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

April 6, 2005

Docket No. 03008702 License No. 37-00993-05

Marsha Rowe
Chief Operating Officer
Mercy Fitzgerald Hospital
1500 Lansdowne Avenue
Darby, PA 19023

SUBJECT: INSPECTION 03008702/2004001, MERCY FITZGERALD HOSPITAL, DARBY, PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Ms. Rowe:

On February 2 and 5, 2004, Penny Lanzisera of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of two incidents involving possibly leaking or contaminated sources implanted into two patients. Additional information provided in your correspondence dated February 12, 19, and 24, April 27, May 5, May 11, May 21, and July 13, 2004, was also examined as part of the inspection. The findings of the inspection were discussed with you and other members of your organization at the conclusion of the inspection on February 5, 2004. In addition, the final conclusions were discussed with Mr. John Babu, your Radiation Safety Officer, on April 1, 2005, and with you on April 5, 2005. The enclosed report presents the results of this inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations and guidance are available at the NRC Web sites listed below or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03008702/2004001

NRC Web site addresses
NRC regulations
http://www.nrc.gov/reading-rm/doc-collections/cfr/
Licensing guidance
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/
General Policy and Procedure for NRC Enforcement Actions
http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf
206 of the Energy Reorganization Act of 1974
http://www.nrc.gov/who-we-are/governing-laws.html

cc:
John C. Babu, Radiation Safety Officer
Commonwealth of Pennsylvania

Distribution:
D. J. Holody, RI

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NOTICE OF VIOLATION

Mercy Fitzgerald Hospital
Darby, PA

Docket No. 03008702
License No. 37-00993-05

During an NRC inspection conducted on February 2 and 5, 2004, three 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 listed below:

A. 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, on January 23 and 26, 2004, the licensee did not make surveys 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. Specifically, after the completion of a brachytherapy implant conducted on January 23, 2004, surveys conducted of equipment, facilities, and patients were inadequate in that the licensee failed to adequately assess the extent of the contamination, including possible public exposure and patient thyroid and whole body dose from suspected contaminated or leaking seeds.

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

B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.475 requires, in part, that before each shipment of any Class 7 (radioactive) materials package, the offeror must insure by examination or appropriate tests, that the external radiation and contamination levels are within the allowable limits in 49 CFR Parts 171-178. 49 CFR 173.443(a) requires, in part, with exceptions not applicable here, that for beta and gamma emitting contaminants, the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for transport, at the beginning of transport, not exceed 4 Becquerel per square centimeter on any single wiping material, divided by the surface area wiped and divided by the efficiency of the wipe procedure. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the non-fixed contamination levels.

Contrary to the above, on January 27, 2004, the licensee delivered to a carrier for transport a package which contained iodine-125 brachytherapy sources suspected to be leaking and/or contaminated, and the licensee did not determine the non-fixed contamination level prior to offering the package for transport.

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

C. 10 CFR 35.40(a) requires, in part, that each written directive for brachytherapy must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material.

Contrary to the above, on February 5, 2004, the brachytherapy written directive was not signed by the authorized user before the administration of the therapeutic dose. Specifically, the written directive was not signed by the authorized user prior to completion of the brachytherapy procedure and release of the patient from the operating room.

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

Pursuant to the provisions of 10 CFR 2.201, Mercy Fitzgerald Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 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). 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, (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. 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 to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site at http://www.nrc.gov/reading-rm.html. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This _6th_ day of _April_ 2005

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03008702/2004001
Docket No.	03008702
License No.	37-00993-05
Licensee:	Mercy Fitzgerald Hospital
Location:	1500 Lansdowne Avenue Darby, Pennsylvania 19023
Inspection Dates:	February 2 and 5, 2004
Date Followup Information Received:	February 12, 19, and 24, April 27, May 5, May 11, May 21, and July 13, 2004

Inspector: ***/RA/*** 4/5/05

Penny Lanzisera
Senior Health Physicist

Approved By: ***Original signed by Pamela J. Henderson*** ***April 5, 2005***

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Document Name: E:\Filenet\ML050960180.wpd

