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337 Distillery Hill Road Benton, PA 17814

Gamma Irradiator Service, LLC

Phone 570-925-5681 * Fax 570-925-5370 * NRC LIC# 37-30850-01 * PA LIC# PA-1157

03036438

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

The intent of this letter is to submit information necessary to allow Gamma Irradiator Service, LLC to obtain a Quality Assurance Procedure. This procedure will create a location to provide access and ease of use to find information contained in our other procedures as well as providing information regarding Gamma Irradiator Service, LLC ability to conform to proper quality control and assurance. The addition of our GIS Document Control procedure and the GIS – CAR (Corrective Action Report) will be the only documents that have been created in conjunction with the Quality Assurance Procedure. No other procedures have been altered or modified in any way. Hard copies will be mailed to the address listed before this paragraph along with the emailed versions that will be sent.

Attachment List:
NRC Form 313
Cover Letter with Company Header
GIS QAP
GIS Document Control
GIS - CAR

NRC FORM 313 (02-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 02/29/2016

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [x] B. AMENDMENT TO LICENSE NUMBER 37-30850-01
- [ ] C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

Gamma Irradiator Service, LLC
337 Distillery Hill Road
Benton, PA 17814

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Various temporary job sites.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Christopher Nostrand

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
5709255681	2406047959

BUSINESS EMAIL ADDRESS

chris@gammais.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY: N/A AMOUNT ENCLOSED $: 0

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Christopher Nostrand, RSO		2-4-16

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (02-2016)

Gamma Irradiator Service, LLC

GIS QAP

QUALITY ASSURANCE PROCEDURE

APPROVED BY:

D. Terry Stout, President	Chris Nostrand, RSO	Chad Gunther, QA Director
DATE 2/4/16	DATE 2/4/16	DATE 2/4/16

NRC Contact Information:

NRC Operations Center 301-816-5100
NRC Region I 610-337-5000

INTRODUCTION

Gamma Irradiator Service, LLC maintains a Quality Assurance Procedure as described in this manual.

1.0 Documentation - Master Index of QA Procedures and Implementation

Implementing Document*	Title	Description
QAP 1.0	Quality Assurance Procedure	Table of established procedures/plans for GIS's documented QA/QC Procedure,
QAP, 2.0	Organizational Chart	Identifies GIS internal organization-al structure and relationships in per-formance of activities affecting quality.
QAP 3.0	Applicability and Scope of QA Procedure	Describes the focus of GIS's Quality Assurance Procedure
QAP 4.0	Control of Documents, Materials, Parts, Equipment, and Services	Identifies the steps taken to ensure control of paperwork and maintaining quality parts and instruments.
QAP 5.0	Audits	Identifies the measurements taken to ensure all aspects of the QAP are being followed on an annual basis.
QAP 6.0	Corrective Actions	Identifies the necessary steps taken when a non-conforming material is found.
QAP 7.0	Transportation of RAM	Describes the steps taken to ensure a sound QA Procedure to enable Type B shipping of RAM.
GIS, AP 004 (Attachment)	Authorized Work	This procedure identifies the activities that can be performed within the scope of the license.
GIS, 014 (Attachment)	Unloading/Loading Sources	This procedure describes the necessary steps for the safe unloading and loading of high activity quantities of Cs or Co irradiator sources

GIS, EMP-001 (Attachment)	Emergency Procedures	Identifies the steps necessary to take when an emergency occurs. Contains a list of the State's office to be contacted if one occurs.
GIS, GMP-002 (Attachment)	Preventative Maintenance Procedure	This procedure identifies the steps needed to take before preventative maintenance work takes place. Verifies which category can be worked on, and a list of steps we take when we perform the maintenance.
GIS, RSM (Attachment)	Radiation Safety Manual	This manual describes the entire Radiation Safety Program, including but not limited to: posting, ALARA, worker qualifications, audit program, record maintaining, etc to meet 10 CFR 20.1101; 20.2102; and 30.32.
GIS, REL-003 (Attachment)	Relocation Procedure	This procedure specifies the requirements for jobs in which an irradiator will be relocated and/or prepared for shipping.
GIS, ALA-001 (Attachment)	ALARA Procedure	This procedure outlines and defines the concept of ALARA as well as what it takes to follow the concept.
GIS Doc Control (Attachment)	GIS Document Control	Provides the steps and actions taken to ensure documents are being kept accordingly to rules and regulations.
GIS – CAR (Attachment)	Corrective Action Report	This report is used when a customer complaint or 10 CFR Part 21 failure of a part occurs.

