CALIBRATION IRRADIATIONS OF CUSTOMER SUPPLIED DOSIMETERS WITH ^{60}Co GAMMA RAYS

Purpose

The purpose of this procedure is to describe the setup, measurement, and reporting procedures for irradiation of customer supplied dosimeters.

Scope

This procedure covers the irradiation of passive dosimeters in the NIST ^{60}Co Gammacell irradiators. The irradiator dose rates are comparable to those used in the radiation processing industry. Customer-supplied dosimeters are irradiated at prescribed temperatures and returned to the customer with an absorbed-dose irradiation certificate.

Definitions

Absorbed dose to water – the energy absorbed from ionizing radiation per unit mass of water: 1 J/kg = 1 Gy.

Gammacell User Log Book – for maintaining a log of every irradiation for each irradiator.

High-Dose Irradiations Databook – for maintaining a record of irradiations for each calibration job.

Single-hole vial geometry – the vial is made up of a polystyrene cylindrical cup with a screw cap and has a hole diameter slightly larger than the alanine pellets (5 mm) and a wall thickness of 3.7 mm. This is mounted on a polystyrene rod with a cavity for two quality control alanine dosimeters, which is mounted to a 6 mm thick polycarbonate base disk to locate the alanine pellets in the geometrical center of the radiation field of each irradiator. This provides a reproducible geometry as well as approximate electron equilibrium conditions.

Five-hole cup – A polystyrene cylinder with five equidistant holes, used for electronic equilibrium build-up material when irradiating tape tabs, perspex or ampoule dosimeters.

Tape tabs - Alanine pellets welded between two sheets of polyethylene terephthalate. Pellet remains within barcoded packaging when being measured using an EPR spectrometer providing full and constant traceability of the dosimeter.

Quality control (QC) alanine dosimetry – alanine dosimeters that are employed routinely to achieve and sustain a predefined level of quality.

Equipment

Essential Equipment	Calibration Method	Calibration Frequency
^{60}Co Vertical Beam Source	Water Calorimeter	See RPD Procedure 6
MDS Nordion Gammacell 45	Comparison to Vertical Beam Source	Determined by Control Charts
MDS Nordion Gammacell 232	Comparison to Gammacell 45 Source	Determined by Control Charts
Hopewell Designs, Inc. GR420	Comparison to Gammacell 45 Source	Determined by Control Charts
Platinum Thermometer	External Service	As Needed
Type-T Thermocouple	Comparison to Platinum Thermometer	As Needed
FTS ThermoJet Temperature Forcing System (controls sample temperature)	N/A	N/A
MPI ThermalAir TA5000A Forcing System (controls sample temperature)	N/A	N/A

Health and Safety Precautions

Radiation safety

Potential radiation hazards include contamination resulting from leakage of radioactive material from any of the ^{60}Co sealed sources and accidental external exposure of personnel to gamma radiation from the ^{60}Co irradiators.

The irradiators associated with this procedure are located in a controlled access space. Rooms containing ^{60}Co sources have been designated as High Radiation Areas. The doors to the facility are posted with cautionary signs to indicate the presence of radioactive materials. Whole body dosimetry is required for everyone entering the facility. Radiation safety training and assessment services are provided by the NIST Radiation Safety Division (RSD). Additional training is performed by the Radiation Facility Owner (RFO). Use of the facility must be arranged in advance with the RFO.

Authorized users are required to complete three training sessions. Two of these trainings are offered by RSD and must be taken annually. One is a general radiation training course while the second is specifically oriented to irradiator users. The third is a hands-on training session given by the RFO, which shall include hands-on demonstrations of the various operating modes of the irradiator. RFO-authorized source users are granted use of the facility after completion of all three sessions. The list of source users is maintained by RSD and kept up to date through submission of the NIST-365 form. Manipulation of the irradiator beyond that provided by the control panel shall be restricted to maintenance or other operations under the direction and supervision of the RFO.

A logbook shall be kept near each irradiator and shall contain the following information: date and time of usage; username, agency, division, and phone number; type of sample or purpose of use. All maintenance, testing, and abnormal behavior of the irradiator shall be recorded in the logbook.

Hazard Mitigation

Sources showing any evidence of leakage or contamination shall not be used. The potential for source leakage in each irradiator is minimal because the source is encapsulated in metallic shielding and welded shut. In addition, the source is fixed within the heavily shielded housing of the irradiator body. The RSD performs routine leak checks semiannually in all irradiators.