EXECUTIVE SUMMARY

Mercy Fitzgerald Hospital
NRC Inspection Report No. 03008702/2004001

An announced special inspection was performed on February 2 and 5, 2004, to review the circumstances surrounding a possible medical event that was reported to NRC Region I by NRC Region III and confirmed with the licensee on January 28, 2004. NRC Region III had been notified of the event by the manufacturer. The licensee reported the event as a possible medical event on February 2, 2004. The possible medical event involved suspected contaminated or damaged iodine-125 (I-125) seeds that were implanted in the prostate of a patient on January 23, 2004. The results of thyroid and urine bioassay measurements indicated a single contamination event and ruled out the possibility of an implanted leaking source. Additionally, following an implant for a second patient on January 30, 2004, with 99 I-125 seeds of approximately 0.336 millicuries from the same seed manufacturer, the licensee noted positive patient thyroid measurements. Subsequent thyroid and urine bioassay measurements of this patient also ruled out a leaking source and confirmed a single contamination event.

The State of Illinois inspected the seed manufacturer and concluded that the seed manufacturer's procedures and testing for all shipped seeds were adequate to have identified contaminated seeds. Additionally, the State of Florida inspected the company used by the licensee to pre-load Mick applicator cartridges with seeds. The State of Florida noted that no leak testing was performed on the seeds or cartridges by this company, however surveys were conducted at the completion of each order and the daily surveys and package surveys conducted on the days of loading the seeds in question, did not demonstrate any indication of contamination from leaking seeds.

Based on the bioassay data collected, interviews conducted of licensee staff, the results of the manufacturer's investigation, and the results of the inspections conducted by the States of Illinois and Florida, the NRC concluded that in both cases a single contamination event occurred and that neither patient was likely to have accumulated 50 rads to the thyroid from the events.

Within the scope of this inspection, the following safety concerns and violations were identified: failure to perform adequate surveys to assess the extent of contamination of equipment and patients following positive equipment and patient bioassay measurements on January 23 and 26, 2004 (Section IV); failure to survey for contamination a return package containing potentially leaking or contaminated seed(s)[Section IV]; and failure of the authorized user to sign the written directive prior to completion of the procedure for the implant observed on February 5, 2004 (Section II).

REPORT DETAILS

I. Event Descriptions

a. Inspection Scope

The inspection focused on a review of the prostate implant program and the circumstances surrounding the reported events of leaking or contaminated seeds. The inspection of the events consisted of observations by the inspector, interviews with involved personnel, and a selected examination of records describing the event and followup actions. A chronology of the event is described below.

b. Observations and Findings

Prostate Implant Program

The licensee performs approximately 35 permanent implants for prostate cancer annually. Since 1992, the licensee has conducted approximately 350 cases. The licensee started purchasing iodine-125 seeds from Bard Brachytherapy approximately 4 years ago.

Incident Chronology

January 14 Licensee ordered 100 I-125 seeds of 0.336 millicurie/seed from Bard Brachytherapy Inc. for case to be conducted 1-23-04 and 115 seeds of 0.336 millicurie/seed for case to be conducted 1-30-04.

January 16 Bard Brachytherapy, Inc. shipped 100 SourceTech Model STM 1251 (Lot I40002844) seeds of 0.336 millicurie/seed to Custom Care Pharmacy for inclusion into Mick applicator cartridges for first case. The contained activity of seeds are 1.7 times the apparent activity (which corrects for the shielding of the titanium capsule). The seeds were leak tested prior to shipment and showed less than 0.005 microcuries of removable iodine-125 activity. The manufacturer's representative indicated that seeds are not released unless there is less than 3 nanocuries of contamination present on seeds.

January 19 Custom Care Pharmacy confirmed the assay of 10 of the seeds and found all within +/- 5 % of the manufacturer's midpoint apparent activity measurements. 10 seeds each were loaded into 10 cartridges and shipped to the licensee for the first case.

January 21 AMP received 1st shipment of seeds and measured dose rates at package surface and at 3 feet. Measurements are 0.1 milliRoentgen (mR)/hour. No swipe of package or package contents is performed.

