February 22, 2002

Mark Moore
Chief Executive Officer
Community Hospitals of Indiana, Inc.
1500 North Ritter Avenue
Indianapolis, IN 46219

SUBJECT: NRC INSPECTION REPORT 03001625/2002-001(DNMS) AND
NOTICE OF VIOLATION - COMMUNITY HOSPITALS OF INDIANA, INC.

Dear Mr. Moore:

This refers to the routine inspection conducted on January 24, 2002, at Community Hospital East, Indianapolis, Indiana. This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of the selected examination of procedures and representative records, observations of activities, and interviews with personnel. At the conclusion of the inspection, the findings were discussed with your radiation safety officer and other members of your staff.

The NRC also reviewed the circumstances, root and contributing causes, and your staff's proposed corrective actions related to the loss of licensed material involving a seed that contained a nominal 0.327 microcuries of iodine-125 on August 29, 2001. In accordance with 10 CFR 20.2201(a)(1)(ii), your staff reported the loss of licensed material to the NRC on August 29, 2001.

During the inspection, your conduct of licensed activities was generally characterized by safety-conscious nuclear medicine operations. We are concerned, however, about one violation of NRC requirements identified during the inspection. The violation involved failure to secure from unauthorized removal or access licensed materials (an iodine-125 seed) that were used in an unrestricted area at Community Hospital South. Although the security violation resulted in no actual safety consequences, maintaining licensed material secure or under constant surveillance is an important deterrent in preventing theft or unauthorized removal of licensed material and unnecessary radiological hazards to members of the public. In addition to the violation, the NRC is concerned about the Community Hospital East staff's use of a dosimetry system that was not calibrated. Specifically, your medical staff used a radiation measurement system that had not been calibrated within the past two years to assay and calibrate the dose output of the iridium-192 contained in the High Dose Rate (HDR) Afterloader. This practice is contrary to good medical physics practices and accepted industry standards as described in American Association of Physics in Medicine (AAPM) publications "Code of practice for brachytherapy physics," Medical Physics, Vol. 24, No. 10, October 1997 and AAPM Therapy Committee Task Group 40.

B-19

The violation is cited in the enclosed Notice of Violation (Notice). Please note that you are required to respond to this letter, and you should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. In addition to your response to the Notice of Violation, please also describe your corrective actions to ensure that the dosimetry system is calibrated in accordance with accepted industry standards.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response 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/NRC/ADAMS/index.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.

We will gladly discuss any questions you may have regarding this inspection.

Sincerely,

/RA/

Gary L. Shear, Chief
Materials Inspection Branch

Docket No. 03001625
License No. 13-06009-01
Enclosure: Notice of Violation

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NOTICE OF VIOLATION

Community Hospitals of Indiana, Inc.
Indianapolis, Indiana

Docket No. 03001625
License No. 13-06009-01

During an NRC inspection conducted on January 24, 2002, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

1. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

   Contrary to the above, on August 29, 2001, the licensee did not secure from unauthorized removal or limit access to 0.327 microcuries of iodine-125 in a sealed source used at Community Hospital South, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, one iodine-125 seed was lost during a medical implant procedure. The source was not recovered.

   This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Community Hospitals of Indiana, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. In addition, your response should include the most recent calibration record and "as found" condition report associated with the dosimetry system identified in the cover letter. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, 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 20555-0001.

Because your response 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), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 22nd day of February 2002

APPENDIX A
BRACHYTHERAPY INSPECTION RECORD
Region **III**

Inspection Record No.: **2002-001** License No.: **13-06009-01**

Licensee (Name & Address): Docket No.: **030-01625**
Community Hospitals of Indiana, Inc.
1500 N. Ritter Avenue
Indianalpolis, IN 46219

Location (Authorized Site) Being Inspected:

1500 N. Ritter Avenue, Indianalpolis, Indiana

Licensee Contact: **Andrea Browne, Ph.D., RSO** Telephone No.: **(317)355-5413**
Priority: **G1** Program Code: **02230**

Date of Last Inspection: **March 14, 2000**
Date of This Inspection: **January 24, 2002**

Type of Inspection: ( ) Announced (**X**) Unannounced
(**X**) Routine ( ) Special
( ) Initial

Next Inspection Date: **January 2003** (**X**) Normal ( ) Reduced ( ) Extended

Justification for change in normal inspection frequency:

The inspection frequency remains normal in accordance with manual chapter 2800.

