

ACCEPTANCE REVIEW MEMO

Licensee: Pa'ina Hawaii

License No.: [REDACTED]

Docket No.: 030-36974

Mail Control No.: 470601

Type of Action: New Date of Requested Action: 06-23-05

Reviewer Assigned: Date Assigned to Reviewer: 07-06-05

Reviewer(s) Who Performed Review: Torres-Cook

Response Received	Deficiencies Noted During Acceptance Review
1.	
2.	
3.	
4.	

Reviewer's Initials: _____

Date: _____

Branch Chief's and/or SR. HP's Initials: _____

Date: _____

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Action - decommissioning notification should be issued within 30 days.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Termination request < 90 days from date of expiration
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Action to be expedited
		_____ Medical emergency
		_____ Licensee in noncompliance (i.e. no RSO, location of use/storage not on license, radioactive material in possession not on license)
		_____ National Security
		_____ Other (_____)

Branch Chief's and/or Sr. HP's Initials: _____ Date: _____

SISP Review		
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	Non-Publicly Available, Sensitive if <u>any</u> item below is checked
		<input checked="" type="checkbox"/> Radionuclides, forms, and quantities
		<input checked="" type="checkbox"/> Location of RAM
		<input checked="" type="checkbox"/> Building drawings with locations of RAM
		<input checked="" type="checkbox"/> Security of RAM (locks, alarms, etc.)
		<input checked="" type="checkbox"/> SS&D Catalog information
		<input checked="" type="checkbox"/> Specifics of Emergency Plan (routes to and from RAM, response to security events, etc.) <i>Procedures</i>
		_____ Safeguards Information

Branch Chief's and/or Sr. HP's Initials: *RJC* Date: 7/6/05

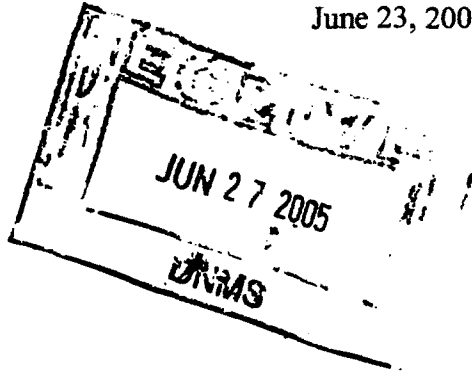
2312

Pa`ina Hawaii, LLC
PO Box 30542
Honolulu, HI 96820

Tel: 808-834-0496, Fax: 808-834-0578, e-mail: Hawaiiexport@aol.com

June 23, 2005

Jack Whitten
Reg. IV, US NRC
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064
800-952-9677



Dear Mr. Whitten:

We wish to apply for a Materials License for an Underwater Irradiator to be located in Honolulu, Hawaii.

Enclosed are two signed copies of the Application for a Materials License. Also enclosed is a CD of the application in Microsoft Word format and a check for \$11,000 to cover the application fee.

Information concerning Financial Assurance will be submitted shortly under separate cover.

We look forward to working with you and your staff.

Sincerely,

Michael Kohn
President

2/10

Application for Material License

For

Pa'ina Hawaii
PO Box 30542
Honolulu, HI 96820

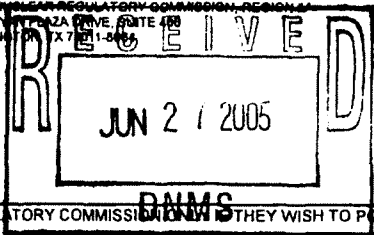
GENESIS II IRRADIATOR™

Rev 00
20 June 2005

<p>NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION (8-1999) 10 CFR 30, 32, 33, 34, 35, 36, 39 and 40</p> <p style="text-align: center; font-size: 1.5em; font-weight: bold;">APPLICATION FOR MATERIAL LICENSE</p> <p style="text-align: right; font-size: 1.5em; font-family: cursive;">Rto</p>	<p>APPROVED BY OMB: NO 3150-0120 EXPIRES 08/31/2002</p> <p><i>Estimated burden per response to comply with this mandatory information collection request 7 4 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 Records Management Branch (T-6 E6). U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs@nrc.gov, and to the Desk Office, 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 current valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</i></p>
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INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETE APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICES SPECIFIED BELOW.

<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p>DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-1415</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</p> <p>IF YOU ARE LOCATED IN</p> <p>CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT. SEND APPLICATIONS TO</p> <p>LICENSING ASSISTANT SECTION NUCLEAR MATERIALS SAFETY BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415</p> <p>ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:</p> <p>SAM NUNN ATLANTA FEDERAL CENTER U.S. NUCLEAR REGULATORY COMMISSION, REGION II 61 FORTSYTH STREET, S.W., SUITE 23785 ATLANTA, GEORGIA 30303-8931</p>	<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p>MATERIAL LICENSING SECTION U.S. NUCLEAR REGULATORY COMMISSION, REGION III 801 WARRENVILLE RD. LISLE, IL 60532-4351</p> <p>ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHING, OR WYOMING. SEND APPLICATIONS TO:</p> <p>NUCLEAR MATERIALS LICENSING SECTION U.S. NUCLEAR REGULATORY COMMISSION, REGION I 511 RIVERSIDE PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-5405</p>
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PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS

<p>1. THIS IS AN APPLICATION FOR (Check Appropriate Item) : A. NEW LICENSE</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code) Pa'ina Hawaii PO Box 30542 Honolulu, HI 96820</p>
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<p>3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED Pa'ina Hawaii [REDACTED] Honolulu, HI 96820</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Andrew Buchan, Pa'ina Hawaii: 415-407-3672 Radiation Protection Program & Administration. Russell Stein, GRAY*STAR, Inc. : 973-398-3331 Technical Information on the irradiator.</p>
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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.

<p>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</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</p>
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p>
<p>9. FACILITIES AND EQUIPMENT</p>	<p>10. RADIATION SAFETY PROGRAM</p>
<p>11. WASTE MANAGEMENT</p>	<p>12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 3-G AMOUNT ENCLOSED \$ 11,000.00</p>

13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTAND 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, 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.

<p>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE Michael Kohn - President, Pa'ina Hawaii</p>	<p>SIGNATURE </p>	<p>DATE June 23, 2005</p>
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FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED \$	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC Form 313, Item 5
Radioactive Material

Radionuclide:

[REDACTED]

Source Manufacturer:

REVISS Services, Inc.
6 Chiltern Court
Asheridge Rd
Chesham
Buckinghamshire, HP5 2PX England

And/or

MDS Nordion, Inc.
447 March Rd
Kanata, ON K2K 1X8 Canada

Source Model No.:

RSL-2089 - Puridec / Reviss Services (see Figure 5-A). The description of the source is on file with the Nuclear Regulatory Commission: Registry Number IL-1082-S-101-S / UK Certificate of Approval GB/343/S-85.

C-188 - MDS Nordion (see Figure 5-B). The description of the source is on file with the Nuclear Regulatory Commission: Registry Number NR-220-S-103-S.

Irradiator Manufacturer:

GRAY*STAR, Inc.
200 Valley Rd. – Suite 103
Mt. Arlington, NJ 07856
Tel 973.398.3331

Irradiator Model No.:

GENESIS II ("Genesis" or "Irradiator")

Maximum Source Activity:

[REDACTED]

Maximum Irradiator Activity:



Depleted Uranium:

Depleted Uranium is not used for shielding or for any other purpose in the Genesis.

NRC Form 313, Item 5
Financial Assurance and Record Keeping for Decommissioning

CERTIFICATION OF FINANCIAL ASSURANCE:

Pa'ina Hawaii will provide Financial Assurance for Decommissioning. The details of this vehicle will be provided under separate cover. The details of the vehicle and the assurance itself will be in place prior to receiving the initial isotope for the unit.

The details will include:

The Principal will be Pa'ina Hawaii. (Applicant).

The financial assurance instrument will be for \$113,000 (as specified by the NRC), and made available in the event that Pa'ina Hawaii fails to satisfy its debts or obligations in respect to decommissioning.

Pa'ina Hawaii reserves the right to change the method of Financial Assurance, but would not do so until a new method of Financial Assurance is submitted to, approved by the NRC and implemented by Pa'ina Hawaii.

Redacted Material

Redacted Material

NRC Form 313, Item 6

Purpose For Which The Licensed Material Will Be Used

The irradiator will be mainly employed for the research and production irradiation of food, cosmetic and pharmaceutical products; however, it may also be employed for a wide range of other materials. There will be no irradiation of explosives, no irradiation of more than small quantities of flammable materials with a flash point below 60 °C (140 °F), and no irradiation of cryogenic materials which are potentially explosive without specific written authorization from the Nuclear Regulatory Commission.