January 23 Written directive prepared by authorized user (AU) for the first patient which indicated that 84 seeds of 0.336 millicurie/seed were to be

implanted into 28 cubic centimeter (cc) volume of the prostate. Patient verified by photo and name. 84 seeds implanted at 10:30 am. The AU indicated that he had trouble discharging the seeds from 2 cartridges of the Mick applicator (Model 200TP) during the treatment, initially removed these cartridges and continued implant, and ultimately re-used one of the problem cartridges to complete the implant. Post implant surveys of the operating room suite after the implant by the AMP indicated readings of greater than 5000 cpm above background of the sterilizer water used during the implant. Measurements of the needles used during the implant were background. After further measurements of the operating room, the seed loading device, and the implant needles, the AMP concluded that external contamination was on the seeds supplied by the manufacturer and notified the seed manufacturer. The patient was removed from the operating room and placed in Room SPU241 at noon and nursing instructed to save linen, trash, and patient urine for monitoring prior to release. Surveys conducted of patient at noon with a Keithley Model 36150 indicated 1.1 mR/hour at the surface and 0.3 mR/hour at 3 feet. 0.5 mR/hour was measured at the bedside.

January 23 Bard Brachytherapy, Inc. shipped 115 SourceTech Model STM 1251 (Lot I40005B27) seeds of 0.336 millicurie/seed to Custom Care Pharmacy for inclusion into Mick applicator cartridges for second case. The seeds were leak tested prior to shipment and showed less than 0.005 microcuries of removable iodine-125 activity.

January 26 Custom Care Pharmacy confirmed the assay of 12 of the seeds and found all within +/- 5 % of the manufacturer's midpoint apparent activity measurements. 10 seeds each were loaded into 7 cartridges and 15 seeds each were loaded into 3 cartridges and shipped to the licensee.

January 26 Post patient discharge survey conducted of 1st patient's room with all measurements at background (200 cpm), except for collected urine, which measures 600 cpm. Patient discharged at 8:30 am and instructions provided to patient to minimize exposure of others.

January 27 16 remaining seeds from 1st case returned to the manufacturer for analysis. AMP surveyed package and found readings of 0.1 mR/hour on contact and at 3 feet from package. No swipe of return package performed.

January 28 RI contacted by RIII about a contact from the seed manufacturer in Illinois indicating that the licensee may have implanted a leaking seed. RI contacted licensee's RSO and was informed that he had just been notified of the incident and had left a message on a Region I inspector's voicemail that morning to report. The RSO had collected the data provided below for the AU and AMP. No bioassays on patient had been performed and the RSO indicated that they would wait until they received the results from the seed manufacturer later this week or next week

before contacting the patient. RI suggested that licensee bring patient in for thyroid bioassay, at a minimum.

AMP received 2nd shipment of seeds and measured dose rates at package surface and at 3 feet. Measurements are 0.1 mR/hour. No swipe of package or package contents is performed.

January 30 Written directive prepared by AU for the 2nd patient which indicated that 100 seeds of 0.336 millicuries/seed were to be implanted into 36 cc volume of the prostate. Patient verified by photo and name. 99 seeds implanted with the same Mick Applicator and 1 seed recovered from the patient's bladder. Recovered seed was not re-implanted. Patient placed in Room SPU241 at noon and nursing instructed to save linen, trash, and patient urine for monitoring prior to release. Surveys conducted of patient at noon indicated 1.0 mR/hour at the surface and 0.3 mR/hour at 3 feet. 0.5 mR/hour was measured at the bedside.

January 30 1st patient returned for scan to view placement of the seeds and the licensee performed a thyroid bioassay and a urine bioassay. Based on the results indicated below, the AU immediately started the patient on a thyroid blocking agent. 2nd patient's thyroid bioassayed with the results indicated below. Based on the results, the AU immediately started the 2nd patient on a thyroid blocking agent. Both patients were informed by the AU of the events and placed on the thyroid blocking agent for one month.

