. The quadratic sum of the two types of uncertainty is then considered to be the combined standard uncertainty, which is in turn multiplied by a coverage factor, of two, to give the expanded uncertainty. This expanded uncertainty is considered to have the approximate significance of a 95 % confidence limit. Table 3 lists the details of the assessment of uncertainty for the air kerma rates determined for the Xoft S700 x-ray beams by the free-air ionization chamber. No uncertainty component is provided for the distance since the air kerma measurement is made at a fixed distance and the uncertainty in the determination of that distance is considered negligible. The positioning of the source is determined by the laser and the ability to align the source to the laser, the uncertainty of which is also considered negligible. Table 4 lists the details of the assessment of uncertainty of the calibration coefficient determined with the calibration of a typical well-ionization chamber. No uncertainty component is included for the positioning of the source inside the well chamber. This uncertainty is negligible as any positioning variation is determined by the source positioning insert. As the estimates of uncertainty vary lightly with sources, methods of measurement, and rate, in each case the largest value is used for the estimate. In an official calibration, measurements could be repeated to maintain optimal conditions.

Safety

The main safety consideration is radiation protection as the typical air-kerma rate at the front face of the Lamperti Chamber is 2×10^{-4} Gy/s. As described below, every effort is made to avoid any possibility of radiation exposure, even though it would be highly unlikely that serious exposures could occur accidentally. All radiation areas in the building are marked with striped tape and dosimeters must be worn by all personnel entering posted areas. Another safety consideration is exposure to high voltage,

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such as exists on the standard chamber during calibration. There is no danger of high voltage related to the x-ray generator because the equipment in use has no exposed high voltage in a normal operating mode. Another safety concern, for which there is a separate safety protocol, is the risk from the liquid nitrogen used to cool the high-purity germanium (HPGe) detector.

Radiation safety

The electronic brachytherapy calibration facility was designed to eliminate any possible exposure to x radiation. Details are listed in the safety protocols posted in the facility. The miniature x-ray tube is interlocked with its power supply in such a way that if the tube is removed from the well chamber measurement position, the high voltage will not be applied. A red-light signal illuminates when the power is on the x-ray source. An interlock barrier prohibits entry into the radiation area. If the electronic eye is tripped, the voltage is removed from the source. Both safety features are seen in Fig 15. A radiation warning light at the control panel turns on when voltage may be applied to the source. The entrance and shielding walls separating the control area from the radiation area, where the x-ray tube is located, are clear, leaded glass, providing radiation shielding while allowing for verification that no person is inside the radiation area.

High-voltage safety

The only danger that exists from high voltage comes from the free-air ionization chamber which operates at 3000 volts and the PTW QA and well chamber, which operate at 300 volts. All voltage applications use safe high voltage connectors with appropriately rated cable, RG59 for the free-air ionization chamber and triax for the ionization chambers operated at 300 volts. To prevent dangerous electric shock, almost all power supplies contain current-limiting resistors in the high-voltage circuit. Common sense and education are dictated when working around chambers that have exposed high-voltage electrodes; any electric shock must be reported to Group leader.

Cryogenic safety

The safety protocol, *Operation of High-Purity Germanium (HPGe) spectrometer liquid nitrogen cooling systems*, is posted in the facility. HPGe spectrometers are cooled by liquid nitrogen auto-fill systems. These systems include a cryogenic storage tank, fill timing device, overflow sensor, and solenoid valve. The posted protocol describes the safety and operational procedures to be followed when using the liquid nitrogen cooling systems of the HPGe spectrometer in 245/H116.

Filing and Retention

The RPD Quality Manager shall maintain the original and all past versions of this RPD Procedure. Copies of the current revision of this Procedure shall be placed in controlled Quality Manuals. Electronic copies of this Procedure are uncontrolled versions.

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Description	Model	Serial number
Lamperti free-air chamber		
Fluke (Hart) thermometer	1504A	9A183
Thermistor probe	5611	071030708
Keithley electrometer	6512	0664954
Keithley electrometer	6514	1218748
Setra barometer	370	3781741
Bertan high-voltage power supply	230-03R	73031-1-A05384
Bertan high-voltage power supply	230-05R	73151-1-A01025
Axxent HVPS		040108-006
Axxent S700 source connector	876-0207-100D	042110-06
Axxent source connector	600805	020514-012
NI controller	NI PXI-1033	136B8AD
Xoft high-voltage power supply	StellarTech	888-0431-000
Xoft controller	XTC-03	7(M-0803)
Xoft interlock controller		9
Canberra HPGe spectrometer	ULD010010FG	12088412
PTW Unidos E electrometer	T10010	00456
PTW ionization chamber	TN34013	00115
Axxent vacuum pump	E500	800193
HDR Axxent x-ray sources	S700	various
Connector lubricant	MS-383H	
Variable flow chemical pump	Fisher Scientific	140519344
MasterFlex LX Pump	07554-90	K16000548
Standard Imagining well-chamber	HDR 1000Plus	A080851
Xoft source holder		V050640

Table 1. Essential equipment to conduct calibrations in the electronic brachytherapy calibration range

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Calibration Order Information					
Required	Dates	Optional Dates			
PO received		Estimated job start			
Estimated completion		Equipment arrival			
Report mailed		Inspection complete			
Equipment returned					

Contact Information					
NIST Technical Contact: Michelle O'Brien x2014					
Company:					
Technical Contact:					
DG Number:					

Instrument Description					
Manufacturer Standard Imagining	Model HDR1000Plus	Serial Number			

Calibration Request and Cost					
SP 250 Cal ID 46012C	Item Description Well-Ionization Chamber	Qty 1	Cost for this Cal ID \$	TOTAL	
46013C	Each additional Source	1	\$		

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Chamber for the Aon Axxent source at 50 KV, shown in 70							
		Relative standard					
		uncertainty, %					
Component	For:	Type A	Type B				
0 1	net charge or current	SQ^{a}, SI^{a}	0.06				
$Q_{\rm net}, I_{\rm net}$	typical value	0.14 ^b					
W/e	mean energy per ion pair	-	0.35				
ρ_0	air density	0.01	0.08				
$V_{ m eff}$	effective volume	0.04	0.01				
kion	ion recombination	0.1					
khumidity	humidity of air		0.03				
k _{att}	attenuation	0.13	0.01				
kel	electron loss	-	0.04				
$k_{ii}k_w$	initial ion mean energy per ion		0.02				
	pair						
ksc	photon scatter	-	0.02				
$k_{ m fl}$	fluorescence reabsorption	-	0.02				
$k_{\rm br}/(1-g)$	effects of bremsstrahlung	-	0.02				
k _{dia}	diaphragm scatter	-	0.10				
<i>k</i> _d	electric field distortion		0.20				
	aperture penetration	negligible					
	chamber face penetration	negligible					
	polarity difference	0.02					
Combined	air kerma	0.22	0.420				

Table 3. Estimated relative standard uncertainties for the determination of air kerma with the Lamperti chamber for the Xoft Axxent source at 50 kV, shown in %

^a Determined as the standard deviation of the mean of the measurement.

^b Typical value for numerous S700 sources measured in 2013/2014.

Table 4. Estimated relative standard uncertainties for well chamber calibrations, shown in %

		Relative standard		
		uncertai	nty, %	
Components	For:	Type A	Type B	
	net charge or current	SQ^{a}, SI^{a}	0.06	
$Q_{\rm net}$, $I_{\rm net}$	typical value	0.32 ^b		
$ ho_0$	air density	0.01	0.08	
k _{humidity}	humidity of air		0.03	
	uncertainty of air kerma from	0.22	0.420	
	Lamperti chamber			
combined	air kerma calibration	0.386	0.3433	
	coefficient			

^a Determined as the standard deviation of the mean of the measurement.

