

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03036438/2011001

Docket No. 03036438

License No. 37-30850-01

Licensee: Gamma Irradiator Service

Location: 337 Distillery Hill Road
Benton, Pennsylvania 17814

Inspection Dates: November 14, 15, and 18, 2011, February 24, 2012,
and telephone exit on April 24, 2012

Date Followup
Information Received: February 7, 2012 and April 21, 2012

Inspector:	/RA/ _____ Kathy Modes Senior Health Physicist Decommissioning Branch Division of Nuclear Materials Safety	04/26/12 _____ date
Approved By:	/RA/ _____ Marc S. Ferdas, Chief Decommissioning Branch Division of Nuclear Materials Safety	04/26/12 _____ date

EXECUTIVE SUMMARY

Gamma Irradiator Service NRC Inspection Report No. 03036438/2011001

An announced safety inspection was conducted at Gamma Irradiator Service (GIS) in Benton, Pennsylvania on November 14, 15, and 18, 2011, and February 24, 2012. An in-office review of additional information provided by GIS continued through April 24, 2012. This inspection was conducted pursuant to the Inspection Manual Chapter (IMC) 2800 and the Inspection Procedures (IP) 87122 and 87126. The IP Focus Elements addressed were 03.01 through 03.07. The inspector interviewed GIS personnel and reviewed records and procedures. The inspector reviewed NRC Event Notification Reports 47334 and 47335 and the status of GIS's completion of actions pursuant to the Confirmatory Action Letter (1-11-001) that was issued to GIS on October 20, 2011 (ADAMS Accession No. ML112930388). The inspector also reviewed GIS's Report of Incident, dated October 30, 2011 (ML113330672).

GIS is a service provider licensee that provides preventive maintenance and other services (i.e., installation, relocation, radiation surveys, realignment, replacement, repair, and leak testing) on self-shielded (Category I) irradiators that have been registered either with the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR 32.210 or with an Agreement State. GIS is authorized under NRC License No. 37-30850-01 and clients include medical facilities, research and development facilities, military, universities, and nuclear power plants.

Based on the results of this inspection, the inspector identified two apparent violations. Specifically:

- GIS did not conduct its program in accordance with the statements contained in the documents listed in their NRC license, as required by Condition 15 of NRC License No. 37-30850-01. Specifically, in a December 31, 2003, facsimile, GIS stated they would have written emergency procedures to cover most of the situations that could be encountered during maintenance of a self-shielded irradiator. GIS did not have comprehensive written emergency procedures to cover likely situations that could be encountered.
- GIS did not limit licensed activities to self-shielded (Category I) irradiators as required by Item 9 of NRC License No. 37-30850-01. Specifically, GIS performed preventive maintenance on a JL Shepherd Model 81-22 at the Army CECOM's facility in Fort Monmouth, NJ in 2003, 2005, 2007 and 2009. The JL Shepherd Model 81-22 is not considered a self-shielded irradiator in accordance with NRC guidance documents (NUREG-1556) and NRC regulations (10 CFR Part 36). The JL Shepherd Model 81-22 is an open beam Category II irradiator. GIS was authorized to service only Category I irradiators.

REPORT DETAILS

I. Organization and Radiation Protection Program

a. Inspection Scope

An announced safety inspection was conducted at Gamma Irradiator Service (GIS) in Benton, Pennsylvania on November 14, 15, and 18, 2011, and February 24, 2012. An in-office review of additional information provided by GIS continued through April 24, 2012. This inspection was conducted pursuant to the Inspection Manual Chapter (IMC) 2800 and the Inspection Procedures (IP) 87122 and 87126. The IP Focus Elements addressed were 03.01 through 03.07. The inspector interviewed GIS personnel and reviewed records and procedures. The inspector reviewed NRC Event Notification Reports 47334 and 47335 and the status of GIS's completion of actions pursuant to the Confirmatory Action Letter (1-11-001) that was issued to GIS on October 20, 2011 (ADAMS Accession No. ML112930388). The inspector also reviewed GIS's Report of Incident, dated October 30, 2011 (ML113330672).

b. Observations and Findings

GIS is a service provider licensee that provides preventive maintenance and other services (i.e., installation, relocation, radiation surveys, realignment, replacement, repair, and leak testing) on self-shielded (Category I) irradiators that have been registered either with the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR 32.210 or with an Agreement State. GIS is authorized under NRC License No. 37-30850-01 and clients include medical facilities, research and development facilities, military, universities, and nuclear power plants.