February 2 2nd patient discharged at 8:45 am and instructions provided to patient to minimize exposure of others. Post patient discharge survey conducted of patient room with all measurements at background (200 cpm), including collected urine. Region contacted at 9:30 am to report 1st patient's thyroid bioassay measurements. Onsite inspection conducted and inspectors informed of 2nd patient. Inspectors performed surveys of all equipment involved in the implant, including the Mick Applicator, ultrasound machine, packaging, operating room table, and seed storage room. Surveys were conducted with a Ludlum Model 44-3 low energy NaI probe connected to a Ludlum Model 16 analyzer. All results were background.

February 3 Discussions with the seed manufacturer indicated that 2 of the 16 seeds returned appeared to be leaking and 14 of the seeds appeared to be damaged. The 14 seeds were found to be free of contamination. The manufacturer was continuing their investigation of the seeds.

February 4 AMP conducted test where decayed iodine-125 seeds were placed in Mick applicator and ejected. The seeds were then swiped and indicated background levels. The physicist concluded that the applicator was now free of contamination.

February 5 On-site inspection conducted to review procedures used during iodine-125 prostate implants. The inspectors observed an implant for a 3rd patient, including the unpacking of the seeds, the preparation of the seeds for implant, the implant of the seeds, and the surveys conducted of the area of use post implant. Since the licensee's RSO initially incorrectly concluded that the thyroid measurements for the first 2 patients could be explained by scatter radiation from the implant area, the licensee carefully surveyed all areas and equipment used, as well as the 3rd patient's thyroid with the implant area shielded. The licensee's surveys of the operating room and equipment post implant for the 3rd patient indicated background readings. In addition, bioassay results for this patient were background. Therefore, the licensee concluded that the positive thyroid uptakes measured for the 1st and 2nd patients were real and not a result of scatter radiation.

Date and Time	**Type of Measurement**	**Instrument Used and Efficiency for I-125**	**Gross Counts Per Minute**	**Back-ground**	**Nano-curies**
Jan. 23 11:00 am	Measurement of Sterilizer Water	Biodex Model 3 with 44-3 NaI probe Efficiency: 100	5000+ (offscale)	200	unknown
Jan. 23 3:30 pm	Measurement of 1st Patient Urine	Biodex Model 3 with 44-3 NaI probe	600 (offscale)	200	unknown
Jan. 28	Thyroid Bioassay of Medical Physicist	Biodex Atomlab 930 Thyroid Uptake System; Efficiency: 0.0027	92	40	8.7
Jan. 28 9:54 am	Thyroid Bioassay of Resident	Biodex Atomlab 930 Thyroid Uptake System	57	42	2.5
Jan. 28 10:42 am	Thyroid Bioassay of Authorized User	Biodex Atomlab 930 Thyroid Uptake System	16	17	0
Jan. 30 11:27 am	Thyroid Bioassay of 1st Patient*	Biodex Atomlab 930 Thyroid Uptake System	9364	23	1540
Jan. 30 2:34 pm	Thyroid Bioassay of 2nd Patient*	Biodex Atomlab 930 Thyroid Uptake System	3035	20	496

Feb. 2 9:09 am	5 cc urine sample from 1st patient (collected 1-30)	Biodex Atomlab 930 Well Counter Efficiency: 100	248	8	0.1
Feb. 4	Thyroid Bioassay of 2nd Patient	Biodex Atomlab 930 Thyroid Uptake System	16000 (12984 when implant area shielded with 2 lead aprons)	18	2160
Feb. 4	5 cc urine sample from 2nd patient	Biodex Atomlab 930 Well Counter	10	13	0
Feb. 20	Thyroid Bioassay of 1st Patient	Biodex Atomlab 930 Thyroid Uptake System	4831	16	803
Feb. 20	Thyroid Bioassay of 2nd Patient	Biodex Atomlab 930 Thyroid Uptake System	5052	16	840
March 24	Thyroid Bioassay of 2nd Patient	Biodex Atomlab 930 Thyroid Uptake System	4781	16	795
April 21	Thyroid Bioassay of 1st Patient	Biodex Atomlab 930 Thyroid Uptake System	1111	??	185

*Started on thyroid blocking agent after bioassay

Based on the above data, the licensee concluded that the 1st patient received 9.65 rads to the thyroid and 5 millirads to the whole body. In addition, the licensee concluded that the 2nd patient received 13.53 rads to the thyroid and 7 millirads to the whole body. For the 1st patient the RSO concluded that most likely a contaminated seed was implanted in the patient. No licensee conclusions were provided concerning the 2nd patient.