^b Typical value for numerous S700 sources measured in 2013/2014.

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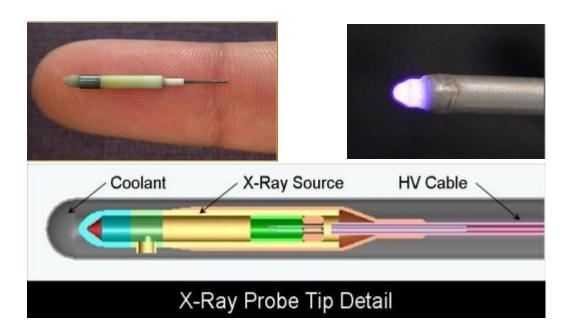


Figure 1a. The Xoft Axxent miniature x-ray source tip detail.

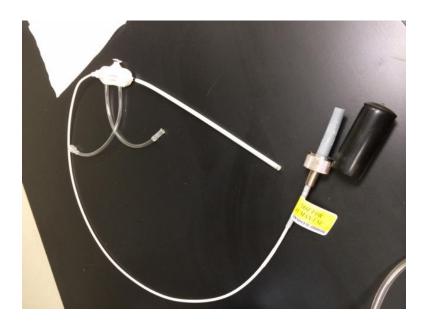
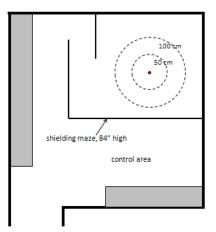
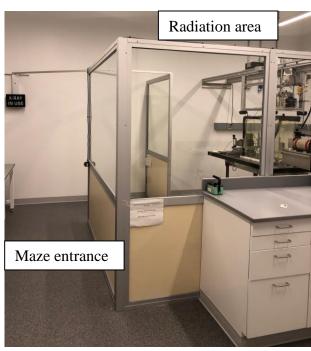


Figure 1b. The Xoft Axxent miniature x-ray source catheter enclosed and HV connector.

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Operator's control area

Figure 2b. NIST facility showing lead glass enclosure.

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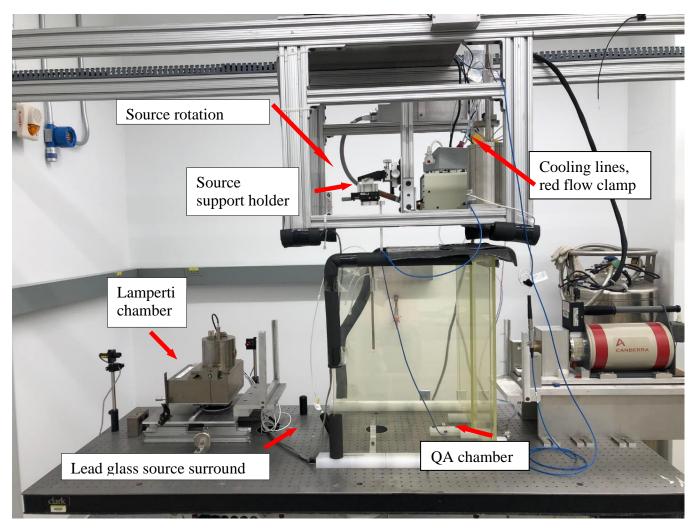


Figure 3. Low Scatter Measurement set-up with the Lamperti FAC.

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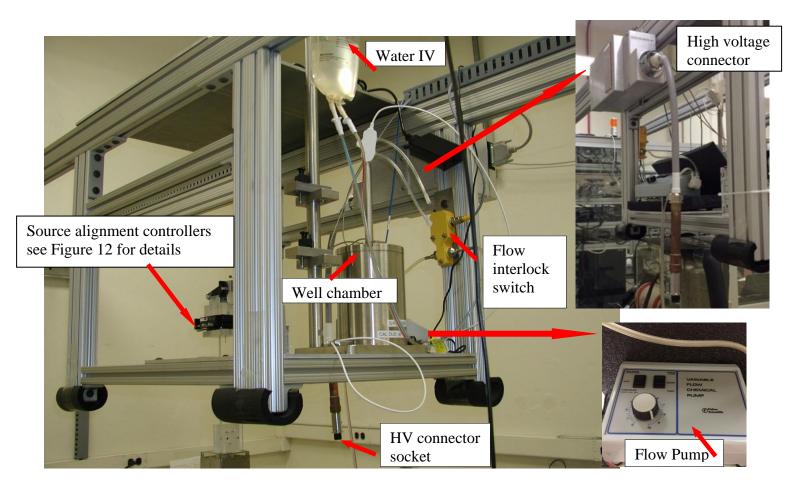


Figure 4. Well-chamber platform with water IV bag, flow pump, which is hidden behind well chamber in large picture so shown in smaller picture, flow interlock and HV connector, also hidden so shown to right.

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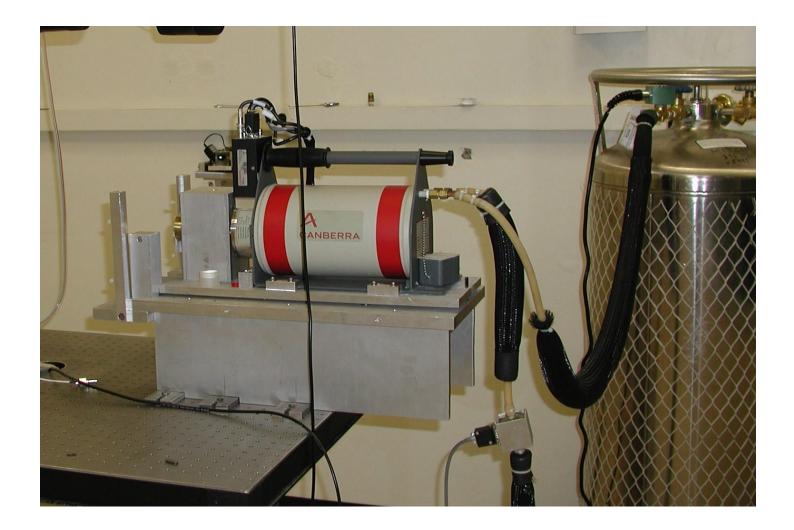
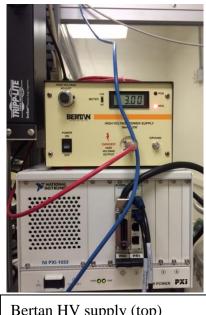


Figure 5. High-purity germanium detector with cooling Dewar.

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Bertan HV supply (top) Labview controller (bottom)

Figure 6. Essential rack mounted equipment.

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Figure 7. Barometer, thermometer and well-chamber electrometer.





Figure 8. Front and back view of the electrometer used with the Lamperti chamber. Back view shows required tri-axial hook up.

