UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

January 6, 1999

EA 98-557

Mark Moore, COO
Community Hospitals of Indiana, Inc.
1500 N. Ritter Avenue
Indianapolis, IN 46219

13-06009-01

SUBJECT: NRC INSPECTION AND NOTICE OF VIOLATION

Dear Mr. Moore:

This refers to the inspection conducted on December 1-2, 1998, at Community Hospital East and Community Hospital North. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with members of your staff.

During the inspection period, your conduct of licensed activities was generally characterized by safety-conscious nuclear medicine operations and sound health physics practices. We are concerned, however, about three violations of NRC requirements that were identified by the NRC inspector involving your brachytherapy program. The violations involve failure to: (1) make a record of iodine-125 seed (seed) use; (2) secure eight seeds from unauthorized access while they were stored in a controlled area; and (3) properly dispose of three seeds.

The violations are cited in the enclosed Notice of Violation. The NRC has concluded that information regarding the reasons for the 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 based on what was described to the inspector during the site exit meeting on December 2, 1998. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response to this letter (if you chose to respond) will be placed in the NRC Public Document Room.

Sincerely,

/s/ J. Madera

John R. Madera, Chief
Materials Inspection Branch 1

Docket No. 030-01625
License No. 13-06009-01

Enclosure: Notice of Violation

cc w/encl: Andrea Browne, Ph.D.

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NOTICE OF VIOLATION

Community Hospitals of Indiana, Inc.
Indianapolis, Indiana

Docket No. 030-01625
License No. 13-06009-01

During an NRC inspection conducted on December 1-2, 1998, violations of NRC requirements were 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 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the names of the individuals permitted to handle the sources, (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

   Contrary to the above, as of December 1, 1998, the licensee failed to make complete records of several iodine-125 brachytherapy source usages as required. Specifically, on several occasions as of December 1, 1998, the licensee failed to make a record of iodine-125 source removals from storage and failed to include the patient's name and room number, and the time of return on records of iodine-125 source returns to storage.

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

2. 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 an unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

   Contrary to the above, on November 3, 1998, the licensee did not secure from unauthorized removal or limit access to eight iodine-125 brachytherapy sources each containing 376 microcuries (i.e., 3008 microcuries total) located in an operating room, a controlled area, nor did the licensee control and maintain constant surveillance of this licensed material.

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

3. 10 CFR 20.2003 requires, in part, that the licensee may discharge licensed material into the sanitary sewerage if, among other things, the material is readily soluble (or is readily dispersible biologically) in water.

   Contrary to the above, on November 3, 1998, three iodine-125 brachytherapy sources each containing 376 microcuries (i.e., 1128 microcuries total) were discharged into the sanitary sewerage, and the sources were not readily soluble in water or readily dispersible biological material.

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

The NRC has concluded that information described to the inspector during the site exit meeting on December 2, 1998, regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket in NRC Inspection Record 98-001 dated January 5, 1999. 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 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).

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, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

If you choose to respond your response will be placed in the NRC Public Document Room (PDR), therefore, to the extent possible, it should not include any personal, privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

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

Dated this 6th day of January 1999

## APPENDIX A

## BRACHYTHERAPY INSPECTION RECORD

Region III

Inspection Record No. 98-001 License No. 13-06009-01

Licensee (Name & Address): Docket No. 030-01625

**Community Hospitals of Indiana, Inc.**
**1500 N. Ritter Avenue**
**Indianapolis, IN**

Licensee Contact: Andrea Browne, Ph.D. Telephone No. 317-355-5865

Priority: 1 Program Code: 02230

Date of Last Inspection: 5/15/97
Date of This Inspection: 12/1-2/98

Type of Inspection: ( x ) Announced ( ) Unannounced
( ) Routine ( x ) Special
( ) Initial

Next Inspection Date 6/99 ( ) Normal ( x ) Reduced ( ) Extended

Justification for change in normal inspection frequency:

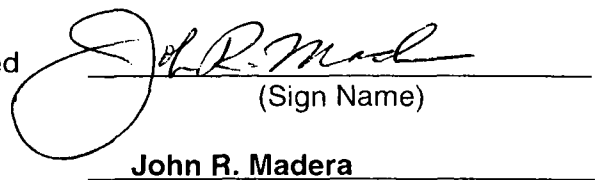
**In accordance with MC2800, an event resulted in a reactive inspection.**