NRC Form 313, Item 6

Purpose For Which The Licensed Material Will Be Used

General Provisions Not Otherwise Stated In The Application:

The Licensee will notify the US Nuclear Regulatory Commission, in writing, at least two weeks before the anticipated receipt of a shipment of cobalt-60.

Irradiation of foods for human or animal consumption in the United States shall be in accordance with the rules and regulations of the US Food and Drug Administration and the US Department of Agriculture.

The Licensee will notify the US Nuclear Regulatory Commission when the Radiation Safety Officer permanently discontinues performance of duties under the license.

The Licensee will notify the US Nuclear Regulatory Commission, in writing, if and when the Licensee's mailing address is changed.

The Licensee will notify the US Nuclear Regulatory Commission if it terminates all activities involving materials authorized under its license.

The Licensee will request a license amendment before it orders isotope in excess of the amount or of a different radionuclide or form other than authorized in the license.

The Licensee will submit a complete renewal application or termination request at least 30 days before the expiration date of the license.

NRC Form 313, Item 7

Individual(s) Responsible For Radiation Safety Program And Their Training And Experience

Radiation Safety Officer (RSO):

The RSO reports directly to the President of the Licensee (see Figure 7-A).

RSO's training and experience:

(See Attachment 7-B)

RSO Responsibilities and Authorities:

Stopping unsafe activities.

Keeping exposures ALARA.

Developing, maintaining, distributing, and implementing up-to-date operating and emergency procedures.

Ensuring that individuals associated with Genesis Irradiatortm operations are properly trained and evaluated.

Ensuring that non-routine operations for the Genesis are consistent with the limitations in the license.

Analyzing potential safety consequences of non-routine operations before conducting any such activities that have not been previously analyzed.

Ensuring non-routine operations are performed by personnel specifically authorized by the US Nuclear Regulatory Commission or an Agreement State to perform those operations (e.g., loading, unloading, or repositioning sources).

Ensuring that personnel monitoring devices (occupational dosimetry) are used and exchanged at the proper intervals and records of the results of such monitoring are maintained by the Licensee.

Ensuring documentation is maintained that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits (10% of 5 rem / yr) or provide personnel monitoring devices (occupational dosimetry).

Notifying proper authorities of safety related incidents such as damage to or malfunction of the Genesis, fire, loss, theft, or attempted theft of licensed materials.

Investigating emergencies and abnormal events involving the Genesis (e.g., malfunctions or damage), identifying cause(s), implement appropriate and timely corrective action(s).

Ensuring that radiation safety program audits are performed at least every twelve months and developing, implementing, and documenting timely corrective actions.

Ensuring transport of licensed material according to all applicable DOT requirements.

Ensuring proper disposal, if required, of licensed material.

Ensuring appropriate records associated with Genesis operations are maintained.
Maintaining an up-to-date license and timely submission of amendment and renewal requests.

Ensuring that when violations of regulations or license conditions or program weaknesses are identified, corrective actions are developed, implemented, and documented.

Controlling all Safe Guard material.

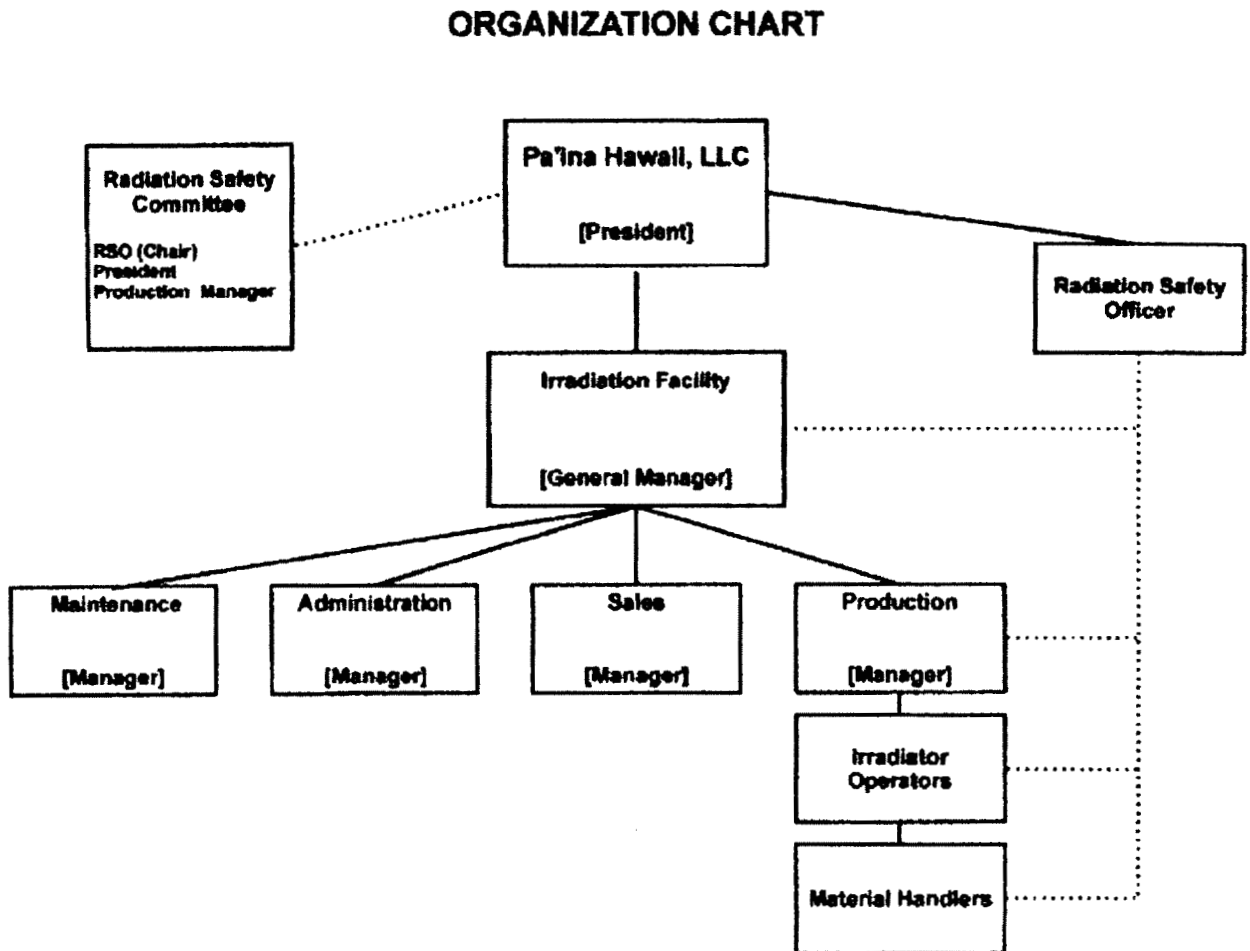
Ensuring that all security systems are compliant and functioning properly.

Ensuring that all security protocols are fully compliant, implemented and enforced.

NRC Form 313, Item 7

Individual(s) Responsible For Radiation Safety Program And Their Training And Experience

Figure 7-A
Organization Chart



NRC Form 313, Item 7

Individual Responsible For Radiation Safety Program And Their Training And Experience

Attachment 7-B

Andrew E. Buchan – RSO Qualifications:

Formal Education:

B.S. Aerospace Engineering (1992) – Boston University, MA.
Harvard School of Public Health (1993) – Occupational and Environmental Radiation Protection (40 hours).
Will complete 40 hour manufacturer's training course on the Genesis Irradiator and information directly applicable to radiation safety at irradiators.

Professional Experience:

2004 - Present	University of California at Merced, CA. Radiation Safety Officer.
2003 - Present	University of California at San Francisco, CA. Radioactive Material Program Supervisor. Emergency Response Team Member.
1998 - 2003	University of California at Santa Barbara, CA. Health Physicist Management of Broad-scope Radioactive Material License.
1992 -1998	Yale University, CT. Health Physics Technician.

Radiation and Radioactive Materials Experience:

Manage all aspects of radioactive materials program.
Review, update and improve standard operating procedures for radiological services.
Manage radiological technicians.
Conduct training for radiological technicians.
Ensure compliance with Material's License.
Emergency responder to radiological incidents.
Maintained radioisotope inventories.
Maintained personnel dosimetry program.
Conducted radiological inspections.
Trained emergency response personnel.
Maintained radiological records.
Coordinated radiological waste program.
Procedure preparation and implementation.

Supervision of decontamination.
Investigation of incidents.
Member of Radiation Safety Committees.
Use of gamma detection and analysis equipment.

NRC Form 313, Item 8

Training for Individuals Working in or Frequenting Restricted Areas

Individuals Working in or Frequenting Restricted Areas:

There are four categories of personnel who may enter the Restricted Area unescorted:

- Radiation Safety Officer (RSO).
- Irradiator Operator (Operator).
- Irradiator Operator In Training (OIT).
- Emergency Response Personnel (ERP).