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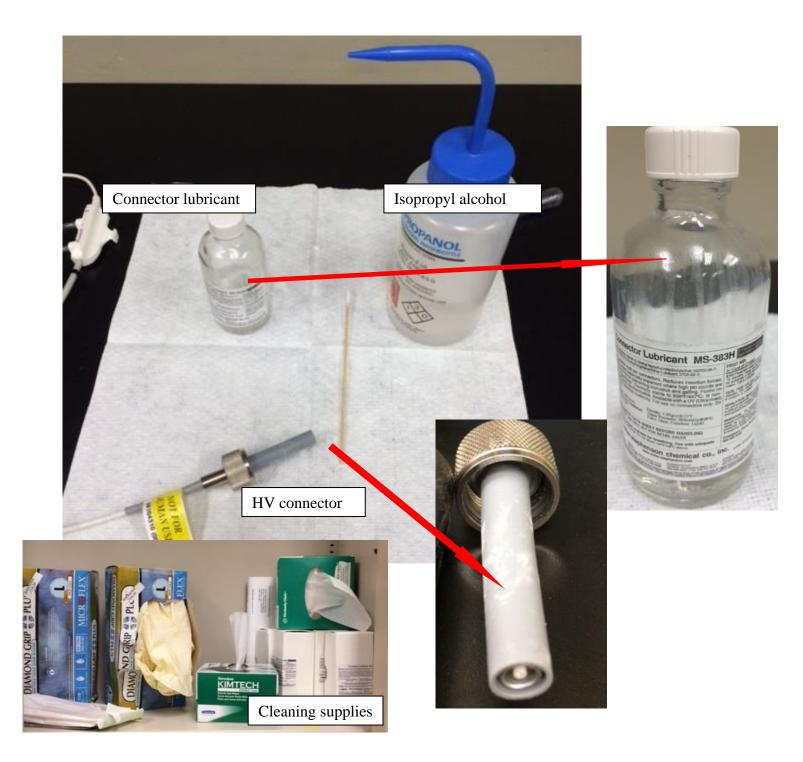


Figure 9. Supplies for cleaning HV connector

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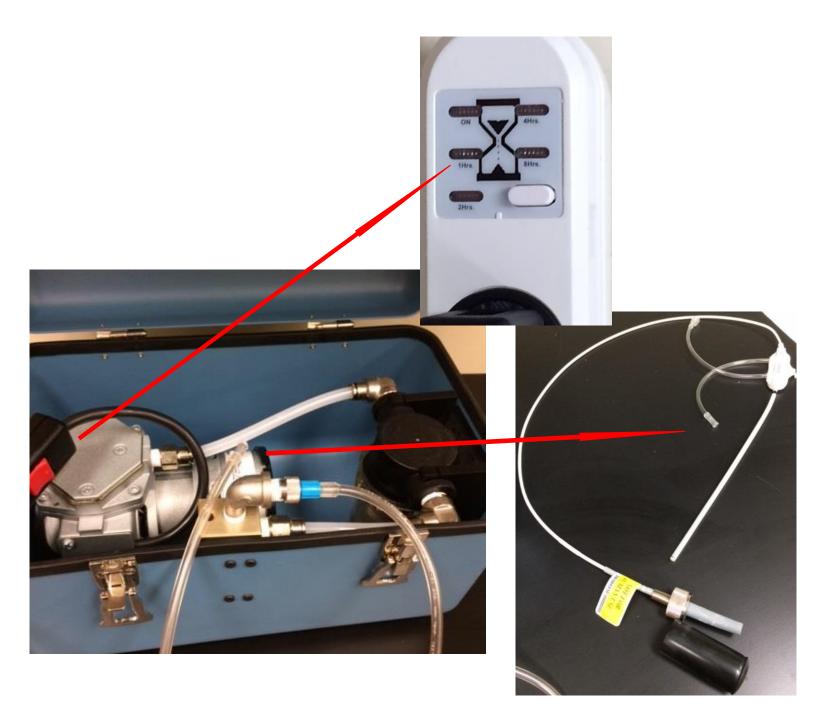
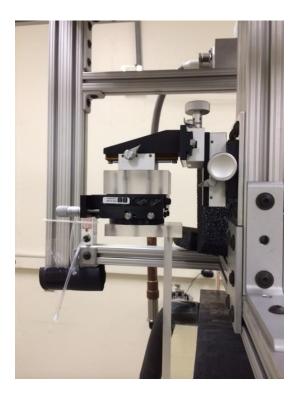


Figure 10. Vacuum pump and drying details.

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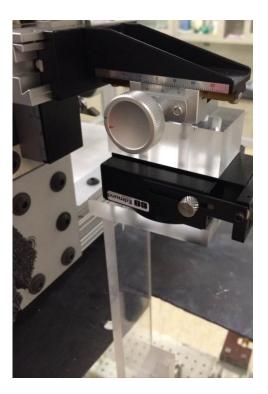
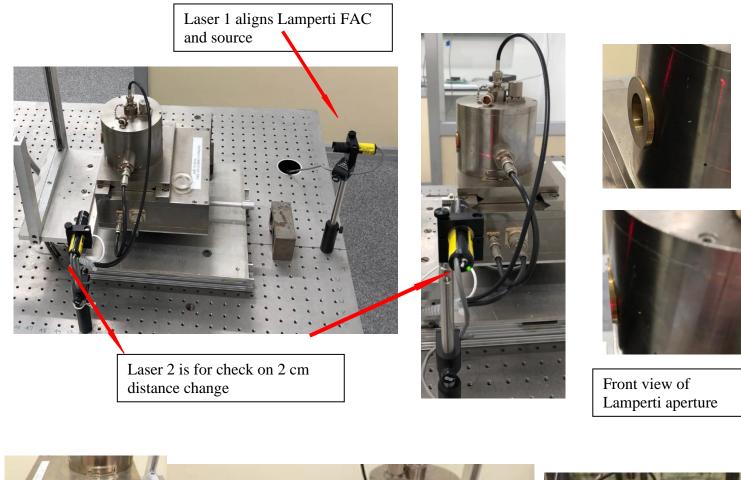


Figure 11. Side views of alignment and rotation adjustments for the source holder.

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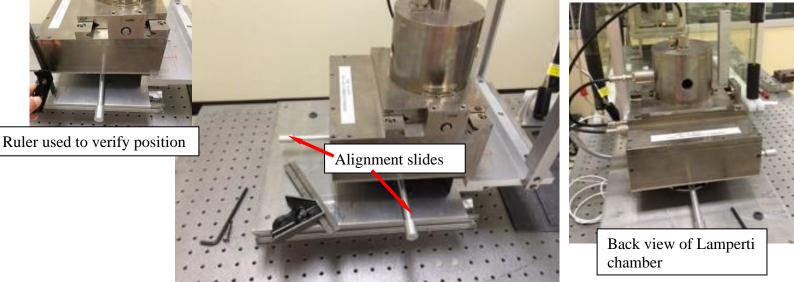


Figure 12. Techniques for Lamperti chamber and source alignment

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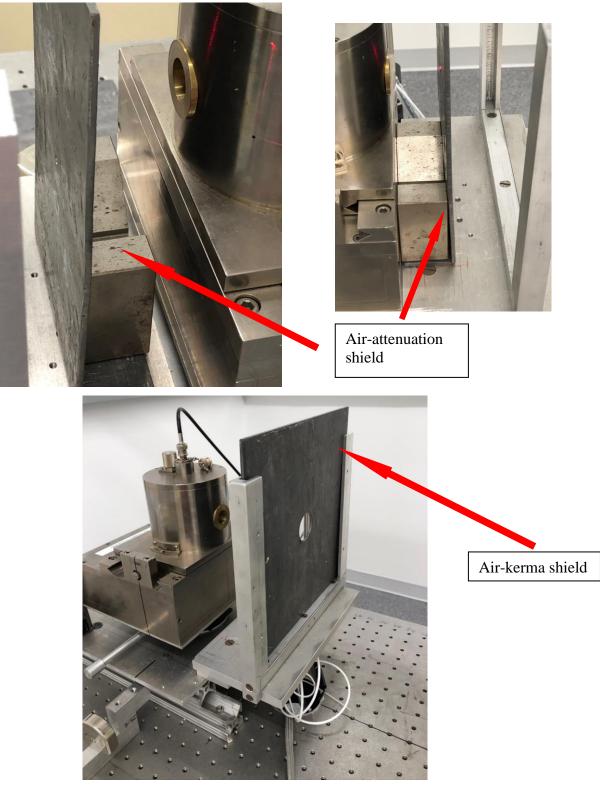
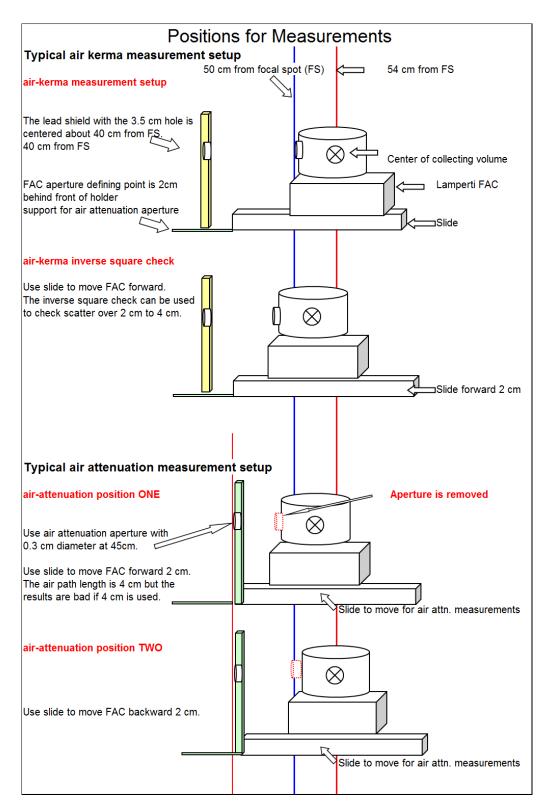