As of March 2010, GIS was operated by a single individual. In March 2010, GIS hired a new employee to work as an assistant. The inspector confirmed that initial training was provided and annual training has been completed. GIS provided training to personnel throughout the year on various topics including specific irradiator models and how to repair these models, safety components on irradiators, current NRC events, ALARA, use of survey instrumentation, NRC regulations, and other operating experience/case histories. The inspector verified that GIS personnel have valid hazmat training certificates for proper packaging of sources back to the manufacturer or relocation. Annual program reviews were completed (May 10, 2010, and June 21, 2011) using the sample audit form in Appendix I of NUREG-1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Service Provider Licenses" and were conducted either by the RSO or the assistant.

GIS calibrates their own survey meters as authorized on their Pennsylvania Agreement State license. They maintain a Bicorn surveyor 2000, Ludlum 14C meter, Ludlum 2241 rate meter, and an Eberline E530 survey meter. Leak tests are taken and analyzed at the client's facility. There had been no leaking sources detected in NRC jurisdiction between January 1, 2009 and April 24, 2012.

The RSO and assistant wear Landauer luxel whole body dosimeters which are exchanged quarterly. Based on Landauer exposure reports, the highest whole body exposures for the last three years are shown in the table below:

	Dosimetry Results in mrem		
	2009	2010	2011
RSO	13	14	11,480
Assistant	-	6	3,600

The dosimetry results for 2011 were a result of an over-exposure event that occurred on October 8, 2011 in New Jersey (see NRC Event Reports 47334 and 47335 for details). GIS was working in the State of New Jersey, an Agreement State, under reciprocity using its Pennsylvania Agreement State license when the event occurred. Due to the over-exposures, the NRC became concerned about the adequacy of the safety and radiological controls implemented by GIS during self-shielded irradiator source reloads and source exchanges, an activity that GIS was authorized to perform in NRC jurisdiction in accordance with their NRC license. The NRC issued Confirmatory Action Letter (CAL) 1-11-001 to GIS on October 20, 2011 (ML112930388), which documented a number of actions GIS agreed to take prior to performing source reloads and source exchanges in NRC jurisdiction. GIS is currently in the process of completing the actions in the CAL and the inspector confirmed that GIS has not performed any source reloads or exchanges since the CAL was issued.

The inspector also confirmed that GIS did not allow personnel to perform radiological work activities for the remainder of calendar year 2011, for those that exceeded the annual dose limit in 10 CFR 20 (5000 mrem) due to the over-exposure event in October 2011.

The inspector performed a review of GIS's operating and emergency procedures. In accordance with Condition 15 of their NRC license, GIS is to abide by commitments made in their new license application dated November 10, 2003 (ML033371063), and subsequent additional information contained in their facsimile dated December 31, 2003 (ML040170045). On page 7-12 of GIS's facsimile, GIS committed to the following:

“Operation and emergency procedures have been written to cover most all situations that will be encountered. Operation and emergency procedures will be maintained and updated to provide the best radiological controls in normal and emergency conditions.”

The inspector noted that GIS's emergency procedure was contained in their radiation safety manual. Their emergency procedures were limited and only addressed what actions personnel should take in the event of a leaking source. The inspector determined that GIS's emergency procedures were not comprehensive and did not cover most of the emergency situations that could be encountered while performing maintenance on shelf-shielded irradiators as required by Condition 15 of their NRC license.

As described in a letter dated April 21, 2012, GIS developed interim guidance on how to respond to emergency events that could be encountered and stated they would submit the NRC their revised written emergency procedures as required by the CAL.

GIS services various makes and models of self-shielded irradiators. The inspector noted that GIS serviced a JL Shepherd Model 81-22 on May 2, 2003; February 25, 2005; June 15, 2007; and May 19, 2009. No preventive maintenance activities were conducted in 2011 because GIS's client (US Army CECOM) had subsequently transferred the JL Shepherd Model 81-22 device. This type and model contained a Cs-137 source of high activity capable of producing dose rates in excess of 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air. The inspector noted that the JL Shepherd Model 81-22 irradiator is classified in the Sealed Source and Device (SS&D) Registry as a Category II (panoramic) irradiator. NUREG-1556 Volume 5, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses" defines shelf-shielded irradiators as Category I irradiators. As a consequence this irradiator would not be considered a self-shielded irradiator in accordance with NRC guidance documents and NRC regulations (10 CFR Part 36). The inspector determined that GIS was not authorized to service a JL Shepherd Model 81-22, because this is a Category II irradiator and GIS was only authorized to service (Category I) shelf-shielded irradiators in accordance with Item 9 of their NRC license.