Discussions with the AUs indicated that seeds jam more often in disposable cartridges and springs fail more often for re-usable cartridges. The AU observed loading seeds indicated that the 1st patient treatment used a re-usable cartridge and that seeds jammed in 2 cartridges, with one of the cartridges ultimately used for the treatment. In addition, the AU was observed re-bending the Mick plunger to straighten prior to treatment and licensee staff indicated that sometimes the implant needles are re-used. However, re-use of the implant needles is not tracked by the licensee.

Notification of the Incident

On January 28, 2004, the licensee's RSO left a message on a Region I inspector's voicemail indicating that contaminated seeds were received and potentially implanted into a patient. On February 2, 2004, the licensee's RSO notified the NRC Operations Center that a possible medical event occurred at the hospital on January 23, 2004, when one or more iodine-125 seeds implanted into the prostate gland of a patient were believed to be contaminated.

On February 6, 2004, the licensee's RSO notified the NRC Region 1 and the Operations Center, that a second iodine-125 prostate implant patient, who was treated on January 30, 2004, had positive thyroid bioassay measurements. The licensee reported that they were investigating the possibility of leaking and/or contaminated seeds. The RSO reported that the left over seeds were swiped for contamination and indicated readings of 1689 counts per minute and 809 counts per minute using both a wet and dry wipe. The instrument used for assessment was not reported, however, the inspector confirmed that the well counter was used.

For both events, the AU indicated that he had notified both the patients and their referring physicians.

Licensee's Corrective and Preventive Actions

The licensee shipped all unused seeds and a 1 cc sample of the sterilizer water from the 1st patient to the seed manufacturer for analysis. On May 4, 2004, the seed manufacturer provided the following results:

- Records indicate that all seeds passed all leak tests, sizing tests, and visual tests prior to shipment, and therefore, were not leaking or damaged when shipped.
- Records of surveys conducted of the facility prior to shipment showed there was no contamination.
- The company used for seed loading into applicators indicated that wipe surveys showed no contamination prior to shipment to the licensee.
- The returned seeds were cleaned and leak tested. Of the 16 seeds returned, 14 passed leak testing. However, all 14 seeds when viewed under a microscope appeared to be damaged and did not pass the sizing test that they had originally passed prior to shipment. One of the remaining seeds was lodged in an applicator cartridge and could not initially be removed. This seed and one additional seed were found to be leaking and damaged.
- No other reports were received from customers concerning leaking or damaged seeds.

Therefore, the seed manufacturer concluded that the problems encountered with the seeds did not originate with them. The State of Florida inspector and the NRC inspector noted that neither the company used for seed loading, nor the licensee swipe incoming or outgoing seeds for contamination.

The AMP performed swipes of all unused seeds from the 2nd patient and noted positive readings. The 16 seeds were sent to an independent vendor for analysis. The independent vendor leak tested each seed individually with a Ludlum 2200 single channel analyzer and examined each seed under a 10x microscope for damage. On February 19, 2004, the independent vendor concluded that all seeds "revealed contamination of less than the maximum limit of 0.005 microcurie per seed." In addition, the independent vendor noted that 9 of the 16 seeds "revealed some slight dents and indentations in the titanium capsule, however, none of the indentations penetrated the cylindrical capsule."