While unoccupied, the doors to the irradiator room are kept closed and locked. The Source Custodian trains all authorized users to perform the safety interlock/indicator checks and to record the results in the facility logbook. Users must inform the Source Custodian if any of the safety interlocks/indicators are not functioning as expected. If any of the interlocks/indicators do not function as expected, the operator cannot use the facility until the interlock/indicator is fixed/replaced.

Loading, unloading, or any repositioning of the source shall not be performed without RSD approval. The irradiator manufacturer or other person authorized by the Nuclear Regulatory Commission (NRC) or an Agreement State will perform non-routine operations such as source loading, unloading and repositioning, electrical troubleshooting of the control console, investigating/remediating removable contamination/leaking sources, (re)installing source cables, and other critical operations requiring special skills or involving the potential for radiation exposure.

Removal of the access panels shall only be allowed by personnel trained to operate and maintain the unit and only under the supervision of the RFO, following approval by RSD. If power is on there are electrical and radiation safety considerations associated with open panels.

Restrictions on the materials to be irradiated are necessary. Irradiation of the following materials is <u>prohibited</u>: explosives, corrosive liquids, radioactive or special nuclear materials, or materials that may give off toxic or corrosive fumes. No flammable materials shall be stored or used in the irradiator area.

During irradiation of liquid samples, an appropriate secondary container shall be provided in the sample chamber such that none of the liquid sample can spill or run out of the chamber. The volume of the secondary container shall be sufficient so as to account for expansion of the sample due to thermal heating and/or chemical reaction.

Emergency Procedures

REMEMBER: Whenever dealing with an emergency, the **SWIM** process should be used.

- Stop and Think – What should be done and how can it be done safely?
- Warn Others – Notify other workers for safe evacuation. Call for assistance immediately.
- Isolate – If appropriate, contain spills, shut down drains and/or ventilation, post warning signs and close off the area.
- Minimize – Move to safe buffer zone away from any direct hazards and minimize movement to prevent spreading.

Any indication of loss of source integrity shall be reported <u>IMMEDIATELY</u> to RSD (x5800) and the RFO

If a calibrated survey meter reading indicates that radiation is present inside the room: Immediately exit the irradiator area and call RSD (x5800, if no one answers call x2222) and the RFO. Wait inside the control area or in the hallway immediately outside the facility until help arrives. Prevent all personnel from entering the irradiator area.

In case electrical power is lost during drawer movement, the assembly will stop immediately at its current position. Verify with a survey meter located in the control area that there is no radiation present. If there is, immediately exit the irradiator area and call RSD (x5800, if no one answers call x2222). Wait inside the control area or in the hallway immediately outside the facility until help arrives. Prevent all personnel from entering the irradiator area.

In case an individual is exposed to high voltage, turn off the main breaker located in the control area and call x2222. Wait inside the control area or outside the facility until help arrives. Visit the NIST Health Unit as soon as possible.

If a fire alarm occurs in the building during operation, no actions are required with respect to the irradiator. The source user should exit the room/building as directed by fire safety personnel.

In case of fire or smoke in the irradiator facility, leave the laboratory immediately and call the NIST Fire Department (x2222), RSD (x5800), and the RFO.

In the unlikely event that the room floods or is otherwise invaded by water, no actions are required with respect to the irradiator. The source user should exit the room and report the incident to RSD (x5800) and the RFO and await further instructions.

If, at any time during an automatic cycle, it is necessary to interrupt the irradiation for any reason the user can press the "STOP" button on the irradiator. The chamber will immediately move to the upward position.

If the irradiator assembly were to stop during movement, completion of the stroke or emergency movement of the drawer assembly is possible by the use of a hand crank. Consult the irradiator manual for details. If this appears to be necessary, the RFO and RSD must be immediately notified and all activity shall cease until further instructions are given by the RFO and RSD.

If abnormal sounds are heard during drawer assembly movement: 1) Chatter and no motion of drawer assembly when the DOWN button is pushed. DO NOT PROCEED WITH THE IRRADIATION; INFORM THE RFO IMMEDIATELY; 2) Chatter and no motion of the drawer assembly when UP button is pushed. IF additional time will not ruin the irradiation in progress, leave the unit as is and call the RFO. If it is important to end the irradiation for programmatic or safety reasons, INFORM THE RFO IMMEDIATELY. THEN, UNDER THEIR SUPERVISION, REMOVE POWER FROM THE UNIT BY UNPLUGGING THE POWER CORD, and raise the drawer assembly with the manual crank; 3) Loud clanks or bangs on lowering or raising the drawer. INFORM THE RFO AT FIRST OCCURANCE.