2.0 STRUCTURE AND AUTHORITY

GIS has an established organizational structure with procedures/plans which ensures that (1) in all areas of quality assurance, the assignment and responsibility for each area is achieved and maintained by appropriately qualified and trained personnel, (2) that conformance thereof is verified by either individuals or groups directly responsible for work performed or in the case of multiple functions, conformance is later verified by other individuals or groups in evaluations or inspections and (3) that quality verification and reporting to management hierarchy precludes conflict of interest. All personnel involved with Quality Assurance/Control have the authority and responsibility, in writing, to stop at any time, the further process of any non-conforming material, work, shipment, delivery or installation with direct recourse to upper management. QA/QC Management personnel have the further authority and responsibility, in writing, to supervise further processing after corrections, for any procedural reason, have been made.

2.0A RAD Worker Structure and Authority - Current Organizational Chart with duties (Including direct and indirect lines of communication)

RSO – In accordance with 10 CFR 30.33(a)(3)

- identifying radiation safety problems, initiating action, and ensuring compliance with regulations
- annual review of the radiation safety program for adherence to ALARA (as low as reasonably achievable) concepts
- annual radiation safety program audit performed and documented
- development, distribution, and implementation of all operating and emergency procedures
- possession, installation, relocation, use, storage, repair, and maintenance of all irradiators are within the limitations of the license and the SS&DR requirements
- quarterly review of personnel occupational dose records
- ensuring all personnel and RAD workers have adequate and proper training
- ensures all RAM is transported within applicable DOT requirements

Quality Assurance Director-

- continual development, distribution, and implementation of all procedures pertaining to quality assurance
- annual internal audit of GIS' procedures and work instructions to ensure compliance
- establishes quality documentation system by writing and updating quality assurance procedures.
- completes quality assurance operational requirements by scheduling and assigning employees; following up on work results.

Field Service Engineer / Authorized Users– In accordance with 10 CFR 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 30.33(a)(3); 10 CFR 30.34(e); 10 CFR 40.32; 10 CFR 70.22.

Before using licensed material, authorized users will receive the training described in Appendix H in NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000.

- complying with regulations/procedures while performing any work in the field
- must wear personal monitoring devices and perform a quarterly review of occupational dose record
- must maintain logs of performed surveys of the irradiators in the field
- must receive training in applicable USNRC/Agreement State and DOT regulations as well as company procedures and safety

3.0 APPLICABILITY AND SCOPE OF QA PROCEDURE, INCLUDING PERSONNEL & CONTROLLED CONDITIONS

3.0A Applicability

A. Statement of Verification of Assessment of Quality Assurance Procedure.

The Officers of the Quality Assurance Procedure (QAP), using daily communications, review the statuses of jobs in regard to purchasing, work-in-progress, corrective actions (if necessary), or completion of whatever phase of operation is currently pertinent to that job. Annual audits to determine compliance as well as for accounting and inventory purposes are performed and reviewed by officers of the QAP.

B. Distribution of Quality Assurance Procedure Manuals.

Each officer of the QAP retains a copy of the QA/QC Procedure Manual. A master copy is kept and a copy is made available to any employee or auditor of GIS, upon request. (Each new employee is made familiar with the manual as a part of the Training Program.) QA records' personnel are responsible for distributing approved revisions to all internal copies of the manual and advising the holders thereof of such revisions.