Definitions:

- Restricted Area - The room in which the Genesis is situated as identified in ITEM 9.
- Unescorted Personnel - The RSO, Irradiator Operator(s), and Operator(s) In Training are, by definition, Unescorted Personnel. These persons have specific training and authorizations described in this Item.
- Escorted - A person or persons may enter the Restricted Area under the condition that they have direct authorization and supervision by the RSO, an Irradiator Operator or an Operator In Training (only after authorized to perform this function by the RSO) and that the RSO, Irradiator Operator or authorized Operator In Training has direct sight, communications and control of the Escorted person(s).
- Attended - The irradiator is 'attended' when an Irradiator Operator or the RSO is at the Licensee's site and the security system is de-activated.
- Shift Irradiator Operator - At any time, only one Irradiator Operator is designated as the Shift Irradiator Operator and is the one specifically responsible for the irradiator while on shift. Any other Irradiator Operators who may be present are responsible to the Shift Irradiator Operator. The Shift Irradiator Operator must be cognizant of anything being performed in the Restricted Area during their shift including operations performed by the RSO.

NRC Form 313, Item 8
Training for Individuals Working in or Frequenting Restricted Areas

Radiation Safety Officer:

Description:

The person responsible for the Radiation Safety Program as outlined in ITEM 7.

Authorization:

The RSO is authorized to take any action necessary to assure the safety and security of the irradiator and the sealed sources; also, to perform all the functions of an Irradiator Operator. These actions are within the regulations of the Nuclear Regulatory Commission and of the Licensee's Material License.

Access:



Occupational Dosimetry:

The RSO wears a personnel dosimeter at all times when in the Restricted Area.

Training:

Training and experience for the RSO is outlined in ITEM 7.

NRC Form 313, Item 8

Training for Individuals Working in or Frequenting Restricted Areas

Initial Training and Experience for Irradiator Operators:

Irradiator Operator:

Description:

A person who operates, monitors, and maintains the irradiator.

Authorization:

The Irradiator Operator is responsible for the safe and secure operation of the irradiator during his / her shift. Irradiator Operators are authorized to operate the irradiator per the Operating Procedures. In addition, the RSO may grant specific authorization to the Irradiator Operator to perform functions that are not part of the Routine Operating Procedures. These actions are within the regulations of the Nuclear Regulatory Commission and of the Licensee's Material License.

The Irradiator Operator is trained and required to follow all Emergency Procedures and to report any breaches in security, breaches of regulations, or any condition that he / she feels may be unsafe.

The Irradiator Operator is authorized to perform routine maintenance under the general authority of the RSO. The Irradiator Operator may perform non-routine maintenance under the specific authority of the RSO.

The Irradiator Operator may escort Escorted Personnel.

Access:



Occupational Dosimetry:

An Irradiator Operator wears a personnel dosimeter at all times when in the Restricted Area.

Training:

Prior to unsupervised operation of the irradiator the Irradiator Operator:

- Will have successfully completed one of the training courses described in Criteria in the section entitled "Initial Training for Irradiator Operators", in NUREG-1556, Vol. 6, dated January 1999.
- Will receive one month of On-the-job training as an Irradiator Operator In Training.
- Will read the Material License.
- Will understand the fundamentals of radiation safety as they apply to irradiators.
- Will understand the requirements of 10 CFR Parts 19, 20, and 36.
- Will understand the operations of the irradiator.
- Will understand the operating and emergency procedures that the individual is required to perform.
- Will understand the case histories of accidents and problems involving commercial irradiators.
- Will understand security systems, procedures and issues.
- Will pass written and oral examinations on all aspects of their training.

This instruction is a minimum of twenty hours.

Before an Irradiator Operator who has not operated the irradiator for more than one year is permitted to operate the irradiator unsupervised, he / she **must** operate the Irradiator for at least one day under supervision. They also **will receive** a safety review regarding the irradiator.

NRC Form 313, Item 8
Training for Individuals Working in or Frequenting Restricted Areas

Annual Safety Reviews and Performance Evaluations for Irradiator Operators:

Refresher training of Irradiator Operators is conducted annually.

The refresher training (a minimum of two hours) includes the following:

Re-reading of the Material License and corresponding application.

Review of the changes in operating and emergency procedures.

Review of the changes in regulations and license conditions.

Review of the reports on recent accidents, mistakes, or problems that have occurred at commercial irradiators.

Review of the relevant results of the Licensee's irradiator inspections and maintenance checks.

A drill to practice an emergency or abnormal event procedure. This drill goes through a procedure using the actual equipment in as realistic a manner as practical.

Each Irradiator Operator, at the end of the refresher training session, takes a written test, which is based on the information covered.

Performance reviews of Irradiator Operators are conducted annually.

The RSO evaluates each Irradiator Operator to ensure that regulations, license conditions, and operating and emergency procedures are followed. The results of the evaluation are discussed with the Irradiator Operator along with instructions on how to correct any mistakes or deficiencies observed.

NRC Form 313, Item 8
Training for Individuals Working in or Frequenting Restricted Areas

Training for Individuals Who Require Unescorted Access:

Irradiator Operator In Training (OIT):

Description:

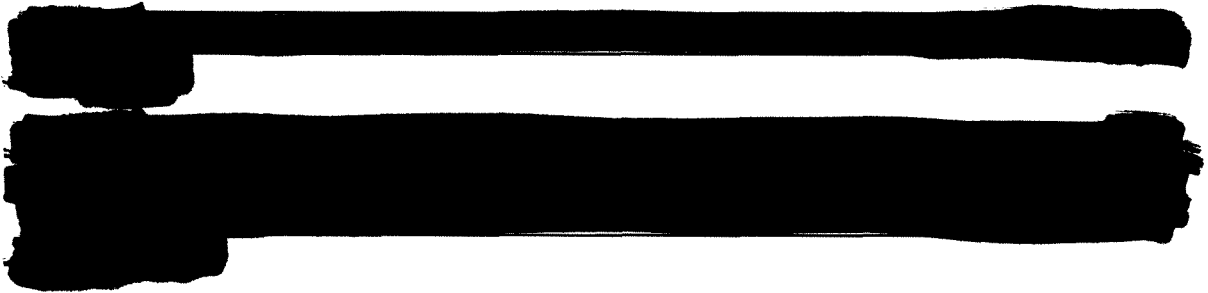
A person who is being trained to become an Irradiator Operator.

Authorization:

The OIT is only authorized to perform operations directed and supervised by the RSO or an Irradiator Operator. This includes supervised On-The-Job training and irradiator operation.

The Irradiator Operator in Training may escort Escorted Personnel only if authorized by the RSO.

Access:



Occupational Dosimetry:

The OIT wears a personnel dosimeter at all times when in the Restricted Area.

Training: [Note: This training occurs BEFORE the OIT is allowed unrestricted access to the Restricted Area. This training IS NOT the Irradiator Operator training stated above.]

The OIT receives training to assure avoidance to radiation exposure and how to properly respond to alarms and alerts. This training is a minimum of four hours in duration and includes:

An understanding of the authority of the RSO and of the Shift Irradiator Operator.

A basic understanding of radiation units and units of radioactivity.

An understanding of all alarms and alerts and how to respond.

A basic understanding of the irradiator and its safety systems (including a walk through of the Restricted Area).

A full comprehension of all signs and postings directly relating to the Restricted Area and the irradiator.

An oral or written exam of the above information.

NRC Form 313, Item 8
Training for Individuals Working in or Frequenting Restricted Areas

Training (familiarization) for Off-Site Individuals (Not Employees Of the Licensee) Who Must be Prepared to Respond to Alarms:

Emergency Response Personnel (ERP):

Description:

Representative members of the local Police Department, Fire Department, Rescue Squad, or similar organizations. The purpose of this training course is to assure that the ERP are familiar with what they can and cannot do in emergency situations.

Authorization:

The ERP are authorized to respond to any emergency within the purview of their respective organization.

Access:

[REDACTED]

Occupational Dosimetry:

Personnel dosimeters are not required.

Training (Seminar):

Instruction is performed annually, is a minimum of two hours in duration, and includes:

- A basic understanding of radiation units and units of radioactivity.
- A basic understanding of the irradiator and its safety systems (including a walk through of the Restricted Area).
- An understanding of the authority of the RSO and of the Shift Irradiator Operator.
- A full comprehension of all signs and postings directly relating to the Restricted Area and the irradiator as they pertain to them.
- A full understanding on how to respond to emergencies and whom to contact in the event of an emergency.

