9/20/96 CE.

MEMORANDUM

To: Accident/Incident File & MD-05-007-03 file From: Ray Manley RM

Date: September 19, 1996

Subject: INVESTIGATION OF A JHMI CS-137 BRACHYTHERAPY INCIDENT

On June 6, 1996, at about 1230 hours Mr. Nathaniel Owrutsky (RHP Licensing) received a telephonic notification from Mr. Stanley Wadsworth (Radiation Safety Officer JHMI) regarding an incident and potential radiation misadministration at Johns Hopkins Hospital under license number MD-05-007-03. He reported (telecon attached) that on Monday, June 3, 1996 at 1650 hours a JHMI physician had implanted five (5) cesium-137 sources in a vaginal applicator. When the physician removed the sources from the applicator on June 5, 1996 at 1650 hours only four sources were in the applicator. The fifth source was found outside of the patient on a lead shield. The source had been placed there by the patient who indicated that she had found it under her buttocks. Initial estimates indicate that the source may have been under the patient for approximately 44 hours. Upon retrieval of the source the licensee conducted a leak test with negative results. Information regarding this notification was reported to Mr. Carl E. Trump, Jr. A tracking sheet was sent to the MDE Secretary describing events on June 11, 1996.

On June 7, 1996, Mr. Trump and this inspector visited the Johns Hopkins Medical Institutions located in East Baltimore City (410-955-370) to investigate the above report. Initial interviews were held with Mr. Stan Wadsworth (Radiation Safety Officer). The requirements of Section D.1209 were discussed with the licensee. Mr. Wadsworth indicated that the root cause of the radiation source being out of the applicator had not yet been determined.

The patient involved was a 33 year old female who was scheduled for two 48 hour Cs-137 GYN therapies with three 12.72 mgRaeq and one 8.32 mgRaeq Cs-137 brachytherapy sources with a single application dose of 2400 Rad and a total brachytherapy treatment dose of 4800 Rad. The patient had also been receiving external beam therapy. The first treatment was administered by Dr. Marc Hurwitz (2nd year Medical Resident) while under the supervision of Dr. Irene Gage (attending physician) on June 3, 1996 at 1650 hours in room 342 of building Nelson 3. Dr. Hurwitz's administration, into a Fletcher Suit Applicator, was his first while not under Dr. Gage's direct supervision. The radiation physicist present was Jeff Frensemeir. On June 5, 1996 at 1650 hours when the treatment was terminated and the sources were removed, one of the them was not located in the applicator. The source location was subsequently identified, by use of a survey meter, as being located on the top of the patient radiation shield located immediately adjacent to the patient's bed. When interviewed by Oncology personnel the patient indicated that she had found the source beneath her at approximately 1100 hours that day.

The time was estimated in conjunction with a TV show that the patient had been watching at the time she found the source. She indicated that she did not know what the object was but placed it on the shield.

The inspection team discussed with Mr. Wadsworth the concern that the licensee has not yet implemented their Quality Management Program (see JHMI June, 1996 MD-05-007-03 broad scope inspection report). Documentation of the patient's treatment plan and written directive is attached. The plan indicates that Dr. Irene Gage is the patient's attending physician, the number and activity of Cs-137 sources to be administered, computer generated isodose curves, and Dr. Gage's signature beneath this therapy's prescribed dose. A brachytherapy plan was prepared by a JHMI radiation dosimetrist calculating the dose received by the patient if the 12.72 mgRaeq had not been properly loaded into the applicator. This calculation indicates that even without the missing dose the patient received 80% of the prescribed dose for this first treatment.

Initial dose estimates, by the RSO, of unintended dose to the patient's skin given the assumptions that the Cs-137 source was located under her buttocks for 42-44 hours and did not migrate from one immediate area was 100 Gray (NCRP). Initial medical evaluation of the patient's skin by Dr. Gage indicated some reddening due to bed sores. Mr. Wadsworth stated that Dr. Gage would be periodically examining the patients's skin for adverse radiation effects.

Mr. Wadsworth indicated that nursing care given to the patient, during the treatment, was conducted by Ms(s) Jennie Walker, Elaine Stewart, and Janet Davis.

Following the initial interview a meeting was held with the following JHMI personnel:

Irene Gage, MD.	Attending Physician
Marc Hurwitz, MD.	Resident Physician
Jeff Frensemeir	Radiation Physicist
Stanley Wadsworth	Radiation Safety Officer

Investigator staff discussions regarding Dr. Gage's oversight of Dr. Hurwitz indicated an active role by the attending physician in the training of Dr. Hurwitz. Dr. Gage's application of the written directive was discussed and reviewed and confirmed that written directives are done for all of her therapies. Dr. Gage mentioned her discussions with staff regarding the possibility that the patient had some how manipulated the source. She further indicated that on the same day as the incident (6/5/96 at approximately 1730 hours) she talked to the patient regarding the incident and it's effects and also to the patient's referring physician (Dr. Ted Trimble) regarding the potential misadministration. She stated that she would continue to periodically examine the patient for skin effects. She stated that no blood work up had been conducted on the patient specific to the incident because the patient had been undergoing external

beam therapy and the blood results would be the same whether the incident had occurred or not.