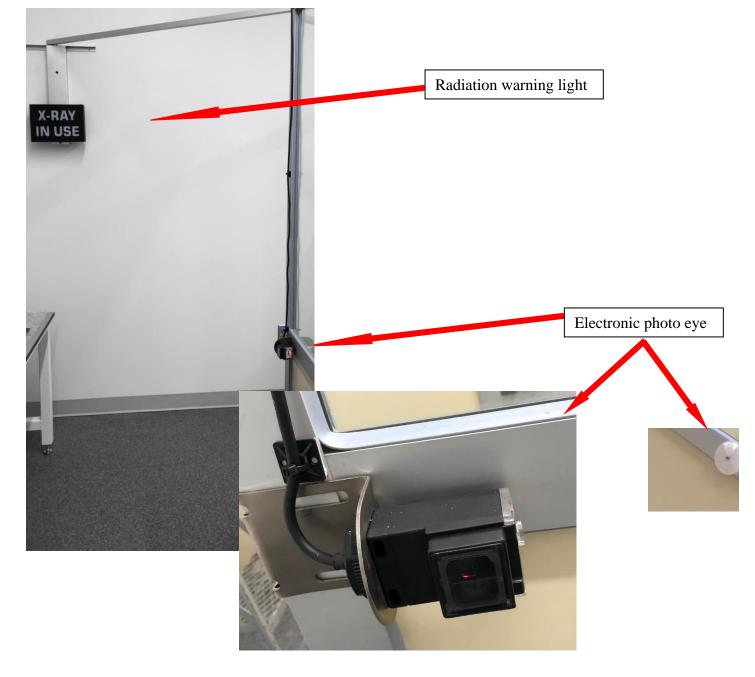
Figure 13. Lead shields used for air-kerma and air-attenuation measurements

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Figure 15. Two radiation safety interlocks.



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Appendix A: Sample Calibration Report

REPORT OF AIR-KERMA CALIBRATION(a)

OF

Name and complete postal address (f)

(p)

Calibrations performed by Michelle O'Brien

Report reviewed by Ronaldo Minniti

Report approved by Michael G. Mitch, Dosimetry Group Leader

James M. Adams Chief of the Radiation Physics Division Physical Measurement Laboratory For the Director of the National Institute of Standards and Technology

Information on technical aspects of this report may be obtained from Michelle O'Brien, National Institute of Standards and Technology, 100 Bureau Drive Stop 8460, Gaithersburg, MD 20899, <u>michelle.obrien@nist.gov</u>, or (301) 975-2014. *Report format revised 12/19* (b,c) Official NIST letterhead is used.

Dosimetry Group Number DG:####-yr NIST ID 46012C and 46013C Order Number: 682.02/O-0000000###-yr (d) Report Date: 00/00/20yr(l) Page 1 of 3(e)

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REPORT OF AIR-KERMA CALIBRATION

OF

address

Radiation Detection Chamber:

Standard Imaging Model HDR1000 Plus (S/N A#######) with the Xoft Source Holder (V#######) Ref ##### Xoft Axxent S700 Sources: #####

(h to k)

Calibration Conditions

Well Chamber: Standard Imaging Model HDR1000 Plus (S/N A043636) with the Xoft Source Holder (V112651) Ref 70088 at a collection potential = +300 V to measure negative current.

Electrometer used for well chamber at NIST: PTW Unidos E SN T10010-00456

The following conditions were used when the sources were energized. All conditions were set and controlled automatically by the Xoft control software.

Xoft Controller settings: Tube voltage was 50 kV and the beam current was 300 µA.

Calibration date: Month/day/year

Temperature range: 294.24 K (21.1 °C) to 295.22 K (22.1 °C) **EXAMPLE**

Pressure range: 99.956 kPa to 100.471 kPa EXAMPLE

The results relate only to the instrument calibrated in this report. (m)

Xoft Axxent Source Results and Conditions (Data presented here as examples of quantity.)

Xoft Source	NIST Air-Kerma Rate at 50 cm (Gy/s)	Xoft Controller Filament Current (A)	NIST Calibration Coefficient 295.15 K (22 °C) and 101.325 kPa (1 Atm) (Gy/s/A)	Uncertainty Type A sQ ^a
#####	1.95E-04	1.403	1.713E+03	0.14 ^b
#####	1.67E-04	1.335	1.674E+03	0.14 ^b
#####	2.11E-04	1.367	1.754E+03	0.14 ^b

^a Determined as the standard deviation of the mean of the charge measurement.

^b Typical value for numerous S700 sources measured in 2013/2014.

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Explanation of Terms Used in the Calibration Procedures and Tables (o) <u>Air Kerma:</u> (g)

The air-kerma rate at the calibration position is realized by a free-air ionization chamber for x radiation and is expressed in units of grays per second (Gy/s). (m) This realization of the air kerma establishes the National standard for air kerma, which can be transferred through a suitable measuring instrument, thus establishing traceability to the National standard. For a free-air ionization chamber with measuring volume V, the air-kerma rate is determined by the relation:

$$\dot{K} = \frac{I}{\rho_{\rm air}} V \frac{W_{\rm air}}{e} \frac{1}{1 - g_{\rm air}} \prod_{i} k_{i}$$

where

 $I/(\rho_{air}V)$ is the ionization current, measured by the standard, divided by the mass of air in the measuring volume

 W_{air} is the mean energy expended by an electron of charge *e* to produce an ion pair in dry air; the value used at NIST is $W_{air}/e = 33.97 \text{ J/C}$

 g_{air} is the fraction of the initial kinetic energy of secondary electrons dissipated in air through radiative processes; the value is 0.0 (negligible) for x rays with energies less than 300 keV, and

 $\prod k_i$ is the product of the correction factors to be applied to the standard.

<u>Calibration Coefficient</u>: (g,m,o) The calibration coefficients given in this report for the well chamber are quotients of the air-kerma rate (Gy/s) per ampere collected in the well chamber. The measurements are normalized to a pressure of one standard atmosphere (101.325 kPa) and a temperature of 295.15 K ($22 \circ C$). No correction is made for the effect of water vapor on the instrument being calibrated. The average current used to compute the calibration coefficient is based on measurements with the well chamber at the stated polarity and potential. (q) The calibration coefficients listed in this report can be used to calculate the air kerma through the use of the calibrated test instrument in calibration conditions that approximate those used at NIST, using the same source.