The 16 seeds were returned to the licensee who forwarded them to the seed manufacturer for analysis. The seed manufacturer indicated on May 18, 2004, that "there is noticeable damage to 12 of the 16 seeds received" and that "the damage to these seeds seems to be of the same type as that found from the first incident that occurred January 23, 2004." In addition, the seed manufacturer indicated that "the type of damage to these seeds and the previous set of seeds has not been reported from any other customer nor has this type of damage been seen before." Based on this information, several discussions were conducted with the seed manufacturer and the State of Florida to attempt to ascertain how the unused seeds from the 2nd patient were damaged. The manufacturer indicated that they could send seeds to the source loading company for loading into cartridges with and without proper alignment and view any damage to the seeds with their equipment. The States of Illinois and Florida indicated that they could license this research activity and the State of Florida indicated that their licensee would need to submit an amendment request for such an activity. Discussions with the State of Florida and the seed manufacturer indicated that as of February 28, 2005, Custom Care Pharmacy had not requested an amendment to allow this activity.

In addition, the licensee:

- Changed seed manufacturer;
- Collected bioassay data on 3 subsequent patients and noted background readings;
- Plans to continue conducting bioassay measurements of all future prostate patients until further notice;
- Conducted maintenance on the sterilizer used for iodine-125 seeds to ensure that temperature and pressure readings were within the specifications outlined in Sealed Source and Device Registry (i.e., 273 degrees Fahrenheit and 30 psi);
- Surveyed the sterilizer on February 5, 2004, with a Biodex Model 3 meter and found background results.

c. Conclusions

The NRC does not agree with the licensee in their conclusion that the manufacturer was supplying contaminated seeds. Based on the data provided by the licensee, the seed manufacturer, the seed distributor, and the States of Illinois and Florida, the most likely root cause appears to be damage of one or more seeds during the implant conducted on January 23, 2004, with the contamination from the damaged seed(s) implanted into the patient and failure to fully decontaminate either the Mick applicator, or, if re-used,

the implant needles prior to use for the 2nd patient. It does not appear that a damaged seed was implanted into either the 1st or 2nd patients, however, it does appear that the 2nd patient was cross-contaminated with the residual contamination from the initial seed(s) damage on January 23, 2004. In addition, regarding the licensee's report of leaking seeds left over from the second implant, the inspector noted that if the licensee used their well counter for analysis and assumed the same 100 percent efficiency used for other measurements, then the maximum contamination found on the left over seeds equates to 0.8 nanocuries, which is less than the 5 nanocurie reporting requirement.

The I-125 contamination was taken up in both patients' thyroids and resulted in unplanned dose to the thyroid. All other organs, including the bladder appear to have received only minor additional dose from this contamination. A review of the licensee's dosimetry for the two patients indicates some errors, most notably, the failure to calculate and use the initial intake and uptake when determining the final whole body and thyroid dose for each patient. Calculating weighted intakes using intake retention fractions from Table B35 of the Health Physics Journal dated November 2002, provides initial intakes of 7.6 microcuries and 10.3 microcuries, for patients 1 and 2, respectively. This results in an additional dose of about 30 percent greater than that calculated by the licensee. Additionally, the area under the time-activity curve for each patient was calculated and compared favorably with the above calculation. In conclusion, the dose to the patients' thyroids are still well below 50 rads.

In addition, since neither patient received a dose to another organ (e.g., thyroid) exceeding the dose limits described in 10 CFR 35.3045, the events were not reportable medical events. However, if the leaking sources identified by the manufacturer had been implanted into the 1st patient's prostate, this would have resulted in doses to the thyroid in excess of 50 rads; i.e., a reportable medical event. Therefore, the licensee is reminded to report possible medical events within a timely fashion.

A medical consultant was not contracted since bioassay results indicated that neither patient was likely to accumulate 50 rads to the thyroid from the contamination.

II. Written Directive Procedures

a. Inspection Scope

The licensee's written directive procedures were reviewed during the inspection, with a focused review on the written directives prepared for prostate implants.

b. Observations and Findings

To meet the objectives of 10 CFR 35.40, the licensee's procedures for written directives requires: I) an authorized user will sign and date a written directive prior to implantation of brachtherapy sources; ii) prior to implantation, the patient will be identified by at least two methods and the items in the written directive will be verified by the AMP and AU; and iii) the AU who administers the dose shall date and sign a record of the treatment after the brachytherapy implant is completed.