C. Safety-related Systems, Structures and Components Controlled by Quality Assurance Procedure.

All mechanical and electronic components as well as components and completed systems are controlled and covered by the QAP by specification of the operating manual or the SS&DR, where applicable.

D. Statement of Verification of Resolution of Disputes.

If and when disputes arise concerning the quality of a product, a review of the product's functions, specifications and compatibility with the QA Procedure as well as NRC/Agreement State and DOT criteria is made by the QA officer(s). Reviews are made as needed when all pertinent data is gathered. Agreements are subject to review by the RSO or President for final approval.

E. Statement of Verification that Training Program is Implemented.

GIS maintains a training program for all new employees and employees assuming additional responsibilities. This program provides a thorough examination of the QA Procedure and the purpose of maintaining this program. Each QA officer's authority is delineated and the effect of that authority is demonstrated as well as an explanation of how the employee functions within the QA Procedure.

Due to GIS being a small business, each employee is not only responsible to the QA officer(s), but is directly responsible for his/her own work within the company. Hence, in the training program, each named user is trained (and continuously monitored in the system of checks and balances maintained in the review by the QA officer(s) to whom the employee is responsible) to be effective in the continuous functioning of the QAP. Complete documentation of this program is on file at GIS. (Please see GIS Radiation Safety Manual Section 5.2 for specific items for training of new employees.)

All personnel are adequately licensed or certified when applicable. All required licenses and certifications are kept current. If an employee is not performing to the specifications maintained by GIS, he/she is subject to a retraining program before continuing with his/her responsibilities and duties. If this is not successful, employment is terminated after the appropriate notice has been given and legal responsibilities fulfilled.

F. Statement of Verification that Quality-related Activities are Performed According to Predetermined Measures.

GIS performs all quality-related procedures, i.e., inspections, testing, and maintenance, in accordance with predetermined procedures which specify the equipment to be used and environmental conditions, if necessary. (See GIS AP 004 for authorized work activities)

3.0B Scope

This Quality Assurance Procedure takes into consideration the quality control procedures that will be necessary for satisfactory performance detailed for materials, parts, employee training, ALARA, relocations, RAM handling (source unloading and reloading), plus other duties and responsibilities of GIS employees.

A. Procedures, Documentation and Records

Final inspection forms and records from work are maintained at GIS for a minimum of 5 years, along with all necessary radiological data such as leak test certificates and any other records that pertain to the radiological aspect of the equipment as required by law, regulatory authorities and good quality assurance practices. The final forms should include:

a. Service Report
b. Inspection Report
c. Leak Testing
d. Radiation Survey
e. ALARA review – only prior to source handling activities (loading and unloading)

B. Procedures, Documentation and Records continued

When necessary, forms are also prepared and forwarded to subcontractors covering the various areas of quality control to be checked and then returned to GIS to be maintained in the permanent file.

C. Storage, Packaging, Delivery

QA is responsible for establishing requirements for storage including any special requirements for radioactive materials. Attention is given to government regulations, such as the USNRC/Agreement State and DOT regulations, in addition to contractual specifications.

QA, where applicable, is responsible for assuring that these requirements are met per 10 CFR Part 20 and that records of such inspections are maintained.

A semi-annual shop survey will be performed and maintained to ensure that no contamination of stored radioactive materials occurs.

4.0 CONTROL OF DOCUMENTS, MATERIALS, PARTS, EQUIPMENT, AND SERVICES

4.0A CONTROL OF DOCUMENTATION

A. Verification of documents being in a controlled environment is brought forth in the GIS Document Control instruction. This instruction also verifies that records/documents are subject to storage, preservation, and safe keeping. These QA records also contain documentation concerning the quality and safety of items, activities, and employees which affect the quality and safety aspect.

4.0B CONTROL OF PURCHASED MATERIALS, PARTS, COMPONENTS, EQUIPMENT AND SERVICES

A. Statement of Verification of Procurement Document Planning

The QA Officer(s) and Employees, as applicable, are qualified and responsible for planning of vendor or subcontractor selection, qualifying vendors' or subcontractor's QA/QC Programs, and to establish that materials, parts, components, equipment and/or services to be provided meet satisfactory specifications.

