NRC FORM 464 Part I
(04-2018)

U.S. NUCLEAR REGULATORY COMMISSION

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

NRC	RESPONSE NUMBER
2018-000425	1

RESPONSE TYPE ☐ INTERIM ☑ FINAL

REQUESTER:	DATE:
Doyle Terry Stout	05/03/2018

DESCRIPTION OF REQUESTED RECORDS:

All correspondence requesting the new license for C&C Irradiators, docket # 030-39072, with all supporting documentation procedures including but not limited to radiation safety, work instructions, ALARA, emergency procedure, source transfer, and any drawings submitted.

PART I. -- INFORMATION RELEASED

☑ The NRC has made some, or all, of the requested records publicly available through one or more of the following means: (1) https://www.nrc.gov; (2) public ADAMS, https://www.nrc.gov/reading-rm/adams.html; (3) microfiche available in the NRC Public Document Room; or FOIA Online, https://foiaonline.regulations.gov/foia/action/public/home.

☑ Agency records subject to the request are enclosed.

☐ Records subject to the request that contain information originated by or of interest to another Federal agency have been referred to that agency (See Part I.D -- Comments) for a disclosure determination and direct response to you.

☐ We are continuing to process your request.

☑ See Part I.D -- Comments.

PART I.A -- FEES

AMOUNT
$112.72

☑ You will be billed by NRC for the amount indicated.

☐ You will receive a refund for the amount indicated.

☐ Fees waived.

☐ Since the minimum fee threshold was not met, you will not be charged fees.

☑ Due to our delayed response, you will not be charged fees.

PART I.B -- INFORMATION NOT LOCATED OR WITHHELD FROM DISCLOSURE

☐ We did not locate any agency records responsive to your request. *Note*: Agencies may treat three discrete categories of law enforcement and national security records as not subject to the FOIA ("exclusions"). See 5 U.S.C. 552(c). This is a standard notification given to all requesters; it should not be taken to mean that any excluded records do, or do not, exist.

☑ We have withheld certain information pursuant to the FOIA exemptions described, and for the reasons stated, in Part II.

☐ Because this is an interim response to your request, you may not appeal at this time. We will notify you of your right to appeal any of the responses we have issued in response to your request when we issue our final determination.

☑ You may appeal this final determination within 90 calendar days of the date of this response. If you submit an appeal by mail, address it to the FOIA Officer, at U.S. Nuclear Regulatory Commission, Mail Stop T-2 F43, Washington, D.C. 20555-0001. You may submit an appeal by e-mail to FOIA.resource@nrc.gov. You may fax an appeal to (301) 415-5130. Or you may submit an appeal through FOIA Online, https://foiaonline.regulations.gov/foia/action/public/home. Please be sure to include on your submission that it is a "FOIA Appeal."

PART I.C -- REFERENCES AND POINTS OF CONTACT

You have the right to seek assistance from the NRC's FOIA Public Liaison by submitting your inquiry at https://www.nrc.gov/reading-rm/foia/contact-foia.html, or by calling the FOIA Public Liaison at (301) 415-1276.

If we have denied your request, you have the right to seek dispute resolution services from the NRC's Public Liaison or the Office of Government Information Services (OGIS). To seek dispute resolution services from OGIS, you may e-mail OGIS at ogis@nara.gov, send a fax to (202) 741-5789, or send a letter to: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740-6001. For additional information about OGIS, please visit the OGIS website at https://www.archives.gov/ogis.

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PART I.D -- COMMENTS

In addition to the enclosed records, the following two records are publicly available in ADAMS:

1. ML17318A252 -- C&C Irradiator Service Deficiency Response Letter, dated November 8, 2017.

2. ML17318A391 -- Email, dated November 7, 2017, from NRC to C&C Irradiator Service, requesting additional information regarding its license application.

Records with an ML accession number are publicly available in the NRC's Public Electronic Reading Room at http:www.nrc.gov/reading-rm.html. If you need assistance in obtaining these records, please contact the NRC's Public Document Room (PDR) at 301-415-4737, or 1-800-397-4209, or by email to PDR.Resource@nrc,gov.

Please note that, due to our delay in responding to you, you have incurred fees solely for the review time expended in the processing of your request; no search or duplication fees have been charged.

Signature - Freedom of Information Act Officer or Designee

Stephanie A. Blaney

Digitally signed by Stephanie A. Blaney
Date: 2018.05.03 06:18:08 -04'00'

B2.2
(08-35447-01)

C&C Irradiator Service LLC

L35447
03039072
03226

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

REC RG1 10 13 '17 AM 11 56

The intent of this package is to submit information necessary to allow C&C Irradiator Service, LLC the opportunity to obtain a U.S. Nuclear Regulatory Commission Materials License. C&C Irradiator Service, LLC is a newly formed company in the District of Columbia, but contains two employees that were on Pennsylvania, NRC, and Massachusetts Radioactive Materials Licenses performing this exact type of work for several years. Included in this package will be our credentials, past work experience, and procedures to show our compliance with regulatory requirements. We intend to fully cooperate with any NRC suggestions or recommendations to create a satisfactory radioactive materials program. Attachment A below encompasses the entirety of the package provided for review. We look forward to your favored reply.

Christopher Nostrand, CEO/RSO

Chad Gunther, COO/QA Director

10/1/17

601392
NMSS/RGN1 MATERIALS-002

Attachment A

CCIS – Cover Letter

NRC Form 313

NRC Form 313 with Addendum A

CCIS – QAP: C&C Irradiator Service's Quality Assurance Procedure

CCIS – RSM: C&C Irradiator Service's Radiation Safety Manual

CCIS – EP: C&C Irradiator Service's Emergency Procedure

CCIS – AWA: C&C Irradiator Service's Authorized Work Activities

CCIS – ALA: C&C Irradiator Service's ALARA Procedure

CCIS – T&R: C&C Irradiator Service's 10 CFR Part 37 Compliance

CCIS – PMP: C&C Irradiator Service's General Preventative Maintenance Procedure

CCIS – CAR: C&C Irradiator Service's Corrective Action Report

CCIS – DC: C&C Irradiator Service's Document Control Procedure

CCIS – SRCLUL: C&C Irradiator Service's Load/Unload Source Procedure

CCIS – REL: C&C Irradiator Service's Relocation Procedure

CCIS – Reviewing Official Letter

Chad Gunther Qualifications Document

Chris Nostrand Qualification Document

RSO Authority Letter – Designates CCIS RSO

Small Business Certification Letter

NRC FORM 313 (08-2016) 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: 08/30/2019

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-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocolects.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 CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

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)*

- [x] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

C&C Irradiator Service, LLC
1030 Evarts St. NE
Washington, DC 20018

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Temporary job sites throughout the USA under NRC jurisdiction

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Christopher Nostrand

BUSINESS TELEPHONE NUMBER: (240) 604-7959

BUSINESS CELLULAR TELEPHONE NUMBER: (240) 604-7959

BUSINESS EMAIL ADDRESS: chris@ccirradiator.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 AND 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)
*Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.

FEE CATEGORY: 3N AMOUNT ENCLOSED $ 850.00

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 CONTAINED 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
Chad Gunther, COO/QA Director	Chad Gunther	10/1/17

FOR NRC USE ONLY

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

C&C Irradiator Service LLC

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

NRC Form 313 Addendum A for Questions 5-11

5a. Cobalt 50

Cesium 137

Americium 241

Americium 241: Beryllium

Californium 252

5b. Sealed sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

5c. Not applicable; CCIS does not take possession of customers' sources at temporary job-sites.

6.

(1) Collection of leak test samples; analysis of test samples as a service for other persons as defined in 10 CFR 20.1003.

(2) Installation of sealed sources into or removal of sealed sources from ANSI Category I self-shielded irradiators as described in the licensee's Authorized Work Activities Procedure CCIS AWA dated October 1, 2017 and Procedure for Unloading/Loading Single Source Irradiators Procedure CCIS-LUL dated October 1, 2017.

(3) Relocation, radiation surveys, realignment, repair, routine and non-routine maintenance, and servicing of ANSI Category I self-shielded irradiators and ANSI Category II irradiators that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State as described in the licensee's Preventive Maintenance Procedure CCIS - PMP dated October 1, 2017 and Relocation and Preparation for Shipping Procedure CCIS - REL dated October 1, 2017.

(4) Instruction and training of individuals in the safe use and operation of ANSI Category I self-shielded irradiators and ANSI Category II irradiators that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

(5) Performing preventative maintenance on the custom J.L. Shepherd Mark I Model 25 irradiator as described in the licensee's Authorized Work Activities Procedure CCIS AWA dated October 1, 2017.

7. The users responsible for the radiation safety program will be Christopher Nostrand (RSO/CEO) and Chad Gunther (COO/QA Director). Before using licensed material, authorized users will receive the training described in Appendix D in NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'

8. Please review the attachments for each individual along with the previous licenses listed in those attachments which show the competence and activities already allowed by those licenses. Before working in the vicinity of licensed materials, personnel will have successfully completed training commensurate with assigned duties.

9. The licensee does not take possession of the radioactive material(s) and/or source(s) while at the client's facility. Licensed material may be used only at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.

10. Radiation Safety Program – Please review attachment CCIS – RSM.

11. Waste Management is not applicable to our license request.

Christopher Nostrand, CEO/RSO

C&C Irradiator Service, LLC

chris@ccirradiator.com

10/1/17

C&C Irradiator Service, LLC

CCIS QAP

QUALITY ASSURANCE PROCEDURE

APPROVED BY:

Chris Nostrand, CEO/RSO	Chad Gunther, COO/QA Director
DATE 10/1/17	DATE 10/1/17

NRC Contact Information:

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

INTRODUCTION

C&C 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 CCIS's documented QA/QC Procedure,
QAP, 2.0	Organizational Chart	Identifies CCIS internal organizational structure and relationships in performance of activities affecting quality.
QAP 3.0	Applicability and Scope of QA Procedure	Describes the focus of CCIS'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.
CCIS, AWA (Attachment)	Authorized Work	This procedure identifies the activities that can be performed within the scope of the license.
CCIS - LUL (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
CCIS - EP (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.
CCIS - PMP (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.
CCIS - 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.
CCIS - REL (Attachment)	Relocation Procedure	This procedure specifies the requirements for jobs in which an irradiator will be relocated and/or prepared for shipping.
CCIS - ALA (Attachment)	ALARA Procedure	This procedure outlines and defines the concept of ALARA as well as what it takes to follow the concept.
CCIS Doc Control (Attachment)	CCIS Document Control	Provides the steps and actions taken to ensure documents are being kept accordingly to rules and regulations.
CCIS – 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

CCIS 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 CCIS' 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 CCIS, 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.

CCIS 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 CCIS 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 CCIS. (Please see CCIS 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 CCIS, 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.

CCIS 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 CCIS - AWA 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 CCIS employees.

A. Procedures, Documentation and Records

Final inspection forms and records from work are maintained at CCIS 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 CCIS 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 if sources are present.