NRC Form 313, Item 9
Facilities And Equipment

General Description of the Facility and Site:

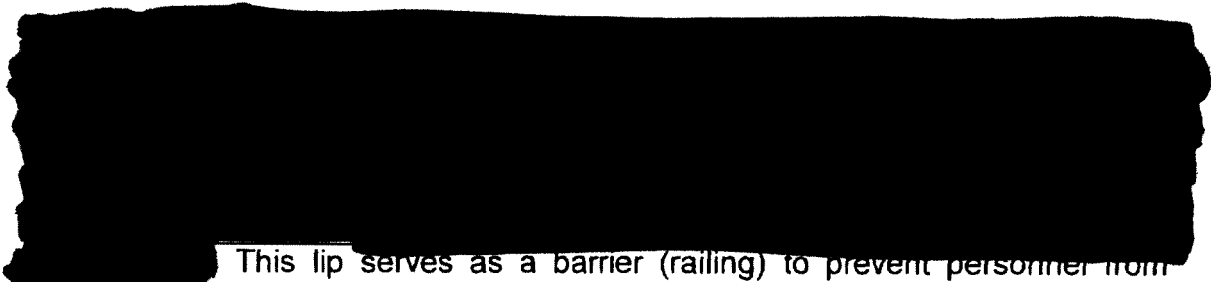
The irradiator is a self-contained 'underwater irradiator' in which the sources always remain shielded under water and people do not have access to the sealed sources or the space subject to irradiation without entering the Pool.

The irradiator is composed of several different components and systems including:

- Access Control.
- Radiation Monitors.
- The Pool including Water Purification System.
- The Source Rack ('Plenum') including helium dry storage.
- Product Conveyor System ('Hoists' and 'Bells').

Each of the above is described in detail after a general description of the Genesis.

General Description:



This lip serves as a barrier (railing) to prevent personnel from accidentally falling into the Pool; it also helps prevent any water [including minor floods] or dirt on the floor from 'falling' into the Pool. The three layers of the Pool's construction provide barriers to any water leaking from the Pool to the surrounding environment. This Pool construction method permits verifying the integrity of the Pool's steel layers prior to the installation on site.



The Plenum is filled with helium to minimize water attenuation of the gamma photons during irradiation. The Plenum is sealed on the top and sides and contains helium gas under pressure to keep the sources dry during normal operations. Helium was selected because it is an inert element, will not chemically react with the source encapsulations, has excellent thermal transfer capabilities and will not significantly dissolve in water.

The Plenum is constructed of stainless steel, compatible with the stainless steel source encapsulations.



The enclosures are welded to a Top Manifold that allows helium

to freely pass from one enclosure to another. The Plenum is completely sealed by welding on the top and sides. The bottom of the Plenum is open. Helium gas enters the plenum through a Helium Supply Tube located on the top of the Top Manifold. The helium gas is under pressure that is equal to the pressure at the bottom of the plenum. This helium under pressure forces the pool water out of the bottom of the plenum and keeps the interior of the Plenum dry. Gas pressure is monitored to assure that the water level does not rise within the Plenum so that the sources remain dry.

[REDACTED]

Each stainless steel Source Holder assembly is compatible with both the source encapsulation and the Plenum material. [REDACTED]

[REDACTED]

The Source Rack has a stainless steel Base Plate. Stainless steel Guide Rods are vertically welded to the base plate. [REDACTED]

[REDACTED]

[REDACTED]

A stainless steel Surge Tank is located on one side of the Pool near floor level. Its primary purpose is to compensate for varying water levels due to pool water displacement from Bell (product container) movement. The Surge Tank is connected to the Pool through a Transfer Opening at or above the Minimum Water Level (shielding integrity water level).

A Water Purification System that includes filtration, de-ionization, and a Water Radiation Monitor (WRM) is mounted above the Surge Tank. The system's placement over the Surge Tank helps prevent any water loss from the Water Purification System should a leak occur. Although the sources are not normally in contact with the Pool Water during routine operations, the Water Purification System is designed and maintained with the assumption that the Pool Water comes in direct contact with the sources (e.g. - during source loading, unloading, or reconfiguration). The discharge pipe (from the Water Purification System to the pool) terminates above the Minimum Water Level. The inlet pipe (from the Surge Tank to the Water Purification System) is located in the Surge Tank and water access, via the Transfer Opening, is at or above the Minimum Water Level. The WRM continuously monitors the filter housing to detect any accumulation of radioactive material. An inline Pool Water conductivity monitor provides input for the prevention of electrolytic corrosion of the Pool or Source Plenum.

A make-up water line is connected to an external water supply. A manual valve is used to add make-up water due to evaporation loss and a check valve prevents Pool Water from inadvertently traveling back into the input water supply. There are no discharges from the Water Purification System.

Product Bells (product containers) are lowered to either side of the stationary Plenum.



In addition to the Water Radiation Monitor (WRM), an Area Radiation Monitor (ARM) is located over the surface of the Pool. The ARM has remote visual alerts and is audible at all Restricted Area personnel entries.




The product to be irradiated is brought into the Restricted Area on Carts (stacked product carriers). Open-bottomed Bells are suspended from and moved by a rail and trolley system. Three hoist / Bell assemblies are used. (There may be any number of Carts.) Typically, to load the irradiator, the Irradiator Operator lowers a Bell enveloping / engaging a Cart full of product at a loading station. The Bell containing the product is then raised. The Irradiator Operator pushes and holds a button to activate the trolley and move the loaded Bell to a 'START' position on one side of the Pool. The irradiator operation computer detects the Bell in the START position and when ready, automatically moves the Bell over the Pool. The Bell is then automatically lowered into the Pool at one side of the Source Plenum. After irradiation (of one side of the product), the Bell is raised out of the Pool Water, moved further along the rail over the Pool, and lowered to the second side of the Plenum for completion of the irradiation cycle. After completion, the Bell is automatically raised and moved by trolley to the 'FINISH' position on the opposite side of the Pool from the START position. The Irradiator Operator then pushes and holds a button to activate the trolley and move the finished Bell to an unloading station where he / she lowers the Bell, detaches the Bell from the Cart, raises the Bell, and sends it to the initial loading station. The product is removed from the Restricted Area on the Cart. Note: The FINISH position is located above the Surge Tank to recycle water runoff from the Bell. (See figure 9-D.)

The Bells, even if empty, are heavy enough to prevent them from floating in the Pool. They are structurally very strong.

(All surfaces in contact with Pool Water are made of stainless steel.) The Bell is water tight on all sides except for the open bottom. As the Bells are lowered into the Pool, the increased water pressure tries to force the water level in the Bell to raise. A compressed air (or nitrogen) supply tube runs from the hoist mechanism to each Bell. The compressed gas equalizes the pressure and maintains the water level at the bottom of the bell. Inversely, as the Bell rises out of the Pool, the decreased water pressure causes air to escape from the bottom of the Bell. As the bells descend into the pool, the water pressure increases slightly at the bottom of the pool. This "pushes" water up into the Plenum. The Plenum is designed with a buffer space below the Source Holders to allow for water level to vary and yet keep the source encapsulations dry.

All moving parts of the irradiator can be maintained and replaced above the Pool and outside the irradiation zone.

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Construction Schedule for the Genesis Irradiator:

The Genesis will be fabricated in subsections off-site, transported to the Licensee's site, installed / assembled, and inspected. The Genesis will then be loaded with cobalt-60 sealed sources. The schedule for these events is:

- The construction phase (CP) of the irradiator will commence after the initial review of the License Application. [When any and all issues (independent of the installation of the unit) raised by the NRC are resolved to the satisfaction of the NRC.]
- CP+0 months - The construction phase is commenced. Site modifications begin. E.g. foundation for building, construction of building, hole and foundation for the pool are prepared.
 - CP+2 months - Shipment of the Genesis Irradiator pool and Hoist Trolley structure to the Licensee.
 - CP+2 months - Completion of pool installation.
 - CP+2 months - Erection of Hoist Trolley structure.
 - CP+4 months - Shipment of the remaining Genesis Irradiator components to the Licensee.
 - CP+4 months - Installation of remaining Irradiator components.
 - CP+5 months - Completion of Building and Irradiator.
 - CP+5 months - Testing of all systems without cobalt-60.

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Access Control:
(See Figure 9-D)

Redacted Material

Redacted Material

**NRC Form 313, Item 9
Facilities And Equipment**

Shielding:

Not applicable to Pool Irradiators; the sources are shielded by the Pool Water.

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Fire Protection:

Not applicable to Pool Irradiators; the sources are always underwater and not subject to damage by fire.

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Facilities And Equipment


Radiation Monitors:



There are two radiation monitors located in the Restricted Area:

- ARM - Area Radiation Monitor.
- WRM - Water Radiation Monitor.

The detector for the ARM is mounted over the Pool to detect abnormal radiation levels.

The detector for the WRM is mounted directly on the filter housing of the Pool Water Purification System to detect any accumulation of radioactive material on the water filters (contamination concentration point). It 'backs-up' the ARM - Although its position is further from the Pool surface, it detects and alarms should unusually high radiation levels occur above the Pool. An alert automatically turns off the water circulation pump.