Mr. Frensmeir indicated that during the physicist portion of the administration, nothing unusual occurred. Dr. Hurwitz and Mr. Frensemeir described the following general source insertion protocol:

1. The physicist loaded the sources into the carrier from the safe in the correct order of application. The loading inventory and the correct order is verified by a dosimetrist while looking over his shoulder.

2. Prior to administration in the patient's room the sources are inventoried by the physicist.

3. Prior to the implant Dr. Hurwitz described the RAM sources to the patient and what she was to do if a source were found out of the applicator.

4. Dr. Hurwitz confirmed that the proper number of sources were present prior to administration.

5. He at no time had any difficulty with the administration (procedure or device), and stated that it would have been difficult to drop a source while administering it.

The RHP investigators examined and were instructed in the use of the Fletcher Suit Tandem and Ovoids used for the patient source administration. The licensee indicated that they had examined the device and found no mechanical defects. No defects were apparent to the RHP investigation staff, however, it was noted that when the device was rotated slightly more than 90 degrees in either direction the source would fall out.

Dr. Dicello indicated his evaluation of potential skin dose to the patient given the worst case scenario of a 40 hour exposure in a discrete area. Given a 5mm skin exposure depth and hand calculations of 260 Rad/hr the dose was 10,400 Rad. At this dose a skin reaction was anticipated within 7 days.

A followup interview was held with Dr. Gage regarding the inspector's request to speak to the patient to confirm compliance with the reporting regulations and to request the identity of the individual in her room during the therapy. Dr. Gage stated that this interview could take place in the patients room prior to her second therapy on June 13, 1996. Her suggested attendance was herself, this inspector, Dr. Hurwitz and Mr. Wadsworth.

On June 10, 1996 at 1330 hours, this inspector interviewed the following JHMI personnel relevant to nursing care of the incident patient and brachytherapy

treatments in general. JHMI persons interviewed were:

Stanley Wadsworth	Radiation Safety Officer
Carl Granlund	RCU Health Physicist
Joann Nugent	Nursing Manager (Nelson 3)
Jennie Walker	Oncology care nurse
Lucille Cush	Charge nurse

Ms. Walker has been involved with nursing care for radiation therapy patients for eight (8) years. She indicated that she has attended classes involving the radiation safety aspects of treatment care. Nurses assigned to these types of care wear Xetex 415A Alarming Dosimeters for exposure evaluation. At approximately 1000 hours on 6/5/96 she visited the incident patient and noted that the Xetex was chirping at a greater than normal rate. In hind site this now appears to have resulted from the source being dislodged and located on the patient shield. Her reaction was to report the Xetex as malfunctioning. Ms. Walker stated that she had been trained in the wearing and recording of the Xetex, however, had received no training regarding the fact that an increase in the rate of chirp might be due to a dislodged source. She stated that the situation was unusual enough that she cut her stay short in the patient room. Review of her Xetex results for that visit indicated a dose for the visit of 3.0 mRem. Ms. Walker further indicated that she knew of the emergency lead pig in the room but, could not identify what a Cs-137 brachytherapy source looks like. The apparently broken Xetex was reported to the RCU at approximately 1030 hours that morning. The unit was not replaced by RCU personnel till approximately 1400 hours that afternoon. [**note:** A subsequent inspector interview with the RCU tech who replaced this Xetex stated that he exchanged this unit because it's calibration label indicated it was out of calibration. However, followup review showed that the unit was in calibration but the label had not been changed]. Mr. Wadsworth indicated that, in hind sight, the RCU could have, given the circumstances, identified that the source had been dislodged up to five hours earlier. He stated his understanding that all Xetexs were given to the nursing staff with the chirper on high, but, examination of the unit now on the floor showed it to be set on low.

Ms. Walker also informed this inspector that on June 4, 1996 she had to ask a young black male to leave the patient's room. She stated that she did not see him enter the room and estimates, due to the timing of her rounds, that he was not in the room for more than 10 minutes. She further stated that she did not ask the person his name, how long he was in the room, where he was in the room or report the incident to the RCU.

Ms. Lucille Cush is a Charge nurse on Nelson 3 and routinely entered the incident patient's room to administer medications. She stated that she entered the room after Ms. Walker and the chirping of the Xetex was a normal rate. Since the dose reading was 0 mRem she did not enter the result into the nursing log. Subsequent review of the log book (multiple radiation patients) by Ms. Nugent confirmed that no entries have ever been made in the log book by Ms. Cush.