B. Materials Control

Materials Control - Quality Assurance Officer(s), as well as other employees of GIS, will ensure that all non-radiological incoming materials are inspected as received and segregated on job shelves or placed into inventory locations, as applicable.

Non-conforming Materials and Parts will be scrapped or at the very least, labeled and kept segregated from the satisfactory parts to maintain the integrity required to ensure no parts will fall under 10 CFR Part 21.

4.0C CONTROL OF MEASURE AND TEST EQUIPMENT

A. Measuring and Test Equipment

QA Officer(s), along with other GIS employees where applicable, is responsible for maintaining calibration equipment in first class condition, and establishing and maintaining calibration requirements and frequency. Records of all calibrations are maintained for a minimum of five years. QA will monitor all vendors/subcontractors to assure that vendor's/subcontractor's test equipment is properly maintained and calibrated.

B. Statement of Verification that Measuring and Test Equipment are Properly Calibrated.

GIS will monitor and maintain properly calibrated measuring and test equipment, based upon required accuracy, purpose, degree of usage, stability characteristics or other conditions affecting the measurement of the salient characteristics of a particular item. Survey instruments which measure radioactivity are calibrated yearly.

C. Statement of Verification that Measuring and Test Equipment are Identified and Traceable to Calibration Test Data.

GIS will monitor and maintain serial numbers on all measuring and test equipment and requires all calibration test data to reference the instrument's serial number(s). All measuring and test equipment is labeled or tagged to indicate date of next calibration.

D. Statement of Verification that Calibration Meets Appropriate Standards.

GIS will monitor and maintain National Institute of Standards and Technology (NIST) traceable radiation source standards in-house. Additionally, radiation measurement equipment is either re-calibrated yearly to NIST traceable calibration or cross calibrated, with known valid relationships to NIST traceability. Radiation survey instruments are calibrated yearly. Non-radiological measurement and test equipment is calibrated yearly or every two years to NIST traceability or other nationally recognized standards. Other inspection instruments either meet nationally recognized standards or manufacturer's specifications which are documented and are on file at GIS. In the event that no known recognized standard is used for calibration, the parameters of that calibration procedure will be documented. Records on all instruments which measure radioactivity are kept in

current files or archives for a minimum of 5 years and these standards are referenced on all appropriate documentation.

E. Statement of Verification that Measurements are Taken, Documented, and Validated Against Previous Measurements if Instrument is Found to be out of Calibration.

GIS performs new tests or measurements (which are documented) to validate previous inspections in the event that an instrument is found to be out of calibration and notifies appropriate parties, when applicable. Any measuring equipment which is consistently out of calibration will be removed from service and repaired or replaced.

F. Statement of Blood Irradiator Dose Validation Equipment

GIS uses a third-party supplier's dose validation cassette, Ashland's DoseMap™ system, to ensure all irradiated blood products are receiving the FDA's mandatory limits of 15Gy – 50Gy.

5.0 AUDITS

5.0A On an annual basis, GIS conducts internal audits, covering all aspects of the QA Procedure, with emphasis on importance of safety activities in accordance with 10 CFR 20.1101 (c); 10 CFR 20.2102.

A. Statement of Verification that Audits are Conducted in Prescribed Manner.

GIS performs audits in accordance with prescribed procedures and/or check lists. All audits are performed by employees.

The auditor(s) compile and report audit findings, to responsible management, including corrective action suggestions, if required. Management personnel review all audits in all areas covered by the audit. Management personnel, working with audit team(s), are responsible for correcting deficiencies as required after a comprehensive review of the complete audit reports.

B. Statement of Verification that Audits are Scheduled.

GIS schedules internal audits, with direct management participation, with a complete QA Procedure audit, including implementation and emphasis on activities important to safety. Internal audits are scheduled on an annual basis (or as close to an annual basis as small company circumstances and priorities of audit personnel and management permit, such as production, shipments and installations, inventory, etc.) or more frequently if circumstances dictate an immediate audit, such as non-conformances.

