



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

August 20, 2013

Docket No.: 030-36438
EA-13-113

License No.: 37-30850-01

Mr. Doyle Terry Stout
Gamma Irradiator Service, LLC
337 Distillery Hill Road
Benton, PA 17814

SUBJECT: GAMMA IRRADIATOR SERVICE, LLC - NRC INSPECTION REPORT NO.
03036438/2013001; NRC OFFICE OF INVESTIGATIONS REPORT NO.
1-2012-039; AND EXERCISE OF ENFORCEMENT DISCRETION

Dear Mr. Stout:

This letter provides you the results of an investigation that was completed on April 19, 2013, by the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI), regarding Gamma Irradiator Service, LLC (GIS). The OI investigation was conducted to determine whether GIS willfully failed to follow its NRC license (No. 37-30850-01, Amendment 3) requirements when GIS performed maintenance on an NRC licensee's self-shielded irradiator on April 17, 2010. Based on the evidence gathered during the OI investigation, the NRC concluded that a violation of NRC requirements occurred, but did not identify any wrongdoing associated with the violation. On July 15, 2013, Marc Ferdas and Kathy Modes of my staff informed you, by telephone, of this conclusion.

Item 9 of GIS's NRC license, in part, authorizes GIS to install, relocate, survey, realign, replace, repair, maintain, and service self-shielded irradiators that have been registered either with the NRC under 10 CFR 32.210 or with an Agreement State. On April 17, 2010, GIS did not adhere to Item 9 of its license when GIS installed a custom pneumatic tower on an NRC licensee's self-shielded irradiator. Specifically, this change to the licensee's self-shielded irradiator was not registered with the NRC under 10 CFR 32.210 or an Agreement State prior to installation. Therefore, GIS was not authorized under its license, at the time, to service the NRC licensee's self-shielded irradiator with the custom pneumatic tower.

Normally, this violation would have been categorized at a Severity Level III. However, Section 3.5 of the NRC Enforcement Policy (Policy) states, in part, that the NRC may refrain from issuing a Notice of Violation (NOV) for a Severity Level III violation after considering the guidance in the Policy and factors such as the age of the violation and other relevant circumstances, including any that may have changed since the violation occurred. The NRC licensee (not GIS) requested to add a custom pneumatic tower to its self-shielded irradiator. This was issued via license amendment, but did not include registration per 10 CFR 32.210, as normally would be expected. It was determined that GIS misinterpreted this amendment as meeting the requirements of Item 9 of its NRC license, which only authorizes GIS to service self-shielded irradiators that have been registered under 10 CFR 32.210. Also, on July 11,

2012, GIS was issued a similar violation for servicing Category II irradiators, devices GIS was not authorized to work on at the time by its license. In response to the violation, GIS implemented comprehensive corrective actions including the development of a new procedure requiring GIS to verify, prior to performing licensed activities, that it is authorized to service the device. The violation that is the subject of this letter occurred prior to the 2012 violation and the corrective actions taken in 2012 are also applicable to that earlier violation that occurred in 2010. The NRC has decided to, after consulting with the Office of Enforcement, exercise enforcement discretion and not issue a violation in accordance with Section 3.5 of the Enforcement Policy.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be 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>.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

No further action or response is required on your part unless the description in this letter does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should clearly mark your response as a "Reply to an Exercise of Enforcement Discretion, EA-13-113" 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 and a copy to the Enforcement Officer, Region I, within 30 days of the date of this letter.

Should you have any questions regarding this letter, please contact Mr. Marc Ferdas at (610) 337-5022.

Sincerely,

/RA/

William M. Dean
Regional Administrator

2012, GIS was issued a similar violation for servicing Category II irradiators, devices GIS was not authorized to work on at the time by its license. In response to the violation, GIS implemented comprehensive corrective actions including the development of a new procedure requiring GIS to verify, prior to performing licensed activities, that it is authorized to service the device. The violation that is the subject of this letter occurred prior to the 2012 violation and the corrective actions taken in 2012 are also applicable to that earlier violation that occurred in 2010. The NRC has decided to, after consulting with the Office of Enforcement, exercise enforcement discretion and not issue a violation in accordance with Section 3.5 of the Enforcement Policy.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be 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>.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

No further action or response is required on your part unless the description in this letter does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should clearly mark your response as a "Reply to an Exercise of Enforcement Discretion, EA-13-113" 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 and a copy to the Enforcement Officer, Region I, within 30 days of the date of this letter.

Should you have any questions regarding this letter, please contact Mr. Marc Ferdas at (610) 337-5022.

Sincerely,

/RA/
William M. Dean
Regional Administrator

DOC NAME: S:\Enf-all\Enforcement\Proposed-Actions\Region1\Gamma Irradiator Service EOD EA-13-113rev2.docx
SUNSI Review Complete: _____ After declaring the document "An Official Agency Record" it **will** be released to the Public.
To receive a copy of this document, indicate in the box: "C" = Copy w/o attached/encl "E" = Copy w/attached/encl "N" = No copy
ML13233A336

X SUNSI Review/ CJC		X Non-Sensitive <input type="checkbox"/> Sensitive			X Publicly Available <input type="checkbox"/> Non-Publicly Available	
OFFICE	RI/DNMS	RI/DNMS	RI/DNMS	RI/ORR	HQ/OE	FSME
NAME	KModes/KNM*	MFerdas/MSF*	JClifford/BW for	DHolody/DJH*	NColeman via email*	MBurgess via email*
DATE	07/22/13	07/22/13	07/23/13	07/23/13	08/15/13	08/15/13
OFFICE	HQ/OGC	RI/OI	RI/RA			
NAME	MClark via email*	JTeator/JAT*	WDean			
DATE	08/14/13	08/15/13	08/20/13			

*See previous concurrence OFFICIAL USE ONLY

DISTRIBUTION

OEMail

W. Dean, RI RA

D. Lew, RI DRA

D. Holody, RI

M. McLaughlin, RI

C. Crisden, RI

J. Clifford, DNMS, RI

D. Collins, DNMS, RI

M. Ferdas, RI, DNMS

K. Modes, RI, DNMS

J. Teator, RI

D. Bearde, RI

Region I OE Files (with concurrences)

M. Burgess, FSME

R. Sun, FSME

R Zimmerman, OE

N. Hilton, OE

N. Hasan, OE

K. Beckford, OE

N. Coleman, OE

M. Clark, OGC