Procedures

These are the general customer dosimeter calibration procedures. The Irradiation Facilities Record Book has the dose rates for irradiation geometries, laboratory instructions, and a record of maintenance of the facility maintenance.

Receive Customer Irradiations Inquiry

Upon customer inquiry, calibration service staff will evaluate whether the irradiation can be performed. Calibration service staff will direct customers to shop.nist.gov to place their order. Administrative calibration service staff can provide assistance in setting up a profile in the system. Quotes are not provided by calibration service staff and calibration fee information is updated on the e-commerce platform.

Receipt of Customer Order through shop.nist.gov
Upon receipt of a shop.nist.gov order, calibration service staff will evaluate whether the calibration service can be completed. If accepted, the calibration service staff will change the status to "Accepted" within the e-commerce platform. Calibration service staff will log the order in the Electronic Calibration Log Book with a unique HD number. An Electronic Test Folder (ETF) is created for record maintenance of the calibration order. Relevant documents from the e-commerce platform will be stored in the ETF. After confirmation from the e-commerce platform concerning the payment status, the customer will be notified by the calibration service staff to mail customer dosimeters to the NIST calibration service staff.

Receive/Store Dosimeters
Upon receipt of dosimeter(s) shipment from the customer, the package and contents will be inspected for any damage. If damage has occurred, follow Guide RPD-G07 and notify the customer. Dosimeters are kept in the Irradiation Facility with accompanying paperwork. Update the Electronic Calibration Log Book with dates and dosimeter details.

Establish a Dosimeter Calibration Service Plan
Prior to dosimeter(s) calibration, establish a Dosimeter Calibration Service Plan (DCSP) that will outline the specific actions and details for the completion of the calibration service. The DCSP includes a review of the previous customer jobs or jobs of similar geometry. The DCSP is reviewed by the Dosimetry Group Leader or designated staff member within the quality system to ensure that that the dosimeters are irradiated according to customer's specifications. The DCSP serves as a guide during the calibration service and is retained in the customer's digital test folder upon completion of the calibration services. Store a copy of DCSP in the ETF.

Initiate Irradiation Data Record
Configure the Excel spreadsheet Customer Calibration Template (see Appendix A) in accordance with the DCSP. The worksheet is saved under the HD Customer Irradiation folder under the unique HD number (referred to as HD Irradiation Worksheet). The header information includes the customer and dosimeter details. Once the geometry is selected, the corresponding base dose rate is retrieved from a master list and the irradiation time is calculated. The Timing Worksheet form (see Appendix B) is prepared with customer and dosimeter information. It is a written log with identical information as the HD Irradiation Worksheet.

Prepare Dosimeters for Irradiation

Prepare the dosimeters (alanine dosimeters, film dosimeters, or other previously calibrated customer supplied or NIST calibration geometry). For example, alanine dosimeters are packaged into single hole vial and film dosimeters are sandwiched between polystyrene plates. Arrange all labeled dosimeters in irradiation order with associated Quality Control (QC) pellets that are unambiguously labeled. Customer dosimeters will be placed in a labeled envelope or a bag after irradiation and the QC pellets will be placed in a separate labeled container. Except for the sample being irradiated, all customer samples, QC pellets and Timing Worksheet will be kept together. The calibration service staff changes the order status to “In Process”.

Control Sample Temperature

Samples are normally irradiated at ambient temperature, 22 °C to 25 °C. The GC45 does not require cooling to maintain ambient temperature. Compressed air is blown into the sample chamber of GC232 or GR420 to maintain ambient temperature. This is done by opening the valve of the flow meter mounted on the side of the appropriate Gammacell. Temperature is monitored with a type-T thermocouple placed inside the sample chamber. The type-T thermocouple is calibrated against the high-precision platinum thermometer in the Gammacell sample chamber (in the “up” position) over a temperature range that corresponds to service irradiations. The operational status of the thermocouple is monitored by periodic checks and control charts. Thermocouples that do not perform within the control limits are replaced. The thermocouple calibration protocol can be found in the Irradiation Facilities Record Book.

Start the temperature-recording computer program

Non-ambient temperatures can be achieved using a forced thermally-controlled air cycling system for the GC232 and GR420 for sample irradiation temperatures approximately between -75 °C to +75 °C.

Operate Gammacell

Operate the Gammacell(s) as prescribed for the safe operation of GC45, GC232, and/or GR420, see Appendix C. Log irradiation into Gammacell User Log Book for each irradiator.

Record Irradiation Data

Record all appropriate irradiation data before, during, and after each irradiation as needed to ensure accurate completion of a particular dosimeter irradiation on the customer’s Timing Worksheet form and the HD Irradiation Worksheet. The Timing Worksheet is digitized and stored in the ETF. The HD Irradiation Worksheet will be logged into the High-Dose Irradiations Databook.