<u>Uncertainty</u>: (n) The expanded, combined uncertainty of the calibration described in this report is 0.86 %, of which 0.71 % is assigned to the uncertainty in the air-kerma rate of the NIST beam. The expanded, combined uncertainty is formed by taking two times the square root of the sum of the squares of the standard deviations of the mean for component uncertainties obtained from replicate determinations, and assumed approximations of standard deviations for all other uncertainty components; it is considered to have the approximate significance of a 95 % confidence limit. Dosimetry Group Number DG:#####-yr

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Appendix B: Sample Calibration Spreadsheet

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	Coloulation of Air Korm	a with the Lor	mnorti Chambor									
	Calculation of Air-Kerma	with the Lar	nperti Champer			Dim						
	DATE:		i				ensions					
	xoft value U:	/	1		FA	C center (cm)	•	ka:	u:	u/p:		
	amps	/	4			Airpath (cm)		measured	and calculat	ad values		
	inverse square difference	,I	1			ire Diam. (cm)						
	NIST WC	,/	1		C	Collector (cm)): 1.01346					
	%stdev	/	L									
	customer WC	, ,				corr	rections					
	%stdev	,	(,	ka	a: 1.0087					
	air kerma 0 degree	, —,	1		,	u/p	-					
	120 degree	<i>,</i>	i			Kp		+				
	240 degree	·+	1			Kbr		-				
		/	l		!							
	AVG air kerma	,/	1			Kh						
	%stdev	,I	1			Kfl		l				
	AirKerma/NIST WC	,/	1		/	ke						
	AirKerma/white WC	,/	1		/	Ks						
	%stdev on charge	/	1			ki	ii 1.000					
						к	(I 1.000					
						Kper	n 1.000					
	typical entered data in p	urple	·	typical calcula	ated values in b	lue						
	air kerma											
Date	(C/s)	Temp	Pres	density	1/poV	exp(u/p*p*x)) corrections	Units -R/s	R/s	Gy/s no Ks	Ks	Gy/s
DATE	1.1381E-12	21.4867	751.914	1.19E-03	4238.1	1.0088	0.995007	3.8760E+06	0.0188	1.64E-04	0.9997	1.644E
D	hand entered data											
54cm	charge/60s	C/60 s			FAC 3000 volts	1						
• • • •	0.2055				leakage							
	0.2738	0.0683	0.00114		1.04							
	0.2738				1.44	0.4						
		0.0677	0.00113									
	0.4093	0.0678	0.00113		1.85	0.41						
	0.4771	0.0678	0.00113		2.22	0.37						
	0.545	0.0679	0.00113		2.52	0.3						
	0.613	0.068	0.00113		2.91	0.39						
			1.1381E-12		3.28	0.37						
			0.0011		3.69	0.41						
			0.17%		4.11	0.42						
This type	data collection is repeated	d multiple tim		ce and type c		0.25						
						0.20						
ur-kerama	x each of three angles(0.	120 and 240).	inverse square				5					
	a, each of three angles(0, ′ s kept on one spreadsheet						5					
All data is	kept on one spreadsheet	per source IE	D.				5					
All data is		per source IE	D.				5					
All data is Example o	kept on one spreadsheet	per source IE on, shown wi	D. vith typical data:	calculation an	nd air attenuatio		5					
All data is Example o This is a go	s kept on one spreadsheet of Inverse square calculation ood predictor of adequate so	per source IE on, shown wi ource geometr	D. ith typical data: iry. The agreemen	calculation an	nd air attenuatio ound 1%.	- 6.148E-1						
All data is Example o This is a go dist	s kept on one spreadsheet of inverse square calculatio ood predictor of adequate so airkerma	per source IE on, shown wi ource geometr dist2	D. vith typical data:	calculation an	nd air attenuatio							
All data is Example o This is a go dist 51.5	s kept on one spreadsheet of inverse square calculation ood predictor of adequate so <u>airkerma</u> 1.46E-12	per source IE on, shown wi ource geometr dist2 2652.25	D. /ith typical data: /ry. The agreemen ratio dist	calculation an it should be arc inverse	nd air attenuatio ound 1%. ratio kerma	-6.148E-15						
All data is Example o This is a go dist	s kept on one spreadsheet of inverse square calculatio ood predictor of adequate so airkerma	per source IE on, shown wi ource geometr dist2	D. ith typical data: iry. The agreemen	calculation an	nd air attenuatio ound 1%.	- 6.148E-1						
All data is Example o This is a go dist 51.5	s kept on one spreadsheet of inverse square calculation ood predictor of adequate so <u>airkerma</u> 1.46E-12	per source IE on, shown wi ource geometr dist2 2652.25	D. /ith typical data: /ry. The agreemen ratio dist	calculation an it should be arc inverse	nd air attenuatio ound 1%. ratio kerma	-6.148E-15						
All data is Example o This is a go dist 51.5 54	s kept on one spreadsheet of inverse square calculation ood predictor of adequate so <u>airkerma</u> 1.46E-12	per source IC on, shown wi ource geometr dist2 2652.25 2916	D. ith typical data: ry. The agreemen ratio dist 0.90955	calculation an it should be arc inverse	nd air attenuatio ound 1%. ratio kerma	-6.148E-15						
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Appendix C: Proficiency Test Requirements

General

The proficiency test for this measurement service complies with the NIST QMS ISO/IEC 17025:2017 Appendix F for proficiency testing. This sub-level quality document provides the details of the additional requirements of ISO 17043:2010 for this measurement service proficiency test program.

Design of proficiency testing schemes

The protocol for each proficiency test will include the following details, taken from QMI, Appendix F, but repeated here for thoroughness. Each participant will receive a personalized proficiency test protocol. A sample protocol is provided in this procedure with the required elements identified by the corresponding letter in red font.

- a) the name and location of the NIST *measurement service*;
- b) identification of the *proficiency testing* program manager and other personnel involved in the design and operation of the *proficiency testing* scheme;
- c) the activities to be conducted by NIST *collaborators* and the names and addresses of NIST *collaborators* involved in the operation of the *proficiency testing* scheme; collaborations do not exist for this proficiency test.
- d) criteria to be met for participation if applicable;
- e) the number and type of expected *participants* in the *proficiency testing* scheme;
- f) selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the specific *proficiency testing round*;
- g) a description of the range of values or characteristics, or both, to be expected for the *proficiency test items*;
- h) the potential major sources of errors involved in the area of *proficiency testing* offered;
- i) requirements for the production, quality control, storage and distribution of *proficiency test items*;
- j) reasonable precautions to prevent collusion between *participants* or falsification of results, and procedures to be employed if collusion or falsification of results is suspected;
- k) a description of the information which is to be supplied to *participants* and the time schedule for the various phases of the *proficiency testing* scheme;
- for continuous *proficiency testing* schemes, the frequency or dates upon which proficiency test items are to be distributed to *participants*, the deadlines for the return of results by *participants* and, where appropriate, the dates on which testing or measurement is to be carried out by *participants*;
- m) any information on methods or procedures which *participants* need to use to prepare the test material and perform the tests or measurements;
- n) procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and, where applicable, to determine their biological viability;
- o) preparation of any standardized reporting formats to be used by *participants*;
- p) a detailed description of the statistical analysis to be used;
- q) the origin, *metrological traceability* and *measurement uncertainty* of any *assigned values*;
- r) criteria for the evaluation of performance of *participants*;
- s) a description of the data, interim reports or information to be returned to *participants*;
- t) a description of the extent to which *participant* results, and the conclusions that will be based on the outcome of the *proficiency testing* scheme, are to be made public; and
- u) actions to be taken in the case of lost or damaged *proficiency test items*.

