



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 27, 2005

Docket No. 03009176  
EA No. 04-234

License No. 37-15480-01

Peter Bergman  
Chief Executive Officer  
Good Samaritan Regional Medical Center  
700 East Norwegian Street  
Pottsville, PA 17901

SUBJECT: INSPECTION 03009176/2004001, GOOD SAMARITAN REGIONAL  
MEDICAL CENTER, POTTSVILLE, PENNSYLVANIA SITE

Dear Mr. Bergman:

On November 17 and 23, 2004, Shirley Xu and Penny Lanzisera of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in your correspondence dated November 29 and December 21, 2004, was also examined as part of the inspection. The findings of the inspection were discussed with you, Mr. William Reppy, Ms. Chris Mehlbaum and Ms. Darnell Furer of your organization at the conclusion of the inspection. The findings were also provided to your new Radiation Safety Officer, Dr. Whitmoyer on January 20, 2005. The enclosed report presents the results of this inspection.

Based on the results of this inspection, twelve apparent violations were identified and are being considered for escalated enforcement in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600 (enclosed). The apparent violations indicated an inadequate control of your brachytherapy program and include: failure to confirm that each therapy administration was in accordance with the written directive; failure to calibrate instrumentation used to measure dosages in accordance with nationally recognized standards or the manufacturer's instructions; failure to perform an assessment to determine that the total effective dose equivalent to a member of the public from exposure to a released individual was not likely to exceed 5 mSv (0.5 rem); failure to provide the released

individual, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable; failure to make surveys to locate and account for all sources that had not been implanted; failure to maintain accountability at all times for all brachytherapy sources in storage or use; failure to provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under §§ 35.75; failure to fully review the radiation protection program content and implementation; failure to make surveys to evaluate the magnitude and extent of radiation levels surrounding brachytherapy implant patients; failure to supply and require the use of individual monitoring devices by adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 10 CFR 20.1201(a); and failure to ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

A predecisional enforcement conference, open to the public, to discuss these apparent violations has been scheduled for February 16, 2005, at 1:00 p.m. The NRC announces enforcement conferences to the public by issuing a press release. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed opportunities to identify the apparent violations sooner, corrective actions, significance of the issues, and the need for lasting and effective corrective action. In addition, this is an opportunity for you to point out any errors in our inspection report and for you to provide any information concerning your perspectives on 1) the severity of the violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your action will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for

P. Bergman  
Good Samaritan Regional Medical Center

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review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or [pdr@nrc.gov](mailto:pdr@nrc.gov).

Sincerely,

***/RA by Ronald R. Bellamy Acting For/***

George Pangburn, Director  
Division of Nuclear Materials Safety

Enclosures:

1. Inspection Report No. 03009176/2004001
2. NUREG 1600 (Enforcement Policy)
3. NRC Information Notice 96-28

cc:

Stephen R. Whitmoyer, Radiation Safety Officer  
Commonwealth of Pennsylvania

P. Bergman  
Good Samaritan Regional Medical Center

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U.S. NUCLEAR REGULATORY COMMISSION  
REGION I

INSPECTION REPORT

Inspection No. 03009176/2004001  
Docket No. 03009176  
License No. 37-15480-01  
Licensee: Good Samaritan Regional Medical Center  
Location: 700 East Norwegian Street  
Pottsville, Pennsylvania 17901  
Inspection Dates: November 17 and November 23, 2004  
Date Followup  
Information Received: November 29 and December 21, 2004

	<i>/RA/</i>	1/20/05
Inspectors:	_____ Shirley Xu Health Physicist	_____ date
	<i>/RA/</i>	1/20/05
	_____ Penny Lanzisera Senior Health Physicist	_____ date
Approved By:	<i>/RA by Penny Lanzisera Acting For</i> _____ Pamela J Henderson, Branch Chief Medical Branch	_____ 1/20/05 _____ date

## **EXECUTIVE SUMMARY**

Good Samaritan Regional Medical Center  
NRC Inspection Report No. 03009176/2004001

On November 17 and 23, 2004, a routine inspection was conducted of the Good Samaritan Regional Medical Center limited scope medical license. Additional information was provided by the licensee on December 21, 2004.