Both monitors have an audible alarm and a visible indicator to alert on-site personnel (when the irradiator is attended) and have a manual shut-off that can be operated only by the RSO, Irradiator Operator, or Company Management. The ARM is equipped with a visible indicator that is located at the access door to the Restricted Area 

Location of radiation monitors:

(See figure 9-D).

Type of radiation monitors:

(See item 10 - 'Radiation Safety Program, Radiation Monitors')

Location and types of alarms:

Both monitors have an audible and visual alert. They are located over the Surge Tank.

Personnel specifically trained to respond to the alarms:

RSO.
Irradiator Operator(s).

Alarm set points:

[REDACTED]

Evaluation of area radiation monitor location and sensitivity:

(See above)

Acceptance testing of area radiation monitor:

For both the initial test and for periodic testing, radioactive check sources are used to confirm the operability and sensitivity of both the ARM and WRM. They are also used to confirm the operability of the alarms and their control of subsystems [REDACTED]

NRC Form 313, Item 9
Facilities And Equipment


Irradiator pool:

Typically, irradiator Pools are constructed on-site. After excavation, a concrete Pool is 'formed' and poured. After the concrete is allowed to cure, a stainless steel liner is affixed to the inner Pool face. However, this system does not allow the constructor to perform a water leak test with a high level of confidence. Therefore, for the Genesis, a unique fabrication method is employed as follows:

The Pool is made of two steel tanks, one inside the other. Steel separators (I-beams) provide for rigidity and independent hydrostatic pressure testing of the two tanks. Both tanks are leak checked off-site by filling the gap between the tanks with water and inspecting for leaks both inside and outside the assembly.

The irradiator Pool is fabricated off-site. After on-site excavation, the Pool formed from the two tanks is lowered onto a concrete foundation. An Engineer's Report (separate) analyzes and specifies the specific back fill procedures and materials around the outside of the Pool. The six-inch space between the tanks is then filled with concrete and a concrete floor around the Pool is constructed.

Pool liner:

The inner pool surface in contact with the Pool Water is made of  thick welded stainless steel.

High and Low Water Level indicators and their locations:
(See Figure 9-F)

The Pool is clearly marked with four water level indicators: 'WATER LEVEL WITH 2 BELLS', 'WATER LEVEL WITH 1 BELL', 'WATER LEVEL WITH 0 BELLS', and 'MINIMUM WATER LEVEL'. The first three are each high and low water level operating ranges depending on how many Bells are in the Pool. The Minimum Water Level provides sufficient water to adequately shield the radiation sources.

Pool Water Purification System:
(See Figure 9-G)

The Pool has a Water Purification System capable of maintaining a conductivity of twenty microsiemens per centimeter or less and enough clarity to allow for visual inspection of the Source Plenum and Pool interior. Both the inlet and discharge pipes for the Water Purification System are functionally above the Minimum Water Level. A Surge Tank is located on one side of the Pool. The primary purpose of

this tank is to help compensate for changes in the water level due to displacement by the Bells entering and leaving the Pool. The Water Purification System is located directly over the Surge Tank. In the event of an unanticipated leak in the Water Purification System, most, if not all, of the water drains back into the Surge Tank. As the Bells exit the Pool, they move over the Surge Tank so that any runoff from the Bells is returned to the water system. The Surge Tank is connected to the Pool via a transfer connection. The transfer occurs above the Minimum Water Level.

The Water Purification System has filters to trap particulate matter in the Pool Water. Also, an ion-exchange bed removes any anions or cations that could have an effect on Pool Water conductivity. A Water Radiation Monitor detector is placed on the filters as mentioned in Radiation Monitors above.

A meter monitors the Pool Water conductivity continuously. This meter is calibrated once a year. During the calibration period, the conductivity may not be measured; however, the calibration period is less than one week.

Various pressure gauges are located on the system to monitor its performance and to determine when the filters and ion exchange medium need replacement. A water pump provides for continuous circulation. Should water flow stop, the water pump is shut down automatically, and the Irradiator Operator notified by an alert. If the water is below the intake line the water pump stops and the above notification occurs.

Means for replenishing Pool Water:

A Make-Up water pipe is connected to the Water Purification System from the external water supply. It has a manual valve that may only be operated by the RSO or Irradiator Operator. The Make-Up water compensates for water loss due to evaporation. There is a meter to monitor the amount of Make-Up water added. A check valve assures that water cannot back-flow from the Water Purification System into the water supply. There are no discharge pipes leading from the Water Purification System.

Barrier used to prevent personnel from falling into the pool:

The Pool extends vertically forty-two inches above the floor level. This extension acts as a personnel barrier (railing) to prevent a person from accidentally falling into the Pool during routine operations. Accessible footholds have been provided on the inside of the Pool. The footholds allow a person to exit the Pool should they somehow fall into it.

How high radiation doses from radiation streaming are avoided when using long-handled tools or poles:

All tools used in the Pool (e.g. source handling tools) are designed to prevent streaming (e.g. hollow poles are perforated to allow water into the void). Any time a tool is used in the Pool, the RSO or Irradiator Operator uses a hand held survey meter to monitor the radiation levels over the Pool as well as any potential streaming through the tool handle.

Pool outlets more than 0.5 meter below the surface:

There are no outlets or fittings below the Minimum Water Level that would allow water to drain out of the Pool and compromise shielding.

[REDACTED]

[REDACTED]

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Facilities And Equipment

Source rack:
(See Figure 9-H & Figure 9-Ha)

Redacted Material

Redacted Material

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Power failures:

Not applicable to Pool Irradiators: the sources are always in the shielded condition and therefore no power is required to return the sources to a shielded condition.

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Product Conveyer System:

Product irradiation takes place only near the Pool bottom around the Plenum. The product is moved to that location via Bells. All components of the Bells in contact with the Pool Water are made of stainless steel. They are raised and lowered with conventional hoists and stainless steel cable. The safety factor on all lifting components such as the cable is a factor greater than five times the materials' yield strength. Should the cables or their attachments fail, the Bells might drop into the Pool; however, the Limiters, which position the Bells, keep them clear of the Plenum and sources. The Retaining Mechanism that locks the Plenum into position occupies the space in the Pool from the Plenum all the way to the surface. Therefore, a Bell cannot 'fall' and impact the Plenum.

Each Bell has an air supply line. A stainless steel pipe on the top of each Bell extends above the Bell. This pipe is connected to a flexible air supply line. The flexible air line is connected to a retractable reel system located at the hoist mechanism. The purpose of the stainless steel extension, which is curved to prevent radiation streaming, is to prevent radiation damage to the flexible air line. The purpose of this line, as stated in the General Description above, is to maintain the Bell water level. During irradiation, the product is pressurized; however, the water level in the Bell is maintained near the bottom of the Bell.

If the air supply line fails and is open to the water, air would come out of the exposed line and bubble through the water. At no time could pool water be 'drained' through the air supply line.

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Facilities And Equipment

Figure 9-A – The Genesis Irradiator – General Layout:

Redacted Material

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Facilities And Equipment

Figure 9-B – Licensee's Facilities:

Redacted Material

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Figure 9-C – Licensee's Facilities and Surrounding Area:

Redacted Material

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Figure 9-D – Genesis Access Control:

Redacted Material

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Figure 9-E – Genesis Pool Rim:

Redacted Material

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Figure 9-F – Genesis :

Redacted Material

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Figure 9-G -

Redacted Material

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Figure 9-H –

Redacted Material

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Facilities And Equipment

Figure 9-H.a -

Redacted Material

NRC Form 313, Item 9
Facilities And Equipment

Figure 9-1 -

Redacted Material

NRC Form 313, Item 10
Radiation Safety Program

Radiation Safety Program:

Purpose:

The purpose of the Radiation Safety Program is to assure the radiation safety of the irradiator, the ALARA concept, and compliance with all Nuclear Regulatory Commission regulations.

Radiation Safety Committee:

The Licensee operates with a Radiation Safety Committee to implement the Radiation Safety Program.

All changes in irradiator operating procedures or any procedures relating to the movement or handling of radioactive material which could affect the safety of employees or the public are reviewed and approved by the Radiation Safety Committee. Also, the Radiation Safety Committee approves all license changes before they are submitted to the Nuclear Regulatory Commission.

The Radiation Safety Committee is composed of:

The Radiation Safety Officer.

Chairman and Secretary of the Committee. Responsible for implementation and documentation of all decisions and approvals.

The President.

Responsible for assuring that the company can meet any obligations outlined in the procedures.

The Production Manager.