Summary of Findings and Actions:
( ) No violations cited, clear U.S. Nuclear Regulatory Commission Form 591 or regional letter issued
( ) Non-cited violations
( ) Violation(s), Form 591 issued
(**X**) Violation(s), regional letter issued
( ) Follow up on previous violations

Inspector(s) /RA/ Date 2/21/02
C.R. Martin, Health Physicist

Approved /RA/ Date 2/22/02
Gary L. Shear, Chief, M.I.B

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. **AMENDMENTS AND PROGRAM CHANGES**:
(License amendments issued since last inspection, or program changes noted in the license.)

AMENDMENT #	DATE	SUBJECT
52	**11/14/2001**	**Add Intravascular Brachytherapy (IVB) & authorized user physicians .**
51	**08/30/2001**	**Add authorized user physicians.**
50	**05/14/2001**	**Add authorized user physicians.**
49	**02/26/2001**	**Add IVB & authorized user physicians.**
48	**06/30/2000**	**Add authorized user physicians.**

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters ; and orders.)

The last inspection, conducted on March 14, 2000, resulted in no violations of NRC requirements and a clear Form-591 was issued in the field. The previous inspection, conducted on May 19, 1999, also resulted in no violations of NRC requirements and a clear Form-591 was issued in the field.

3. INCIDENT/EVENT HISTORY:
(List any incidents or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

NMED EVENT 010965
The inspector conducted a follow-up to this NMED event report. On August 29, 2001, the licensee reported the loss of a single iodine-125 source-seed with a nominal activity of 0.327 microcuries. The licensee did not recover the seed.

According to the licensee, there have been no additional events, incidents, or misadministrations since the last inspection. The inspector confirmed this through a review of the events listed in the NMED database prior to the inspection.

PART II - INSPECTION DOCUMENTATION

* References that correspond to each inspection documentation topic are in Inspection Procedure (IP) 87118, Appendix B, "Brachytherapy Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; Radiation Safety Officer (RSO) and chairman of Radiation Safety Committee (RSC); authorized locations of use; type, quantity, and frequency of byproduct material use)

Mark Moore, CEO
E. Randal Wright, Hospital Administrator - East Campus
Katherine Steffen, Director of Radiation Oncology
Andrea Browne, Ph.D., Radiation Safety Officer (RSO)
Carl Warner, Medical Physicist
Kenneth DeBowles, Technical Specialist Nuclear Medicine
Jerry Buchman, Lead Nuclear Medicine Technologist
Nuclear Medicine Technologists

This licensee, located in Indianapolis, was a large community medical center with authorization to use materials in Sections 35.100, 35.200, 35.300, 35.400, and 35.500. Licensed materials were used and stored as authorized by the NRC license at: (1) Community Hospital East, 1500 N. Ritter Avenue, Indianapolis; (2) Community Hospital South, 1402 E. County Line Road, Indianapolis; (3) Community Hospital North, 7150 Clearvista Drive, Indianapolis; and (4) Breast Diagnostic Center, 7250 Clearvista Drive, Indiapolis, Indiana.

Nuclear Medicine
The nuclear medicine department was staffed with three full-time and two part-time technologists who perform approximately 320 diagnostic nuclear medicine procedures/month. Call back and weekend work was infrequent and usually handled by the part-time technologists. The majority of these procedures were technetium-99m bone imaging and other typical diagnostic procedures.

Community Hospital East has an agreement with local Cardiologists to refer patients needing cardiac studies to their clinic. The hospital performs no cardiac studies on their premises.

The department receives daily unit doses as needed from a licensed nuclear pharmacy. All waste was either held for decay-in-storage (DIS) or returned to the radiopharmacy. Typically, in a year, the hospital treated 12 patients with a radiopharmaceutical therapy of >30 mCi iodine-131 and 60 cases of hyperthyroidism using <30 mCi of I-131. Radioiodine was obtained from the nuclear pharmacy in capsule form.

Radiation Oncology

The radiation oncology department was staffed with six physician authorized users, two medical physicists, and two dosimetrists. Iridium-192 was used in Nucletron MicroSelectron HDR remote afterloading brachytherapy for typically 240 patient treatments per year. Cesium-137 in temporary brachytherapy implants for typically two patients per year. Iridium-192 was used in intravascluar brachytherapy (IVB) for approximately four patients per week since November 2001. Iodine-125 seeds in prostate implants for approximately two patients per month.

No violations of NRC requirements were identified during this inspection.