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 CCIS 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 CCIS, 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 CCIS 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.

CCIS 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.

CCIS 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.

CCIS 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 CCIS. 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.

CCIS 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

CCIS 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, CCIS 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.

CCIS 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.

CCIS 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 CCIS.

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.

CCIS 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 CCIS - CAR 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 CCIS is registered as an authorized user unless a shipper of record is used during the use of the Type B package. CCIS does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the

future it becomes prudent for CCIS 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 CCIS 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 CCIS 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.

CCIS Radiation Safety Manual

C&C Irradiator Service, LLC

Forward

This Radiation Safety Program has been put together with procedures and guidelines to be consistent with ALARA principles. Service work is often not in the classification of routine maintenance, however to those who perform the service on a regular basis, the work becomes an everyday practice. This program isn't designed to replace the proper hands-on training needed to perform daily operations in a safe and consistent manner. As with health physics technicians in commercial nuclear power plants, job qualifications are only granted when task completion and knowledge of the job is reviewed and signed off. The utmost priority of the service technician is to present, upon completion of work, a radiologically-safe device that has been performance tested and confirmed to be operating within manufacturer's specifications, or to identify what repair or maintenance needs to be performed in order to return the device to original specifications for safe operation.

This Manual is meant to cover NRC license requirements, so some information is included that may be relevant for one regulator but not the other. Information not applicable to a particular regulator may be regarded as a point of information.

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Emergency telephone numbers

CEO / RSO Christopher V. Nostrand 240-604-7959

COO / QA Director Chad Gunther 570-912-2389

For NRC incident notification

NRC Operations Center 301-816-5100

Definitions

1. **ALARA** - as low as reasonably achievable; this statement means that personnel dose is of the utmost concern, and that every possible consideration should be weighed towards decisions keeping the individual as well as the collective man rem dose as low as possible.

2. **ALARA Document** - A review of job task that takes a procedure step by step and reviews each task for the engineering controls, planning, hold points, shielding and use of remote handling tools, bore scope, camera or mirrors needed to ensure the lowest dose possible for the job. An ALARA Document shall be completed prior to (and as soon as the source transfer procedure is developed) the start of a high-risk job. All personnel involved in the job will be trained on the specific tasks involved with the procedure and the ALARA document present. Specifics of each individual and his responsibilities will be documented.

3. **Category I** - Self-contained, dry source storage irradiators, defined as American National Standard N43.7. An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration.

4. **Category II** - Panoramic, dry source storage irradiator, defined as American National Standard N43.10. A controlled human access irradiator in which the sealed source is contained in a dry container constructed of solid materials, and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

5. **Custom sealed sources or devices** - Sealed sources or devices containing sealed sources built to the unique specifications of a given user. Custom sealed sources and devices that contain activity greater than 200 millicuries of Radioactive Material must be submitted to the NRC or Agreement State for evaluation and registration.

6. **CPM** - observed counts on a scaler or frisker per minute; to find disintegrations per minute, divide by the decimal efficiency for the instrument being used.

7. **DPM** - Disintegrations Per Minute; observed net counts per minute (net counts = observed cpm – the background cpm) divided by the instrument's efficiency, e.g. if efficiency is 10 % then the net counts would be divided by 0.10 to give dpm.

8. **MDA** - Minimal Detectable Activity: the lowest activity an instrument can reliably detect for a specific radionuclide and survey methodology.

9. **Radiation Surveys** - The task of surveying, with a properly calibrated survey instrument, for the presence of radioactivity in the form of dose rates or surface contamination.

10. **Division of Responsibilities** - A document that lists the responsibilities for each licensee that is involved with a high-risk job.

11. **Leak Test** - The task of determining if a source is considered to be leaking (a leaking source is >0.005 uCi or 185 Bq of removable contamination).

12. **Dosimetry** - A film badge (OSL or TLD) used for the purpose of monitoring an individual for occupational exposure to ionizing radiation, which is recorded and becomes a permanent record.

13. **Interlock** - A mechanical, electrical, or combination of means to prevent access to high radiation area.

14. **Safety system** - A combination of interlocks, relays, micro-switches and key switches to prevent unauthorized use and/or exposure to high radiation fields.

15. **RSO** - Radiation Safety Officer; the person responsible for the overall radiation safety program.

16. **Area monitor** - an instrument to detect increased levels of radiation, with either a visual or audible indication, or both, that alarms above a predetermined trigger point.

17. **N.I.S.T.** - National Institute of Standards and Technology

18. **SS&DR** - Sealed Source and Device Registry; a list of registered devices and sources showing the maximum curie loading and any "Conditions of Normal Use" and "Limitations and Other Considerations of Use". In addition, the SS&DR may list recommendations by the manufacturers such as working life of the source, environmental conditions, temperature, vibrations, etc.

19. **Authorized User** - A person designated as a level II Health Physicist, listed on the license, with the training, experience, and knowledge to provide reasonable assurance that services involving licensed material will be provided in a safe manner, will maintain security and prevent unauthorized access, and emergencies will receive the appropriate response. Before using licensed material, authorized users will

receive training described in Appendix H in NUREG-1556, Vol 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Providers Licenses", dated November 2000.

20. **Non-Routine Maintenance** - NUREG-1556 Volume 5 appendix P defines "non-routine maintenance" as "Installation of the sealed source/device, initial radiation survey, repair or maintenance involving or potentially affecting components, including electronics, related to the radiological safety (e.g., the source, source holder, source drive mechanism, shutter, shutter control or shielding) relocation, replacement, and disposal of sealed sources, alignment, removal or a sealed source/device from service, and any other activity during which personnel could receive radiation doses exceeding NRC limits."

21. **Routine Maintenance** - Section 8.10.9 of NUREG 1556 Volume 18 defines "Routine Maintenance" as cleaning, lubrication, changing batteries, relays, or fuses. This can be any maintenance tasks that the manufacturer acknowledges can be performed by the customer in accordance with the instructions in the user's manual, and which do not involve the source, device shielding, or safety interlocks.

22. **Preventative maintenance** - The task of inspection, testing, and/or replacement of worn parts to ensure the irradiator performs according to the Sealed Source and Device Registration and complies with the manufacturer's operating manual. When completed, the device is tested to ensure that the irradiator performs in a radiologically-safe condition as designed.

23. **SRD** - self-reading dosimeter: a pocket ion chamber that responds to the amount of gamma radiation received, sometimes called a Pocket Ion Chamber or **PIC**. The dosimeter is charged by a charger and returned to zero on the scale; as the SRD receives radiation it changes the reading on the scale (scale is viewed by holding the SRD up to the light and looking through the appropriate end).

24. **Geiger-Mueller (GM)** - a detector that is more sensitive to lower levels of radiation because it has the largest pulse size.

25. **Emergency** - A situation that poses an immediate risk to health, life, property or environment.

26. **Electronic Alarming Dosimeter (EAD)** - a personnel dosimeter capable of measuring gamma and x-rays that typically has an alarm function for either dose, dose rate or a combination of.

27. **Response Test** - Evaluation of a survey meter to determine its qualitative response to radiation.

28. **High-Risk Job** - Any job such as source exchange where the potential for an unshielded beam from the source exists and will be covered by a separate ALARA procedure.

29. **OSL** - Optically-Stimulated Luminescence; OSLD and Thermo-Luminescent Dosimeters (TLD) are personnel dosimeters that are quite similar in that both respond to the absorption of energy from

ionizing radiation by trapping electrons that are excited to the conduction band by the interactions. Unlike TLD, in which electrons are released from the traps by the application of heat, the trapped electrons in an OSL dosimeter are released by the application of green light from a laser or LED light source.

30. **Single-source Assembly** - An assembly on one operator rod that includes the tungsten shielding, the special form source(s), and the spacer between the source(s). Multiple sources inside of the source holder with a spacer may be used in order to achieve a larger 100% dose area for an improved isodose curve such as a JL Shepherd model Mark 1 or give different dose rates such as a JL Shepherd model 89.

Posting requirements

3.0. High Radiation Area signs are posted in areas where an individual could receive a deep dose equivalent of 100 millirem in one hour at 30 cm from the source or the surface where the radiation penetrates. High Radiation Areas could be present during source transfers and signage should be posted at the 100 millirem boundary. Radiation Area signs should be posted in areas where an individual could receive a 5 millirem deep dose equivalent in one hour at 30 cm from the source or the surface where the radiation penetrates. Signs for Radioactive Materials Areas should be posted where items or containers of radioactive materials in quantities exceeding 10 times the values provided in Appendix C of 10 CFR Part 20 are used, handled, or stored.

3.1. When temporary postings are placed, a radiation survey shall show the room or area with boundaries, along with measured dose rates at the boundaries. All posting shall be consistent with 10 CFR Part 20 requirements. Labeling on all devices should meet the requirements of the U.S. NRC for labeling of Radioactive Material containers.

ALARA

4.0 The ALARA concept is an excellent foundation for any radiation safety program; when practiced it allows for the lowest dose to be received by occupationally exposed personnel. Service personnel should receive less than 5 millirem per week average. If personnel routinely exceed this, an investigation to determine the cause shall be performed by the RSO. Extremity dosimetry shall be worn, if calculated exposures exceed 100 millirem DDE per job and 5 times whole body exposure. All measures shall be considered when planning for a source transfer or any other high-risk activity, e.g. shielding, mirrors, cameras and monitors, remote handlers, use of time and distance, dose estimates, and practice with dummy sources, mock up, or dry run.

4.1 ALARA Review Document: Any time a source exchange (high risk) job is planned, an ALARA Review Document will be generated in accordance with CCIS - ALA procedure. Before a job begins, the completed document shall be reviewed, including all steps in the source transfer procedure and specifically addressing conditions that could change dose rates and increase personnel exposure. Examples of steps that should be addressed include, but are not limited to: engineering controls for restriction of source movement, prevention of shielding

reduction, practice run, additional shielding, stops for transfer shield drawer hold points, dose calculations based on time and expected exposure rates, and the ready availability of all needed tools for emergency operation (long reach handlers, etc.)

Qualifications for Service Technicians

5.0. Each individual should be able to comply with 10 CFR part 37 to be qualified to perform preventative or non-routine maintenance on Category I or Category II devices. Individuals shall complete 40 hours of Health Physics and a minimum of 8 hours of hands-on for each model of device to be worked on. The on-the-job training shall be in the presence of a named authorized user or the RSO. When the individual has demonstrated the proper Health Physics knowledge, knowledge of the emergency procedures, understanding of the limitations of the license, mechanical and electrical aptitude, and the ability to read wiring diagrams, he will be given a written (for new training) or oral (for refresher) test. Upon successful completion of the written or oral test, the individual will be approved, by RSO signature, to work on that model.

5.1. Being qualified to perform non-routine maintenance does not authorize the individual to change any conditions on the device such as source removal, reduction in shielding (other than for normal non-routine operations which is temporary and does not create a high radiation area), change of safety systems from original configuration or a modification that would change the SS&D for that device.