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
( ) Followup on previous violations

Inspector(s) Robert G. Gattone Jr. Date 1/6/99
(Sign Name)

Robert G. Gattone, Jr.
(Print Name)

Approved  Date 1/6/99

(Sign Name)

John R. Madera

(Print Name)

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

**"NR" MEANS "NOT REVIEWED"**
**"VMS" MEANS "VIOLATION OF MINOR SAFETY SIGNIFICANCE"**

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

| AMENDMENT # | DATE | SUBJECT |
|---|---|---|
| **45** | **8/8/97** | **Added an authorized user** |
| **46** | **7/29/98** | **Added and deleted authorized users** |

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

**No violations were identified during the last two years or two inspections, whichever was longest.**

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.)

**On 11/4/98, the licensee reported to the NRC Ops Center that three I-125 seeds each containing approximately 376 microcuries were lost. The reactive inspection was in response to the reported event. However, a routine inspection was also done since the licensee was coming due for an inspection in the near future. The inspector interviewed license staff, reviewed selected records, and toured facilities to collect information about the sequence of events regarding the loss, causes of the event, and corrective actions to prevent a similar event.**

**The inspector reviewed the order sheet dated 10/15/98 requesting 64 I-125 seeds (seeds) for a prostate implant. The inspector reviewed the receipt record and confirmed that the**

licensee performed all package surveys as required. Licensee staff performed an inventory to confirm the presence of 64 seeds upon receipt on 10/30/98. Additionally, the licensee measured the activity of selected sources.

The inspector reviewed the written directive dated 11/2/98 requesting 56 seeds at 376 microcuries each for a prostate implant, and the document contained all of the required information. (Note: The licensee typically ordered extra seeds in case the authorized user decided to use more than originally intended) Based on staff interviews and reviews of selected records, the licensee implemented its QMP program to deliver the prescribed dose.

On 11/3/98, a dosimetrist removed the seeds from storage. As of 12/1/98, the licensee didn't realize that the provisions of 10 CFR 35.406(b) applied to permanent implant sources (e.g., seeds). Therefore, on several occasions as of December 1, 1998, the licensee failed to make a record of iodine-125 source removals from storage. After the dosimetrist removed the seeds from storage, he transported them in a transport pig to the OR.

The dosimetrist used remote handling tools to transfer the seeds from the transport pig to a sterilizer pig. The sterilizer pig was used, in part, to contain the seeds during sterilization inside of an autoclave. The sterilizer pig containing the seeds was placed within a sterilizer pack (or small box) prior to placement within the autoclave. During sterilization, the dosimetrist stayed at the autoclave to maintain security.

Immediately after sterilization, the dosimetrist performed an ambient exposure rate survey of the autoclave to confirm no seeds were left inside. As soon as the sterilizer pig was removed from the sterilizer pack, the dosimetrist performed an ambient exposure rate survey of the sterilizer pack to confirm that no seeds were left inside.

The licensee implanted the 56 seeds as intended. Therefore, 8 seeds remained in the sterilizer pig in the OR.

Normally, the dosimetrist would have transferred and counted the remaining seeds from the sterilizer pig to the transport pig followed by an ambient exposure rate survey of the area (including linens, floor, patient, urine, area of use, etc.). The licensee released the patient because the exposure rate was < 0.45 mR/hr at one meter.

On 11/3/98, the dosimetrist forgot to transfer (and count) the seeds from the sterilizer pig to the transport pig. The survey was conducted with the lid on the sterilizer pig. Therefore, the seeds were shielded and not detected during the survey. The inspector reviewed the record of the post implant ambient exposure rate survey (including linens, floor, patient, urine, area of use, etc.).

Normally, the dosimetrist would have brought the remaining seeds back to the storage area in the transport pig and put the seeds into Decay-In-Storage (DIS). When placing

the seeds into DIS, the dosimetrist would record the number and activity of sources returned to storage, the date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage. As of 12/1/98, the licensee didn't realize that the provisions of 10 CFR 35.406(b) applied to permanent implant sources (e.g., seeds). Therefore, on several occasions as of December 1, 1998, the licensee failed to record the patient's name and room number, and the time of return on records of iodine-125 source returns to storage (i.e., DIS).

