March 31, 2005

EA 04-234

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

SUBJECT: NOTICE OF VIOLATION

Dear Mr. Bergman:

This letter refers to the routine unannounced NRC inspection conducted at your facility in Pottsville, Pennsylvania on November 17 and 23, 2004, as well as an in-office review of information you provided to the NRC in letters dated November 29 and December 21, 2004. Based on the inspection, twelve apparent violations of NRC requirements were identified. The results of the inspection were discussed with you and members of your staff during an exit meeting following the inspection on November 23, 2004. The findings were also provided to your new Radiation Safety Officer, Dr. Stephen Whitmoyer, on January 20, 2005.

On January 27, 2005, we sent you a letter which contained the inspection report and described the apparent violations. The violations appear to indicate a lack of appropriate oversight and control of your brachytherapy program, including a programmatic weakness in the implementation of written directives. Therefore, our letter also informed you that the NRC was considering escalated enforcement action in accordance with its enforcement policy and you were provided an opportunity to address our concerns at a predecisional enforcement conference.

In a telephone conversation on January 19, 2005, with Ms. Penny Lanzisera of my staff, your Director of Radiology, Mr. William Reppy, indicated that you would be available to attend a predecisional enforcement conference. On February 16, 2005, a predecisional enforcement conference, open for public observation, was conducted with you and your staff to discuss the apparent violations, their causes, and your corrective actions. At this conference, Mr. Walter Robinson, your consulting Physicist admitted, on your behalf, that the violations occurred, with the exception of one of the twelve apparent violations. After careful consideration of the basis for contesting the apparent violation, the NRC maintains that the violation occurred for the reasons described later in this letter.

Collectively, the twelve violations are of concern to the NRC because (1) failure to provide adequate oversight of your radiation protection program could lead to unacceptable safety consequences for patients and members of the public, and (2) inadequate control of your brachytherapy program could result in excessive radiation exposures to individuals. Given that the violations represent a programmatic weakness in the implementation of your brachytherapy program, in general, and the use of written directives, in particular, the violations are

categorized as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600. The NRC is also concerned that the violations were not identified during your audits of the facility.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $3,000 is considered for a Severity Level III violation. Because your facility has not been the subject of 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 VI.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included, but were not limited to: (1) discontinuing brachytherapy operations at the hospital effective February 16, 2005; (2) a commitment to immediately submit an amendment request to remove your brachytherapy and radiopharmaceutical therapy programs from your license; (3) implementation of a brachytherapy checklist for the two cases performed since the inspection to ensure that the nurses were trained, the written directives were complete, and surveys were conducted, and; (4) immediately labeling your cesium-137 source storage container.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation without a civil penalty for this Severity Level III problem. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The apparent violation that you contested involved the failure to adequately calibrate your dose calibrator in accordance with 10 CFR 35.60 and the manufacturer's instructions. The dose calibrator had been calibrated using technetium-99m, principally a gamma emitting isotope. Since a physician prescribed a dosage of phosphorus-32 (P-32), which is a pure beta emitting isotope, for patient treatment, a specific calibration for P-32 should also have been performed. At the enforcement conference, you contested this apparent violation, on the basis that the dose calibrator manufacturer provided an isotope correction factor of 550 (x100) to use to convert the instrument measurement to the proper P-32 activity.

After considering the information developed during the inspection, the additional information provided at the enforcement conference, information obtained from the manufacturer during a telephone call on March 25, 2005, and information provided by your staff on March 28, 2005, the NRC has concluded that the dose calibrator was not properly calibrated for P-32. Specifically, the manufacturer’s dose calibrator documentation provided by your staff indicates a calibration setting number of 750 (x100) in Table II, instead of 550 (x100). In addition, the manufacturer’s comments in Table II state that the value is for “estimation use only.” Discussions with the manufacturer confirmed that the manufacturer instructs its clients to perform a specific calibration for P-32 to determine the correction to be applied for P-32 measurements. The specific calibration for P-32 was not performed for your dose calibration, and therefore, a violation occurred.

The NRC has concluded that since you are discontinuing your brachytherapy and radiopharmaceutical therapy programs, a response to the violations associated with this

program is not required. The information regarding the reasons for the other violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter, in the inspection report issued on January 27, 2005, in the additional information you provided at the February 16, 2005, conference, and in your request to amend your license dated February 18, 2005. Therefore, you are not required to respond to these violations unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. However, as noted at the enforcement conference, if you plan in the future to reinitiate brachytherapy or radiopharmaceutical therapy licensed activities at the hospital, corrective actions for the violations associated with these programs must be addressed in detail prior to approval of the associated license amendment.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response (if you choose to provide one) will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room). To the extent possible, your response should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its web site at http://www.nrc.gov; select **What We Do, Enforcement,** then **Significant Enforcement Actions.**

Sincerely,

/RA/ JWiggins for

Samuel J. Collins
Regional Administrator

Docket No. 030-09176
License No. 37-15480-01

Enclosures: 1. Notice of Violation
2. Enforcement Conference Summary

cc w/encls:
Commonwealth of Pennsylvania
Walter Robinson

Mr. Peter Bergman

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NAME	JWray		DHolody		PHenderson PL for		GPangburn FMC for		KFarrar	
DATE	02/02/05		03/31/05		03/03/05		03/29/05		03/03/05	

OFFICE	HQ/OE		RI/ORA					
NAME	FCongel*		SCollins JTW for					
DATE			03/31/05					

Not needed based on conversation with SMerchant (OE) and GMorrell (NMSS) to JWray on 03/30/05

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ENCLOSURE 1

NOTICE OF VIOLATION

Good Samaritan Regional Medical Center
Pottsville, PA

Docket No. 030-09176
License No. 37-15480-01
EA 04-234

Based on an NRC inspection conducted at your facility in Pottsville, Pennsylvania on November 17 and 23, 2004, as well as an in-office review of information you provided to the NRC in letters dated November 29, December 21, 2004, and March 28, 2005, twelve violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violations are set forth below:

A. 10 CFR 35.40(b) requires, in part, that the written directive for brachytherapy must 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).