The inspectors concluded that the licensee does not actively oversee their brachytherapy program. The licensee has relied on a single authorized user and their consultant physicist to ensure that the brachytherapy program is in compliance. Lack of management oversight of the program has resulted in multiple apparent violations, including 10 CFR 35.40, 35.41, 35.60, 35.75, 35.404, 35.406, 35.410, 20.1501, 20.1502, and 20.1904. These multiple apparent violations indicate a programmatic problem in the licensee's brachytherapy program. In addition, the licensee has not performed an adequate audit of their entire radiation protection program including their brachytherapy program. This is an apparent violation of 10 CFR 20.1101.

## REPORT DETAILS

### **I. Organization and Scope of the Program**

#### a. Inspection Scope

The inspector toured the licensee's facility; interviewed several clinical and administration personnel; and reviewed records in order to establish the current scope of the licensee's programs and confirm that the programs were operating safely and within the bounds of the NRC license and the regulations.

#### b. Observations and Findings

The licensee is a community hospital authorized for medical uses permitted by 10 CFR 35.100, 35.200, 35.300, and 35.400.

The Nuclear Medicine Department has a hot lab and two cameras. Full staffing is two nuclear medicine technologists, and one chief technologist. A typical daily workload includes diagnostic studies of 10 patients. The licensee primarily uses unit dosages, with bulk Technetium-99m pertechnetate available for kit preparation. Therapeutic radiopharmaceuticals are used for outpatient treatments only with primarily Phosphorous-32 (P-32), Samarium-153 (Sm-153) and Strontium-89 (Sr-89). Sm-153 and Sr-89 are unit dosages. P-32 is received as a bulk dosage and the activity is calculated and adjusted for the treatment.

Approximately 16 implants treatments have been conducted in the past 3-4 years, using Cesium-137 (Cs-137), Iridium-192 (Ir-192) and iodine-125 (I-125) for inpatient and outpatient treatment.

The RSO is a physician authorized user. He is on-site daily. The RSO relies on the consulting physics service to perform periodic audits and to oversee the brachytherapy program. The consultant is onsite monthly.

#### c. Conclusions

No safety concerns were identified.

### **II. Management Oversight of the Program**

#### a. Inspection Scope

The inspector reviewed the minutes of Radiation Safety Committee (RSC) meetings held since the last routine inspection and reviewed reports of periodic audits performed by their consultant.

#### b. Observations and Findings

RSC meetings were held quarterly. RSC membership includes representatives of senior management, the Radiation Safety Officer, and authorized users from nuclear medicine and radiation oncology areas. According to the minutes from RSC meetings conducted from February 12, 2003 to November 29, 2004, the radiation oncology member was not present at the meetings. The RSC meeting minutes frequently indicate that there were no brachytherapy procedures performed based on the Quality Management Plan quarterly audit performed by the consulting physicist. However, for several quarters, implant cases were performed and not reviewed. In addition, as of November 23, 2004, annual audits of the licensee's radiation protection program that were presented at their RSC meeting were inadequate in that they did not include a review of the brachytherapy program and did not identify personnel exceeding ALARA I radiation exposure levels (see Section VII).

The inspector observed that licensee management, the RSC, and the Radiation Safety Officer did not provide effective oversight of the licensed program in that, they did not fully review the radiation protection program content and implementation.

c. Conclusions

The failure of the licensee to periodically (at least annually) review the entire radiation protection program content and implementation, including the brachytherapy program is an apparent violation of 10 CFR 20.1101. In addition the failure to identify and resolve issues involving personnel exceeding ALARA goals implies that the program review in this area is also inadequate.

### III. Facilities and Equipment

a. Inspection Scope

The inspector toured the licensee's Nuclear Medicine facilities, the patient room area used for low dose-rate brachytherapy; and the radioactive sealed source storage room. The inspector evaluated the adequacy of the facilities and the equipment provided for each specific use to assure that radioactive materials could be used safely and that radiation exposures to workers and members of the public could be maintained ALARA.

b. Observations and Findings

The facilities and equipment were as described in the license and in general, adequate to ensure safety. However, the inspectors identified a labeling concern in the sealed source storage area. This issue is described in greater detail in section VIII. Survey instruments were calibrated as required by the regulation. The inspector noted that the licensee did not calibrate their dose calibrator for all isotopes and geometries used. Specifically, on October 8, 2004, the licensee received 50 millicuries (mCi) of liquid P-32 in three vials and used 5 mCi for the patient dose. This required them to measure the dosage in the dose calibrator. The dose calibrator was not calibrated for P-32 or the vial geometry used. Additionally, a volumetric analysis was not performed on the dosage.

c. Conclusions

The failure of the licensee to calibrate their dose calibrator for all isotopes and geometries used is an apparent violation of 10 CFR 35.60(a) and (b).