Responsible for assuring that any proposed procedures are not in conflict with existing written or unwritten procedures used by the Irradiator Operators on a day-to-day basis

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Radiation Safety Program

Facility Start-Up:

Because this application is for the first irradiator to be operated by the Licensee, there are some On-the-Job training guidelines that are difficult to meet during operational startup. The Licensee is fully aware of its responsibilities as well as the intent of the regulations.

The following two areas outline how the Licensee will train the RSO and Irradiator Operators during the facility startup so that the personnel have sufficient qualifications to operate the irradiator safely:

RSO Training - First months of operations:

The RSO will receive the manufacturer's training course and will be directly involved with the installation and trial runs of the irradiator prior to receipt of cobalt. It is anticipated that this will take about three months.

Irradiator Operator Qualifications - First month of operations:

Prior to unsupervised operations of the irradiator, the Irradiator Operators In Training will receive and be tested on all training as outlined in Item 8 of this application with a modified On-the-Job training regimen. During the first month of operations, the Licensee will certify an Irradiator Operator only after they have completed the following On-the-Job training:

- 1) Operate the irradiator (as a simulator) without cobalt-60 for at least one week. This operation will be both supervised and unsupervised. The training will be as close to actual operations as practical assuming that cobalt-60 was installed. [Note: If cobalt-60 is installed prior to the Irradiator Operator In Training having completed this task, the following task may be used in lieu of this task. The total time for tasks 1 and 2 would be a minimum of 2 weeks.]
- 2) Operate the irradiator after the installation of cobalt-60 for at least one week supervised by the RSO. [Note: More than one Irradiator Operator In Training may be 'operating' the irradiator during these supervised sessions.]
- 3) Operate the irradiator after the installation of cobalt-60 for at least one week with at least one other Irradiator Operator In Training and/or supervised by the RSO. However, this task may only be performed after the Irradiator Operator(s) In Training have successfully completed their formal training and testing. [Note: More than one Irradiator Operator In Training may be 'operating' the irradiator during these sessions.]

During this period, the RSO will closely scrutinize and monitor all Irradiator Operators In Training.

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Radiation Safety Program

Audit program:

The Licensee's Radiation Safety Program implements an Audit Program based on NUREG-1556, Vol. 6, Appendix K "Suggested Audit Checklist for 10 CFR 36 Irradiators".

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Radiation Safety Program

Survey Instruments:

The Licensee will use survey instruments that meet the Criteria in the section entitled "Radiation Safety Program – Instruments" in NUREG-1556, Vol. 6, dated January 1999.

Each survey meter is calibrated by the manufacturer or other person authorized by the Nuclear Regulatory Commission or an Agreement State to perform survey meter calibrations. Survey meters will be calibrated every 12 months.

As a minimum, two survey instruments will be maintained on site. At least one will be functional at all times: the second instrument may be sent off-site for repair and / or calibration.

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Radiation Safety Program

Radiation Monitors:

The Licensee will use radiation monitors that meet the Criteria in the section entitled "Radiation Safety Program – Instruments" in NUREG-1556, Vol. 6, dated January 1999.

Each radiation monitor is initially calibrated by the manufacturer or other person authorized by the US Nuclear Regulatory Commission or an Agreement State to perform radiation monitor calibrations. The radiation monitors are not calibrated on a routine basis. However, they are response checked and compared to the calibrated radiation survey meters. The response check also verifies that they perform their specific tasks.

Area Radiation Monitor:

Detector type – Geiger-Mueller.

Range – 0.1 mR / hr – 1 R / hr (minimum).

High Alarm – adjustable threshold set at 1 mR / hr.

Water Purification System Radiation Monitor:

(Same as Area Radiation Monitor)

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Radiation Safety Program

Material Accountability:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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Radiation Safety Program

Occupational Dosimetry:

The Licensee's occupational dosimetry program, as required by 10 CFR Parts 20 and 36, may be examined by the Nuclear Regulatory Commission during inspections.

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Public Dose:

The Licensee's program to control doses received by individual members of the public may be examined by the Nuclear Regulatory Commission during inspections.

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Radiation Safety Program

Security:

The security of licensed material is always considered to be extremely important. However, due to recent heightened concerns over terrorism, the issue of security is emphasized. Thus, additional steps have been taken to insure that the licensed material is not stolen or otherwise released to the environment by those who may wish to intentionally harm others. The security aspects of the design and operation are kept on file as Safeguard Information.

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Source Temperature:

The Genesis Irradiator uses a static helium system for source storage. Below are calculations to estimate the maximum temperature of the sources under conservative assumptions.

A thermocouple well has been provided in the Top Manifold to allow for temperature readings of the inside of the Plenum. This is to allow for temperature measurements to be taken if requested by the source suppliers. If a measurement is to be performed, the Plenum would be raised, a thermocouple inserted into the thermocouple well and attached via wires to a reading device at the top of the pool. After the measurement is performed, the thermocouple, wires and reader are removed. This procedure would not take place during normal operations and the bells would not be in the pool.

Thermal Projections Based on "Worse Case" Assumptions:

Reducted Material

Redacted Material

References:

Frankfort, J.H., S. Haram and S. Wallach, "An Industrial Gamma Irradiator for Medical Supplies", United States Atomic Energy Agency, Division of Technical Information, Associated Nucleonics, Inc., Garden City, New York, 1960, p. 68.

Shappert, L.B., "A Guide for the Design, Fabrication, and Operation of Shipping Casks for Nuclear Applications, Oak Ridge National Laboratory, Oak Ridge, TN, 1970, pp. 132-136.

NRC Form 313, Item 10
Radiation Safety Program

Routine Operations:

<u>No.</u>	<u>Procedure Title</u>	
GI-101	Routine Operation	(attached)

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Radiation Safety Program

Non-routine operations:

The irradiator manufacturer or other person authorized by the Nuclear Regulatory Commission or an Agreement State will perform non-routine operations such as source loading, unloading, and repositioning; investigating / remediation removable contamination / leaking sources; and other critical operations requiring special skills or having the potential for radiation overexposures.

OR

The Licensee will perform the following non-routine operations as outlined:

<u>No.</u>	<u>Procedure Title</u>	
GI-201	Source Repositioning	(*)
GI-202	Source Loading	(*)
GI-203	Source Unloading	(*)
GI-204	General Radiation Survey	(attached)
GI-205	Irradiator Commissioning	"
GI-206	Alert Response - Radiation Monitors	"

* (Available for review at the Licensee's site – Safeguard Info.)

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Radiation Safety Program

Emergency procedures:

<u>No.</u>	<u>Procedure Title</u>	
GI-301	Abnormal Radiation Level	(attached)
GI-302	Suspected Personnel Overexposure	"
GI-303	Unauthorized Entry In Restricted Area	"

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Radiation Safety Program

Leak tests:

For new sources:

Certificates from the transferor that leak tests have been performed within six months before the transfer are obtained.

Periodic Leak Test (Six Month Intervals):

Every six months (or less), the Plenum will be raised and contamination smears will be performed on representative portions of the interior of the Plenum. The smears will be tested for cobalt-60 contamination.

For Pool Water:

A radiation monitor is used on the Pool Water Purification System. The alarm set-point is set as low as practical, but high enough to minimize false alarms. As permitted in the Emergency Operating Procedures, the alarm set-point may be set to a higher level if necessary to operate the Pool Water Purification System to clean up contamination in the pool if required.

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Radiation Safety Program

Maintenance procedures:

Procedure Title

Operation of Helium System	(see procedure summary)
Leak Test	"
Operation of Water Purification System	"
Water Purification System Filter Replacement	"
Water Purification System Resin Bed Replacement	"
Adding Pool Water	"
Restricted Area Security Response Check	"
Radiation Monitor Response Check	"

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Radiation Safety Program

Maintenance procedures:

Manual Operation of Helium System (Summary)

- Frequency:** When required to purge water from the Plenum, if Helium pressure monitoring gauge is reading below specification.
- Responsibility:** The Radiation Safety Officer or an Irradiator Operator.
- Summary:** Helium gas under pressure is used to maintain the water level within the Plenum. There is a pressure monitoring gauge whose readings correspond with the water level in the Plenum. To displace water in the plenum, a valve is opened on the helium supply system. Visual indication of bubbles being released through the bottom of the Plenum indicate that the water has been displaced. At that point, the valve is closed. The pressure monitoring gauge is read on a shift basis to determine if the water level is appropriate.
- Documentation:** The actions taken, the results, and any corrective actions are documented.

[Note: This function may be performed automatically by the use of a Gas Regulator. Whether manual or automatic, the pressure monitoring gauge will be monitored and recorded. Tank pressure will also be monitored to assure that there is an adequate supply of helium available.]