5.2. Initial training shall consist of 40 hours Health Physics to include:

Fundamentals of Radiation Safety:
- -Characteristics of radiation;
- -Units of radiation dose and quantity of radioactivity;
- -Hazards of exposure to radiation;
- -Levels of radiation from licensed material;
- -Methods of controlling radiation dose (time, distance and shielding);
- -ALARA concept.

Radiation Detection Instruments:
- -Operation;
- -Calibration;
- -Limitations of radiation survey instruments;
- -Radiation survey techniques for measuring fixed and removable contamination
- -Radiation survey techniques for measuring radiation fields;
- -Handling and proper use of personnel monitoring equipment.

Radiation protection equipment and use:
- -Proper use of protective equipment;
- -Decontamination of contaminated equipment.

NRC regulations (10 CFR 19 and 20).
NRC regulations (10 CFR 21, 30, 31, 32, 34, 35, 36, 37, 39, 40, 70, 71) as applicable.
License operating and emergency procedures.
Case histories relevant to operations and lessons learned.
Course examination (Didactic):
-Successful completion of closed-book written or oral examination.
-Review of incorrect answers with student.
Discussion on emergency procedures
Retraining in any areas found to be deficient

5.3 Refresher Training shall be a minimum of 8 hours annually with review of the above plus current events and lessons learned.

5.4 Records will include date of training, topics covered, list of attendees, including name of trainer. New training will include a written test and documents will be retained forever as part of a user's record. Refresher training will include an oral test and documents will be retained for 5 years.

Operating and Emergency Procedures

6.0. Verification of Authorized Work Procedure: reference Document CCIS - AWA. No work will be performed unless work activities have been confirmed to fall within the allowed licensed activities.

6.1 Responsibilities of customer and service provider

Devices that are serviced at the customer's facility will be serviced under the C&C Irradiator Service, LLC license. C&C Irradiator Service, LLC will comply with facility's rules for maintaining control of radioactive material and security while service work is being performed, and will also comply with all facility requirements for safety including postings. In addition, C&C Irradiator Service, LLC may use additional locks or tag outs to control use while service is being provided. Any degradation of the safety system or any part of the device that could cause failure will be identified and recommendations made to the customer.

Routine maintenance only will be performed on ANSI Category II irradiators. If source exchange work is to be performed **(for Category I irradiators only)**, possession of sealed sources will remain on the customer's license until transferred to an authorized NRC or Agreement State licensee. Only authorized licensed shippers will be used for transportation of radioactive sources and/or devices. **Any high risk jobs such as source transfers or source reloads (for Category I irradiators only) will incorporate the guidance of the CCIS - EP Emergency Procedures if a problem arises during the process.** An agreement titled **"Division of Responsibilities"** will be incorporated during high risk jobs that define the licensees involved and what the responsibility of each licensee is during the job evolution. **This document will be signed by each licensee's representative and maintained on file for inspection with the work package. This document shall include, but is not limited to, items such as: division of security responsibility, division of dose monitoring, division of possession of the source, the division of responsibilities if site cleanup is required, the division**

of work tasks, and safety responsibilities. This agreement will be tailored to each high risk job specifically instead of being a generalized document due to every job's variation.

6.2. Instructions for handling and use of radioactive material (all devices)

All personnel working under the C&C Irradiator Service, LLC license will be monitored for radiation exposure using a self-reading dosimeter or electronic dosimeter and NVLAP approved dosimetry. Personnel working on a routine basis providing service under the C&C Irradiator Service, LLC license shall have completed the 40 hour health physics class (refresher training annually) and be monitored for radiation exposure with a TLD, OSL or film badge, and a self-reading dosimeter or electronic dosimeter. Extremity monitors will be worn for High-Risk source loading, exchange, or reloading activities. Operation and use of devices shall be consistent with the manufacturer's recommendations and Emergency Procedures in the manual for the device for which service is being provided. Personnel working on all devices shall use a calibrated and operational survey meter in the area at all times. ALARA will be practiced when servicing all devices. Personnel shall comply with the customer's security of licensed material when service is being performed. A smear survey of portions of the device (per manufacturer's recommendation) most likely to show if a source is leaking, shall be taken prior to service work, if applicable. If smear results **are greater than 0.005 µCi (185 Bq), follow the guidance in CCIS - EP Emergency Procedures.** Determine if the smears are the same isotope as in the device by using a single or multi-channel analyzer. If a source is determined to be leaking (≥ 0.005 µCi) immediately remove from service and assist the customer, if requested, to develop a plan for decontamination, repair, or disposal.

6.3. Instruction for self-shielded irradiators and Calibrators (ANSI Category I)

Self-shielded irradiators and calibrators are basically of three distinctive designs. The first design is with stationary sources in which a drawer moves the sample to the position of the shielded sources. The second design is also with stationary sources in which a drum rotates the sample chamber to face the source. The third design is with a moveable source that repositions the source into the shielded sample chamber, exposes the sample, and then returns to the shielded position. The moveable source design usually has more than one interlock to prevent the chamber door from opening with the source in the irradiate position. On this type of irradiator, the door must be locked closed when working on the source operator or inside the tower to prevent exposure outside the door area. Locking can be accomplished with mechanical interlocks, padlocks or electrical interlocks. Use of seals to the access path of safety-related parts should be used to confirm that no unauthorized access has been attempted. Please Note: If a seal is broken or shows evidence of tampering by an un-authorized individual, notification to the responsible regulatory authority may be required.

The manufacturer's procedures for inspection, maintenance, source exchange and operations that involve access to the sealed source(s) and safety systems, if applicable, shall be followed. Procedures required to perform routine and non-routine maintenance on these irradiators includes but is not limited to the following: leak test, check of operator or drawer for smooth operation, check of all interlocks and safety systems, source centering, pneumatics, drives, lubrication per manufacturer's recommendation, micro switches, relays, timers, and mechanical wear on parts. Replacement parts will be in conformance with the parts that have been identified in the sealed source and device registration and in agreement with the manufacturer's

recommendation. Any non-manufacturer supplied replacement components or the use of materials (e.g, lubricants) other than those specified or recommended by the manufacturer will be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration before they are used.

A dose rate survey of the device will be recorded along with the results of the leak test. Detailed dose rate surveys will be taken on devices at Irradiate and Load positions with measurements in transit. The Irradiator Inspection/Performance Test report acts as the procedure for guidance to ensure all components are tested as needed for all irradiators. Service will not be completed until after an Inspection/ Performance Test List is completed and after operating the unit enough times to ensure proper operation of the safety and interlock system.

Procedures required to perform preventive maintenance are the same as for performing non-routine maintenance and include all tasks as specified.

Procedures required to perform source loads, reloads, and transfers are specified in the required ALARA Review Document, which will detail the job-specific step by step procedures to be followed. Reference CCIS ALA document. As a minimum, all tasks specified in the procedures for performing non-routine maintenance will be performed for these high-risk jobs.

At this time, C&C Irradiator Service is not authorized to remove or install hardening.

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits. Only the RSO, an Authorized user, or personnel under their direct supervision with documented training on the Category I model being serviced, can perform work on the device; personnel will follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns at all times.

6.4. Irradiator relocation: Reference CCIS - REL document. The hazards of an irradiator relocation are not the radiological concern but the movement itself. For all irradiators with moveable sources that are being relocated, the source(s) (if they are the moveable type such as a Mark 1) will be locked down in the same manner as if it were being readied for transport, using the manufacturer's recommended process. Items to take into consideration when relocating are floor loading, walk down of the travel path noting any floor changes or ramps, and elevator rated load capacity. Security must be arranged with the customer prior to moving. Equipment for the actual move may include engine lifts, roll-A-lifts, and pallet jacks; pry bars, cribbing, steel plates for irregularities in the floor or entrance or exit off an elevator; and a calibrated survey meter for use during irradiator movement. If equipment fails during movement and the irradiator or calibrator falls or topples over, there would be insignificant risk of the source becoming dislodged or exposed. Reference CCIS - EP Emergency Procedures for steps to follow.

6.5 EMERGENCY PROCEDURES

CCIS - EP will be readily available and accessible to CCIS staff at all times.

Self-shielded Irradiators and Calibrators: Emergency Procedures will follow the recommendation in the manufacturer's operator's manual for normal service work (note: a source stuck in the shielded position does not constitute an emergency but it does constitute the need for a well-developed plan prior to execution). Non-routine work such as source transfer or reloading of sources will require a separate ALARA Review Document to address ALARA, and detailed step by step procedures with hold points incorporated into the reload or source transfer procedure, specific to the device being worked on. A requirement for a dry run will be included in the ALARA Review Document for all high-risk jobs. This is so that everyone involved, including the customer, has a clear understanding of what the procedure is in the event of an emergency.

All personnel involved shall have a documented meeting prior to any source transfer or reload (or any other high-risk job). At this meeting all personnel will be made clear in their duties associated with the team effort. If there is a question about procedure at any time, it is the team member's duty to stop and ask for clarification before continuing work. Exits and low dose rate areas shall be identified and discussed at the pre-job meeting and in the ALARA Review Document.
To help prevent a source from becoming unshielded, the ALARA Review Document will address the specific precautions based on the steps in the source transfer procedure, type of transfer involved, location and/or room design, and training. Personnel will follow the requirement to wear all required dosimetry including extremity monitors.

An emergency situation may be one of the following examples, although this is not a comprehensive list:

- The irradiator device falls or topples over
- An alarm from an area monitor, Electronic Dosimeter, or an off scale self-reading dosimeter or PIC
- An over-exposure event takes place, including public dose limits in unrestricted areas
- A source becomes unshielded or dislodged and a safe setting is unattainable
- A source becomes stuck in an unshielded position
- A security threat arises

Anytime there is an emergency, work will immediately cease. More detail on Emergency Procedures is summarized in CCIS Emergency Procures (CCIS - EP), including a ready reference to the points of contact in Agreement States, taken from the website at http://nrc-stp.ornl.gov/asdirectory.html.

Health Physics Instrumentation

7.0. Dose rate instruments should be capable of measuring dose rates in the anticipated range for the device and the work being performed. Examples are preventative maintenance and normal service work. A calibrated operating survey meter with an upward range of 100 mR/hr would be sufficient for these tasks. If performing source transfers, a meter capable of 10,000 R/hr may be required and should be spelled out in the ALARA review.

All dose rate instruments will be calibrated annually. Survey meter calibration program published in Appendix J of NUREG-1556, Vol. 18, "Consolidated Guidance about Service Providers Licenses" dated November 2000, will be followed. C&C Irradiator Service, LLC reserves the right to upgrade survey instruments as necessary.

7.1. Portable instruments used in the field can be CCIS supplied or customer supplied. Instruments will be verified to be calibrated and operational before being used in the field. Instruments used to verify smears will have thin window GM detectors to identify possible leaking sources. C&C Irradiator Service may use customer's instrumentation if isotopic identification is needed.