The inspector confirmed that an appropriate written directive was prepared and signed for the 1st and 2nd patients and that the patients were verified prior to implantation. The inspector also confirmed that the AU verified the plans of treatment with the AMP prior to implantation. A written record of the treatments were appropriately prepared and signed and dated by the AU who was involved in the implantation.

For the case observed on February 5, 2004, the inspector noted that the AU and AMP verified the components of the written directive, however the AU had not signed the written directive by the end of the implant. The AMP indicated that sometimes the AU forgets and signs the written directive later.

c. Conclusions

The licensee's implementation of their procedures for written directives specific to prostate implants is inadequate and does not meet the requirements of 10 CFR 35.40. Specifically, for the implant conducted on February 5, 2004, the written directive was not signed by the AU either prior to the start or by the completion of the implant. This is a violation of 10 CFR 35.40.

III. Facilities and Equipment

a. Inspection Scope

The inspection reviewed the licensee's equipment used for surveys in this incident. Surveys conducted by the licensee included area radiation level surveys, radioactive contamination surveys, and bioassay measurements. The calibration of the equipment used for each survey and the adequacy of the instrumentation for the survey conducted was reviewed.

b. Observations and Findings

The instrumentation used, along with the background measurements and efficiencies of the instruments are provided in the table in Section I. As noted in the table, background measurements or exact measurements were not always documented by the licensee. The Biodex Atom Lab 930 sodium-iodide uptake probe was checked for efficiency for iodine-125 on February 11, 2004, using a 16 microcurie iodine-125 source. The Biodex Model 3 with 44-3 probe was last checked for efficiency for iodine-125 on July 8, 1999.

c. Conclusions

The licensee's instrumentation used for surveys conducted of their facility and the patients were appropriate for the use and were adequately calibrated. No violations of 10 CFR Part 20 or 10 CFR Part 35 requirements were identified.

IV. Radiation Surveys

a. Inspection Scope

The inspection reviewed the licensee's surveys conducted as a result of these two events. Surveys conducted by the licensee included area radiation level surveys, radioactive contamination surveys, and bioassay measurements. The adequacy and promptness of the surveys were reviewed.

b. Observations and Findings

The licensee routinely surveys the applicator, cartridges, sterilizer water, patients, and patient facilities for contamination and radiation levels following implants. However, upon finding contamination and radiation levels in excess of that normally seen in sterilizer water and the 1st patient's urine, the licensee failed to conduct comprehensive surveys of their facilities and patients to ascertain the extent of the contamination. For instance, as of January 28, 2004, the licensee had not surveyed the Mick applicator, the sterilizer, or the 1st patient's thyroid for contamination. Only upon prompting from the NRC did the licensee assess the possible exposure of patients and the extent of contamination of their facilities and equipment. In addition, the licensee does not survey for contamination incoming or outgoing seed shipments and on January 27, 2004, the licensee shipped potentially contaminated or leaking seeds to the manufacturer and did not survey the package or package contents for contamination.

c. Conclusions

The surveys conducted of the equipment, facilities, and patients were inadequate in that the licensee failed to promptly assess the extent of the contamination and dose from suspected contamination or leaking seeds. This is a violation of 10 CFR 20.1501.

Surveys of the returned prostate implant seeds containing a suspected contaminated or leaking seed did not include removable contamination surveys. This is a violation of 10 CFR 71.5 and 49 CFR 173.475.

V. Exit Meeting

An exit meeting was conducted on February 5, 2004, with the licensee's staff identified at the end of this report to discuss the preliminary findings. On April 1, 2005, the inspector informed the licensee of the final results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee
*Marsha Rowe, Vice President, Operations
*John Babu, Radiation Safety Officer
*Leslie Tupchong, M.D., Authorized User
*C. Jules Rominger, M.D., Authorized User and Radiation Safety Committee Chair
*Nozar Babanoury, Authorized Medical Physicist
*Gregory G. Chabitnoy, Administrative Director
Jorge Garcia-Young, M.D., Resident
Pierre Ghyned, M.D., Urologist

*Indicates presence at exit meeting on February 5, 2004