Analyze Quality Control

The QC pellet doses are measured as described in Procedure RPD-P-12. If the measured dose is within control limits (±5 %), the quality check is successful.
If the measured dose is beyond the control limits, halt all irradiations. Notify the Dosimetry Group Leader and designated Calibration Service Staff. Start a detailed note in the ETF during the investigation into the source of the discrepancy. If the discrepancy cannot be resolved, the irradiations must be repeated. Summarize any issue and resolution in the summary of the ETF and include the record in the Irradiation Facilities Record Book (referencing the HD number and date).

Return Dosimeters

After all irradiations have been completed and QC pellets have been validated to be within control limits, the dosimeters are shipped back to the customer. The dosimeters are packaged appropriately to avoid any damage during transit. The HD Irradiation Worksheet copy is included.
Some dosimeters may have temporal readout requirements. Therefore, upon customer request, irradiated customer samples may be released with a partially completed HD Irradiation Worksheet. This will be outlined in the DCSP and noted in the ETF.

Issue certificate and close folder

Once the quality check is successful, write a report entitled “Absorbed-Dose Irradiation Certificate.” An example is shown in Appendix D. Reference to a previous customer report or the use of a template may be used in the preparation. Include an annotated draft of the certificate in the ETF. A checklist, found in Appendix F, for HD irradiation services is filled out and included in the ETF. The preparer sends the ETF and the electronic certificate for review. They are sequentially routed to the reviewer, Group Leader and Division Chief (as designated on the certificate) for review and an electronically certified signature. The certificate with the electronically certified signatures is returned to the preparer. The preparer submits the report to the e-Commerce platform and notifies the Calibration Administrative Staff of the completion of the work. The order status changes to “Completed”. Upon customer request, the preparer may send the electronic certificate by email or/and send a printed copy of the electronically signed certificate. The Administrative Staff will change the order status to “Closed”.

Determination of Uncertainties

The basis for the determination of uncertainties associated with high-dose irradiations is the *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results* [1]. The purpose of this section is to explain the derivation of the various components of uncertainty for absorbed-dose certification. The values for the uncertainty components are listed in Appendix E.

Water Calorimetry: This is the published uncertainty from realization of the gray (Gy) [2].

Source Ratio Data: This is the statistical determination of uncertainty from the measurement of ratios of electron paramagnetic resonance (EPR) signal response for water calorimetry geometry vs. Gammacell geometry.

Geometry Correction Factor: This is the statistical determination of uncertainty from the measurement of ratios of EPR signal response for single-hole vial geometry vs. film block, Perspex, or ampoule geometry.

Field Uniformity: This is a Type-B estimate of uncertainty for radiation field uniformity within a dosimeter volume.

Timer: This is a Type-B estimate of uncertainty for the timer readout relative to the shortest irradiation time interval.

Decay Correction: This is a Type-B estimate of uncertainty for the ^{60}Co half-life value.

Traceability

The SI unit of absorbed dose is the Gy. For this service, the Gy is realized through water calorimetry measurements in the Vertical Beam ^{60}Co Gamma-Ray Source [2]. Lower dose measurements are first transferred to GC45 and then higher dose measurements are transferred from GC45 to GC232 and GR420 calibration sources by source-rate ratio measurements using alanine dosimetry. These transfer measurement protocols were first described in the NIST SP250-44 and later partially revised as described in a NIST Journal of Research manuscript [3, 4]. All data and analysis is recorded in the Internal Calibrations Databook.

Upon mutual agreement, dosimetry comparisons are performed with the high-dose calibration facility of the National Physical Laboratory of the United Kingdom. Dosimeters from each facility are exchanged, measured, and the results compared. Larger (i.e., among more laboratories) international comparisons occur approximately every 10 years [5]. These data are summarized in the High-Dose International Comparisons Databook.