7.2. Instruments used in the field shall have an audible alarm to alert the service personnel if a change in condition occurs. For high risk jobs, such as source exchange, an alarming area monitor with remote detector and audio/visual indications shall be used.

7.3. Detectors for instruments listed are GM, Ion Chamber, and NaI (Tl) 2" x 2". Instruments read in various quantities such as cpm, dpm, mR/hr, R/hr, and uR/hr. Instruments used should have the capability of detecting alpha, beta and gamma radiation.

7.4. Following is a partial list of Health Physics instruments available for use*:

(1) Eberline E-530 w/44-6/HP-270 Probes
(2) Eberline E-520 w/HP-270/260/210 Probes
(2) RadAlert Inspectors with GM probe
*C&C Irradiator Service reserves the right to upgrade survey instruments as necessary.

Audit Program

8.0. An audit of license compliance will be performed on an annual basis. Audits will include the ALARA program to ensure that personnel receive the lowest exposure possible. The Auditor will note any recommendations or deficiencies on all audits performed; corrective actions will immediately be taken to correct any violation of the license, NRC orders, NRC or State of PA regulations, NRC Confirmatory Action letter, or any other Regulatory Authority commitments. Audit should follow guidance in NUREG-1556, Vol. 18, Appendix I.

Occupational Dosimetry

9.0. A TLD, OSL, or film badge shall be worn at all times when performing service work. The customer facility may also require their dosimetry to be worn. Additionally, a calibrated PIC or ED shall be worn while performing service work; the self-reader should not be more than 25% of full scale at start of the job. Dosimeter readings shall be noted prior to the start and after the finish of each job. High risk jobs such as source transfers additionally require the use of extremity monitors.

9.1. Records of all occupational doses shall be maintained for any personnel that are monitored.

9.2. Individuals will be monitored in accordance with the criteria in the section entitled "Occupational Dose" in

NUREG-1556, Vol. 18, "Consolidated Guidance about Materials License: Program-Specific Guidance about Service Provider Licenses" dated November 2000. Only a NVLAP-approved dosimetry provider will be used.

9.3. When working with devices containing neutron sources such as J.L. Shepherd model 149, neutron dosimetry will be issued and worn. A calibrated working survey meter capable of detecting and calibrated for neutrons will be used while working with any neutron source. Dose for neutron exposure will be calculated based on the neutron dose rate and the time in that dose field. This calculated exposure will be recorded on the dosimeter dose data sheet.

Radiation Surveys and Leak Test

10.0. A leak test shall be taken prior to start of the job (and specifically when servicing portions of the device with the potential for contamination) to determine if the source is leaking. Smears or swabs shall be taken in the area most likely to show contamination if the source was leaking per manufacturer's recommendation. This smear or swab will be checked with a detector/instrument capable of determining if the source is leaking (a leaking source has greater than 0.005 uCi or 185 Bq).

10.1. Dose rate surveys at contact and 30 cm shall be taken on each device and recorded on the "Irradiator Inspection/Test Report" or an individual survey sheet. If doses in excess of public dose limits in unrestricted areas are noted, then the site RSO, the C&C Irradiator Service RSO, NRC Operations Center, and the Agreement State contact (if applicable) will be notified.

10.2. Any smear or swab that shows greater than 1000 dpm will be followed up with area smears to assess the situation. If the follow up smears indicate contamination, the RSO for the facility shall be notified as well as the RSO for C&C Irradiator Service.

10.3. All leak test smears shall be returned to the C&C Irradiator Service shop to be counted on a digital counter if not counted on a digital meter in the field. All instruments for leak test will be verified to be within the ± 2 sigma value or 95% confidence level determined at the time of calibration. The results will be recorded and a leak test certificate issued to the facility (if requested) stating the results (or recorded on the Inspection Test Report). Leak tests involving source exchange will be taken prior to and after completion of transfer.

10.4 Radiation surveys of the shop for contamination and dose rates surveys should be quarterly but in no case greater than 6 months as this survey also includes leak test and inventory of any licensed source (if sources are available).

10.5. Surveys on incoming radioactive material packages shall comply with all aspects of 10 CFR 20.1906 and will have a smear taken on outer and inner surfaces. A dose rate survey shall be performed prior to opening packages to ensure the dose rates at contact and 1 meter (or TI) on the package are consistent with markings on the label. All packages will be monitored for contamination and radiation levels, and shall be inspected for degradation of package integrity. All information on the shipping document and/or bill of lading shall be reviewed prior to opening package. If the smears show activity in excess of 4Bq/cm^2 (49 CFR 173.443) then

the package shall be closed back up and the RSO for the job site, RSO for the service provider, final delivery carrier, NRC Operations Center, Agreement State contact (if applicable), and the shipper will be notified.
If any package damage is noted that leads to elevated radiation levels or other potential abnormality with DOT compliance, then the facility RSO, service provider RSO, final delivery carrier, the NRC Operations Center and the shipper will be notified. Package may still be accepted for delivery after consultation with affected parties.

Maintaining Records

11.0. All records for devices and work performed shall be maintained for review by regulatory authorities and customers. C&C Irradiator Service will maintain a history for each device serviced including radiation surveys, leak tests, performance test and check-off sheets. All calibration documents will be maintained for review by regulatory authorities or customers. C&C Irradiator Service will maintain a history of all employees, including personnel dose records for all employees that have been monitored by C&C Irradiator Service. Initial training records will be kept for the lifetime of the worker as part of their employee record. Authorized Work Procedure (CCIS - AWA) documentation will be maintained for 5 years. Audit records will be maintained for 3 years.

Notifications

12.0. C&C Irradiator Service will maintain records of repairs that use replacement parts. All replacement parts will conform to the parts that are listed in the SS&DR and also with the manufacturer's recommendation. CCIS will inform the customer licensee, prior to beginning, that they are performing work and if any failure needs to be reported (10 CFR Part 21.21, Notification of failure to comply or existence of a defect and its evaluation). After maintenance or repair is completed, the irradiator or calibration device will be tested and determined to function as designed before being returned to routine use. The site will be provided with a copy of the completed Inspection/Performance Test report.

12.1. The following table lists a summary of required notifications: "Table 8.4 Typical NRC Incident Notifications Required for Service Provider Licensees" and/or Agreement State Regulators; this notification will be made by the service provider RSO.

Table 8.4 Typical NRC Incident Notifications Required for Service Provider Licensees.

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i)
Extremity dose greater than 0.5 Sv (50 rem) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems)	none	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Filing petition for bankruptcy under 11 U.S.C.	none	immediately after filing petition	10 CFR 30.34(h)
Expiration of license	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities at entire site	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months at the entire site	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)

Note: Telephone notifications shall be made to the NRC Operations Center at (301) 816-5100 or (301) 951-0550.

ADDENDUM TO Radiation Safety Manual

Operating and Emergency Procedures Relating to Service Work on Panoramic or open air collimated devices (ANSI Category II)

13.0. Service work may be provided on panoramic or open air collimated irradiator devices (ANSI Category II). Examples of these devices include J.L. Shepherd Models 81, 28, 78-2M and 142. Verification of Authorized Work Procedure: reference Document CCIS - AWA. No work will be performed unless work activities have been confirmed to fall within the allowed licensed activities.

13.1 Responsibilities of customer and service provider

Devices that are serviced at the customer's facility will be serviced under the C&C Irradiator Service license. C&C Irradiator Service will comply with facility's rules for maintaining control of radioactive material and security while service work is being performed, and will also comply with all facility requirements for safety including postings. In addition, C&C Irradiator Service may use additional locks or tag outs to control use while service is being provided. Any degradation of the safety system or any part of the device that could cause failure will be identified and recommendations made to the customer. An agreement **(Division of Responsibilites)** between C&C Irradiator Service and the customer will be established that specifies all aspects of the work provided including individual responsibilities, licensed activity responsibilities, safety commitments, and site decontamination or cleanup if necessary. This document will be maintained for inspection.

13.2. Instructions for handling and use of radioactive material (all devices)

All personnel working under the C&C Irradiator Service license will be monitored for radiation exposure using a self-reading dosimeter or electronic dosimeter and NVLAP approved dosimetry. Personnel working on a routine basis providing service under the C&C Irradiator Service license shall have completed the 40-hour health physics class (refresher training annually) and be monitored for radiation exposure with a TLD or OSL or film badge, and a self-reading dosimeter or electronic dosimeter. Extremity dosimeters will also be worn. Operation and use of devices shall be consistent with the manufacturer's recommendations and Emergency Procedures in the manual for the device for which service is being provided. Personnel working on all devices shall use a calibrated and operational survey meter in the area at all times. ALARA will be practiced when servicing all devices. Personnel shall comply with the customer's security of licensed material when service is being performed. A smear survey of portions of the device (per manufacturer's recommendation) most likely to show if a source is leaking, should be taken prior to service work if applicable. If smear results are greater than 0.005 µCi (185 Bq), follow the guidance in CCIS - EP, Emergency Procedures.

13.3. Operating and Emergency Procedures

The types of service work that may be performed on ANSI Category II irradiators include routine preventive maintenance, service repair work, testing/inspection of irradiators, leak test performance, and irradiator relocation or removal. The manufacturer's procedures for inspection, maintenance, and test of safety systems,

If applicable, shall be followed.

Emergency Procedures

Dislodged Source or exposed source:

1. Immediately exit the area.
2. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).
3. Keep others out of area, post area, verify dose rates, lock doors or post barricades to ensure that dose to members of the public does not exceed 0.002 rem in 1 hour in unrestricted areas (10 CFR 20.1301).
4. Evaluate worker dose received using dosimetry.
5. Develop a recovery plan in conjunction with facility RSO (evaluate the need for a Planned Special Exposure that may be needed in accordance with 10 CFR part 20.1206) with long reach tools, shielding and dose estimates; document actions.

6. Lead Bricks affixed to JL Shepherd 81 beam port insufficient or fail:
    1. If source is raised, immediately lower source to shielded position.
    2. Check personal dose rates on electronic dosimeter or PIC.
    3. If overexposure or alarming dosimeter have occurred follow procedure above.
    4. Place device in safe secure condition.
    5. Contact CCIS RSO.

Over Exposure Event:

1. Stop all work; immediately exit the area.
2. Evaluate dosimetry and make notifications per 10 CFR Part 20.2202.
3. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).
4. Keep over exposed individuals in areas that are not greater than background.

Alarming Dosimeter or Area Monitor:

1. Anytime there is an alarm from an area monitor, electronic dosimeter, or an off scale self-reading dosimeter, work will immediately cease. All personnel will exit the area until all determinations are made as to the reason for such alarm.
2. If an off-scale survey meter condition exists, exit the area until a determination can be made if the meter is faulty or there is a radiological problem.
3. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).
4. Keep others out of area, post area, verify dose rates, lock doors or post barricades to ensure that dose to members of the public does not exceed 0.002 rem in 1 hour in unrestricted areas (10 CFR 20.1301).
5. Evaluate worker dose received using dosimetry.
6. Develop a recovery plan in conjunction with facility RSO; document actions.

