



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

July 11, 2012

EA-12-088

Doyle Terry Stout
Owner and Radiation Safety Officer
Gamma Irradiator Service
337 Distillery Hill Road
Benton, PA 17814

SUBJECT: GAMMA IRRADIATOR SERVICE - NOTICE OF VIOLATION - NRC Inspection
Report No. 03036438/2011001

Dear Mr. Stout:

This letter provides you with the U.S. Nuclear Regulatory Commission (NRC) enforcement decision for the apparent violations identified during an NRC inspection conducted between November 14, 2011, and April 24, 2012, at Gamma Irradiator Service (GIS) in Benton, Pennsylvania. In addition to the onsite review, the inspection also involved in-office review of additional information provided by GIS in correspondence dated February 7, 2012 (non-public due to the inclusion of sensitive, unclassified, security-related information), April 21, 2012 (ML12115A251¹), and June 27, 2012 (ML12180A283 and ML12180A285). The NRC discussed its findings during a telephonic exit with you on April 24, 2012. The findings were also described in the NRC inspection report (ML121210734) transmitted to you via a letter dated April 26, 2012 (ML121210729). The subject NRC inspection consisted of an on-site examination and in-office review of the status of activities pursuant to the Confirmatory Action Letter (CAL) No. 1-11-001, dated October 20, 2011 (ML112930388), issued to GIS, and other licensed activities as they relate to radiation safety and to compliance with NRC regulations.

GIS is a service provider that is authorized under NRC License No. 37-30850-01 to provide preventive maintenance and other services on self-shielded (Category I) irradiators². On October 8, 2011, GIS was involved in an event wherein several workers were exposed to radiation in an amount in excess of the regulatory limits during a source reload on a Category I irradiator. At the time, GIS was working under reciprocity in the State of New Jersey with another service provider, and, therefore, regulatory oversight for that matter is within the

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

² References to Category I and II irradiators follow the definitions in American National Standard N43.7.

jurisdiction of New Jersey (an Agreement State). Although the event occurred in that Agreement State, the NRC issued CAL No. 1-11-001 to GIS because the overexposure that occurred in New Jersey raised questions regarding the adequacy of the safety and radiological controls and procedures implemented by GIS, which would be used during source reloads and exchanges while in NRC jurisdiction.

In the letter dated April 26, 2012, the NRC indicated that two apparent violations of NRC requirements were identified during the NRC inspection. In telephone conversations on May 16, 2012, and June 27, 2012, Mr. Marc Ferdas of my staff informed you that the NRC was considering escalated enforcement for one of the apparent violations, in accordance with the NRC Enforcement Policy, and that we had sufficient information regarding the apparent violation and your corrective actions to make an enforcement decision without the need for a pre-decisional enforcement conference (PEC) or a written response from you. You indicated that a PEC would not be necessary and that GIS did not plan to submit a written response. Therefore, based on the information developed during the inspection, the NRC has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

The first violation involved the failure to limit licensed activities to Category 1 self-shielded irradiators, as required by Condition 9 of GIS's NRC license. Specifically, the NRC identified that GIS performed preventive maintenance on a panoramic (Category II) irradiator in 2003, 2005, 2007, and 2009. GIS personnel indicated to the NRC that they had believed a minor temporary modification they made to the Category II irradiator (installing a beam plug) prior to performing the maintenance essentially made the device a Category I irradiator. However, the NRC concluded that this modification did not change the irradiator type. Further, the NRC concluded that the violation impacted the NRC's regulatory process because the NRC was not provided an opportunity to review and approve GIS's program for servicing Category II irradiators to ensure its adequacy. Panoramic irradiators have a greater risk for radiation exposure and require a different set of controls and procedures than those used for Category I irradiators. Therefore, the violation has been categorized at Severity Level (SL) III in accordance with the Enforcement Policy.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because GIS has not been the subject of NRC escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC has concluded that credit is warranted for GIS's corrective actions taken to address the violation. Specifically, GIS: (1) conducted an extent of condition review and verified that there were no other instances in NRC jurisdiction in which GIS had conducted licensed activities involving panoramic irradiators; (2) provided training to GIS personnel on the difference between Category I and II irradiators, and also reinforced to their personnel that GIS is only authorized to work on Category I irradiators; and, (3) developed a procedure directing GIS to first verify that it is authorized to work on an irradiator prior to performing licensed activities. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous NRC escalated enforcement action, I have been authorized, after consultation with the Director,

Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III violation constitutes an escalated enforcement action that may subject you to increased inspection effort in the future.