References

1. NIST Technical Note 1297, Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results, 1994.
2. Domen, S.R., A sealed water calorimeter for measuring absorbed dose, J. Res. Natl. Inst. Stand. Technol., 99, pp. 121 – 141, 1994.
3. Radiation Processing Dosimetry Calibration Services and Measurement Assurance Program, Humphreys, J.C., Puhl, J.M., Seltzer, S.M., McLaughlin, W.L., Desrosiers, M.F., Bensen, D.L., Walker, M.L. 1998 NIST Special Publication 250-44.
4. CCRI supplementary comparison of standards for absorbed dose to water in ^{60}Co gamma radiation at radiation processing dose levels, D.T. Burns, P.J. Allisy-Roberts, M.F. Desrosiers, V. Yu. Nagy, P.H.G. Sharpe, R.F. Laitano, K. Mehta, M.K.H. Schneider, Y. Zhang, Radiat. Phys. Chem. 75 (2006) 1087-1092.
5. Discovery of an Absorbed-Dose / Dose-Rate Dependence for the Alanine-EPR Dosimetry Systems and Its Implications in High-Dose Ionizing Radiation Metrology, M.F. Desrosiers, J.M. Puhl, S.L. Cooper, NIST J. of Res., 113 (2008) 79-95.
6. Radiation Processing Dosimetry Calibration Services: Manual of Calibration Procedures, J. C. Humphreys, M. F. Desrosiers, D. L. Bensen, J. M. Puhl, S. M. Seltzer, W. L. McLaughlin, M. L. Walker. 1998 NIST Special Publication 250-45.

Records

Record	Contents/Purpose	Location
Irradiation Facilities Record Book	Records dose rates for irradiation geometries, laboratory instructions, and a record of maintenance of the facility	245/Irradiation facility
Electronic Calibration Log Book	A HD number is assigned to all accepted orders and logs calibration details.	In the High Dose folder
Gammacell User Log Book for each irradiator	^{60}Co irradiator logs	245/Irradiation facility
High-Dose Irradiations Databook	Records all final HD Irradiation Worksheet	245/B0020
Internal Calibrations Databook	Source ratio measurements and data analysis	245/B0020
High-Dose International Comparisons Databook	Interlaboratory measurement comparisons data summaries	245/B0020

Filing and Retention

All paper copies of customer files are stored in the test folder for that service until they can be digitized and stored in ETF at which time it can be destroyed. The ETF is stored in OneNote. All customer-related electronic files are stored in the "High Dose" folder on the shared network drive. The Radiation Physics Division (RPD) Quality Manager shall maintain the original and all past versions of this RPD Procedure.

Appendix A – Example Irradiation Worksheet

H:\Irradiations\customer irradiations\db2121- Irradiation Worksheet.xlsx

NIST High-Dose Service

Contact:	Ms. Gray	Test Identifier:	HD2121
Company:	RAD sterilizers	Date:	7/8/2021
City, State:	Philadelphia, PA	Irradiations Performed By:	ABC

Customer Dosimeter: Alanine pellets
Dosimeter details: Lot 212121
Irradiation Temperture: 23 °C

Temperature, during irradiation, was controlled with a shower of air blowing down onto the samples and was monitored with a type-T thermocouple. Irradiations details are found in the tables below. A certificate will be issued after quality check measurements and the review process.

Source: **GC207** **Geometry:** **Single-Hole Vial** **Transit dose time:** **4.50 s**
Reference Date: **12/31/2020** **Stem Height:** 87 mm
Reference Dose Rate: **2.29 kGy/h**
☐ Si Correction ☐ Dewar Correction

Dosimeter Identification	QC	Irradiation Start Date	Irradiation Start Time	ET	DCF	Irradiation Stop Date	Irradiation Stop Time	Total Hours	Irradiation Time	Current Dose Rate	Total Dose, kGy	Average Temperature
completed												
3.00 kGy	21-3a,b	7/8/21	8:00:00	189.63	0.934	7/8/21	15:13:56	0.234	0:13:56	2.14	3.00	23
2.00 kGy	21-2a,b	7/8/21	10:00:00	189.42	0.934	7/8/21	10:55:58	0.934	0:55:58	2.14	2.00	23
1.00 kGy	21-1a,b	7/8/21	13:00:00	189.54	0.934	7/8/21	13:27:57	0.467	0:27:57	2.14	1.00	23

Source: **GC232** **Geometry:** **Single-Hole Vial** **Transit dose time:** **3.00 s**
Reference Date: **12/31/2020** **Stem Height:** 87 mm
Reference Dose Rate: **0.454 kGy/h**
☐ Si Correction ☐ Dewar Correction

Dosimeter Identification		Irradiation Start Date	Irradiation Start Time	ET	DCF	Irradiation Stop Date	Irradiation Stop Time	Total Hours	Irradiation Time	Current Dose Rate	Total Dose, kGy	Average Temperature
completed												
0.500 kGy	21-.5a,b	7/8/21	11:00:00	189.46	0.934	7/8/21	12:10:40	1.179	1:10:40	0.424	0.50	23
0.300 kGy	21-.3a,b	7/8/21	14:00:00	189.58	0.934	7/8/21	14:42:23	0.707	0:42:23	0.424	0.30	23