2. MANAGEMENT OVERSIGHT:
(Management support to radiation safety; RSC; RSO; program audits or inspections; as low as reasonably achievable (ALARA) reviews; control and supervision by authorized users)

The inspector reviewed select RSC meeting minutes, 2000 to the present. The last meeting was held on December 20, 2001. Meetings were held every quarter and attendance satisfied the quorum requirements. Agenda items were pertinent and it appeared that the hospital management provided adequate support to the radiation safety program.

No violations of NRC requirements were identified.

3. FACILITIES:
(Facilities as described; uses; control of access; engineering controls; shielding; maintenance by authorized persons; remote afterloader facilities; pulsed-dose-rate afterloader facilities; low-dose-rate afterloader facilities; interlocks; patient monitoring; approved locations of use)

Nuclear Medicine

The inspector determined that the licensee's facilities observed during the inspection were the same as those described in the licensee's NRC license application and supporting material. The nuclear medicine technologist informed the inspector that the hot lab was locked during normal and off-hours to prevent unauthorized access by individuals.

Radiation Oncology

The inspector determined that the licensee's treatment and source storage rooms observed during the inspection, were the same as described in the licensee's application and supporting material. The medical physicist informed the inspector that the rooms and source safe were locked at all times to prevent unauthorized access (inspector verified that the storage room and source safe were locked).

The HDR was located in a shielded treatment room. Keys to the console and the treatment room were kept by the physicists. The treatment room and the console were locked after-hours and when unattended.

The treatment room was equipped with a PrimeAlert 10 radiation monitor. The monitor was visible upon entry and has a separate backup battery. The licensee's medical physics staff checked the monitor daily and recorded the test on the daily safety log sheet. At the time of this inspection, the inspector verified that the door interlock properly functioned and the remote radiation detectors were functional. Constant communication with the patient was achieved with the use of two CCTVs and an intercom. The licensee stated that it would halt all HDR treatments if the viewing system or the intercom was inoperable. The inspector observed that the CCTV and intercom were operable. The inspector also determined that the backup battery to the HDR unit was functional.

The door to the treatment room was equipped with an electrical interlock. The interlock was activated if the door was opened from the outside. The inspector determined that the interlock was operable. The licensee confirmed that the interlock was tested each day the HDR unit was used. The inspector reviewed the daily safety check log sheet and noted nothing unusual.

No violations of NRC requirements were identified.

4. EQUIPMENT AND INSTRUMENTATION:
(Operable and calibrated survey instruments and dosimetry; procedures; 10 CFR Part 21 procedures; calibration records; fixed radiation monitors; backup power supplies for monitors and afterloaders; equipment inspected as scheduled; emergency equipment; calibration and maintenance by authorized persons)

Nuclear Medicine

The licensee possessed a calibrated and operable dose calibrator. Constancy checks were preformed daily using a Co-57 vial source. Linearity checks were performed quarterly and accuracy checks were performed annually. The inspector reviewed a random sample of dose calibrator test records for year 2000 to present and did not identify any unusual test results or violations of NRC requirements. The department possessed survey instruments calibrated annually by the manufacturer. Instrumentation available in the department was found to be operable, calibrated, and commensurate with the types and quantities of licensed material found in the department.

Radiation Oncology

Radiation survey instruments available in department were found to be operable, calibrated, and commensurate with the types and quantities of licensed material found in the department. However, the licensee's dosimetry system was found to have exceeded the recommended two year frequency and no intercomparison was performed. The system consisted of a Standard Imaging HDR-1000 plus well chamber and a Keithly 35040 electrometer. The last calibration performed by the University of Wisconsin-Madison was on February 18, 1999.

The licensee's dosimetry system was normally calibrated by the University of Wisconsin-Madison, Department of Medical Physics, Accreditation Dosimetry Calibration Laboratory on a two year frequency. The dosimetry system had successfully passed previous calibrations without repairs or modifications. However, the licensee's medical physicist performed a quarterly test of the system using a NIST traceable cesium-137 source. The quarterly test results were consistent throughout the period in which the system was outside its calibration periodicity. Therefore, the inspector concluded that the system was apparently functioning accurately.

The licensee maintained long forceps, wire cutters, and a shielded container in the treatment room in the event of an emergency. The inspector verified that licensee staff was familiar with the HDR emergency procedures. The licensee stated that it has not experienced an emergency situation to date.