Medical Emergency:

1. Put work in safe condition if possible, then stop and assist injured individual if needed.
2. Contact facility RSO.
3. Follow site specifics for a medical emergency.

Fire:

1. Put work in safe condition, if possible.
2. Exit the area per site specifics, contact facility RSO.
3. If entering the area after a fire, monitor dose rates to verify that the source integrity has been maintained.

Flood:

1. Put work in safe condition, if possible.
2. Exit the area per site specifics, contact facility RSO.
3. If returning to an area that has been flooded, monitor for dose rates and contamination.

Irradiator fails to function as designed:

1. Determine if the failure could cause a substantial safety hazard per 10 CFR part 21.21.
2. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50) and 10 CFR 21.21 as applicable.
3. Repair if possible to restore to a safe operating condition. If repair cannot be made, remove the unit from service until it can be repaired.

Leaking Source:

1. If removable contamination in excess of 0.005 μCi is detected on a source, restrict access to the room, notify the facility RSO and CCIS RSO, and take additional area smears. Document locations and contamination level of each smear.
2. Request that facility RSO immediately lock and tag the irradiator out of service.
3. Develop a plan for decontamination, repair or disposal, in consult with the facility RSO.
4. Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).

Device topples over or Rigging fails:

1. Immediately perform a dose rate survey to ensure the source has not been dislodged. If elevated dose rate other than what is anticipated or visual damage to the irradiator (that may cause the source to leak) immediately exit the area.
2. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).
3. Keep others out of area, post area, verify dose rates, lock doors or post barricades to ensure that dose to members of the public does not exceed 0.002 rem in 1 hour in unrestricted areas (10 CFR 20.1301).
4. Evaluate worker dose received using dosimetry.
5. Secure the device from unwanted movement and verify that it cannot move any more.
6. If the dose rates are acceptable and visual damage is observed that may cause a source to leak, perform a smear survey for contamination.
7. Develop a recovery plan in conjunction with facility RSO.
8. If specialized equipment is needed, arrange to acquire equipment and recover as needed.

Security Threat

1. For high-risk jobs where a source is being transferred, CCIS will comply with the security for the site.

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Table 8.4 Typical NRC Incident Notifications Required for Service Provider Licensees.

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems)	none	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Filing petition for bankruptcy under 11 U.S.C.	none	immediately after filing petition	10 CFR 30.34(h)
Expiration of license	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities at entire site	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months at the entire site	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)

Note: Telephone notifications shall be made to the NRC Operations Center at (301) 816-5100 or (301) 951-0550.

The following is a ready reference to the points of contact in Agreement States, taken from the website at http://nrc-stp.ornl.gov/asdirectory.html but is subject to change.

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Authorized Work Activities

This procedure is to govern licensed work activities within the scope of the license.

1. Verification of licensed activities will be verified by one or more of the following:
   a. Sealed Source and Device Registration
   b. Customer's license, personnel, or licensee documentation
   c. Manufacturer's brochure
   d. Manufacturer's web site
   e. Manufacturer's Technical Manual or user's manual
   f. Verification from NRC Regulatory Authorities

No work will be performed unless work activities fall within the allowed licensed activities under the scope of the license. Verification will also be performed and documented for areas of exclusive Federal jurisdiction.

The irradiator make and model on which this license authorizes preventive maintenance and service work and that apply to this procedure are:

Category I

1. J.L. Shepherd Mark 1 Series (Registration Number CA 598-D-104-S)
2. J.L. Shepherd Model 484 (Registration Number CA 598-D-113-S)
3. J.L. Shepherd Model 89 (Registration Number CA 598-D-108-S)
4. J.L. Shepherd Model 143 (Registration Number CA-598-D-103-S)
5. J.L. Shepherd Model 109 (Registration Number CA 598-D-116-S)
6. CIS-US Model IBL 437 (Registration Number MA 0219-D-813-S)
7. Gammacell 40 (Registration Number NR-1307-D-101-S or NR-0169-D-132-U)
8. Gammacell 1000 & 3000 (Registration Number NR-1307-D-102-S or NR-0220-D-840-S)
9. Eberline 1000B (Registration Number NR-8105-D-805-S)
10. Gammacell 220 (Registration Number NR 0220-D-831-S or NR-8135-D-804-S)
11. Gammacell 200 (Registration Number NR-8003-D-802-S)
12. Gammator Model M, M34, M38, G50, G100, G150 and G 200 (Registration Number NR-0880-D-806-S)
13. J.L. Shepherd Model Gammacell 220R (Registration Number CA 598-D-118-S)
14. J.L. Shepherd Model 142-MA (Registration Number CA 598-D-131-S)
15. J.L. Shepherd Model 149 Series (Registration Number CA 598-D-109-S)
16. J.L. Shepherd Model Mark IV Dosimeter Irradiator (Registration Number CA 598-D-105-S)
17. Custom Device Mk 1-25 SN 1032 with Ao of 780 curies of Cs-137 located at Uni. of Michigan

Category II

18. J.L. Shepherd Model 28 (Registration Number CA 598-D-106-S)
19. J.L. Shepherd Model 81-8, 81-8EXT, 81-10, 81-12, 81-12EXT, 81-14, 81-16, 81-18, 81-20, 81-22, 81-24, 81-26 (Registration Number CA 598-D-115-S)
20. J.L. Shepherd Model 142 (Registration Number CA 598-D-114-S)
21. J.L. Shepherd Model 78-2M (Registration Number CA 598-D-107-S)

The irradiator make and model on which this license authorizes source loading/unloading and that apply to this procedure are:

Category I

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2. J.L. Shepherd Model 484 (Registration Number CA 598-D-113-S)
3. J.L. Shepherd Model 89 (Registration Number CA 598-D-108-S)
4. Gammacell 40 (Registration Number NR-1307-D-101-S or NR-0169-D-132-U)
5. Gammacell 1000 & 3000 (Registration Number NR-1307-D-102-S or NR-0220-D-840-S)

ALARA Procedure

The ALARA concept is an excellent foundation for any radiation safety program; when practiced it allows for the lowest dose to be received by occupationally exposed personnel. The primary ALARA principles are use of time, distance, and shielding to minimize the radiation dose received by a worker. The ALARA Procedure is a formal review process to discuss details of a high- risk job so that dose can be as low as reasonably achievable. This procedure is for jobs wherein the potential exists for exposure to an unshielded source (usually during source transfers). The items below list all the controls that should or can be utilized and will be considered in each task or step of the source transfer or any other high-risk procedure.

1. Primary Shielding
2. Engineering controls
3. Training
4. Communication
5. Long reach handlers
6. Remote observation
7. Emergency conditions
8. Job task
9. Dose evaluation
10. Hold points
11. Verifications
12. Instrument Response check
13. Dosimetry
14. Documented pre-job briefing
15. Mock up or dry run prior to source movement
16. Area radiation monitor and instruments for use

Additional Detail:

1. Primary shielding is typically lead or DU that is placed between the source and the device or transfer shield exterior to minimize radiation levels at locations where personnel may be present.

2. Engineering controls are items such as temporary shielding, long reach tooling, alarming meters, and physical stops to prevent unwanted movement of the source.

3. Training shall consist of mock up or dry run, task authorization, engineering controls, instrument response checks, hold points, communications, use of tooling, lessons learned and review of operating and emergency procedures.

4. Communications shall be discussed to address that each person involved in the transfer of sources shall have a clear understanding of each process in the procedure and limitations. Use of pass-back communication required. Understanding is communicated with all personnel that any perception of an unsafe condition is cause for any individual to voice a Stop command. Furthermore, understanding is communicated that all personnel have the opportunity to voice any questions, concerns, process improvements, etc.

5. Evaluate the need for long reach handlers.

6. Remote observation would discuss the use of bore scope, cameras or mirrors to keep dose as low as possible.

7. Evaluation and an emergency plan will be developed based on the type of transfer, location, room size, source size, type of transfer shield setup, etc.

8. Job task will be addressed in the pre-job briefing and define who can do what and when.

9. Dose evaluation will be calculated for the various steps in the transfer procedure for whole body and extremities.

10. Hold points are places in the procedure where one person verifies that the preceding step has been completed and will give the thumbs up or repeat the steps until the process is complete. Use of pass-back communication required.

11. Verifications would be used after hold points to ensure that a step in the procedure has been completed successfully.

12. Evaluation of instrument response checks will be determined based on the transfer procedure e.g.: response test after securing a meter for proper operation if the instrument has an alarm, test the alarm function etc.

13. Dosimetry shall be evaluated for the type of transfer to be performed. Also, relocation of dosimetry may be required: the dosimeter may be worn on the shirt pocket, shirt collar, lanyard, belt, etc. so that the highest potential dose rate is recorded.

14. Pre-job briefing will be conducted prior to the start of any transfer. The items discussed will be in the ALARA Document and will address all concerns prior to starting the job with the source transfer procedure.

15. A mock-up with all involved in the work or if a mock-up is not possible, then a dry run will be performed prior to moving any sources.

16. Area Radiation monitor will be evaluated: where to locate, how to response test, and actions to take when responding to an alarm.

The above items will be used to develop a pre-job discussion so a formal instruction can be provided prior to starting the job. The attachment B will have a check off sheet after the final review of the Source Transfer Procedure.

Trustworthy and Reliable Determination

Due to using and maintaining unescorted access to category 1 and category 2 quantities of radioactive material (RAM), C&C Irradiator Service, LLC (CCIS) must comply with 10 CFR part 37. Below are CCIS' procedures and explanations on how they will meet the requirements brought forth in this part.

Access authorization program per 37 Subpart B

The reviewing officials (RO) for CCIS will consist of Christopher V. Nostrand and will head the access authorization program that will provide individuals with unescorted access to category 1 and category 2 RAM.

Before a background investigation can take place, the RO must receive consent to review the individual's information by means of a signed agreement. A thorough background investigation will take place following the written consent from the individual. The investigation shall include items such as:

A. Fingerprinting and FBI identification card along with a criminal history check in accordance with 37.27. The licensee shall notify the individual that his or her fingerprints will be submitted for a review of his or her criminal history record. The individual will retain the right to challenge the results of the law enforcement agency that contributed to the criminal history check within 10 days after the individual is notified of the results. CCIS will receive a confirmation receipt from the individual stating they were granted the opportunity to challenge the results within the allocated 10 days before any adverse determination has been made.

B. Verification of true identity by use of reviewing an official identification document (driver's license, passport, birth certificate). Licensee will review and document the type of identification used and will make a photocopy of the item in accordance with 37.31. Licensee will certify identification was reviewed properly and maintain the certification and all related documents upon inspection

C. Employment verification from the previous 7 years from the date of the application or since the individual turned 18, whichever is shorter

D. Education verification to confirm the individual has participated during the time period given

E. Character and reputation determination including reference checks solely based upon whether the individual can be deemed trustworthy and reliable

If a previous employer, educational institution, or reference fails to provide information within 10 days after the initial request, the licensee may use an alternate source to gather more information.