ET = Elapsed Time = Days since the reference date
DCF = Decay correction factor = EXP(-LN(2)/1925.2*elapsed days), half life of Co-60 = 1925.2 days
Irradiation Time = Value Set on Timer = Total Hours converted to clock time, minus seconds to account for transit dose equivalent time

Appendix B – Example Timing Worksheet

Irradiation ID: RAD Sterilizers HD2121		Performed By: ABC	
Geometry: Single Hole		Si or Dewar Correction: NA	
Irradiator ID: GC207 and GC232		Reference Dose Rate: 2.62 kGy/hr and 0.518 kGy/hr	
Dosimeter Info: Alanine, Lot T212121			

Sample:	3.00 kGy	Date:	7/8/2021	Timer Check:	1:24:01
Irradiation Time:	1:24:00	Start Time:	8:00:00	Temperature:	23 °C
QC Lot/Label:	21-3a, 21-3b	Stop Time:	9:24:00	Note:	GC207
Sample:	2.00 kGy	Date:	7/8/2021	Timer Check:	55:58
Irradiation Time:	0:55:58	Start Time:	10:00:00	Temperature:	23 °C
QC Lot/Label:	21-2a, 21-2b	Stop Time:	10:55:58	Note:	GC207
Sample:	1.00 kGy	Date:	7/8/2021	Timer Check:	1:24:01
Irradiation Time:	0:13:27	Start Time:	13:00:00	Temperature:	23 °C
QC Lot/Label:	21-1a, 21-1b	Stop Time:	13:13:27	Note:	GC207
Sample:	0.500 kGy	Date:	7/8/2021	Timer Check:	1:10:40
Irradiation Time:	1:10:40	Start Time:	11:00:00	Temperature:	23 °C
QC Lot/Label:	21-.5a, 21-.5b	Stop Time:	12:10:40	Note:	GC232
Sample:	0.300 kGy	Date:	7/8/2021	Timer Check:	42:23
Irradiation Time:	0:42:23	Start Time:	14:00:00	Temperature:	23 °C
QC Lot/Label:	21-.3a, 21-.3b	Stop Time:	14:42:23	Note:	GC232
Sample:		Date:		Timer Check:	
Irradiation Time:		Start Time:		Temperature:	
QC Lot/Label:		Stop Time:		Note:	
Sample ID:		Date:		Timer Check:	
Irradiation Time:		Start Time:		Temperature:	
QC Lot/Label:		Stop Time:		Note:	
Sample:		Date:		Timer Check:	
Irradiation Time:		Start Time:		Temperature:	
QC Lot/Label:		Stop Time:		Note:	
Sample:		Date:		Timer Check:	
Irradiation Time:		Start Time:		Temperature:	
QC Lot/Label:		Stop Time:		Note:	

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Appendix C – Gammacell Operations

The unit consists of an annular source permanently enclosed within a lead shield, a cylindrical drawer, and a drive mechanism to move the drawer up or down along the vertical source centerline. The radiation level around the devices is less than 0.05 mSv/hr (5 mR/hr) at 30 cm (12 in) from the surface for all modes of operation.

Definitions

Collar. The collar sits on top of the head and allows access to the sample chamber. The collar doors must always be closed when the drawer assembly is in motion.

Drawer Assembly. This assembly consists of four parts: the top shielding plug, the drawer top, the sample chamber, and the drawer bottom. This entire assembly moves vertically through the inner head plug and the head. The overall length of travel is 50 cm.

^{60}Co Sources. The source cage contains a cylindrical array of 48 pencil positions. The drawer assembly passes through the source array and locates the sample chamber at the geometrical center of the array during irradiations.

Sample Chamber. The access door of the sample chamber opens to allow items up to about 15 cm in diameter and 20 cm high to be inserted.

Drawer Movement. The unit is designed for complete stroke operation only, that is, a single stroke down or a single stroke up.

Geometry attenuation factor

All dose measurements are done with alanine-EPR measurements in the single-hole geometry. Four alanine pellets are stacked inside a polystyrene vial, see below. This vial is elevated to the center field of the chamber using a support rod.

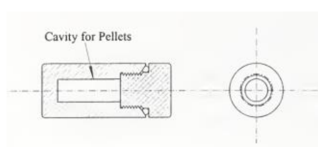

Figure modified from [6]: A polystyrene alanine vial.

Other calibrated geometries include: five-hole cup for tape tab, Perspex, and ampoule (see below), film sheet, polystyrene cube, and a polystyrene cup for live cultures.