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Preparation of proficiency test items

The proficiency test well chamber must meet the stated stability specifications of the manufacturer. The well chambers have been determined appropriate for use through published comparison studies or history of use. The NIST *proficiency testing* calibrates each using the calibration procedure associated with this service. The NIST *proficiency testing* program uses the same acquisition and storage procedures as the calibration service. The well chamber procured for proficiency testing quality assurance chamber is dedicated to that purpose. The NIST *proficiency testing* program uses the same type chambers as are used for the calibration service. Upon the completion of the measurements at NIST, the original shipping container will be used to ship the chamber back to the customer.

Homogeneity and stability

As stated previously the stability and performance of the well chamber that is being used as the transfer standard must meet the published stability specifications. The performance of the well chamber is evaluated upon receipt according to the calibration procedure. After measuring the homogeneity and stability of the source in the primary standard according to the calibration procedure, the source is used to assess the reproducibility of the well chamber. The collected charge from the well chamber is statistically analyzed in the same manner as stated in the calibration procedure.

Only stable sources will be accepted for use by NIST. Since the NIST QA procedure requires stability for the well chamber measurements, any change in the reproducibility of a single source measurement above 0.2 % may require an investigation into the well chamber, support equipment or rejection of the source.

If the source completes the procedure at NIST with acceptable stability and is found to become unstable at the participant's facility, using the acceptable stability limits of the said facility, NIST should be notified and the source should be excluded from the measurement comparison. If a source expires during use, the facility should notify NIST. The results of the expired source during use would not be used. If the source expires at the conclusion of the measurement test, it is at the discretion of the participant to include the results. It is the choice of the participant to use source data that is above the 0.2 % level of reproducibility. The uncertainty component would need to be adjusted for the instability per source.

Statistical design

The same statistical design is used for the proficiency test data as is used for the calibration service. Each source is measured at least three times in each chamber by NIST and the average is used for the well chamber measurement. The standard deviation on the charge measurement is used in the uncertainty analysis. The proficiency test is a direct comparison of the measured calibration coefficients determined at NIST and the participating facility. The criteria for the comparison are established by the accreditation program, not by NIST. NIST will not provide the normalized error or the Z-score.

Assigned values

The calibration coefficient determined through the proficiency test process is clearly explained in the calibration service, the proficiency test protocol and the proficiency test report. The details are repeated here. The

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calibration coefficients for the well chamber are quotients of the air-kerma rate (Gy/s) per ampere collected in the well chamber. The air-kerma rate at the calibration position is realized by a free-air ionization chamber for x radiation and is expressed in units of grays per second (Gy/s). This realization of the air kerma establishes the National standard for air kerma, which can be transferred through a suitable measuring instrument, thus establishing traceability to the National standard. The calibration coefficients used for the proficiency test are revealed at the end of the test in the form of a report issued to the participant. Early disclosure of the results is not allowed.

Choice of method or procedure

The participant must have a linking traceable measurement of air-kerma in order to participate in a proficiency test. The participant agrees to use the well chamber provided by the source manufacturer. Using the participant's established measurement methods and procedures, the participant should provide NIST with the calibration coefficient(s) for the well chamber found at their facility for each source in units of air-kerma rate (Gy/s) at 50 cm per ampere.

Operation of proficiency testing schemes - Instructions for participants

The proficiency test is requested by the participant and the coordination of the test date is established on a mutually agreed upon schedule. The instructions for the test are provided in the test protocol.

Proficiency test items handling and storage

The sources and well chambers are stored in the laboratory where the test is conducted at NIST.

Packaging, labelling and distribution of proficiency test items

The packaging of the sources and the well chamber is established by the manufacturer who provides them for the test. Well chambers and sources must all have unique serial numbers which are documented in the NIST reports.

Data analysis and evaluation of proficiency testing scheme results

The data analysis and records are handled according to the calibration service. Evaluation of performance is conducted by NIST staff. The evaluation is limited to a direct comparison as a percent difference. Generally, NIST commentary is not provided, since that is left to the accrediting body which would analyze the results applying the established criteria. NIST would include, in the proficiency test report, commentary, where applicable, on an educational basis if the participant encounters complications.

Reports

The NIST **proficiency testing** report for each proficiency test will include the following details, taken from QMI, Appendix F, but repeated here for thoroughness. A sample NIST report is provided in this

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procedure with the required elements identified by the corresponding letter in red font. NIST **proficiency testing** reports include the following, unless it is not applicable, or the NIST *proficiency testing* program has valid reasons for not doing so:

- a) the name and contact details for the NIST *proficiency testing* program;
- b) the name and contact details for the coordinator;
- c) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report;
- d) an indication of which activities are performed by the *participant(s)*;
- e) the date of issue and status (e.g. preliminary, interim, or final) of the report;
- f) page numbers and a clear indication of the end of the report;
- g) a statement of the extent to which results are confidential;
- h) the report number and clear identification of the proficiency testing scheme;
- i) a clear description of the *proficiency test items* used, including necessary details of the *proficiency test item's* preparation and homogeneity and stability assessment;
- j) the *participants'* results;
- k) statistical data and summaries, including *assigned values* and range of acceptable results and graphical displays;
- l) procedures used to establish any assigned value;
- m) details of the *metrological traceability* and *measurement uncertainty* of any assigned value;
- n) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;
- o) assigned values and summary statistics for test methods/procedures used by each group of participants (if different methods are used by different groups of participants);
- p) comments on *participants'* performance by the NIST *proficiency testing* program and technical advisers;
- q) information about the design and implementation of the *proficiency testing scheme*;
- r) procedures used to statistically analyze the data;
- s) advice on the interpretation of the statistical analysis, only when applicable; and
- t) comments or recommendations, based on the outcomes of the *proficiency testing round*, only when applicable.

When it is necessary to issue a new or amended report for a *proficiency testing scheme*, the report includes the following:

- a) a unique identification;
- b) a reference to the original report that it replaces or amends; and
- c) a statement concerning the reason for the amendment or re-issue.

Communication with participants

The NIST calibration ordering system includes the option to request proficiency testing and provides the following details.

- a) documented eligibility criteria for participation;
- b) confidentiality arrangements; and
- c) details of how to apply.

If changes to the *proficiency test scheme* design or operation are required, the participant will be notified by email. If the results conclude in a performance that the participant needs to appeal, a retest will be offered at the

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expense of the participant, after an investigation by NIST and the participant. The participant must communicate the error of the previous test and the reason for the request to retest. If an error was made by NIST, the proficiency test will be repeated at no expense to the participant. If no reason is determined for poor performance, the test can be repeated at the expense of the participant.

The communication with the participant is documented in the data file associated with the proficiency test. If statements of participation or performance are issued by a NIST *proficiency testing* program, the statements will contain sufficient information as to not be misleading.

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Sample Protocol

PROFICIENCY TEST PROTOCOL FOR AIR KERMA MEASUREMENTS OF ELECTRONIC BRACHYTHERAPY SOURCES

For

A NIST proficiency test is being conducted to test the ability of your calibration facility to transfer a measurement of air kerma and to provide NIST traceability.

NIST Technical Coordinator (b): Michelle O'Brien

Laboratory Technical Contact (e): Name of Contact

Start Date of Test: Month, Year (k)

Anticipated Completion Date of Test: Month, Year (k)

Information on technical aspects of this measurement comparison may be obtained from (b) Michelle O'Brien, National Institute of Standards and Technology, 100 Bureau Drive Stop 8460, Gaithersburg, MD 20899, <u>michelle.obrien@nist.gov</u>, (301) 975-2014.