Grandfathering will be provided to all individuals already granted unescorted access to category 1 and category 2 quantities of RAM under the Fingerprint Orders. However, reinvestigations will take place every 10 years and shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with § 37.27, and this will include individuals that were previously grandfathered in as well.

CCIS will maintain an approved for unescorted access list; anyone terminated must be removed from the list no later than 7 business days. All of the documents associated with the background investigation for the trustworthiness and reliability status will be retained by CCIS for 3 years after the date where the individual no longer needs unescorted access to category 1 or category 2 quantities of RAM.

If an individual is denied unescorted access to category 1 or category 2 RAM, they will be escorted by an individual deemed trustworthy and reliable and will be under the supervision of the trustworthy and reliable individual at all times when using the category 1 or category 2 RAM.

CCIS will maintain background information on an individual under 10 CFR 37 subpart B in a system of files that are restricted to only the individuals granted permission to review these files. Information will not be disclosed to anyone other than the individual, a representative of the individual, or those with the need to access the information during the process of granting or denying unescorted access

37.41 Security Program

CCIS does not possess quantities of category 1 or category 2 RAM. However, CCIS will follow each licensee's security program in accordance with 37.41 while using aggregated category 1 or category 2 radioactive material at the licensee's facility.

37.71 Additional requirements for transfer of category 1 and category 2 quantities of radioactive material.

Though CCIS never takes possession of radioactive material during a transfer, CCIS will confirm that the receiver of the RAM is authorized to do so by means of the NRC's license verification system (LVS) or by contacting the license issuing authority.

If neither of the previously mentioned verification authorities can be reached, CCIS will maintain the right to request to review the receiver's license to insure they are authorized to accept the type, form, and quantity of the RAM being transferred. CCIS will also request a written certification by the receiver that they are indeed authorized to receive the RAM. The certification will include license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. CCIS shall confirm the authorization by the NRC's LVS or the license issuing authority by the next business day.

37.75 Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.

Due to CCIS preparing aggregated quantities of category 1 or category 2 radioactive materials for shipment, we will implement preplanning and coordinate the departure and arrival times at a no-later-than timeline for the transferor and receiver of the RAM, respectively.

CCIS will ensure the license issuing agency, whether it be the NRC or another license issuing agency, will be aware of the planned transfer, as well as security at the transferor's facility, security at the receiver's facility, and security during transit as well.

CCIS will provide the details in accordance with 37.75 in their work instructions for each particular job, as each job varies. CCIS will also document and retain the preplanning and coordination of the transfer for 3 years after the date of the transfer being completed

37.77 Advance notification of shipment of category 1 quantities of radioactive material.

CCIS will notify the NRC or other license issuing agency 14 days before the transport will take place either electronically or by mail in accordance with 37.77(a)(1)(2)(3). The notification will include all specified material according to 37.77(b)(1)(2)(3)(4)(5)(6)(7) and will be retained for 3 years after the transfer is completed or the cancellation notice is sent in.

CCIS will promptly notify the NRC or agreement state contacts if a revision or cancellation is required in accordance with 37.77(c)(1)(2)(d).

37.101 Form of Records & 37.105 Inspections

CCIS will retain all records, either original or electronically produced, according to the time periods specified throughout 10 CFR part 37. If a period is not specified, CCIS will retain copies of requires documentation until given permission by the license issuing authority or until the facilities' licenses are terminated.

Preventative Maintenance Procedure

PART 1: ANSI CATEGORY I:

The irradiator models on which this license authorizes service work and that apply to this procedure are:

1. J.L. Shepherd Mark 1 Series (Registration Number CA 598-D-104-S)
2. J.L. Shepherd Model 484 Series (Registration Number CA 598-D-113-S)
3. J.L. Shepherd Model 89 Series (Registration Number CA 598-D-108-S)
4. J.L. Shepherd Model 143 Series (Registration Number CA-598-D-103-S)
5. J.L. Shepherd Model 109 Series (Registration Number CA 598-D-116-S)
6. J.L. Shepherd Model Gammacell 220R (Registration Number CA 598-D-118-S)
7. J.L. Shepherd Model 142 Series (Registration Number CA 598-D-131-S)
8. J.L. Shepherd Model 149 Series (Registration Number CA 598-D-109-S)
9. J.L. Shepherd Model Mark IV Dosimeter Irradiator (Registration Number CA 598-D-105-S)
10. Gammacell 40 (Registration Number NR-1307-D-101-S or NR-0169-D-132-U)
11. Gammacell 1000 & 3000 (Registration Number NR-1307-D-102-S or NR-0220-D-840-S)
12. Gammacell 220 (Registration Number NR 0220-D-831-S or NR-8135-D-804-S)
13. Gammacell 200 (Registration Number NR-8003-D-802-S)
14. Gammator Model M, M34, M38, G50, G100, G150 and G 200 (Registration Number NR-0880-D-806-S)
15. Eberline 1000B (Registration Number NR-8105-D-805-S)
16. CIS-US IBL 437 Models B, G, H (Registration Number MA 0219-D-813-S)

Prerequisites:

1. Verify work procedure is authorized via CCIS - AWA.
2. Verify Irradiator make and model is authorized.
3. Determine identities of all personnel involved in the job.
4. Determine adequacy of training and experience.
5. Determine adequacy of dosimetry.
6. Determine availability of equipment and instrumentation. Replacement parts will be in conformance with the parts that have been identified in the sealed source and device registration and in agreement with the manufacturer's recommendation. Any non-manufacturer supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer will be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration before they are used.
7. Verify ready availability of CCIS - EP for use in emergency procedures.

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits. Only personnel with documented training on the Category I model being serviced can perform work on the device; personnel will follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns at all times.

Preventative maintenance will be completed with the Irradiator Inspection/Performance Test Report. Test of all items listed in the specific Irradiator Inspection/Performance Test Report will be identified as OK with a yes or no. Any items that are deficient will be corrected and noted in the comment section. A typical procedure for preventative maintenance of Category I irradiators is outlined below:

1. Perform a dose rate survey with the highest contact and 30 cm reading.
2. Perform a leak test prior to working on the device.
3. Test all electrical components for tight connections and relay operability. Test switches independently to ensure switches used in the safety system have not failed closed. Check timers against a calibrated stopwatch for accuracy.
4. Check mechanical components for wear and replace as needed. Drive motors, bearings, chains, sprockets and set screws will be checked, lubricated and/or adjusted as needed.
5. Check pneumatic systems for leakage (internal and external); if multiple sources are used then system will be checked for unison.
6. Operate the device enough times to ensure proper operation.
7. Any items that cannot be corrected will be noted. If failed items are part of the safety system, the device will be tagged out of service until the problem is corrected. Determine if the failure could cause a substantial safety hazard per 10 CFR part 21.21. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50) and 10 CFR 21.21 as applicable.
8. Upon completion of service visit, provide a copy of the Irradiator Inspection/Service Reports to the customer. Communicate any problems or recommendations.

PART 2: ANSI CATEGORY II:

The irradiator models on which this license authorizes service work and that apply to this procedure are:

1. J.L. Shepherd Model 28 (Registration Number CA 598-D-106-S)
2. J.L. Shepherd Model 81-8, 81-8EXT, 81-10, 81-12, 81-12EXT, 81-14, 81-16, 81-18, 81-20, 81-22, 81-24, 81-26 (Registration Number CA 598-D-115-S)
3. J.L. Shepherd Model 142 Series (Registration Number CA 598-D-114-S)
4. J.L. Shepherd Model 78-2M (Registration Number CA 598-D-107-S)

Prerequisites:

1. Verify work procedure is authorized via CCIS - AWA.
2. Verify Irradiator make and model is authorized.
3. Determine identities of all personnel involved in the job.
4. Determine adequacy of training and experience.
5. Determine adequacy of dosimetry.
6. Determine availability of equipment and instrumentation. Replacement parts will be in conformance with the parts that have been identified in the sealed source and device registration and in agreement with the manufacturer's recommendation. Any non-manufacturer supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer will be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration before they are used.
7. Verify ready availability of CCIS - EP for use in emergency procedures.

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive lethal radiation doses. Only personnel with documented training on the Category II model being serviced can perform work on the device; personnel will follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns at all times.

Preventative maintenance will be completed with the Irradiator Inspection/Performance Test Report. Test of all items listed in the specific Irradiator Inspection/Performance Test Report will be identified as OK with a yes or no. Any items that are deficient will be corrected and noted in the comment section. A typical procedure for preventative maintenance of Category II irradiators is outlined below:

The following procedures will be followed in the general order as listed:

1. Service provider personnel will wear all required dosimetry. However, based upon previous occupational dose reports from the last 5 years, whole body doses have not exceeded 100 millirem/year. Therefore, extremity monitors will not be required while performing non-routine maintenance other than during a source exchange. A calibrated PIC or ED shall also be worn while performing service work; the self-reader should not be more than 25% of full scale at start of the job. Dosimeter readings shall be noted prior to the start and after the finish of each job.

2. Use only those survey meters that have been verified to be appropriately working and calibrated.

3. Operate the device in normal mode to define if the device is operating properly following the instructions in the operation manual.

4. Verify that the source is in the stored position (green light illuminated) then remove the key from the control panel. From the control room (if one is available), disconnect the air supply or electrical power to the source drive so the source cannot move.

5. Perform a dose rate survey as the irradiator room is entered; the survey instrument will be kept on while in the area at all times.

6. Perform a leak test of the area most likely to show contamination (per manufacturer's recommendation; see Section 13.2) prior to working on the device.

7. Insert the beam plug (if available); this shielding will remain in place until the service work is completed. (b)(7)(F)

8. (b)(7)(F)

10. Test all electrical components for tight connections and relay operability. Test switches independently to ensure switches used in the safety system have not failed closed. Check timers against a calibrated stopwatch for accuracy.

11. Test all safety interlocks independently per 10 CFR part 36 to ensure proper operation such as scram switches, set-up switch, photo-cells, door switches, audible and visual alarms, etc.

12. Check mechanical components for wear and replace as needed. Cables, drive motors, bearings, chains, sprockets and set screws will be checked, lubricated and or adjusted as needed.

13. Check pneumatic systems for leakage (internal and external).

14. Reconnect the air or electrical supply and operate the device enough times to ensure proper operation.
15. Any inspection items that cannot be corrected will be noted. If failed items are part of the safety system, the device will be tagged out of service until the problem is corrected. Determine if the failure could cause a substantial safety hazard per 10 CFR part 21.21. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50) and 10 CFR 21.21 as applicable.
16. Upon completion of service visit, provide a copy of the Irradiator Inspection/Service Report to the customer. Document in writing on the service report given to the customer any problems or recommendations.