C. Statement of Verification of Qualifications of Audit Personnel.

Qualifications for lead auditors and audit personnel have been established using current industry standards or on the basis of work experience at GIS.

D. Statement of Verification of Audit Reporting and Response.

Audit and/or corrective action reports are subject to time constraints, as determined at audit scheduling, or interim meetings. In the event that a corrective action cannot be implemented immediately, a schedule for implementation and completion dates will be determined by management.

E. Statement of Verification of Audit Follow-up Action.

Audit team leader(s) and management are responsible for verification of timely response and adequacy of audit reports, and that corrective actions have been accomplished.

6.0 CORRECTIVE ACTION

A. Statement of Verification that Corrective Actions / Customer Complaints are Reported.

GIS does not unconditionally accept or use non-conforming materials for use in a product. In the event that an inspection determines there is such nonconformity, such as malfunction, deficiency, or defectiveness, the QA Department documents and reports nonconformance. QA, when applicable, evaluates the problem and establishes the need for corrective with use of the CAR – GIS form for corrective actions. Corrective action from failure of a part due to normal usage and wear will not be required.

B. Statement of Verification that Corrective Action Proceedings are Completed.

In the event of a corrective action or customer complaint, the personnel of the QA program, when applicable, evaluate all aspects of the discrepancy and determine the kind of corrective action to be taken to avert reoccurrence. This process is documented accordingly before the corrective action is taken and inspected.

7.0 Type B Transportation of RAM

A. Before the use of any package for the shipment of licensed RAM subject to 10 CFR 71 Subpart H, approval of the QAP shall be obtained from the Nuclear Regulatory Commission (NRC). The QAP shall be filed with the NRC Office of Nuclear Material Safety and Safeguards (NMSS) and shall include a discussion of which requirements of 10 CFR 71 Subpart H are applicable and how they are satisfied.

B. The QAP is applicable to packaging owned by another party and for which GIS is registered as an authorized user unless a shipper of record is used during the use of the Type B package. GIS does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for GIS to undertake any or all of these QA functions, the QAP will be revised accordingly.

C. The QAP applies to the following materials and components regarding shipping of RAM:

i. Shipping/use of Type B packaging, i.e. RAM other than fissile material in excess of Type A quantities, including the design, fabrication, assembly, and testing of such packaging by the Type B third party owner already approved for those activities by the NRC.

ii. Design, fabrication, assembly, and testing of the Type B container by GIS shall not be permitted by this QAP.

D. The activities, quality of materials, and components identified in the QAP shall be controlled to an extent consistent with their importance to safety and as necessary to assure conformance to the approval of each individual package used to ship RAM. Activities affecting quality shall be accomplished under controlled conditions and include the use of appropriate equipment, suitable environmental conditions, and assurance that all prerequisites have been satisfied. Special controls, processes, test equipment, tools, and skills shall be taken into account to attain the required quality. This requirement is primarily met by the preparation, review, and approval of and adherence to the QAP and supporting documents.

E. Other considerations for supporting documents include:

i. Information provided from the packaging provider, e.g. packaging documentation, certification and procedures.

ii. Safety measures commensurate with the shipment.

iii. Qualification or certification of equipment and personnel, (e.g. equipment rating and personnel training) including proficiency testing of personnel (e.g. use of equipment, mock-up training).

iv. Handling instructions (e.g. package assembly and loading, unloading and opening of the package, transport and storage).

v. Required records and forms.

F. The status and adequacy of the QAP and supporting documents are reviewed by the Owner, RSO, and QA Director:

i. Every five years

ii. Following major regulatory changes or

Changes to QAP 7.0 as well as documents or procedures supporting QAP 7.0 are reviewed by the Owner, RSO, and QA Director and are reviewed and approved by the NRC.