Report format 6/2020

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Scope, Method and Traceability (a, d, e, f, g and q)

This (e) single participant proficiency test has been requested by *Participant Name* to fulfill the testing requirement for accreditation body, if applicable. Three electronic brachytherapy sources (g) were evaluated using the NIST Lamperti primary free-air ionization chamber, and a NIST well chamber in the (a) NIST Electronic Brachytherapy facility in building 245, room H116. NIST determined the air-kerma rate in units of grays per second (Gy/s) for each source at a distance of 50 cm using the Lamperti chamber. (q) This realization of the air kerma establishes the National standard for air kerma, which can be transferred through a suitable measuring instrument, thus establishing traceability to the National standard. The NIST well chamber was used to measure the stability of the source output.

The criteria (d) for the test are the participant must have a linking traceable measurement of air-kerma. The well chamber to serve as a transfer instrument for the proficiency test has been provided by the manufacturer along with the sources. Using their established measurement methods and procedures, the participant should provide NIST with the (f) calibration coefficient(s) for the well chamber found at their facility for each source in units of air-kerma rate (Gy/s) at 50 cm per ampere. The measurements are normalized to a pressure of one standard atmosphere (101.325 kPa) and a temperature of 295.15 K (22 °C). No correction is made for the effect of water vapor on the instrument being calibrated. The average current used to compute the calibration coefficient is based on measurements with the well chamber at the stated polarity and potential. At the conclusion of the test, each calibration coefficient will be compared to the NIST calibration coefficient and the results will be provided as a percent difference from the NIST measured value. The results reveal the degree to which the participating calibration facility can demonstrate proficiency in calibrating a well-ionization chamber under the conditions of the said facility at the time of the test. The comparative results and the NIST uncertainty will be included in a NIST report issued upon the completion of the test.

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Conditions for the Chamber and Sources in the NIST Facility: (k and m)

All well chamber current measurements were normalized to one standard atmosphere and 22 degrees Celsius. Use of the chamber at other pressures and temperatures requires normalization of the ion currents to these reference conditions. The average current used to compute the calibration coefficient is based on measurements with the well chamber at the stated polarity and potential. The values of the calibration coefficients were determined using the procedures outlined in the NIST quality measurement system for service ID 46012C.

Well Chamber used: Standard Imaging Model HDR1000 Plus (S/N ###) with the Xoft Source Holder (V112651) Ref 70088 at a collection potential of + 300 V to measure negative current.

Electrometer used for well chamber: PTW Unidos E SN T10010-00###

The following conditions were used when the sources were energized. All conditions were set and controlled automatically by the Xoft control software.

Geometry of measurements: If applicable, the angles relative to the FAC will be listed, however the average value will be used.

Environmental conditions of storage of sources while at NIST: The safe handling procedures of the manufacturer are used and the sources are kept at safe laboratory conditions between 20° C and 24° C and relative humidity < 50 %.

Xoft Source SN	Air-Kerma (Gy/s)	Filament Current (A)	Tube Voltage (kV) / Beam Current (µA)
924201	1.95E-04	1.403	50/300
914533	1.67E-04	1.335	50/300
914568	2.11E-04	1.367	50/300

Xoft Axxent Source Conditions

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Participant Shipping Address and Dates (b and u)

Following is the contact information required for the proper shipment of the well chamber and electronic brachytherapy sources. After the request for the proficiency test by the participant has been processed through the NIST payment system, an agreed upon date will be established for the shipment of the well chamber to NIST, at the owner's expense. At the completion of the NIST determination of the calibration coefficients for the sources with the proficiency test well chamber, the well chamber and the sources will be shipped to the participant, at the owner's expense. After the results have been provided to NIST electronically and NIST deems the test complete, the sources and the well chamber should be returned to the source manufacturer following instructions from Xoft. Instruments submitted for testing must be shipped in reusable containers.

The tracking abilities associated with the participant's shipper will be used to track the shipment of the sources and chamber from NIST. The participant selects the shipping insurance, and it is responsible for lost or damaged shipments. Since the duration of use of the sources has a limitation, this proficiency test is a single participant test.

Ship participant's well chamber to NIST:

Ship Date: month/day/year Shipped to: NIST 100 Bureau Dr. Bldg 245, Rm H116 Stop 8460 Attn: Michelle O'Brien Gaithersburg, MD 20899-8460 Phone: 301-975-2014 Email: michelle.obrien@nist.gov

Return participants's well chamber and sources to:

Ship Date: month/day/year Shipped to: complete address Email: Telephone:

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Initial Stability Check and Quality control of Sources and well chamber (i and n)

Only well-ionization chambers known to be stable and reproducible are accepted for use for proficiency testing. NIST performs stability checks involving redundant measurements in highly reproducible geometry prior to shipping the well chamber. The included chamber insert must be used by the participant.

Only stable sources will be accepted for use by NIST. Since the NIST QA procedure requires stability for the well chamber measurements, any change in the reproducibility of a single source measurement above 0.2 % may require an investigation into the well chamber, support equipment or rejection of the source.

If the source completes the procedure at NIST with acceptable stability and is found to become unstable at the participant's facility, using the acceptable stability limits of the said facility, NIST should be notified and the source should be excluded from the measurement comparison. If a source expires during use, the facility should notify NIST. The results of the expired source during use would not be used. If the source expires at the conclusion of the measurement test, it is at the discretion of the participant to include the results.

Format of Participant Results (o and r)

The participant should provide NIST with the calibration coefficient(s) for the well chamber found at their facility for each source in units of air-kerma rate (Gy/s) at 50 cm per ampere, normalized to 295.15 K ($22 \,^{\circ}$ C) and 101.325 kPa (1 Atm) limiting the value to significant digits. The equipment used for the measurement should be provided in a report with details to include the model and serial number of the well chamber, most recent calibration history, the bias potential and the electrometer identification. The date of the calibration, the complete uncertainty budget and a description of the geometry, should be included in the participant's results. The method the participant used to calculate the calibration coefficient should be included in the report.

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Format of Final NIST Report (s)

The results presented to the participant, at the conclusion of the test, will be in a table similar to that below. The NIST value for each source coefficient is an average.

Xoft	NIST Calibration Coefficient	Participant Calibration Coefficient	Difference
Source	295.15 K (22 °C) and 101.325 kPa (1	295.15 K (22 °C) and 101.325 kPa (1	in Percent
	Atm)	Atm)	
	(Gy/s/A)	(Gy/s/A)	
ID#	1.234E+03		-0.01
ID#	5.678E+03		0.23
ID#	9.101E+03		0.45

Comparative Results for the Well Chamber

The uncertainty provided for each source measurement is the type A determined as the standard deviation of the mean of the charge measurements. The expanded, combined uncertainty of the calibration described in the report is that assigned to the uncertainty in the air-kerma rate of the NIST beam using the FAC.

Confidentiality, Collusion and Falsification of Results (j and t)

The identification of the test results will stay confidential and secure on the NIST server, with limited access by the authorized quality management system (QMS) calibration staff. Summary reports may be published but the identification of the participant will be withheld. It is the responsibility of the participant to provide the proficiency test results to the accreditation organization. Collusion is prevented since sources with different ID's are used and the sources have limited lives and the well chambers have unique serial numbers. If collusion or falsification of the results is suspected then the test will be terminated, fees applied and another test, with an associated fee, will be required.

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Potential Source of Errors (h)

Differences in measurement geometry can contribute to errors. The stability during the life span of the source could contribute to errors. Failure to normalize data to 295.15 K (22 °C) and 101.325 kPa (1 Atm) will result in an error. The voltage output of the power supply for the source could contribute to an error in the test.

Statistical Design (d, p and r)

Each source is measured at least three times in each chamber by NIST and the average is used for the well chamber measurement. The standard deviation on the charge measurement is used in the uncertainty analysis. The proficiency test is a direct comparison of the measured calibration coefficients determined at NIST and the participating facility. The criteria for the comparison are established by the accreditation program, not by NIST. NIST will not provide the normalized error or the Z-score.