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 (CCIS - CAR) 10/1/17

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.

Document Control

CCIS 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.

CCIS 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 CCIS 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.

Procedure for Unloading/Loading Self-Shielded Irradiators

This procedure describes the necessary steps for the safe unloading and loading of high activity (Ci quantities) of cesium or cobalt irradiator sources at customers' facilities. By following this process, the source will remain shielded at all times during any transfer. This procedure is typically used for sources that must be removed to clean and hone the source tube, and for sources that must be removed for shipping. The source to be unloaded will be removed from the irradiator and placed into a transfer shield, then either transferred back into the irradiator or into a shipping cask. If it is a new source installation, the new source to be loaded will be removed from its shipping cask, loaded into a transfer shield, and then transferred into the irradiator.

Prerequisites:

1. Verify work procedure is authorized via CCIS AWA.
2. Verify Irradiator make and model is authorized.
3. Determine identities of all personnel involved in the job. All source loading/unloading jobs require a two-individual minimum.
4. Determine adequacy of training and experience. All personnel involved in the source transfer shall participate in a mock-up prior to actual source transfer; if a mock-up is not possible, then a dry run involving all personnel will be performed prior to moving any sources.
5. Determine adequacy of dosimetry.
6. Determine if all personal protective equipment (PPE) is available for use at appropriate times. PPE may include, safety shoes, hard hats, safety glasses, etc.
7. Determine job responsibilities of each person involved in the job.
8. Determine availability of all necessary equipment and instrumentation.
9. Verify ready availability of CCIS - EP for use in emergency procedures. All personnel involved with the source transfer process shall review this document.
10. Ensure site security and facility notifications.

Definitions:

Source removal tool: This is a rod with threads appropriate for the source being removed; this tool is inserted through the restrictor shield on the transfer shield.
Single-source Assembly: An assembly on one operator rod that includes the tungsten shielding, the special form source(s), and the spacer between the source(s). Multiple sources inside of the source holder with a spacer may be used to achieve a larger 100% dose area for an improved isodose such as a JL Shepherd model Mark 1 or give different dose rates such as a JL Shepherd model 89.
Restrictor shield: This is the shield that bolts on the top of the transfer shield and limits source movement to within the transfer shield cavity only. The through hole is smaller than the diameter of the source.
Source stop tool: This is a fixture that is attached to the irradiator device shield by a bolt or nut to prevent unwanted source movement out of the shield.
Retaining washer or nut: This is a factory piece that prevents removal of the source from the irradiator without the use of an angle grinder or similar tool.
Operator: This is a rod that raises and lowers the source within the source tube of the irradiator between its shielded and irradiate positions.
Roll pin: This is a fastener that secures the operator rod to the tungsten shield.

Interface Plate: This is a steel plate that attaches to the transfer shield and the model irradiator that the source is being transferred from or to.
Tungsten shield: This is part of the source assembly that includes the source capsule, source capsule holder (which holds the source capsule in an aluminum cup) and tungsten. The tungsten is attached to the source capsule holder containing the source capsule inside; the tungsten is not removed from the source assembly.
Work Instructions: These are specific instructions for the job, location and irradiator that the source is being transferred from or into and follows the source reloading procedure with only minor deviations specific to the job.

Equipment:

- Rigging Company or
- Gantry Crane or forklift with greater than 25% of the total lift
- Chain hoist rated for 25% greater than the weight of the lift
- Chains or slings with capacity rated 25% greater than the lift
- For Gammacell 40 Irradiators, a table for horizontal transfer with rating of at least 3000 lbs or gantry crane with 2 hoists
- Cribbing as needed
- Rigging such as eye bolts, shackles etc.
- Alarming dosimeter (ED) and high range self-reading dosimeter for each individual involved in the job
- Calibrated survey meter with a range to 5 R/hr or greater.
- Calibrated lower range survey meter 1 – 200 mR/hr with audible speaker
- Personnel dosimeters (TLD, OSL or film) for each individual involved in the job
- Finger ring dosimeters for each hand of those individuals involved in the source transfer work
- Alarming area monitor with remote detector such as Ludlum Model 375 or equivalent
- Hand tools and power tools
- Vacuum (if cleaning source tube)
- Smears or swipes
- Lead bricks for additional shielding as needed
- Interface plate for the Model on which the transfer is being performed; the interface plate attaches to the device and to the transfer shield.
- Source shipping cask (Note: This procedure assumes a Neutron Products Inc. (NPI) or EnergySolutions shipping cask will be used. If a different shipping cask is used, then new procedures will be written and regulatory approval obtained before utilizing.)
- Source transfer shield

This procedure applies to self-contained, dry source storage irradiators, defined as American National Standard N43.7 as Category I: an irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration. The irradiator make and models that apply to this procedure are:

1. J.L. Shepherd Mark 1
2. J.L. Shepherd Model 484
3. J.L. Shepherd Model 89
4. Gammacell 40

5. Gammacell 1000
6. Gammacell 3000

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits. Only personnel with documented training on the Category I model being serviced can perform work on the device; personnel will follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns at all times. The ALARA philosophy (principles of Time, Distance, Shielding) and general safety rules and good practice shall be used to limit personnel exposure.

Generic Procedures:
Minor deviations that do not degrade the safety of personnel or alter the SS&D registration from this process, consistent with the specifics of various Category I models, may be made with the concurrence of the C&C Irradiator Service RSO. The following labeled "Work Instructions" (WI) detail the steps and considerations to transfer the source from the irradiator to the transfer shield, and from the transfer shield to the irradiator.

Part 1: Preparation of Irradiator for Source Unloading
1. **COMPLETE** the ALARA review and pre-job brief prior to performing any work.

2. **ENSURE** that the work space has enough room. Minimum requirements for gantry crane are approximately 10' by 10' by 10'. If the irradiator is in a location where a forklift may be used, this can be substituted for a gantry crane. If the room is not adequate, then the irradiator will need to be moved to a suitable level location.

3. If a gantry crane is used, **ASSEMBLE** for desired height installing chain hoist and trolley; then test for proper operation.

4. **PERFORM** a dry run of source transfer using a dummy source and following all steps as would be followed for the actual source transfer.

5. **POST** and restrict entry into areas in which 2 mR/hr can be exceeded.

6. **MOVE** the transfer shield to a location where the source is to be unloaded.

7. **CONFIRM** all personnel are in place, with proper dosimetry on, that all instrumentation and tools are in place, and that all instrumentation is turned on and operable, and has been response tested in the condition and placement that they are being used.

8. **DISCONNECT** irradiator air and electrical supply as applicable.

9. **ENSURE** the irradiator door is locked, the attenuators are "in" and the source is "off", as applicable.

10. **REMOVE** tower cover or irradiator outer shell.

(b)(7)(F)

PROCEED WITH CAUTION: This step may cause elevated radiation levels to be present. Be conscientious to maintain ALARA practices and be aware of instrument readings.

(b)(7)(F)

PROCEED WITH CAUTION: This step may cause elevated radiation levels to be present. Be conscientious to maintain ALARA practices and be aware of instrument readings.

11. **STOP** point: have a briefing to review job duties and positions during the transfer. Review communications plan for all to know when the source is going to be moved; verification from both individual technicians will be noted.

12. **CONFIRM** there is a calibrated and operable survey meter near the drawer and in view of the source technician during source movement, and that survey meter is turned on and operable, and has been response tested in the condition and placement that it is being used.

PROCEED WITH CAUTION: This step may cause elevated radiation levels to be present. Be conscientious to maintain ALARA practices and be aware of instrument readings.

13. **MOVE** the source slowly into the transfer shield. If any restrictions are felt, the source will be returned to the irradiator shield and transfer steps will be repeated. (Typically, the transfer shield and the shipping cask may have slight misalignment; repeat step 5) If this occurs a second time, the source will be returned to the irradiator shield and the transfer will be stopped until the problem is resolve

14. **Stop** the process if step 14 cannot be completed, check dose rates, step away to a low dose rate area, discuss status and next steps with CCIS personnel and client RSO, and evaluate the need to apply the Emergency Procedures CCIS - EP document.

15. **CLOSE** the drawer and lock shut once the source is fully moved into the transfer shield.

PROCEED WITH CAUTION: This step may cause elevated radiation levels to be present. Be conscientious to maintain ALARA practices and be aware of instrument readings.

(b)(7)(F)

PROCEED WITH CAUTION: This step may cause elevated radiation levels to be present. Be conscientious to maintain ALARA practices and be aware of instrument readings.

(b)(7)(F)

10. **CONFIRM** there is a calibrated and operable survey meter near the drawer and in view of the source technician during source movement.

11. **NOTE** the source assembly in the NPI shipping cask is shielded from dose rates by the tungsten shield attached to the source assembly.

PROCEED WITH CAUTION: This step may cause elevated radiation levels to be present. Be conscientious to maintain ALARA practices and be aware of instrument readings.

(b)(7)(F)

PROCEED WITH CAUTION: This step may cause elevated radiation levels to be present. Be conscientious to maintain ALARA practices and be aware of instrument readings.

(b)(7)(F)

21. **TEST** irradiator for proper operation >35 times or sufficient times to ensure proper operation. Additionally, test all features of the safety system. Document all work on the Service Report and the Irradiator Inspection Test Report.

Procedure for Relocation and Preparation for Shipping

This procedure specifies the requirements to follow for jobs in which an irradiator will be relocated and/or prepared for shipping.

Prerequisites:

1. Verify work procedure is authorized via CCIS - AWA.
2. Verify Irradiator make and model is authorized.
3. Verify floor loading, elevator load capacity, and travel path to be adequate.
4. Verify security arrangements have been made.
5. Address RAMQC in transit, if applicable, in accordance with Increased Control Item #3B from NRC Order EA 05-090.
6. Ensure that only authorized, licensed shippers will be used for transportation of radioactive sources and/or devices.

   Note: CCIS will not be the shipper of any RAMQC sources, but will contract with an approved shipper.

7. Verify proper source lock down fixtures are available.
8. Verify rigging equipment is rated for the relocation or move.
9. Verify availability of CCIS - EP for use in emergency procedures.
10. Establish job plan and determine ALARA Hold Points.

Equipment:

1. Hydraulic Roll-A-Lifts, rollers, pallet jack or other suitable method for moving.
2. Cribbing, ratchet straps or slings as required.
3. Sufficient quantities of dosimetry and calibrated, operable survey meters.
4. Protection for flooring if needed.
5. Hand tools as required.
6. Motorized mover as required.
7. Plates for elevator if required.
8. Shims for leveling the irradiator if required.
9. PPE including, but not limited to, gloves, safety glasses, hard hats, safety shoes, etc will be worn at the appropriate times during this process.

Personnel:

1. Determine identities of all personnel involved in the job.
2. Determine adequacy of training and experience.
3. Determine adequacy of dosimetry.
4. Determine job responsibilities of all personnel involved.