The second apparent violation involved GIS's failure to have comprehensive written emergency procedures which describe how GIS would handle likely situations that could be encountered while performing maintenance on a Category I irradiator, as required by Condition 15 of its NRC license. The NRC inspector identified that GIS's emergency procedures only addressed what actions GIS personnel should take in the event of a leaking radioactive source, and did not cover most of the other emergency situations that could be encountered while servicing Category I irradiators. GIS indicated to the NRC that GIS had considered a leaking source to be the most likely emergency situation it would encounter. The NRC recognizes that during this NRC inspection, and in previous NRC inspections, GIS personnel verbally described to the NRC inspector what actions were expected to be taken in a variety of emergency situations. Therefore, the NRC concluded that GIS personnel were aware of how to deal with various emergencies, but that GIS hadn't documented expected response actions in a written procedure, as required. Consequently, this violation has been categorized at SL IV in accordance with the Enforcement Policy.

The NRC has concluded that information regarding: (1) the reason for the violations under NRC jurisdiction; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in this letter; in NRC Inspection Report No. 03036438/2011001; in letters from GIS dated February 7, April 21, 2012, and June 27, 2012; and in telephone records dated January 25, 2012 (ML12032A014), April 19, 2012 (ML121150447), and April 24, 2012 (ML121160547). Therefore, you are not required to respond to this letter unless the descriptions in the aforementioned correspondence do not accurately reflect your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure as well as your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

D. Stout

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To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,

/RA Original Signed by David C. Lew for/

William M. Dean
Regional Administrator

Docket No. 03036438
License No. 37-30850-01

Enclosure: Notice of Violation

cc: w/enclosure
Commonwealth of Pennsylvania
State of New Jersey

D. Stout

4

To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,

/RA Original Signed by David C. Lew for/

William M. Dean
Regional Administrator

Docket No. 03036438
License No. 37-30850-01

Enclosure: Notice of Violation

cc: w/enclosure
Commonwealth of Pennsylvania
State of New Jersey

Distribution:
See next page

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*HQ to perform a quick review. ** see previous concurrence page

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NOTICE OF VIOLATION

Gamma Irradiator Service
Benton, Pennsylvania

Docket No. 03036438
License No. 37-30850-01
EA-12-088

During an NRC inspection conducted between November 14, 2011 and April 24, 2012 (which included an on-site inspection as well as an in-office review of information provided by Gamma Irradiator Service (GIS) in correspondence dated February 7, and April 21, 2012), for which an exit meeting was conducted on April 24, 2012, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Condition 9 of NRC License No. 37-30850-01 authorizes, in part, that GIS may perform installation, relocation, radiation surveys, realignment, replacement, repair, maintenance, and servicing of only self-shielded irradiators (Category I) that have been registered with either the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

Contrary to the above, on May 2, 2003, February 25, 2005, June 15, 2007, and May 19, 2009, GIS performed maintenance activities on a JL Shepherd Model 81-22 irradiator, which is not a self-shielded (Category I) irradiator but, rather, is a panoramic (Category II) irradiator.

This is a Severity Level III violation (Section 6.3).

- B. Condition 15 of NRC License No. 37-30850-01 states, in part, that GIS shall conduct its program in accordance with the statements, representations, and procedures contained in the facsimile dated December 31, 2003.

Page 7-12 of the GIS facsimile dated December 31, 2003, states, in part, that 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.

Contrary to the above, as of February 24, 2012, GIS did not have written emergency procedures which covered most situations that would be encountered while performing maintenance on a Category I irradiator.

This is a Severity Level IV violation (Section 6.3).

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in this letter; in NRC Inspection Report No. 03036438/2011001; in letters from GIS dated February 7, 2012, April 21, 2012, and June 27, 2012; and in telephone records dated January 25, 2012, April 19, 2012, and April 24, 2012. Therefore, you are not required to respond to this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the descriptions in the aforementioned correspondence do not accurately reflect Gamma Irradiator Service's corrective actions or its position. In that case, or if you choose to

respond, clearly mark your response as a "Reply to a Notice of Violation – EA-12-088," and send it to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 11th day July, 2012