Source exchange and routine maintenance/service on the HDR unit was performed by the device manufacturer. This maintenance was performed quarterly with a full inspection performed annually. The last service was performed on November 7, 2001, and included a source exchange. Review of the vendor's service reports for 2000 and YTD 2001 found nothing unusual.

One concern was identified for failure to calibrate the dosimetry system every two years as recommended (see Report item 17).

5. MATERIAL USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; afterloader sources approved; security and control of licensed materials; and procedures for receipt and transfer of licensed material; source installation and replacement by authorized persons; patient surveys and release)

Nuclear Medicine

Packages were delivered to the hot lab. The hospital provided a key to the pharmacy so that packages can be secured within the hot lab, when delivered during off-hours. The inspector reviewed the package receipt survey log for year 2000 to present, which indicated that radiation levels and removable contamination on incoming and outgoing packages were within regulatory limits. Interviews with technologists confirmed that they were aware of package survey requirements.

The inspector reviewed select patient administration records (including written directives for iodine-131) and compared the dose administrated with the dose indicated in the patient treatment record. In all cases reviewed, the inspector did not identify any instance where the administered dose exceeded that indicated in the patient treatment chart, and when applicable, patients were released in accordance with 10 CFR 35.75.

Radiation Oncology

The inspector reviewed select radiation oncology treatment records (IVB, prostate implants, gynecological implants) and compared the dose administrated with the dose indicated in the patient treatment record. In all cases reviewed, the inspector did not identify any instance where the administered dose exceeded that indicated in the patient treatment chart, and patients were released in accordance with 10 CFR 35.75.

The inspector reviewed select HDR patient treatment records. These records indicated that the licensee delivered doses as indicated in the patient treatment plan and performed a patient survey immediately following treatment. All patient surveys indicated background readings.

The inspector determined that the HDR source was exchanged quarterly. The medical physicist determined the source output following installation, before patient treatment, and monthly thereafter. The inspector reviewed these source calibration calculations with a physicist and found all source calibrations within 1% of the expected value.

During the inspection, the inspector determined that licensee staff lost and subsequently failed to control from unauthorized access one iodine-125 source-seed (nominal activity 0.327 microcuries) following a prostate implant procedure at Community Hospital South on August 29, 2001. The licensee's medical physics staff could only account for 106 of the 107 iodine-125 source-seeds. The loss and subsequent failure to secure or maintain constant surveillance of the iodine-125 source-seed against unauthorized removal was identified as a violation of 10 CFR 20.1801 and 10 CFR 20.1802.

The licensee's physics staff believed the vendor may have shorted the order by one seed, but was unable to verify this because no receipt count was performed. The nuclear medicine technologist assayed the seeds however, she did not perform a receipt count to verify the shipment matched the order. Without a receipt count, the physics staff could not compare the initial quantity of seeds with the number of implanted and excess seeds. The licensee identified the failure to verify source-seed quantity upon receipt from the vendor as the root cause of the event.

The licensee's radiation safety and medical physics staff conducted an extensive search of Community Hospital South facilities without success; the source-seed was not recovered.

Licensee corrective actions included: (1) an extensive search of hospital facilities; (2) a procedure modification at Community Hospital South for "seed implants" to verify source-seed order quantity upon receipt.

One violation of NRC requirements was identified (see Report item 17).

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL :
(Radiological survey locations and frequencies; leak tests; inventories; handling of radioactive materials; records and reports; public doses; unrestricted area surveys; use of protective clothing; proper waste disposal; shielding)

Nuclear Medicine

Based on record reviews and discussions with licensee personnel, the inspector determined that daily exposure-rate and weekly contamination surveys, had been adequately performed by the nuclear medicine staff. The licensee stores volatile iodine in a dedicated fume hood within the hot lab with negative airflow, therefore public dose from effluents was minimal.

Based on record reviews and discussions with licensee personnel, the inspector determined that source leak test and source inventory, had been adequately performed in accordance with NRC regulatory requirements.

Radiation Oncology

The radiation oncology staff performed brachytherapy source inventory in accordance with NRC regulatory requirements. The licensee's leak test frequency and leak testing was in accordance with regulatory requirements. Leak test results were less than 0.005 μCi. The inspector performed a confirmatory physical inventory of the licensee's sources stored within the safe and in the storage room, no deficiencies were noted.

The inspector reviewed the licensee's procedures for brachytherapy source inventory and accountability systems for post implantation. Both systems were adequate to ensure that all sources were accounted for during pre/post-implantation procedures. Note: the licensee modified the "seed implants" procedure on September 11, 2001 to require a source receipt count .