The Irradiator make and models that apply to this procedure are:
ANSI CATEGORY I:

1. J.L. Shepherd Mark 1
2. J.L. Shepherd Model 484
3. J.L. Shepherd Model 89
4. J.L. Shepherd Model 143
5. J.L. Shepherd Model 109
6. J.L. Shepherd Model Gammacell 220R
7. J.L. Shepherd Model 142-MA
8. J.L. Shepherd Model 149 Series
9. J.L. Shepherd Model Mark IV Dosimeter Irradiator
10. CIS-US Model IBL 437
11. Eberline 1000B
12. Gammacell 40
13. Gammacell 1000
14. Gammacell 3000
15. Gammacell 220
16. Gammacell 200
17. Gammator Model M,M-34,M-38, G50, G100, G150and G200

ANSI CATEGORY II:

18. J.L. Shepherd Model 28
19. J.L. Shepherd Model 81
20. J.L. Shepherd Model 142
21. J.L. Shepherd Model 78-2M

Typical procedure for relocation or moving to be loaded for shipping:

BEFORE:
Prepare the irradiator for moving by removing outside shell, etc. Perform a leak test to confirm the absence of removable contamination on accessible surfaces where contamination might be found if a leaking source was present. Relocation of an irradiator from floor to floor or building to building will require that moveable sources such as in Gammacell 40, Mark 1, or Model 81 will have the source locked in the stored position. The procedure to lock down a source will follow the manufacturer's recommended method for shipping with use of mechanical stops Irradiators with non-moveable sources such as the IBL 437C, Gammacell 1000, or Gammacell 3000 will have the sample drums locked to prevent movement and/or damage to the bearings. (In the event a sample drum rotates, the dose rate does not change.)

DURING:

Implement ALARA Hold Points at crucial transport points, for example: the elevator, loading dock, doorway frames, etc. In this way, control to prevent the device from toppling or the rigging from failing is maximized.

The document CCIS - EP shall be immediately accessible and available to all workers. If device topples or rigging fails, immediately perform a dose rate survey to ensure the source has not been dislodged. If elevated dose rate other than what is anticipated or visual damage to the irradiator (that may cause the source to leak) immediately exit the area and follow all guidance in CCIS - EP Emergency Procedures. Evaluate worker dose received using dosimetry worn. Secure the device from unwanted movement and verify that it cannot move any more. If the dose rates are acceptable and visual damage is observed that may cause a source to leak, perform a smear survey for contamination. Develop a recovery plan in conjunction with facility RSO. If specialized equipment is needed, arrange to acquire equipment and recover as needed.

AFTER:
After the move is completed, reassemble the irradiator as required. Level the irradiator and test the unit 35 times or sufficient times to ensure proper safe operation. Complete the Irradiator Inspection/Performance Test Report and the Service Report.

C&C Irradiator Service LLC

(b)(7)(F)

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Professional Achievements

Radiation Safety / Procedures

- Wrote a Quality Assurance Program for Gamma Irradiator Service, LLC based on Nuclear Regulatory Commission's guidelines.
- Wrote a procedure for Gamma Irradiator Service, LLC based upon the increased controls and security guidelines of irradiators for 10 CFR Part 37.
- Created documents for Out-of-State reciprocity to work on radioactive materials in various states, Canada, and Puerto Rico
- Assisted in renewal of Gamma Irradiator Service, LLC's Radioactive Materials Licenses for Pennsylvania and the Nuclear Regulatory Commission in 2015

Leadership

- Initiated and assisted in creating a partnership between Gamma Irradiator Service, LLC and Precision X- Ray Inc. to offer a line of X-ray systems to new customers.
- Lead day-to-day operations as assistant RSO
- Performed daily business activities to enable Gamma Irradiator Service LLC to run smoothly (invoicing, scheduling, maintaining proper insurances, withholding taxes, field service preventative maintenance, repairs, relocations, dose validations, and decommissioning)

Licensing

- Currently listed on Pennsylvania License PA-1157 to work with multiple isotopes of radioactive material
- Currently listed on NRC License 37-30850-01 to work with multiple isotopes of radioactive material
- Formerly listed on Massachusetts License 20-9734 under Pharmalucence to work on devices containing Cesium-137.
- Deemed Trustworthy and Reliable by Nuclear Regulatory Commission T&R order EA-09-293. (Review docket #030-36438)

Chris Nostrand

1030 Evarts St. NE
Washington, D.C. 20018
(b)(6)
chris@ccirradiator.com

Objective

Obtain an NRC radioactive materials license to perform calibrations, source transfers, preventative, routine and non-routine maintenance on a variety of category 1 and 2 devices containing cesium 137 or cobalt 60 amongst other isotopes.

Gamma Irradiator Service - Apprentice **12/15/09**

Preventive, routine and non-routine maintenance of category 1 and 2 devices conducted under direct supervision of the RSO. Over 2000 hours of training in the presence of the RSO, nuclear generating facilities radworker training programs and hookwork combined with over 600 hours of direct RSO supervised OTJ device specific training.

Gamma Irradiator Service -Authorized user **3/22/11**

Authorized user of PA DOE Radioactive materials license 1157 on 3/7/11 and NRC 37-30850-01 on 3/22/11.

Duties included moving, source transfer, calibration, preventative, routine and non-routine maintenance of category 1 and 2 devices at various temporary jobsites in the continental U.S.A. Worked with a team to write and re-write all of Gamma Irradiator Services procedures.

Pharmalucence – Field service engineer **3/5/14**

Added to MA license 20-9734 for the maintenance of JBL437-c devices. Preventative, moving, calibration, routine and non-routine were all authorized while still being listed as authorized user of both PA 1157 and NRC 37-30850-01.

Gamma Irradiator Service – Radiation Safety Officer **4/23/14 to present**

Responsibilities included implementation of radiation protection program; ALARA principles and adherence to NRC approved procedures and compliance with agreement state and federal regulations. Duties also included all authorized user duties listed above. Worked to successfully renew the Gamma Irradiator service license with the NRC and Pennsylvania DOE.

C&C Irradiator Service LLC

To: USNRC

From: Chief Operating Officer, Chad Gunther

Subject: Delegation of Authority for Radiation Safety Officer

Christopher Van Nostrand has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radioactive material. He possesses several years of experience as RSO for NRC and the State of Pennsylvania Radioactive Materials Licenses. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of radioactive material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer, as well as anyone else that is involved in a particular job, has the authority to immediately stop any operations involving the use of radioactive material in which health and safety may be compromised or may result in non-compliance with NRC requirements.

Sincerely,

Chad Gunther

Chad Gunther, COO/QA Director

10/1/17
Date

This form serves as a certification used to identify a small entity, and is exempt from Office of Management and Budget clearance. 5 C.F.R. 1320.3(h)(1).

NRC FORM 526
(08-2017)
10 CFR 171

U.S. NUCLEAR REGULATORY COMMISSION

CERTIFICATION OF SMALL ENTITY STATUS FOR THE PURPOSES OF ANNUAL FEES IMPOSED UNDER 10 CFR PART 171

(Effective August 29, 2017)

If you have QUESTIONS, e-mail them to: SmallEntity.Resource@nrc.gov

SEE IMPORTANT INSTRUCTIONS FOR NRC FORM 526 -- PLEASE READ CAREFULLY
DO NOT COMPLETE OR RETURN THIS FORM IF YOU DO NOT QUALIFY AS A SMALL ENTITY
A Licensee that is a subsidiary of a large entity, including foreign entities, does NOT qualify as a small entity.

NAME AND ADDRESS OF LICENSEE *(as it appears on the invoice)*:	INVOICE NUMBER	BUSINESS TELEPHONE NUMBER
C&C Irradiator Service, LLC 1030 Evarts St. NE Washington, DC 20018		(240) 604-7959
	DOCKET NUMBER	CONTACT NAME Christopher Nostrand

EMAIL ADDRESS	COMPANY WEBSITE ADDRESS	CONTACT TELEPHONE NUMBER
chris@ccirradiator.com	www.	(240) 604-7959

SIZE STANDARDS (Check only 1 box below).		MAXIMUM ANNUAL FEE PER LICENSED CATEGORY (See Items 2 and 3 on back)
1. SMALL BUSINESS A for-profit concern that is not engaged in manufacturing with average GROSS receipts of $7.0 million or less over its last 3 completed fiscal years. For further information see 1a and 1b of attached instructions.	☐ A. $485,000 TO $7,000,000 ☑ B. LESS THAN $485,000	$ 4,100 $ 850
2. MANUFACTURING INDUSTRY A manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months. NAICS BUSINESS CODE (See 1b and 1e of attached instructions): _____	☐ A. 35 to 500 EMPLOYEES ☐ B. LESS THAN 35 EMPLOYEES	$ 4,100 $ 850
3. SMALL ORGANIZATION A not-for-profit organization that is independently owned and operated and has annual GROSS receipts of $7.0 million or less. For further information see 1a and 1b of attached instructions.	☐ A. $485,000 TO $7,000,000 ☐ B. LESS THAN $485,000	$ 4,100 $ 850
4. SMALL GOVERNMENTAL JURISDICTION (INCLUDING PUBLICLY SUPPORTED EDUCATIONAL INSTITUTIONS) A government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. For further information see 1f of attached instructions.	☐ A. 20,000 TO 49,999 POPULATION OF JURISDICTION ☐ B. LESS THAN 20,000 POPULATION OF JURISDICTION	$ 4,100 $ 850
5. SMALL EDUCATIONAL INSTITUTION THAT IS NOT STATE OR PUBLICLY SUPPORTED Only applicable to such small educational institutions if they have 500 or less employees. For further information see 1b and 1f of attached instructions.	☐ A. 35 to 500 EMPLOYEES ☐ B. LESS THAN 35 EMPLOYEES	$ 4,100 $ 850

CERTIFICATION

This certification MUST be signed by the owner of the entity named above or an official empowered to act on behalf of the entity.

I certify that the above named NRC licensee qualifies as a small entity under the size standards established by the NRC for its licensees in 10 CFR 2.810. The licensee qualifies as a small entity under the specific size standard indicated above.

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. The submittal of willful false statements is punishable by fine or imprisonment, or both, and for purposes of this certification, may result in revocation or suspension of the license.

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.	TYPED OR PRINTED NAME AND TITLE	SIGNATURE	DATE
	Chad Gunther, COO/QA Director	Chad Gunther	10/1/17

See Attached Instructions

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee	Date
	October 16, 2017
	License Number(s)
C&C Irradiator Service, LLC ATTN: Chad Gunther, COO/QA Director 1030 Evarts St., NE Washington, DC 20018	08-35447-01
	Mail Control Number(s)
	601392
	Licensing and/or Technical Reviewer or Branch
	Commercial, Industrial, R&D, & Academic Branch (Branch 2)

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 10/01/2017

The initial processing, which included an administrative review, has been performed.

☐ **Amendment** ☐ **Termination** ☑ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☑ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link:** http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239