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Sample Report

FINAL REPORT OF PROFICIENCY TEST FOR AIR KERMA MEASUREMENTS OF ELECTRONIC BRACHYTHERAPY SOURCES

For Participant's complete mail address Xoft Sources: ID####, ID#### and ID#####

Calibrations performed by Michelle O'Brien (c)

Report technical review by Ronaldo Minniti (c)

Report approved by Michael G. Mitch, Dosimetry Group Leader (c)

James M. Adams Chief of the Radiation Physics Division Physical Measurement Laboratory For the Director of the National Institute of Standards and Technology

Information on technical aspects of this report may be obtained from Michelle O'Brien, National Institute of Standards and Technology, 100 Bureau Drive Stop 8460, Gaithersburg, MD 20899, <u>michelle.obrien@nist.gov</u>, or (301) 975-2014. (a,b)

Report format version 6/2020.

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Proficiency Testing Scheme (i, q)

Three electronic brachytherapy sources were recently evaluated for stability using a NIST primary freeair ionization chamber and the specified well chamber for this proficiency test. NIST determined the airkerma rate in terms of Gy/s for each source at a distance of 50 cm using the Lamperti chamber. The well chamber was used to measure the stability of the source output and served as a transfer instrument. After the shipment of the sources and the return of the well chamber to the participant, the measurements were repeated at their facility. The participant provided NIST with the calibration coefficients for the well chamber from measurements made at their facility for each source in units of the NIST air-kerma rate (Gy/s) at 50 cm per ampere and the associated uncertainty. Each calibration coefficient is compared to the corresponding NIST calibration coefficient. The results reveal the degree to which the participating calibration facility demonstrates proficiency in calibrating a well-ionization chamber under the conditions of the said facility at the time of the test. The air kerma values have all been adjusted due to changes to the air density correction which resulted in changes to the calibration coefficients. The results relate only to the instrument calibrated in this report.

Calibration Conditions at NIST

Well Chamber used at NIST: Standard Imaging Model HDR1000 Plus (S/N A######) with the Xoft Source Holder (V112651) Ref 70088 at a collection potential = +300 V to measure negative current.

Electrometer used for well chamber at NIST: PTW Unidos E SN T10010-00456

The following conditions were used when the sources were energized. All conditions were set and controlled automatically by the Xoft control software.

Xoft Controller settings: Tube voltage was 50 kV and the beam current was 300 μ A.

Calibration date: Month/day/year

Temperature range: 294.24 K (21.1 °C) to 295.22 K (22.1 °C)

Pressure range: 99.956 kPa to 100.471 kPa

Stability Assessment: Only stable sources are acceptable for the NIST proficiency test. The NIST QA procedure requires stability for the well chamber and primary chamber measurements; any change in the reproducibility of a single source measurement above 0.2 % may require an investigation into the well chamber, support equipment or rejection of the source.

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Xoft Source ID	NIST Air-Kerma Rate (Gy/s)	Xoft Controller Filament Current (A)	NIST Calibration Coefficient 295.15 K (22 °C) and 101.325 kPa (1 Atm) (Gy/s/A)	Uncertainty Type A sQ ^a
######	1.95E-04	1.403	1.713E+03	0.14 ^b
######	1.67E-04	1.335	1.674E+03	0.14 ^b
######	2.11E-04	1.367	1.754E+03	0.14 ^b

Xoft Axxent Source Conditions at NIST

^a Determined as the standard deviation of the mean of the charge measurement.

^b Typical value for numerous S700 sources.

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Participant's Calibration Conditions as reported by Participant (d, j)

Well Chamber: Standard Imaging Model HDR1000 Plus (S/N A######) with the Xoft Source Holder (V112651) Ref 70088 at a collection potential = +300 V to measure negative current.

Electrometer used for well chamber: Standard Imaging, Inc. Model Supermax S/N P111024

Calibration completion date: month/day/year

Xoft Source ID	NIST Calibration Coefficient 295.15 K (22 °C) and 101.325 kPa (1 Atm) (Gy/s/A)	Participant Calibration Coefficient 295.15 K (22 °C) and 101.325 kPa (1 Atm) (Gy/s/A)	Difference in Percent
######	1.713E+03	1.700E+03	-0.76
######	1.674E+03	1.679E+03	0.30
######	1.754E+03	1.773E+03	1.06

Comparative Results for the Well Chamber (k)

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Explanation of Terms, Establishment of Assigned Values and Metrological Traceability (m)

Air Kerma: The air–kerma rate at the calibration position is realized by a free-air ionization chamber for x radiation and is expressed in units of grays per second (Gy/s). This realization of the air kerma establishes the National standard for air kerma, which can be transferred through a suitable measuring instrument, thus establishing traceability to the National standard. For a free-air ionization chamber with measuring volume V, the air-kerma rate is determined by the relation:

$$\dot{K} = \frac{I}{\rho_{\rm air}V} \frac{W_{\rm air}}{e} \frac{1}{1 - g_{\rm air}} \prod_{i} k_{i}$$

where

 $I/(\rho_{air}V)$ is the ionization current, measured by the standard, divided by the mass of air in the measuring volume

 W_{air} is the mean energy expended by an electron of charge *e* to produce an ion pair in dry air; the value used at NIST is $W_{air}/e = 33.97 \text{ J/C}$

 g_{air} is the fraction of the initial kinetic energy of secondary electrons dissipated in air through radiative processes; the value is 0.0 (negligible) for x rays with energies less than 300 keV, and

 $\prod k_i$ is the product of the correction factors to be applied to the standard.

Calibration Distance: The calibration distance is that between the radiation source and the detector center or the reference line.

Calibration Coefficient: The calibration coefficients given in this report for the well chamber are quotients of the air-kerma rate (Gy/s) per ampere collected in the well chamber. The measurements are normalized to a pressure of one standard atmosphere (101.325 kPa) and a temperature of 295.15 K (22 °C). No correction is made for the effect of water vapor on the instrument being calibrated. The average current used to compute the calibration coefficient is based on measurements with the well chamber at the stated polarity and potential. The calibration coefficients listed in this report can be used to calculate the air kerma through the use of the calibrated test instrument in calibration conditions that approximate those used at NIST, using the same source.

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Statistical Design: (l, n, r)

Each source is measured at least three times in each chamber by NIST and the average is used for the well chamber measurement. The standard deviation on the charge measurement is used in the uncertainty analysis as the type A uncertainty component. The proficiency test is a direct comparison of the measured calibration coefficients determined at NIST and the participating facility. The criteria for the comparison are established by the accreditation program, not by NIST. NIST will not provide the normalized error or the Z-score.

Uncertainty: (m)

The expanded, combined uncertainty of the calibration described in this report is 0.86 %, of which 0.71 % is assigned to the uncertainty in the air-kerma rate of the NIST beam. The expanded, combined uncertainty is formed by taking two times the square root of the sum of the squares of the standard deviations of the mean for component uncertainties obtained from replicate determinations, and assumed approximations of standard deviations for all other uncertainty components; it is considered to have the approximate significance of a 95 % confidence limit.

Comments and advice: (p, s, t)

Generally, NIST commentary is not provided, since that is left to the accrediting body which would analyze the results applying the established criteria. The expectations are on the PT customer and their accrediting body to use the purchased PT report as they find necessary within their own quality system. The NIST PT results do not mean, and should not be implied to mean, evaluation, endorsement, or certification of commercial firms' products and services.

Confidentiality, Collusion and Falsification of Results

The identification of the test results will stay confidential and secure on the NIST server, with limited access by the authorized quality management system (QMS) calibration staff. Summary reports may be published but the identification of the participant will be withheld. It is the decision and the responsibility of the participant to provide the proficiency test results to the accreditation organization. If collusion or falsification of the results is suspected then the test will be terminated, fees applied and another test, with an associated fee, will be required.

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