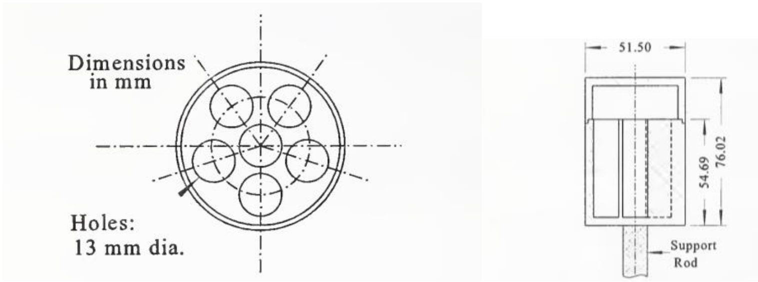

Figure modified from [6]: Five-hole cup.

The geometry attenuation factor and the QC geometry measurement factor are experimentally determined during geometry calibrations.

The geometry attenuation factor modifies the dose rate to deliver the known dose to dosimeters in a given calibrated geometry. These factors are listed in a master table that is linked to the Customer Irradiation Worksheet Template. They are accessed via a drop-down menu. There is a check box that applies the dewar correction factor for non-ambient irradiations. There is a dose-to-silicon factor that can also be applied upon customer request.

The QC dosimeters are typically located in a cavity inside the support rod. Because the QC dosimeters are not in the same position as the customer dosimeter, the QC geometry measurement factor is applied to correct for the difference.

Appendix D – Example Certificate

National Institute of Standards and Technology

ABSORBED-DOSE IRRADIATION CERTIFICATE

NIST Service Identification Number 49010C and 49011C

Dosimeter
Alanine Dosimeters Lot 212121

Customer
RAD Sterilizers, Inc.
2100 Gamma Way
Philadelphia, PA 19121

ATTN: K. Gray
Reference: PO# 2121-1234

Irradiation performed by Ileana M. Pazos

Reviewed by Lonnie Cumberland

Report approved by
Michael G. Mitch, Leader
Dosimetry Group

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

Information on technical aspects of this certificate may be obtained from Ileana M. Pazos, NIST, 100 Bureau Drive Stop 8460, Gaithersburg, MD 20899, 301-975-4121, ileana.pazos@nist.gov.

NIST
National Institute of Standards and Technology
U.S. Department of Commerce

REFERENCE HD2121
682.02/O-00123456789-21
NIST DB 1055/121–122
July 23, 2021
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RAD Sterilizers supplied alanine dosimeters. The dosimeters were irradiated using gamma radiation from a calibrated ^{60}Co irradiator, the NIST Gammacell 220-232. During irradiation, the dosimeter pellets were contained in a polystyrene vial. The dates of irradiation, values of dose rate, absorbed dose, and mean irradiation temperature were as follows:

Dosimeter Identification	Date of Irradiation	Dose Rate (kGy/h)	Irradiation Temp. ˚C	Absorbed Dose kGy(H_2O)
0.300 kGy	July 8, 2021	0.424	23	0.300
0.500 kGy	July 8, 2021	0.424	23	0.500
1.00 kGy	July 8, 2021	0.424	23	1.00
2.00 kGy	July 8, 2021	0.424	23	2.00
3.00 kGy	July 8, 2021	0.424	23	3.00

UNCERTAINTIES AND RELATED FACTORS IN HIGH-DOSE IRRADIATIONS

High-Dose Irradiations in Standard Geometries using the NIST ^{60}Co Gammacell 220-232

(Expanded uncertainty: ±1.2 % at a 95 % confidence level)

The high-dose irradiations at NIST involve the administration of ^{60}Co gamma radiation under environmentally controlled conditions. The dose values from Alanine-Electron Paramagnetic Resonance (EPR) dosimetry are traceable to the quantity absorbed dose to water as directly realized by the NIST primary standard water calorimeter and are corrected by certain modifying factors (such as the geometry attenuation factor and source decay factor). The irradiated dosimeters, adjusted for dosimeter parameters, may be used to derive a calibration curve where dosimeter response is the dependent variable and absorbed dose is the independent variable. The absorbed dose value(s) given in this report can be used to check the accuracy of customer measurement systems and to verify the capabilities of those systems to both transfer and maintain traceability of measurement results. The absorbed dose values(s) relate only to the dosimeters in this report.