Please review the attached documents listed under GIS QAP Section 1.0 to obtain a better understanding and more detailed descriptions of our remaining procedures. Please do not hesitate to contact us via telephone, email, or fax if you have any questions or concerns pertaining to any part of our program. We strive to provide our customers the best possible service and our regulators with the clearest understanding of how we meet the rules and regulations to make this happen.

337 Distillery Hill Road , Benton, PA 17814

Gamma Irradiator Service, LLC

Phone 570-925-5681 Fax 570-925-5370 NRC LIC# 37-380850-01 PA LIC# PA-1157

CORRECTIVE ACTION REPORT (CAR)

1. FACILITY	2. CUSTOMER CONTACT	3. PART TYPE / COMPLAINT

4. IRRADIATOR MODEL & SERIAL NUMBER	5. DATE RECEIVED	6. CAR NUMBER

7. DEFICIENCY ☐ MAJOR ☐ MINOR

ISSUE:

CORRECTION OF ISSUE:

8. PERSON SUBMITTING CAR

NAME / TITLE	SIGNATURE AND DATE

9. UPPER MANAGEMENT REVIEWER

NAME / TITLE	SIGNATURE AND DATE

10. QAP RESPONSE TO CORRECTIVE ACTION AND CORRECTION OF ISSUE ANSWER

11. QAP DETERMINATION ☐ ACCEPTED ☐ REJECTED	12. CLOSE DATE

Corrective Action Report (GIS - CAR) 8/10/15

337 Distillery Hill Road , Benton, PA 17814
Gamma Irradiator Service, LLC
Phone 570-925-5681 Fax 570-925-5370 NRC LIC# 37-380850-01 PA LIC# PA-1157

Corrective Action Report (CAR) Instructions

Block 1. Enter facility name.

Block 2. Enter customer name.

Block 3. Enter part type that failed or customer complaint .

Block 4. Enter irradiator model and serial number.

Block 5. Enter the date the failure or complaint was received.

Block 6. Enter CAR number for tracking and record keeping.

Block 7.
1. Check the block that indicates whether the identified deficiency is assigned as a Major or Minor finding.

Blocks 8 and 9. QAPs initiating a CAR must sign and date in Block 8 and the Upper Management Reviewer signs and dates in Block 9.

Block 10. Upon review of the CAR, the QAP will write a response in regards to the correct of the issue that is proposed in block 7 of the CAR.

Block 11. The QAP selects Accept or Reject to the response in the correction of issue in block 7.

Block 12. The QAP enters a close date after QAP and the Upper Management Reviewer accepts the correction of the issue.

GIS Document Control

GIS has established this procedure so that all documents and revisions under the control of the QA Program are subject to review and concurrence. Documents which fall under this procedure include, but are not limited to, QA Manuals, operating and maintenance procedures, qualifications of personnel, inspection and test procedures, audits, calibrations, and corrective action reports.

GIS uses a storage facility or office which minimizes risk of elemental, zoological or botanical damage. All current, permanent, or temporary records are stored within folders or binders and are placed in steel filing cabinets. Measures are established for replacement, if possible, for lost or damaged records. This may include electronic copies as well. Measures have been established to restrict entry of unauthorized personnel into storage areas.

QA records contain documentation concerning the quality and safety of items, activities, and employees which affect quality and safety areas. Documents and records will be maintained for the duration stated in the GIS Radiation Safety Manual Part 11.0. QA personnel revise and update them annually or as required. Each change in procedures will be documented and submitted to the Nuclear Regulatory Commission for approval if required after each department has reviewed and approved submittal to the NRC. Each document change submitted to the NRC will require a revision subtitle to ensure all departments are aware of the changes and for better document traceability as well. A document that is under revision will not be used until approval by the NRC. The current approved copy of the procedure will be in effect until the revision is approved and official.

All present versions of the documents and their changes will be kept in a history file for reference and review in accordance with 10 CFR 35.2026 and past versions will be kept for a minimum of five years.

This is to acknowledge the receipt of your letter/application dated

2-4-16, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (37-30850-01)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 590281.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader