

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
Genesys Regional Medical Center
Nuclear Medicine Department
One Genesys Parkway
Grand Blanc, MI 48439

2. NRC/REGIONAL OFFICE
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351

REPORT NUMBER(S) 2011-001

3. DOCKET NUMBER(S)
030-34188

4. LICENSEE NUMBER(S)
21-26740-01

5. DATE(S) OF INSPECTION
February 10-16, 2011

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied

_____ Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Deborah A. Piskura		2/16/2011
Branch Chief	Tamara E. Bloomer		2/16/2011

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Genesys Regional Medical Center Nuclear Medicine Department One Genesys Parkway Grand Blanc, MI 48439 REPORT NUMBER(S) 2011-001		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4351	
3. DOCKET NUMBER(S) 030-34188	4. LICENSE NUMBER(S) 21-26740-01	5. DATE(S) OF INSPECTION Feb. 10-16, 2011	
6. INSPECTION PROCEDURES 87130, 87131, & 87132		7. INSPECTION FOCUS AREAS 03.01-03.08	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 02120	2. PRIORITY 3	3. LICENSEE CONTACT Stephen Messana, D.O., RSO	4. TELEPHONE NUMBER 810-606-5000
---------------------	------------------	---------------------------------------------------	-------------------------------------

- Main Office Inspection Next Inspection Date: Feb. 2014
 Field Office Inspection Radiation Oncology Center, 302 Kensington Avenue, Flint, MI
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This licensee was a large medical institution (400+ bed hospital) authorized to conduct licensed activities at two locations in the Flint, Michigan area. This licensee's authorization included materials in Sections 35.100, 35.200, 35.300, 35.400, and other calibration/reference sources. The licensee retained a consulting physicist who audited the nuclear medicine radiation safety program on a quarterly basis (last 12/09/2010).

The nuclear medicine department was staffed with 9 technologists who performed approximately 350+ diagnostic nuclear medicine procedures monthly which included a full spectrum of diagnostic imaging studies. The licensee received unit doses and bulk Tc-99m for kit preparation. The licensee administered cardiac studies in a separate nuclear cardiology department within the hospital. The licensee maintained an active therapy program and administered several I-131 dosages for CA, whole body follow up studies, and hyperthyroidism (capsules only). No beta-emitting radiopharmaceuticals were administered since the previous inspection.

The radiation therapy activities were performed by contract staff. The licensee administered 1-2 I-125 permanent prostate implants each year. At the time of this inspection, the implant program was inactive with the last case performed in 2009. The inspector noted that post-treatment plans for four I-125 implants (implanted in 2009, 2008 and 2007) indicated a D90 less than 80%. Upon further review by the staff, the authorized user noted that the contouring, which was originally performed by the medical physicist, appeared to extend beyond the treatment site. This resulted in an increased the volume of prostate which would significantly affect the parameters used to calculate the D90. The staff re-generated post plans for these patient cases with the final D90 ranging between 90 and 110+%. The licensee forwarded these revised plans to the inspector for further review. The inspector expressed concern about the need to ensure that the all staff involved with prostate implants, question/investigate any post-plan which may not appear to result in an administered dose within 20% of the prescribed dose.

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the nuclear medicine and radiation oncology departments; and independent measurements. The inspector observed the administration of several diagnostic nuclear medicine procedures. The inspector reviewed the post-treatment plans for four implants with physics personnel. The inspection included observations of dose calibrator QA checks, security of byproduct material, use of personnel monitoring, package receipts, and patient surveys.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 2/16/2011

NUMBER OF PAGES: 2
(including this page)

SEND TO: Joy Finkenbinder

LOCATION: Genesys Regional Medical Ctr

FAX NUMBER: 810 - 606 - 9560 **VERIFY BY CALLING SENDER**

FROM: Debbie Piskura
(SENDER)

TELEPHONE NUMBER: 630 - 829 - 9867 FAX NUMBER: 630 - 515 - 1259

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

FAX NUMBER: 810 - 606 - 9560

VERIFY BY CALLING SENDER

FROM: (SENDER) Debbie Piskura

TELEPHONE NUMBER: 630 - 829 - 9867 FAX NUMBER: 630 - 515 - 1259

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

NRC FORM 388 (R111) (1-2004)

PRINTED ON RECYCLED PAPER

DATE, TIME
FAX NO./NAME
DURATION
PAGE(S)
RESULT
MODE

02/16 00:58
18106069560
00:00:25
02
OK
STANDARD
ECM

TIME : 02/16/2011 00:59
NAME : USNRC REGION 3 DNMS
FAX : 6305151259
TEL :
SER.# : 000A7J925770

TRANSMISSION VERIFICATION REPORT