The uncertainty cited above is pertinent to absorbed dose in water in calibrated geometries. A detailed list of the various sources of uncertainty and estimates of the magnitude of those uncertainties that make up the overall uncertainty given above may be obtained through the Internet (https://www.nist.gov/programs-projects/basic-metrology-high-dose-dosimetry-uncertainty-tables) or by requesting such information from NIST. The uncertainties are divided into two types: A and B. Type A uncertainties are those evaluated by statistical methods, often associated with random effects. Type B uncertainties are those evaluated by other means, often associated with systematic effects.

Type A Uncertainties

The combined standard uncertainty evaluated by statistical methods is ±0.28 % at an approximate level of confidence of 68 %.

Type B Uncertainties

The combined standard uncertainty based on scientific judgment is estimated to be ±0.55 % at an approximate level of confidence of 68 %.

Expanded Uncertainty

The Type A and Type B uncertainties have been combined in quadrature (the square root of the sum of the squares) and multiplied by a coverage t-factor of 2.0 to yield an expanded uncertainty of ±1.2 % at an approximate level of confidence of 95 %.

Appendix E - Sample Table of Uncertainty

	GC232 Calibration Geometry Dose Rate		
d.f.	Uncertainty Source	Type A (%)	Type B (%)
6	Water Calorimetry in Vertical Beam	0.16	0.51
7	GC232/GC45 Source Ratio Data	0.08	
7	GC45/B036 Source Ratio Data	0.17	
3	Geometry Correction Factor (Perspex)	0.10	
	Field uniformity		0.01
	Timer Error (irradiation time > 8min)		0.20
	^{60}Co Decay Correction		0.02
	sqrt(sum)	0.27	0.55
effective d.f.	combined in quadrature		0.61
19	t-factor for 19 d.f at 95.45 %		2.14
	Expanded Uncertainty at 95.45 % conf.		**1.3**

Other standard irradiation geometries used in GC232, as well as other geometries in GC45 and GR420, will have slightly different values for source ratio uncertainty and geometry correction factor uncertainty. In those cases, the expanded uncertainty remains unchanged at 1.3 %. For more specialized geometries, such as low-temperature irradiations held inside a Dewar, additional components of uncertainty must be included and the uncertainty recomputed.

Appendix F - **Checklist for High-Dose Irradiation Services**

QM Checklist for High-Dose Irradiation Services

NIST ID: HD2121

Preliminary Analysis

- ✓ An irradiation geometry matching this type of dosimeter/sample has been previously calibrated (Yes/No).

  - If Yes, verify that all conditions/corrections were the same as those used in previous job(s)

  - If No, explicitly note all differences from previous job(s)
- ✓ The correct customer geometry (e.g. stem height, etc.) for the samples has been identified. Or, if a stem is not used, the geometry is confirmed as correct according to the dose-rate calibration.
- ✓ The customer requested irradiation temperature has been confirmed.
- ✓ Verify that Irradiation facility temperature and humidity are in the ambient range prior to, and post, irradiation.
- ✓ Ensure that customer dosimeters and QC dosimeters have been stored in ambient conditions and have equilibrated prior to irradiation for at least 24 hours.

Within the Databook Record Spreadsheet

- ✓ The header fields are all checked for accuracy: contact, company, date, HD#, etc.
- ✓ The written description correctly identifies the dosimeters and the irradiation geometry including the stem height and any surrounding materials as well as customer desired irradiation temperature.
- ✓ The base dose rate used is a number from the current year's dose-rate sheet, and both the reference date and the transit dose time are correct.
- ✓ The cells on the row which calculate elapsed time, decay correction factor, current dose rate, total hours, irradiation time, stop date, and stop time have all been checked for having the proper formulas.
- ✓ The values have been entered correctly for start date, start time, total dose and they match with the handwritten record of the irradiation worksheet.
- ✓ After each irradiation, the independent backup timer was noted and confirmed the time as recorded in the spreadsheet.

QM Checklist for High-Dose Irradiation Services

Within the Logbook Record Spreadsheet

Y:\CALIBS\GammaLogBook

HD number	HD2121
Company name	RAD Sterilizers
Dosimeter Type	Alanine
Dates of Irradiation	7/8/2021
Dose levels	0.3, 0.5, 1, 2, 3 kGy
GC	GC232
12/31/20XX	2021
Base Dose Rate	0.454 kGy/h
Geometry	Single Hole
Stem Height	87 mm
Dewar	NA
Irradiation Temperature (°C)	23 °C
Facility Temperature (Ave, High, Low)	22.3, 22.8, 22.0 °C
Facility Humidity (Ave, High, Low)	35, 42, 31 %
EPR Measurements	all within ±3% from target
Geometry Correction Factor (GCF)	1
Temperature Correction Factor (TCF)	1.0011

Signed by: ABC Date: 7/23/2021