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Radiation Safety Program

Maintenance procedures:

Leak Test (Summary)

- Frequency: When required, but, as a minimum, once every six months.
- Responsibility: The Radiation Safety Officer.
- Summary: Smears are performed on the interior of the Plenum. Each smear will cover at least 100 square cm. The smears are surveyed for radiation to make sure they are mailable to a licensed service provider. The smears are analyzed to verify that there are no leaking sources. If any of the samples indicate the possibility of contamination, a smear of every source will be performed and analyzed.
- Documentation: The actions taken, the results, and any corrective actions are documented.

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Radiation Safety Program

Maintenance procedures:

Operation of Water Purification System (Summary)

- Frequency:** Continuous.
- Responsibility:** The Radiation Safety Officer or an Irradiator Operator.
- Summary:** The Water Purification System is normally operated continuously to maintain the conductivity of the pool water below regulatory requirements under normal circumstances. However, it may be shut down for maintenance or repair.
- Documentation:** The actions taken, the results, and any corrective actions are documented.

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Maintenance procedures:

Water Purification System Filter Replacement (Summary)

Frequency: Approximately one week after loading new sources or having a shipping cask in the pool.

Performed By: The Radiation Safety Officer.

Summary: The Water Purification System filters are replaced approximately one week after a source loading or having a shipping cask in the pool. Used filters are surveyed for radiation to assure they (or representative samples thereof) are available to an analytical laboratory. The filters are analyzed to verify that there are no leaking sources or contamination from the shipping cask. If representative samples are sent, the residual filter is maintained on site in a safe and secure manner until the analytical results are received. Upon receipt of the analytical results, the filters, samples, and / or residual filters are disposed of in accordance with regulatory requirements.

Documentation: The actions taken, the results, and any corrective actions are documented.

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Radiation Safety Program

Maintenance procedures:

Water Purification System Resin Bed Replacement (Summary)

Frequency: When required or when specified by Resin Bed supplier.

Performed By: The Radiation Safety Officer.

Summary: If the conductivity of the pool water is rising or it is a scheduled replacement of the resin bed, the resin bed will be replaced. A representative sample of a water filter used toward the end of the specified resin bed's period of operation is surveyed for radiation to assure it is mailable to an analytical laboratory and analyzed to assure that the resin bed can be released from the site.

Documentation: The actions taken, the results, and any corrective actions are documented.

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Radiation Safety Program

Maintenance procedures:

Adding Pool Water (Summary)

Frequency: As necessary.

Responsibility: The Radiation Safety Officer or an Irradiator Operator.

Summary: All Pool Water (original filling and make-up) is processed through the Water Purification filters and resin bed prior to entering the Pool. Measures are taken to assure that the Pool water level is not allowed to fall below the Minimum Water Level or overflow the Pool.

Documentation: The actions taken, the results, and any corrective actions are documented.

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Radiation Safety Program

Maintenance procedures:

Restricted Area Security Response Check (Summary)

Frequency: As a minimum, once every six months.

Responsibility: The Radiation Safety Officer.

[REDACTED]

Documentation: The actions taken, the results, and any corrective actions are documented.

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Radiation Safety Program

Maintenance procedures:

Radiation Monitor Response Check (Summary)

Frequency: As a minimum, once every six months.

Responsibility: The Radiation Safety Officer.

Summary: A gamma emitting check source is use to verify that the Area Radiation Monitor and Water Radiation Monitor are working properly and that they issue the associated visual and audible alerts. Remote alert indicators are checked for proper functioning. The monitors' ability to deactivate associated equipment (e.g. – product Bell movement) is also verified. A calibrated hand held survey meter is used to verify that the radiation monitors' readings are nominally accurate.

Documentation: The actions taken, the results, and any corrective actions are documented.

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Administrative procedures:

<u>No.</u>	<u>Procedure Title</u>	
GI-001	Procedure Control	(*)
GI-002	Radiation Safety Program Audit	(*)
GI-003	Records Maintenance	(*)
GI-004	Posting Requirements	(*)
GI-005	Occupational Dosimetry	(*)
GI-006	Irradiator Operator Training	(*)
GI-007	Emergency Response Personnel Training	(*)
GI-008	Radiation Safety Officer Training	(*)
GI-009	Background Verification for Unescorted Access	(*)

* (Available for review at the Licensee's site)

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Transportation:

The Licensee does not transport licensed radioactive material. The Licensee contracts with service licensees (sealed source manufacturers) that are licensed by the Nuclear Regulatory Commission or an Agreement State who then acts as the shippers.

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Radiation Safety Program

Minimization of Contamination:

See responses to the criteria for the following sections:

- Radioactive Material – Sealed Sources And Devices.
- Facilities And Equipment – Irradiator Pools.
- Radiation Safety Program – Operating Procedures.
- Radiation Safety Program – Emergency Procedures.
- Radiation Safety Program – Leak Tests.
- Waste Management – Sealed Source Transfer And Disposal.

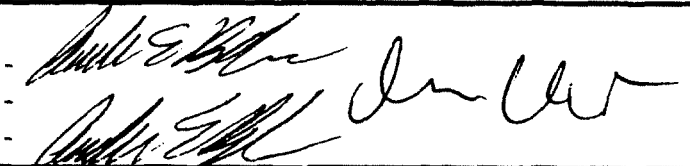
**NRC Form 313, Item 11
Waste Management**

Sealed source disposal is accomplished by a licensed or permitted vendor specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform those operations. The RSO verifies that the vendor used by the Licensee is licensed for the activities that they conduct and maintains copies of the vendor's licenses.

When practicable, contractual arrangements will be made with the source supplier for the return of sealed sources. The contracts are available for NRC review.

Filter and resin bed material will not be released until an analysis is performed for radioactive contamination.

When filter samples are sent for analysis, any portion of the sample not sent to the laboratory is retained until the analysis results are received. This residual material is then disposed of in accordance with regulatory requirements.

Section: Routine Operation	Subject: Routine Operation
Approved: Radiation Safety Officer President Production Manager	

1. Purpose:

- 1.1. To establish the radiation safety procedure used for the operation of the Irradiator.

2. References:

- 2.1. 10 CFR 36.13.c Specific Licenses For Irradiators.
2.2. 10 CFR 36.53 Operating And Emergency Procedures.

3. Forms:

- 3.1. GI-101-01.

4. General Requirements:

- 4.1. The Shift Irradiator Operator performs this procedure for each shift the Irradiator is operated.
- 4.1.1. The Radiation Safety Officer or Irradiator Operator also performs this procedure at least once per week when the Irradiator is not in use.
- 4.1.2. The Radiation Safety Officer or Irradiator Operator performs this procedure whenever they initially enter the Restricted Area when the Irradiator is not in use (e.g. visit to the facility during a non-working weekend).

5. Procedure:

- 5.1. Start of shift:
- 5.1.1. Check remote Area Radiation Monitor indicator before entering the Restricted Area to assure it is working properly.
- 5.1.2. Unlock and open the Main Door to the Restricted Area (if closed).
- 5.1.3. Remove your personal dosimeter from the rack and clip to self.

[REDACTED]

5.1.5. Perform handheld Survey Meter check.

5.1.5.1. Check battery status.

5.1.5.2. Check reading with check source.

5.1.6. Enter Restricted Area.

5.1.7. Perform radiation check over Pool; record on Log.

[Note: 5.1.7 through 5.1.18 need not be performed in order specified.]

5.1.8. Turn off meter and return it to its storage shelf.

5.1.9. Check ARM reading; record on Log.

5.1.10. Check WRM reading; record on Log.

5.1.11. Check Pool Water circulation pressure; record on Log.

5.1.12. Check Pool Water conductivity; record on Log.

5.1.13. Check Pool Water circulation system visually for leaks; record on Log.

5.1.14. Check Helium Pressure; record on Log.

5.1.15. Check [REDACTED] Plenum Locking Mechanism; record on Log [REDACTED]

5.1.16. Check Pool Water level; record on Log.

5.1.17. Note any unusual observation on Log.

5.1.18. Review prior Log (all sheets since your last Log or the previous four Log sheets).

5.1.19. Sign and date Log.

5.2. During shift:

5.2.1. Process product in accordance with production procedures.

5.2.2. Note any unusual observation on Log.

5.3. End of shift:

5.3.1. Note any unusual observation on Log.

5.3.2. If the Irradiator is not to be left [redacted] verbally communicate security and safety status of the operation to the next Shift Operator.

5.3.3. Place Bells in "Secure" Position [redacted]

5.3.4. Close and lock all doors except the personnel door.




5.3.5. Remove your personal dosimeter and place it back on the rack.

5.3.6. Exit the Restricted Area and assure the personnel door is locked and the Restricted Area is secure [redacted]

[redacted]

Revisions:

Rev	Date	Comments
00	06/20/05	Original Release

Section: Non-Routine Operation	Subject: General Radiation Survey
Approved: Radiation Safety Officer -  President -  Production Manager - 	

1. Purpose:

- 1.1. To perform a general radiation survey of the facility and to record radiation levels inside and outside the Restricted Area.