The radiation oncology department performs exposure-rate surveys in all adjacent areas to the brachytherapy source storage and treatment rooms. All survey results in the adjacent areas (unrestricted) were at background levels, <0.02 mR/hr.

No violations of NRC requirements were identified.

7. TRAINING AND INSTRUCTIONS TO WORKERS:
(Training and retraining requirements for authorized users and operators; documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency response and training for operators, physicians, nurses, and medical physicists; use and supervision by authorized users)

The licensee provides annual training to the nuclear medicine staff. During the inspection, the inspector discussed with licensee representatives radiation safety training given to the staff. From those discussions, the inspector determined that technologists working in the nuclear medicine department were knowledgeable and trained prior to beginning their duties with licensed materials and annually thereafter. The radiation oncology staff received annual QMP training. The inspector determined that the licensee's training program sufficiently addressed radiation safety.

No violations of NRC requirements were identified.

8. OPERATING AND EMERGENCY PROCEDURES FOR REMOTE AFTERLOADERS:
(Operating and emergency procedures posted; procedures approved; required persons present during afterloader use; surveys in unrestricted areas; leak testing; inventories)

The licensee possessed a Nucletron MicroSelection HDR remote afterloading device which contained an iridium-192 source of 9.422 curies as of January 9, 2002. A copy of the HDR device operating and emergency procedures were posted at the console. The inspector found these procedures to be the same as those referenced in the license application and supporting documentation. The medical physicist stated that during patient treatment, the authorized user and the medical physicist were physically present at the console. At the conclusion of each patient treatment, the licensee performed a patient survey and recorded the results on the patient's treatment worksheet.

No violations of NRC requirements were identified.

9. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; access control; dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

The inspector reviewed radiation exposure dosimetry records from December 2000 to present. The inspector also observed the use of personnel dosimetry by the staff while handling licensed materials. Based on those reviews and observations, the inspector determined that licensee personnel were issued whole body and extremity dosimetry, exchanged on a monthly basis. The licensee also performs a thyroid bioassay on each person who prepared or administered therapeutic quantities of I-131 in accordance with 10 CFR 35.315(a)(8). The inspector reviewed select bioassay and patient treatment records that indicated no individual received a thyroid burden in excess of the hospital's action level.

The inspector determined that personnel radiation exposures were ALARA and that no individual exceeded NRC regulatory limits. The following table summarizes the maximum annual personnel exposures in millirem:

Year	TEDE	SDE	LDE	Extremity
2001	692	687	671	5,030

2000 472 466 455 1,749

No violations of NRC requirements were identified.

10. QUALITY MANAGEMENT (QM) PROGRAM, MISADMINISTRATIONS, AND REPORTABLE EVENTS:
(Verify QM program administration and records and reports of misadministrations and events)

The licensee was following its most recent QMP revision of August 20, 2001. The licensee's RSO reviewed the hospital's nuclear medicine QMP annually. The RSO reviewed 100% of the cases and found no misadministrations or recordable events. The radiation oncology department reviews its cases at the conclusion of each treatment (medical physics staff reviews 100% of the cases). This review included independent verification of the calculations and treatment planning for each case. No misadministrations or recordable events were identified. All findings were reported to the radiation safety committee.

No violations of NRC requirements were identified.

11. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents and compactors; license conditions for special disposal methods)

The hospital does not dispose of licensed material via the sanitary sewer system. Waste generated by the department was allowed to decay a full 10 half-lives. The waste was then surveyed in a low background area and if the radiation levels were indistinguishable from background, the waste was discarded as non-radioactive waste. Review of the licensee's DIS log found no violations of NRC requirements.

No violations of NRC requirements were identified.

12. DECOMMISSIONING:
(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted.)

This licensee maintains all records of surveys, leak tests, and disposal/transfers for future decommissioning purposes.

No violations of NRC requirements were identified.

13. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; HAZMAT communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

The inspector reviewed the last record of radioactive material shipment (source exchange) and determined that the licensee followed DOT requirements.

No violations of NRC requirements were identified.

14. NOTIFICATIONS AND REPORTS:
(Overexposure and misadministration reports; administrative changes in RSO, authorized users, and physicist; reports to individuals)

The licensee made one report concerning a lost iodine-125 source-seed with a nominal activity of 0.327 microcuries on August 29, 2001. The report was timely and contained the required information.

No violations of NRC requirements were identified.

15. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; area postings; and labeling of containers of licensed material)

During the inspection, the inspector observed that areas within the licensee's facility where radioactive materials were used and stored were adequately posted with appropriate radiation postings to warn individuals of the radiation hazards. Also, the inspector observed that sealed sources, radiopharmaceuticals, and waste containers had appropriate labels to identify the radioactive materials in them. The nuclear medicine hot lab was posted with emergency/decon procedures. The brachytherapy source storage room was posted with emergency/notification procedures, emergency call list, and a list of authorized source handlers. Also, the inspector observed that the HDR unit had appropriate labels to identify the radioactive materials contained within.

No violations of NRC requirements were identified.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas, both restricted and unrestricted, surveyed and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date.)

NRC survey instrument used:
Rotem Ind. Model - RAM GAM 1, C No. 046813
Calibration Due Date: August 21, 2002

A side-by-side comparison of the licensee's survey instruments and the inspector's instrument was made with a 1 μCi Cs-137 check source. All instruments were within 20% agreement.

The inspector performed direct radiation measurements in and around the licensee's hot lab which indicated similar results as noted in the licensee's survey records, < 2 mR/hour. Radiation levels in the unrestricted areas outside the hot lab, imaging rooms, and stress room were at background, <0.02 mR/hr.

Maximum radiation levels measured on the brachytherapy source safe was 0.37 mR/hr. Radiation levels outside the brachytherapy source storage room and adjacent areas were similar to the licensee's results, background <0.02 mR/hr. Radiation levels outside the HDR therapy room and adjacent areas during treatment were a maximum of <0.05 mR/hr.

Maximum radiation levels on the HDR unit's main source safe were <3.0 mR/hr and 3.09 mR/hr at 10 cm from the device head.

No violations of NRC requirements were identified.

17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs), AND OTHER SAFETY ISSUES:
(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

1. **Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. Title 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.**

Contrary to the above, on August 29, 2001, the licensee did not secure from unauthorized removal or limit access to 0.327 microcuries of iodine-125 in a sealed source used at Community Hospital South, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, one iodine-125 source-seed was lost during a medical implant procedure. The source was not recovered.

This is a Severity Level IV violation (Supplement IV).

2. **The licensee's dosimetry system was normally calibrated by the University of Wisconsin-Madison, Department of Medical Physics, Accreditation Dosimetry Calibration Laboratory on a two year frequency. The system consisted of a Standard Imaging HDR-1000 plus well chamber and a Keithly 35040 electrometer. The NRC is concerned that the unit was not calibrated at the recommended frequency. However, the licensee's medical physicist performed a quarterly test of the system using a NIST traceable cesium-137 source. The quarterly test results were consistent throughout the period in which the system was not within calibration. In addition, the dosimetry system had successfully passed previous calibrations without repairs. Therefore, the inspector concluded that the system was apparently functioning accurately.**

The regional letter issued to the licensee contained a request to include the most recent calibration record and "as found" condition report associated with the dosimetry system identified above.

A regional letter containing the notice of violation and NRC concern was issued to the licensee.

18. PERSONNEL CONTACTED:

[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).]

Mark Moore, CEO Community Health system

*** E. Randal Wright, Hospital Administrator - East Campus**

#* Katherine Steffen, Director of Radiation Oncology

#* Andrea Browne, Ph.D., Radiation Safety Officer (RSO)

*** Carl Warner, Medical Physicist**

Kenneth DeBowles, Technical Specialist Nuclear Medicine

 # Jerry Buchman, Lead Nuclear Medicine Technologist

Several nuclear medicine technologists were also contacted

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting

19. PERFORMANCE EVALUATION FACTORS:

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight		( ) Y (**X**) N
B.	RSO too busy with other assignments		( ) Y (**X**) N
C.	Insufficient staffing		( ) Y (**X**) N
D.	RSC fails to meet or functions inadequately	( ) N/A	( ) Y (**X**) N
E.	Inadequate consulting services or inadequate audits conducted	( ) N/A	( ) Y (**X**) N

Remarks (consider the above assessment and/or other pertinent performance evaluation factors (PEFs) with regard to the licensee's oversight of the radiation safety program):

NONE.

20. Special Conditions or Issues:
(Special license conditions; year-2000 effects of computer software)

NONE.

PART III - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOW UP ON PEFs:

There were no negative PEFs noted during this inspection.

2. DEBRIEF WITH REGIONAL STAFF:
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer)

The inspector discussed the inspection findings with the acting branch chief.

END