On 11/3/98, the dosimetrist forgot to enter the seeds into DIS.

After the dosimetrist left the OR, an OR nurse took a table with equipment (including the sterilizer pig with the lid on and seeds inside) to the "Wash Room" for cleaning. The licensee did not secure from unauthorized removal or limit access to eight iodine-125 brachytherapy sources each containing approximately 376 microcuries (i.e., approximately 3008 microcuries total) located in an operating room, a controlled area, nor did the licensee control and maintain constant surveillance of this licensed material.

An Instrument Technician received the sterilizer pig in the Wash Room with other surgical instruments to clean. He couldn't remember if the sterilizer pig lid was on or off. Upon receipt, he tossed the entire sterilizer pig into a large sink that contained sudsy water. The Instrument Technician believed he wiped the sterilizer pig briefly before putting it in rinse water and then on a towel to air dry. He didn't remember seeing the I-125 seeds. The Instrument Technician believed his hands were in the sink to clean the sterilizer pig and other instruments for a total of one minute.

On the way to work early on 11/4/98, the dosimetrist remembered not transferring the seeds from the sterilizer pig to the transport pig. The dosimetrist immediately brought a survey instrument to the OR to look for the seeds, and he saw that the OR had been cleaned. Through conversations with OR staff, the dosimetrist learned that the sterilizer pig went to the Wash Room. The dosimetrist performed an ambient exposure rate survey of the sinks of the Wash Room, and found three seeds on the bottom of a sink. Two additional seeds were found in the trap just below the drain strainer. In an attempt to find the three remaining seeds, the trap was disassembled and a survey meter was used to extend the ambient exposure rate survey into accessible pipe, but no additional sources were found. The licensee's plumber indicated that the seeds were probably forced down the drain with the running water. The inspector performed an ambient exposure rate survey of accessible areas of the sink drain hardware, and the results were indistinguishable from background.

The license surmised that the remaining three seeds went to the sanitary sewer system, and resulted in the Instrument Technician's hands receiving 33 mrem. Three iodine-125 brachytherapy sources each containing approximately 376 microcuries (i.e., approximately 1128 microcuries total) were discharged into the sanitary sewerage, and the sources were not readily soluble in water or readily dispersible biological material.

**The licensee's corrective actions to prevent recurrence of a similar event included: (1) documentation of the removal of permanent implant sources from storage using the same procedure that had been used for temporary implant sources; (2) revision of its record of seeds into DIS to include all of the information required to record the return of sources to storage; (3) adding a line on the post implant survey record to remind the staff to transfer remaining seeds to the transport container; and (4) requiring that post implant surveys include the sterilizer pig contents (i.e., survey with the lid off of the container).**

**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.*

1. 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, COO of Hospitals**
**Bill Corley, President**
**Randy Wright, COO**
**Joe Heckman, Director of Outpatient Services**
**Debbie Dirr, Team Leader for Radiation Oncology**
**Andrea Browne, Ph.D., RSO**

**Brachytherapy was performed at the East facility exclusively. One full time dosimetrist**

**and one half time dosimetrist were involved with treatment planning and handling of 35.400 sources. Gynecological applications with Cs-137 were conducted about once per year. Permanent prostate implants were performed about weekly with I-125 seeds. Four R.T.s were also involved with the brachytherapy program.**

**About two HDR treatments were conducted weekly with the authorized Nucletron HDR unit. Gynecological treatments were most common, and bronchial treatments were less common. The HDR unit was serviced by Nucletron exclusively.**

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 RSO was responsible for day-to-day oversight of the radiation safety program at all three locations.**

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 )

**The inspector toured the brachytherapy storage room, and it was as authorized. Brachytherapy sources were locked in a shielded safe.**

**The licensee experienced no HDR device malfunctions.**

**The HDR facility had a door at each entrance and it was properly posted.**

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)

**The licensee used a Victoreen MN 450P, SN 793 that was last calibrated on 11/10/98 by Syncor.**

**Based on staff interviews, personnel were aware of proper HDR emergency response. The inspector observed that a pig, wire cutters and remote handling tools were kept near the HDR unit.**

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)

**HDR console keys were removed and secured when the unit was not used.**

**The last HDR source was installed on 10/8/98 by Nucletron. The source was not used until after it was calibrated on 10/12/98.**

**The inspector observed licensee staff perform HDR treatment planning and QMP implementation during a treatment. Required staff were available during the treatment. The staff performed a radiation survey of the patient prior to patient release.**

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)

**The inspector observed licensee staff perform a physical inventory of the Cs-137 and Sr-90 sources. No discrepancies were identified. The Sr-90 source was in a locked container that was properly labeled.**

**The licensee possessed a Nuclear Associates MN 67-850, SN B450-12 Sr-90 eye applicator that contained 150 mCi in 8/76 (see Attachment A).**

**The inspector reviewed the licensee's records of I-125 seed inventory to evaluate I-125 source control during implants conducted on 5/1/98, 10/9/98, and 10/30/98. The records showed no discrepancy in source inventory.**

**The inspector reviewed the Cs-137 source inventory records dated 9/23/98 and 6/25/98.**

**Based on record review and staff interviews, the licensee generated source use logs for a Cs-137 implant done on 4/20/98.**

**The licensee had not used its Cs-137 needles since the last leak test on 7/11/94.**

**The inspector reviewed the Cs-137 tube source leak test record dated 7/23/97.**

**The inspector reviewed the Sr-90 eye applicator leak test records dated 6/25/98, 11/20/97, and 5/22/97.**

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 following was noted by the inspector while watching licensee staff perform checks on the HDR unit:**

- **A key interlock switch was used to prevent dual operation of the HDR unit and an X-ray device in the same room.**
- **Daily checks included source position accuracy within one millimeter.**
- **A Primealert MN 35 was operational and visible at the entrance.**
- **The intercom was checked daily.**
- **The Primealert's battery backup was checked.**
- **The HDR emergency procedures were posted near the console.**
- **Video monitors were operational.**
- **Treatment interrupt and emergency stop hardware was checked and operational (a reset was required).**
- **The door interlock was checked and operational (a reset was required).**
- **The staff was trained to use a survey instrument if the Primealert malfunctioned.**
- **The staff was trained not to use the HDR unit if the interlock malfunctioned.**
- **Applicators were checked before use.**

**No HDR malfunctions had occurred.**

**The facilities were as authorized.**

**Based on an interview, the HDR nurse received adequate annual training from Nucletron.**

**The inspector reviewed selected HDR training records.**

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 inspector observed that the emergency procedures were posted at the HDR console.**

**Licensee staff stated that a survey instrument would be used if the HDR room monitor malfunctioned.**

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 observed that an HDR nurse wore her film badge during the process of caring for an HDR patient.**

| | 1998 | 1997 | 1996 | 1995 | 1994 |
|---|---|---|---|---|---|
| **WB max (mrem)** | **140** | **300** | **220** | **620** | **340** |
| **Extremity max (mrem)** | **980** | **1400** | **1220** | **1990** | **1670** |
| **DPW max (mrem)** | **m** | **20** | **60** | **N/A** | **N/A** |

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

**The RSO stated that the license had not identified any misadministrations or recordable events.**

**Per TI-2000/028 (Expires 9/1/2000):**

1. **The inspector verified that the licensee had in their possession and utilized, a certificate of calibration for its one and only Sr-90 ophthalmic applicator in their possession (see Attachment).**

2. **The inspector confirmed by independent calculation, the adequacy of the licensee's corrections for radioactive decay of the Sr-90 source.**

3. **The licensee possessed a Nuclear Associates MN 67-850, SN B450-12 Sr-90 eye applicator.**

**The inspector reviewed Sr-90 eye applicator written directives dated 3/14/96 and 9/10/97**

**in addition to associated records to evaluate implementation of the QMP. Written directives contained all required information. The authorized user held the applicator during treatments. Dual patient ID was performed. Treatment times were checked by the physicist. A stopwatch was used to time the treatments. The licensee properly implemented its QMP.**

**The inspector observed that licensee staff generated a proper written directive prior to an HDR treatment that was observed on 12/1/98.**

**Based on staff interviews and reviews of selected records, the licensee's HDR QMP involved proper dual patient ID, Ir-192 decay correction, and authorized user review and approval of treatment plans prior to treatment. The licensee audited about 80% of its HDR cases. The inspector reviewed HDR written directives dated 10/19/98 and 10/22/98, and 3/9/98. Additionally, the inspector reviewed selected records and interviewed licensee staff to evaluate the licensee's implementation of actions taken to prevent a misadministration similar to that which occurred during the last inspection period. The inspector confirmed that: (1) the licensee revised its written directive form for HDR tandem/ovoid applications to remind the staff to add the ovoid radius to the prescribed distance from the ovoid surface when calculating the source to point distance; and (2) the backup physics team was rotated through HDR about monthly to stay familiar with HDR treatment planning protocols. The QMP was implemented as required.**

**Based on staff interviews and reviews of selected records, the licensee's 35.400 QMP was implemented for the implant conducted on 4/20/98. The licensee recorded the result of the patient survey post explant and prior to release.**

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)

**I-125 sources were disposed via DIS.**

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.)

**Based on staff interviews, the licensee was knowledgeable regarding 10 CFR 30.35(g) and 30.36.**

13. TRANSPORTATION: NR
(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)

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

**Per 10 CFR 20.2201, the licensee provided its written report of the aforementioned loss via letter dated 11/19/98.**

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

**The inspector observed that the brachytherapy storage area was properly posted.**

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.)

**The inspector used a RAM GAM MN 4-0030, SN 1893-072 that was last calibrated on 2/24/98.**

**The inspector measured a maximum of 1.4 mR/hr at 10 cm from the surface of the HDR safe on 12/1/98, and the source was installed on 10/8/98. LC19 limited the exposure rate to 1 mR/hr at 10 cm. The discrepancy had no safety significance.**

**Subsequent to the site inspection, Sandy Frazier informed the inspector that LC19 had an error. LC19 will be corrected to limit the exposure rate to < 0.25 mR/hr at 100 cm.**

**The inspector measured a maximum of 50 mR/hr at the surface of the Sr-90 applicator storage box which was stored inside of a shielded, locked, labeled cabinet inside of the locked source storage room.**

**The inspector measured a maximum of 0.8 mR/hr at the surface of the brachytherapy source storage safe.**

**The inspector surveyed the surface of the wall adjacent to the HDR console during a patient treatment, and the result was indistinguishable from background (i.e., < 0.05 mR/hr).**

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. **VIO/10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) The names of the individuals permitted to handle the sources, (2) The number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; (3) The number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.**

   **Contrary to the above, as of December 1, 1998, the licensee failed to make complete records of several iodine-125 brachytherapy source usages as required. Specifically, on several occasions as of December 1, 1998, the licensee failed to make a record of iodine-125 source removals from storage and failed to include the patient's name and room number, and the time of return on records of iodine-125 source returns to storage.**

2. **VIO/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 an unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.**

   **Contrary to the above, on November 3, 1998, the licensee did not secure from unauthorized removal or limit access to eight iodine-125 brachytherapy sources each containing 376 microcuries (i.e., 3008 microcuries total) located in an operating room, a controlled area, nor did the licensee control and maintain constant surveillance of this licensed material.**

3. **VIO/10 CFR 20.2003 requires, in part, that the licensee may discharge licensed material into the sanitary sewerage if, among other things, the material is readily soluble (or is readily dispersible biological) in water.**

   **Contrary to the above, on November 3, 1998, three iodine-125 brachytherapy sources each containing 376 microcuries (i.e., 1128 microcuries total) were discharged into the sanitary sewerage, and the sources were not readily soluble in water or readily dispersible biological material.**

**An enforcement panel was held to determine the proper enforcement action in this case (see Attachment B).**

18. PERSONNEL CONTACTED:
    [Identify licensee personnel contacted during the inspection (including those individuals

contacted by telephone).]

**Debbie Dirr, Team Leader for Radiation Oncology**
***Barb Summers, Team Leader**
***#Andrea Browne, Ph.D., RSO**
**Morgan Tharp, M.D., Authorized User**
***Michael Mullinix, M.D., Authorized User**
**Carl Warner, Clinical Physicist**
**Darryl Bolin, Dosimetrist**
**Theresa Dallas, HDR R.N.**
**Louann Graham, OR R.N.**

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):

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

**See Part III, Item 3.**

**PART III - POST- INSPECTION ACTIVITIES**

1. REGIONAL FOLLOWUP ON PEFs:

**None**

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

**See Part II, Item 16.**

3. YEAR-2000 ISSUES:
(Convey, to the NMSS Year-2000 Coordinator, all year-2000 licensee-identified problems and corrective actions taken.)

**The RSO stated that the licensee evaluated its computers, and the licensee verified that the computers were Y2K compliant.**

ATTACHMENT A

ISOTOPE PRODUCTS LABORATORIES 1800 NO. KEYSTONE ST., BURBANK, CALIFORNIA 91504
(213) 843-7000

12

# DATA SHEET

CUSTOMER: Nuclear Associates P.O.# 8590 DATE: 9/6/76

CATALOG # 67-850 QUANTITY: 1

CAPSULE TYPE: BF90Ti-150

NATURE OF ACTIVE DEPOSIT: Strontium Titanate in Silver Matrix

ACTIVE DIAMETER: 8.7 mm

BACKING: Aluminum

COVER: 0.127 mm Titanium

| ISOTOPE | SOURCE # | ACTIVITY | CALIB. DATE | UNCERTAINTY |
|---|---|---|---|---|
| Sr-90 | B-450-11 | 150 mCi | 8-20-76 | * |

REMARKS: * Output measurement:

Rads/Sec ±5%: 133

Activity Distribution: ±2%

(Radiochromic Film Attached)

ATTACHMENT B

GATTONE

FAX TRANSMITTAL - ONE PAGE ONLY

TO: Tripp Jamerson

FROM: [illegible]

EA REQUEST & ENFORCEMENT STRATEGY FORM

Del.Case: ____ 1st Panel: ✓ Post Panel: ____ Re-Panel: ____ Post Caucus: ____ Re-Caucus: ____ Other: ____

EA 98-557

**EATS Data Entry Information**

Date of Request: 12/17/98 Region: III Case Type: H Small Entity ☐ No ☐ Yes

Licensee: Community Hospitals Facility (Unit)/Location: Indianapolis IN

Doc. No.: 030-01625 Last Day of Insp.: 12/2/98 ID Date: 11/4/98

Date OI Ref.: ____ OI Rpt No.: ____ OI Rpt Date: ____ Conf. Closed ?: ____

Referral to DOJ: ____ Action Date DOJ: ____ Recommended Action: D (Decline) or P (Prosecute)

Summary of Facts: Failure to secure control licensed material. Improper disposal

Inspection Rpt No. 98-09 Keywords for SLIVs and NCVs: ____

*REMARKS FOR EATS ON BACK* ES: JD

Significance: Actual ____ Potential ✓ Regulatory ____; SALP Area(s) ____

1. SL IV Supp IV.D.9
Details: Failure to secure control licensed material

SL III Supp IV.D.9
Details: Failure to make a record of brachytherapy source use

SL IV Supp IV.D.9
Details: Improper disposal of licensed material

2. A. *Risk Significant Case?* ✓ Yes ☐ No; 2. B. *Regulatory Significance?* ☐ Yes ☐ No: ____

3. *Prior Escalated Action?* ☐ No ☐ Yes EA: ____ Date: ____

4. Lic.ID? ☐ No ☐ Yes / ☐ Lic. Credit ☐ No Credit ☐ Inad. Info ☐ NA Explain: ____

5. *Corrective Action?* ☐ Lic. Credit ☐ No Credit ☐ Inad. Info Explain: ____

6. *Conference Needed?* ☐ No ☐ Yes Explain: ____

7. CP? ☐ No CP ☐ Base CP ☐ Double Base CP ☐ Other: ____

8. *Discretion or Order Needed?* ☐ No ☐ Yes Explain: ____

9. Willfulness Involved? ✓ No ☐ Yes: ☐ OI investigating ☐ OI needs to be notified ☐ OVOE dispute memo needed ☐ Additional OI coordination needed ☐ Awaiting DOJ ☐ Needs coordination with DOJ

10. Program Office Represented? ☐ No ✓ Yes: C Jones 11. OGC Represented? ✓ No ☐ Yes: ____

12. *Action?* ☐ No violation ☐ Re-panel ☐ Conference Letter ☐ Choice Letter ✓ SL IV NOV ☐ Re-Caucus ☐ Region Issues Esc. Action ☐ Submit to OE for Quick Review ☐ Submit to OE for Full Package Review ☐ DEDE Review ☐ Commission ☐ Disagreement ☐ Other: ____

13. Comments: ____

14. Approved: B
Date: 12-18-98
Faxed: ____

TOTAL P.01