37-30850-01
03036438/2011001

April 21, 2012

US Nuclear Regulatory Commission Region 1

Director, Division of Materials and Safety Nuclear Regulatory Commission Region 1

Subject: Corrective actions

Attn: Kathy Modes, Mark Ferdas

Dear Sir or Madam

In regards to the audit/meeting on 2/24/2012 an observation was made that I was in violation of my license for performing preventative maintenance on J.L. Shepherd Model 81 Beam Irradiators that have dose rates greater than 500 Rem/hr at 1 meter. Attached is the letter sent to the PA DEP dated March for the same violation in addition Gamma Irradiator Service has ceased work on any beam or panoramic irradiator that meets the requirements of Part 36 (greater than 500 rem at 1 meter). On March 8 2012 a review was made on all devices serviced to determine if others were Cat 2 irradiators no others found. Training was performed on March 9 th with the named user as to the definitions of Cat 2 and Cat 1 irradiators and Gamma Irradiator Service license currently only allows Cat 1 service work. In addition new emergency procedures have been developed (attached is the GIS-EMP-001) and is incorporated into the new revised Radiation Safety Manual the GIS EMP-001 is a single sheet that will be laminated and kept in the front of the Radiation Safety Manual. Training on April 6th was performed on the initial steps to take in case of an emergency (GIS-EMP-001)*and upon acceptance of the third party review additional training will be performed on the new Radiation Safety Manual and all new procedures with lessons learned. Gamma Irradiator Service will commit to upgrade its program for the safest possible standards with training and discussions.

Sincerely,

Doyle Terry Stout
Owner Radiation Safety Officer
Gamma Irradiator Service

NRC License 37-30850-01
PA-1157

Emergency Procedures

Dislodged Source or exposed source:

1. Immediately exit the area
2. Keep others out of area post area, verify dose rates, lock doors or post barricades insure that dose to members of the public does not exceed .002 rem in 1 hour in unrestricted areas (10 CFR 20.1301).
3. Evaluate dose
4. Develop a recovery plan (evaluate the need for a Planned special exposure that may be needed in accordance with 10 CFR part 20.1206) with long reach tools, shielding and dose estimates, document actions.
5. Make notifications per Table 8 in the Radiation Safety Manual (10 CFR part 30.50).

Over Exposure Event:

1. Stop all work
2. Evaluation of dosimetery and notifications per 10 CFR Part 20.2202.
3. Notify facility RSO and regulatory authorities as required keep over exposed individuals in areas that are not greater than background.

Alarming Dosimeter or Area Monitor:

1. Anytime there is an alarm from an area monitor, electronic Dosimeter or an off scale self-reading dosimeter work will immediately be put in a safe condition work will cease and exit the area (***in the case where multiple alarms are going off immediately exit the area***) until all determinations are made as to the reason for such alarm, and corrective actions are made. If an off scale survey meter is acquired exit the area until a determination can be made if the meter is faulty or there is a real problem.

Medical Emergency:

1. Put work in safe condition if possible then stop and assist injured if needed.
2. Follow site specifics for a medical emergency.

Fire:

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

Flood

1. Exit the area per site specifics. If returning to an area that has been flooded monitor for dose rates and contamination.

Irradiator Fails to function as designed:

1. Determine if the failure could cause a substantial safety hazard per 10 CFR part 21.21
2. Repair if possible to restore to a safe operating condition if repair can not be made remove the unit from service until it can be repaired.

Leaking Source:

1. If a source is in excess of .005 μCi of removable radioactive material. Restrict access to the room, notify the customer facility's RSO and the Gamma Irradiator Service RSO, and take additional area smears document locations and contamination of each smear.
2. If a source is determined to be leaking ($\geq$ .005 μCi) immediately remove from service develop a plan for decontamination, repair or disposal with the customer. Make notifications per 10 CFR 35.3067.

ATTN: Ms. Lisa A. Forney

909 Elmerton Ave.

Harrisburg, PA 17110

In response to PA Notification letter dated March 2 2012

EFACTS Enforcement ID Number 28029

Per Definition of 10 CFR Part 36 "*Irradiator*" means: A facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources, in air or water, as applicable for the irradiator type, **but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.**

When the Beam Plug is bolted in the Beam Port this makes the unit the same as a Mark 1with the door closed. The Beam plug contains the area subject to irradiation within the device even if the source is moved into the irradiate position. To be exposed with this device, one would have to defeat all the interlocks and use tools to remove the beam plug. In both the Mark 1 and the Model 81 the door or the beam plug contains the irradiation within the device.

§ 20.1601 Control of access to high radiation areas.

(a) The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features--

(1) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

(2) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(b) In place of the controls required by paragraph (a) of this section for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(c) A licensee may apply to the Commission for approval of alternative methods for controlling access to high radiation areas.

(d) The licensee shall establish the controls required by paragraphs (a) and (c) of this section in a way that does not prevent individuals from leaving a high radiation area.

(e) Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that--

(1) The packages do not remain in the area longer than 3 days; and

(2) The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

(f) Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this part and to operate within the ALARA provisions of the licensee's radiation protection program.

§ 20.1602 Control of access to very high radiation areas.

In addition to the requirements in § 20.1601, the licensee shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in 1 hour at 1 meter from a radiation source or any surface through which the radiation penetrates.

Per Part 20.1602 the Beam Plug is bolted in and requires tools to access the irradiation area this maintains that even if the source is moved in to irradiate, the dose rates wouldn't be much different than the shield its self. Based on the definition of *"Irradiator"*, I do not believe that a violation is justified. However, my corrective action is to not service Model 81 with dose rates greater than 500 Rad/hr at 1 meter until my license is amended and a technical interpretation of the definition for *"irradiator"*, stated in 10 CFR Part 36 **(in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel),** is more clearly defined for better compliance.

Sincerely,

Doyle T. Stout

Gamma Irradiator Service.

Doyle T. Stout 3/8/2012