Contrary to the above, between January 2000 to October 2004, certain written directives did not contain the information specified in 35.40(b). Specifically, for some written directives issued on October 8, 2004, June 16, 2004, October 30, 2004, May 8, 2003, May 30, 2002, October 17, 2002, January 30, 2001, January 15, 2001, and November 1, 2000, either the treatment sites or the total doses were not included on the written directives, or the total doses were not well defined.

B. 10 CFR 35.41(a) states, in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, on October 30, 2003, the licensee did not implement written procedures to provide confidence that each administration was 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. Specifically, 10.5 millicuries of iodine-125 was permanently implanted into a patient and an approximate dose of 5000 centiGray was noted on the written directive, with the final dose to be determined in post-implant dosimetry. However, 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.

C. 10 CFR 35.75 (a) states that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Contrary to the above, on October 30, 2003, the licensee released a patient containing 10.5 millicuries of iodine-125 and did not perform an assessment to determine that the total effective dose equivalent to any other individual from exposure to the released individual was not likely to exceed 5 mSv (0.5 rem).

D. 10 CFR 35.75 (b) states that a licensee shall 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).

Contrary to the above, on October 30, 2003, the licensee released an individual from the hospital but did not provide the individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable. Specifically, the licensee released from the hospital an individual implanted with 10.5 millicuries of iodine-125, and did not provide written instructions to the released patient.

F. 10 CFR 35.404 (a) requires, in part, that a licensee, immediately after implanting sources in a patient or a human research subject, make a survey to locate and account for all sources that have not been implanted.

Contrary to the above, from January 2001 to October 2004, the licensee did not make surveys to locate and account for all sources that had not been implanted in patients.

E. 10 CFR 35.406 requires, in part, that a licensee maintain accountability at all times for all brachytherapy sources in storage or use and maintain a record of the brachytherapy source accountability.

Contrary to the above, from January 2001 to October 2004, the licensee did not maintain accountability at all times for all brachytherapy sources in storage or use and did not maintain a record of the brachytherapy source accountability. Specifically, during that period, sources were removed from storage without the knowledge of the licensee and no record of the removal was made.

F. 10 CFR 35.410 requires, in part, that a licensee 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, and include such subjects as size and appearance of the brachytherapy sources.

Contrary to the above, as of November 17, 2004, the licensee did not provide certain radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and could be released under §§ 35.75. Specifically, the nursing staff had not been instructed on the size and appearance of cesium-137 and iridium-192 brachytherapy sources.

G. 10 CFR 20.1101 requires, in part, that a licensee to periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, prior to November 23, 2004, the licensee did not adequately review the radiation protection program content and implementation. Specifically, annual audits of the licensee's radiation protection program were inadequate in that they did not include a review of the brachytherapy program.

H. 10 CFR 20.1301(a) requires, in part, that a licensee conduct operations so that the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year.

10 CFR 20.1501(a) requires, in part, that a licensee make or cause to be made, surveys that--(1) may be necessary for the licensee to comply with the regulations in this part; and (2) are reasonable under the circumstances to evaluate--(I) the magnitude and extent of radiation levels;(ii) concentrations or quantities of radioactive material; and (iii) the potential radiological hazards.

Contrary to the above, from January 2000 to October 2004, the licensee did not make surveys to evaluate the magnitude and extent of radiation levels surrounding brachytherapy implant patients. Specifically, following completion of temporary implants, surveys were not conducted to determine that the exposure rate in an unrestricted area was within regulatory limits.

I. 10 CFR 20.1502(a)(1) requires, in part, that each licensee 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).

Contrary to the above, as of November 23, 2004**,** the licensee did not supply and require the use of individual monitoring devices by all 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). Specifically, the licensee did not monitor a radiation oncologist's radiation exposure and this individual performed brachytherapy and was likely to receive a dose in excess of 10% of the limits in 10 CFR 20.1201(a).

J. 10 CFR 20.1904(a) requires, in part, that the licensee ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, etc.) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, on November 23, 2004, the licensee did not ensure that each container of licensed material bear a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." Specifically, a container holding approximately 100 millicuries of cesium-137 sealed sources did not bear a label indicating the presence of radioactive material.

K. 10 CFR 35.60(a) requires a licensee, who performs direct measurements in accordance with 10 CFR 35.63, to possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

10 CFR 35.60(b) requires the licensee to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, on October 8, 2004, the licensee had not calibrated the dose calibrator in accordance with nationally recognized standards or the manufacturer's instructions and did not properly measure the activity of P-32 before it was administered to a patient. Specifically, the licensee (1) applied an incorrect isotope correction factor; (2) failed to verify the correction factor; and (3) failed to perform a volumetric measurement of the dosage.

These violations represent a Severity Level III problem (Supplement VI).

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in the letter transmitting this Notice, in NRC Inspection Report No. 030-09176/2004-001 issued on January 27, 2005, and during a predecisional enforcement conference conducted on February 16, 2005. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA 05-005" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest the violation, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document 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.

Dated this 31st day of March 2005