#### **IV. Material Receipt, Use, Transfer, and Control**

a. Inspection Scope

The inspector observed the receipt of radiopharmaceuticals in the Nuclear Medicine Department and the use of radioactive materials. The inspector also interviewed clinical and administration personnel; made independent measurements of areas of use and reviewed a selection of pertinent records from these areas in order to evaluate the adequacy of the licensee's program for receipt, use, transfer and control of radioactive materials.

b. Observations and Findings

Radiopharmaceutical orders are placed by the Nuclear Medicine Department staff and delivered directly to the hot lab in Nuclear Medicine. The brachytherapy sealed sources are ordered by the radiation oncologist and delivered to the Nuclear Medicine Department. The staff in the Nuclear Medicine Department conduct the package survey and place the licensed material in the locked sealed source storage room. The inspector observed that proper procedures were used for the receipt and storage of radioactive materials.

From January 2001 to October 2004, the licensee performed approximately 16 implant cases. After implanting sealed sources into patients, the licensee did not account for all sources that had been implanted. For example, on June 16, 2004, an Ir-192 implant was performed. A total of 22 seeds were received and 20 were implanted. The licensee did not record the number of seeds in storage or use, nor the location of storage or use.

From January 2001 to October 2004, there were no records made to document when and how many sealed sources were removed from the storage room and how many seeds were brought back after each use. The licensee did not maintain accountability at all times for all brachytherapy sources in storage or use and did not maintain any records of brachytherapy source accountability.

c. Conclusions

The failure of the licensee to maintain accountability at all times for all brachytherapy sources in storage or use and to maintain a record of the brachytherapy source accountability is an apparent violation of 10 CFR 35.406(a).

## V. Training of Workers

a. Inspection Scope

The inspector interviewed and observed clinical radiation workers to evaluate their ability to perform their jobs safely.

b. Observations and Findings

Training is conducted by the consulting physicist periodically. Personnel in the Nuclear Medicine Department appeared knowledgeable about safe radiation safety practices. However, the licensee did not provide radiation safety instruction, initially and at least annually, to nursing personnel caring for brachytherapy patients who cannot be released under the provisions of 10 CFR 35.75. Specifically, as of November 17, 2004, the nursing staff had not been instructed on the size and appearance of Cs-137 and Ir-192 brachytherapy sources.

c. Conclusions

The failure to provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under §§ 35.75 is an apparent violation of 10 CFR 35.410.

## VI. Radiation Surveys

a. Inspection Scope

The inspector interviewed clinical radiation workers; observed the performance of routine surveys; and reviewed a sampling of survey records.

b. Observations and Findings

The licensee conducts daily area radiation level surveys and weekly area contamination surveys in Nuclear Medicine Department. However, the licensee did not make surveys to evaluate the magnitude and extent of radiation levels surrounding brachytherapy implant patients. Specifically, from January 2000 to October 2004, following completion of temporary implants for inpatients surveys were not conducted on all cases to determine that exposure rates in unrestricted areas and to members of the public were within regulatory limits. In addition, surveys were not done on all implant cases to locate and account for all sources that had not been implanted.

c. Conclusions

The failure to survey to locate and account for all sources that have not been implanted immediately after implanting sources in a patient or a human research subject is an apparent violation of 10 CFR 35.404(a).

The failure to conduct radiation safety surveys to ensure the total effective dose equivalent to individual members of the public from the licensed operation meet the requirements of 20.1301(a) is an apparent violation of 10 CFR 20.1501(a).

The failure to conduct an assessment to determine that the total effective dose equivalent to any other individual from exposure to the released patient was not likely to exceed 5 mSv (0.5 rem) is an apparent violation of 10 CFR 35.75(a).