2. References:

- 2.1. 10 CFR 36.25 Shielding.
- 2.2. 10 CFR 36.57 Radiation Surveys.

3. Forms:

- 3.1. GI-204-01 General Radiation Survey Report.

4. Equipment:

- 4.1. Handheld survey meter.

5. General Requirements:

- 5.1. The Radiation Safety Officer, an Irradiator Operator, or an Irradiator Operator in Training performs this procedure.
- 5.2. Radiation readings are taken at the following elevations:
 - 5.2.1. Locations A-H At 30 cm above the Pool rim.
 - 5.2.2. Locations I-P At Pool rim.
 - 5.2.3. Locations Q-MM (User defined around facility).

6. Procedure:

- 6.1. Record the radiation levels at the locations identified in Figure 1 on form GI-204-01.

- 6.2. The Radiation Safety Officer reviews and signs the completed form GI-204-01.

Revisions:

Rev	Date	Comments
00	06/20/05	Original Release

Figure 1:




Redacted Material

Figure 2:

Redacted Material

GENESIS II Irradiator

GI-205

Section: Non-Routine Operation	Subject: Irradiator Commissioning Survey
Approved: Radiation Safety Officer -  President -  Production Manager - 	

1. Purpose:

- 1.1. To perform a radiation survey of the Irradiator and to record radiation levels to assure radiation levels are under 2 mR/hr in personnel access areas.

2. References:

- 2.1. 10 CFR 36.25 Shielding.
- 2.2. 10 CFR 36.57 Radiation Surveys.

3. Forms:

- 3.1. GI-205-01 Irradiator Commissioning Radiation Survey Report.

4. Equipment:

- 4.1. Two handheld survey meters.

5. General Requirements:

- 5.1. The Radiation Safety Officer, an Irradiator Operator, or an Irradiator Operator in Training performs this procedure.
- 5.2. Each person in or near the measurement locations has a handheld survey meter and a personal dosimeter: other personnel may be in the Restricted Area, but must be well back from the edge of the Pool.
- 5.3. A new survey is made whenever sources have been added or removed from the irradiator.
- 5.4. Radiation readings are taken at the following locations:
 - 5.4.1. Location A At / on the Pool rim at the "Start Position".
 - 5.4.2. Location B Directly above the pool as accessible.

5.4.3. Locations C – MM These are user defined optional locations.

6. Procedure:

6.1. Run two empty product Bells completely through a cycle:

6.1.1. If either location detects a response above 2 mR/hr., immediately press emergency stop and take appropriate action. (Notify the RSO.)

6.2. Record the maximum radiation levels and Minimum Shielding Condition (Bell Positions) at the locations identified in Figure 1 on form GI-205-01.

6.3. The Radiation Safety Officer reviews and signs the completed forms GI-205-01.


6.4. Perform a General Radiation Survey with the product Bells in the Minimum Shielding Condition as defined by this procedure.

Revisions:

Rev	Date	Comments
00	06/20/05	Original Release

Figure 1:

Redacted Material

Section: Non-Routine Operation	Subject: Alert Response – Radiation Monitors
Approved: Radiation Safety Officer President Production Manager	

1. Purpose:

- 1.1. To specify the procedure to be followed when the Area Radiation Monitor and / or the Water Radiation Monitor issues an alert.

2. References:

- 2.1. 10 CFR 20.1501 General.
2.2. 10 CFR 36.29 Radiation Monitors

3. Forms:

- 3.1. GI-101-01 Safety Log

4. Equipment:

- 4.1. Handheld survey meter.

5. General Requirements:

- 5.1. The Radiation Safety Officer, an Irradiator Operator, or an Irradiator Operator in Training performs this procedure.

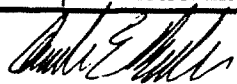


6. Procedure:

- 6.1. When the Area Radiation Monitor and / or the Water Radiation Monitor issues an alert:
- 6.1.1. Immediately direct all personnel in the Restricted Area to exit the Restricted Area.
- 6.1.2. Cautiously, using handheld survey meter and a personal dosimeter, approach the Irradiator to ascertain the actual radiation level.
- 6.1.3. If radiation levels are abnormally high, follow the Abnormal Radiation Level Procedure.

- 6.1.4. Silence the alarm.
- 6.2. Notify the Radiation Safety Officer for further instruction.
- 6.3. Enter the alert and actions performed on form GI-101-01.

Revisions:

Rev	Date	Comments
00	06/20/05	Original Release

Section: Non-Routine Operation	Subject: Abnormal Radiation Level
Approved: Radiation Safety Officer President Production Manager	-  -  - 

1. Purpose:

- 1.1. To specify the procedure to be followed when it has been verified that an abnormal radiation level exists.

2. References:

- 2.1. 10 CFR 20.2203 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.
- 2.2. 10 CFR 36.13 Specific Licenses for Irradiators.
- 2.3. 10 CFR 36.29 Radiation Monitors.
- 2.4. 10 CFR 36.57 Radiation Surveys.
- 2.5. 10 CFR 36.59 Detection of Leaking Sources.
- 2.6. 10 CFR 36.83 Reports

3. Forms:

- 3.1. GI-101-01 Safety Log

4. Equipment:

- 4.1. Handheld survey meter.

5. General Requirements:

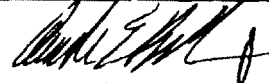


- 5.1. The Radiation Safety Officer or an Irradiator Operator performs this procedure when notified that an abnormal radiation level exists at the facility.

6. Procedure:

- 6.1. Take measures to restrict personnel access in areas with radiation levels exceeding 2 mR/hr.
- 6.2. If practical, determine the source of the abnormal radiation.
- 6.3. Notify the Radiation Safety Officer for further instructions.
- 6.4. If there is a reason to suspect personnel overexposure to radiation, follow the Suspected Personnel Overexposure procedure.
- 6.5. Enter the alert and actions performed on form GI-101-01.

Revisions:

Rev	Date	Comments
00	06/20/05	Original Release

Section: Non-Routine Operation	Subject: Suspected Personnel Overexposure
Approved: Radiation Safety Officer -  President -  Production Manager - 	

1. Purpose:

- 1.1. To specify the procedure to be followed when personnel are suspected of receiving radiation overexposure.

2. References:

- 2.1. 10 CFR 20.1201 Occupational Dose Limits for Adults.
- 2.2. 10 CFR 20.1502 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

3. Forms:

- 3.1. GI-101-01 Safety Log

4. General Requirements:

- 4.1. This procedure is performed by a person(s) when a radiation overexposure is suspected.

5. Procedure: (to be performed by either the person with the suspected radiation overexposure or other person on the premises)

- 5.1. Immediately leave the area of abnormal radiation.
- 5.2. Call the Hospital. Ask for an ambulance response and give your location.
- 5.3. If practical, while waiting for the ambulance to arrive:
 - 5.3.1. Notify the Radiation Safety Officer: or another Irradiator Operator if the RSO cannot be reached.
 - 5.3.2. Enter the incident on form GI-101-01.
 - 5.3.3. Close and lock all doors to the Restricted Area.

- 5.3.4. Return personal dosimeter to the Personal Dosimeter Rack.
- 5.4. Meet the ambulance at the front of the building.
 - 5.4.1. Secure the facility if you are the only one present.
- 5.5. Upon arrival at the Hospital, identify yourself and explain that this is a Radiation Overexposure case.
 - 5.5.1. If you were previously unable to contact the RSO, have the hospital continue to attempt to contact the RSO or other responsible person.

Revisions:

Rev	Date	Comments
00	06/20/05	Original Release

Redacted Material

Redacted Material

Revisions:

Rev	Date	Comments
00	06/20/05	Original Release

JUL - 6 2005

DATE

This is to acknowledge the receipt of your letter/application dated 6/23/05, and to inform you that the initial processing, which includes an administrative review, has been performed.

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

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

The action you requested is normally processed within 90 days.

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

Your action has been assigned Mail Control Number 470601.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Murahan
Licensing Assistant

NRC FORM 532 (RIV)
(9-2003)

BETWEEN:
License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LEMS USE)
INFORMATION FROM LTS

Program Code: 3
Status Code: 3
Fee Category: 0
Exp. Date: 0
Fee Comments:
Decom Fin Assur Regd:
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
Applicant/Licensee: PA'INA HAWAII
Received Date: 20050627
Docket No.: 3036974
Control No.: 470601
License No.:
Action Type: New Licensee

2. FEE ATTACHED
Amount: \$11,000.00
Check No.: 3986

Signed _____
Date _____

3. COMMENTS

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / __/)
1. Fee Category and Amount: _____
2. Correct Fee Paid. Application may be processed for:
Amendment _____
Renewal _____
License _____
3. OTHER _____

Signed _____
Date _____