When questioned by the inspector concerning their work on the JL Shepherd Model 81-22, GIS personnel stated that they thought this type of device would be considered a self-shielded irradiator when they installed the beam plug into the irradiator prior to performing maintenance activities.

In a letter dated April 21, 2012 (ML12115A251), GIS documented the following corrective actions that have been taken:

1. On February 24, 2012, GIS immediately ceased work on any beam or panoramic irradiator that meets the requirement of Part 36 (i.e., greater than 500 rem at 1 meter).
2. On March 8, 2012, GIS completed their extent of condition review to verify that they had not performed licensed activities on other Part 36 irradiators in NRC jurisdiction.
3. On March 9, 2012, GIS provided training to personnel to properly identify Category I and Category II irradiators and to further emphasize that GIS is only authorized to work on Category I irradiators.
4. GIS developed interim emergency procedures which will be incorporated into their Radiation Safety Manual.
5. On April 6, 2012, GIS trained all personnel on the new emergency procedures which included scenarios for (a) a dislodged or exposed source, (b) over-exposure event, (c) alarming dosimeter or area monitor, (d) medical emergency, (e) fire, (f) flood, (g) irradiator fails to function as designed, and (h) a leaking source.

c. Conclusions

Based on the results of this inspection, the inspector identified two apparent violations. Specifically:

- GIS did not conduct its program in accordance with the statements contained in the documents listed in their NRC license, as required by Condition 15 of NRC License No. 37-30850-01. Specifically, in a December 31, 2003, facsimile, GIS stated they would have written emergency procedures to cover most of the situations that could be encountered during maintenance of a self-shielded irradiator. GIS did not have comprehensive written emergency procedures to cover likely situations that could be encountered.
- GIS did not limit licensed activities to self-shielded (Category I) irradiators as required by Item 9 of NRC License No. 37-30850-01. Specifically, GIS performed preventive maintenance on a JL Shepherd Model 81-22 at the Army CECOM's facility in Fort Monmouth, NJ in 2003, 2005, 2007, and 2009. The JL Shepherd Model 81-22 is not considered a self-shielded irradiator in accordance with NRC guidance documents (NUREG-1556) and NRC regulations (10 CFR Part 36). The JL Shepherd Model 81-22 is an open beam Category II irradiator. GIS was authorized to service only Category I irradiators.

II. Exit Meeting

An exit meeting was held by telephone on April 24, 2012 with Doyle Terry Stout, owner and RSO, to discuss the scope of the inspection, the inspector observations and findings, the circumstances surrounding the apparent violations, and the corrective actions taken by GIS.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

#*Doyle Terry Stout, President and Radiation Safety Officer Gamma Irradiator Service (GIS)
#Chris Von Nostrand, GIS assistant

Joseph Deman from the Commonwealth of Pennsylvania

Individual(s) present at entrance meeting

* Individual(s) present at exit telephone call

LIST OF ACRONYMS USED

GIS Gamma Irradiator Service
IP Inspection Procedure
NRC Nuclear Regulatory Commission
O&E Operating and Emergency Procedures
RSO Radiation Safety Officer

PARTIAL LIST OF DOCUMENTS REVIEWED

GIS NRC License No. 37-30850-01 Amendment No. 5 dated April 22, 2011 with Application dated November 10, 2003 (includes GIS Radiation Safety Manual) and Facsimile dated December 31, 2003
NRC Confirmatory Action Letter 1-11-001 dated October 20, 2011
GIS Report of Incident dated October 30, 2011
Various service reports for JL Shepherd Models 81-22 and Mark I irradiators (2003 – 2011)
GIS Emergency Procedure GIS-EMP-001 dated April 2012
GIS Letter dated April 21, 2012 documenting corrective actions
Survey Meter Calibration Records (2010 and 2011)
Training records (2010 and 2011)
Annual Program Review Records (May 10, 2010, and June 21, 2011)
Landauer Exposure Records (2009, 2010 and 2011)
Transportation shipping records (2009 – 2011)
Manufacturer Operating Procedures for JL Shepherd Models 81-22 and Mark I and MDS Nordion Models Gammacell 1000 and 3000
Sealed Source and Device Registration CA-598-D-115-S for JL Shepherd Model 81-22
GIS letter in response to Pennsylvania Notification Letter dated March 2, 2012