## **VII. Radiation Protection and Procedures Requiring a Written Directive**

a. Inspection Scope

The inspector reviewed RSC meeting minutes since the last inspection and observed the use of personnel dosimetry as required by regulation and the licensee's policies. The inspector also reviewed the licensee's written directives for their therapy treatments from January 2001 to October 2004.

b. Observations and Findings

The inspector noted that, in general, exposures of licensee personnel are low. Some personnel using non-NRC regulated devices exceeded the ALARA I radiation exposure levels and the licensee's audits did not identify this issue, as discussed in Section II. In addition, the licensee did not monitor their radiation oncologist's radiation exposure and he was likely to receive a dose in excess of 10% of the limits in 10 CFR 20.1201(a).

The written directives did not contain the information specified in 35.40(b). Specifically, from January 2000 to October 2004, either the treatment site or the total dose were often not included or not well defined on the written directives. Specifically, on October 30, 2004, a patient was implanted with 10.5 mCi of I-125 seeds and the treatment site was not specified on the written directive; on June 16, 2004, a patient was implanted with Ir-192 seeds and the treatment site was not clearly specified on the written directive; on May 8, 2003, a patient was implanted with Cs-137 sources and the total dose and treatment site were not clearly specified on the written directive; on October 17, 2002, a patient was implanted with Cs-137 sources and the total dose was not specified on the written directive; on January 30, 2001, a patient was implanted with Ir-192 seeds and the total dose was not clearly specified on the written directive; on January 15, 2001 a patient was implanted with Cs-137 sources and the treatment site was not clearly specified on the written directive.

The licensee did not implement written procedures to provide confidence that each administration is in accordance with the written directive. Specifically, the licensee's written procedures indicate that a computerized treatment post-plan may be performed to verify

the accuracy of the written directive. On October 30, 2003, 10.5 mCi of I-125 seeds were permanently implanted into a patient and an approximate dose of 5000 centiGray was noted on the written directive, with a notation that the final dose would be determined by post-implant dosimetry. As of November 23, 2004, the licensee had not received the post-implant dosimetry, and therefore, could not confirm that the administration was in accordance with the written directive. In addition, the licensee did not provide this released individual, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable. Specifically, on October 30, 2003, the licensee released this individual and did not provide written instructions to the patient.

c. Conclusions

The failure to monitor a radiation worker's exposure is an apparent violation of 10 CFR 20.1502(a)(1).

The failure to have complete written directives that contain the patient or human research subject's name and the following information; treatment site, the radionuclide, and dose, number of sources, and total source strength and exposure time (or the total dose) is an apparent violation of 10 CFR 35.40(b).

The failure to obtain post-implant dosimetry to confirm that the administration was in accordance with the written directive is an apparent violation of 10 CFR 35.41(a).

The failure to provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem) is an apparent violation of 10 CFR 35.75 (b).

## **VIII. Posting and Labeling**

a. Inspection Scope

The inspection examined the licensee's posting and labeling practices.

b. Observations and Findings

In general, areas of use and storage containers and vials in the Nuclear Medicine Department were posted and labeled, as required. However, during the tour of the facilities, the inspector noted that a container holding approximately 100 mCi of Cs-137 sealed sources did not bear a visible label indicating the presence of radioactive material.

c. Conclusions

The failure to label each container of licensed material with a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL" is an apparent violation of 10 CFR 20.1904(a).

### **IX. Exit Meeting**

On November 17 and 23, 2004, the inspectors met with the individuals noted at the end of this report. The scope of the inspection and the inspectors' observations and findings were discussed. In particular, the inspectors reviewed the apparent violations identified during the inspection and noted the particular concern with inadequate oversight of the brachytherapy program.

## **PARTIAL LIST OF PERSONS CONTACTED**

### Licensee

- \*William Reppy, Director, Radiology and Medical Diagnostic Service
- David J. Moylan, III, M.D. Radiation Oncologist (not presented at exit meetings)
- \*Darnell Furer, Vice President, Patient Care Services
- \*Peter Bergman, President and CEO
- \*Chris Mehlbaum, Chief Technologist, Nuclear Medicine
  
- \*Present at exit meeting.