During this visit to JHMI the inspector also reviewed the calibration of the Bicron meter used by the radiation physicist in the patient's room, reviewed the Cs-137 brachytherapy source inventory records, and conducted a physical inventory of the licensee's brachytherapy safe in specific regard to the Cs-137 sources. No deficiencies were identified. Carl Granlund's estimated dose rates in the patient's room were reviewed. (copy attached)

On June 13, 1996 at about 1300 hours, this writer telephoned the incident patient's referring physician Dr. Ted Trimble (beeper = 1-800-601-5091) regarding JHMI compliance regarding his notification of potential misadministration. Dr. Trimble stated that he was notified of the entire situation on June 5, 1996.

On June 13, 1996 at approximately 1315 hours, this inspector telephoned REAC/TS in Oakridge Tennessee to discuss potential or anticipated incident patient effects from the skin doses estimated by JHMI. Ronald Goans, MD. (Head of Medical Section) estimated that, given the limited information provided by the inspector, a 44 hour, at contact skin focal area skin dose of 10,400 Rad could cause 3rd degree burns and ulceration of the skin. He offered the services of REAC/TS in the form of medical conferencing if the licensee wished to do so.

On June 13, 1996 Mr. Carl Trump, Jr. and this writer visited the licensee with the intention of visiting the incident patient and informing Dr. Gage of REAC/TS offer for assistance. No interview with the patient occurred due to a delay in the operating room implantation of the applicator and the groggy condition of the patient. Dr. Gage stated that she had done extensive questioning of multiple qualified physicians around the country regarding the medical handling of the incident patient. She indicated that she would speak with the Department Head, Moody Wharam, MD., regarding the advisability of calling REAC/TS.

On June 17, 1996, at about 1400 hours this inspector attended a meeting at JHMI Oncology with the following JHMI persons present:

Moody Wharam, MD	Oncology Director
Stanley Wadsworth	Radiation Safety Officer

Dr. Wharam indicated his concern regarding REAC/TS role and stated that Hopkins would not contact them. He also disagreed with RHP speaking with the patient, however, following a telephone call to the institution's lawyers he indicated that if the patient agreed, he would allow it with specific guidelines. Questions asked should only include information received by the patient to show compliance with misadministration reporting requirements and to request the identity of the unauthorized visitor in the room. Persons present would be the inspector, patient and Dr. Gage. The visit would be scheduled the week of June 17-21, 1996. A memo with more specific details is attached.

This meeting was subsequently changed to a telephone conference and scheduled for June 20, 1996, however, at about 1515 hours that day, this writer received a telephone call from Dr. Gage and Dr. Dicello. Dr. Gage informed the inspector that, prior to the planned telephone conversation between JHMI, the patient and RHP (see memo to CET from REM dated 6/18/96), she had interviewed the JHMI misadministration patient. She stated that medical review of the patient still indicated no reddening of the skin resulting from the misadministration. Dr. Gage stated that she had given the patient the fifteen (15) day misadministration report (different from report faxed to RHP) to the patient in accordance with the regulations. The report contained a summary of the misadministration and the statement that the JHMI misadministration report submitted to the RHP is available upon her request. Dr. Gage indicated that she again reviewed the entire incident with the patient.

Dr. Gage indicated that she requested information from the patient regarding who had visited her, in the hospital, during her therapy treatment. The patient informed her that her female friend (present during the interview) had been in the room for a short period of time. When Dr. Gage asked this person how long she was in the room that person indicated that it was for a longer period of time (undefined time) because she had been watching TV with the patient. The patient told Dr. Gage that she had not had any male visitors in the room.

Dr. Gage stated that she then left the room to facilitate the planned telephone conference. Upon returning it was determined that the patient and her friend had left the area. Dr. Gage indicated that she would attempt to contact the patient to get further information.

On July 11, 1996, at about 1030 hours, Mr. Wadsworth called to update the status of JHMI attempts to gain information from the incident patient regarding friend/relatives who entered her hospital room during her receipt of cervical Cs-137 brachytherapy. Mr. Wadsworth stated that Dr. Gage informed him that she had seen the patient on the afternoon of 7/10/96. Dr. Gage asked the patient if she wished to speak with RHP and she answered no. Dr. Gage informed Mr. Wadsworth that in her

opinion it would be detrimental to the patient for JHMI personnel to interview the patient regarding those unauthorized persons in her room. So at this point, JHMI does not know the identity of those unauthorized individuals. It was further discussed regarding the inability to even estimate radiation dose to those unauthorized visitors unless additional information is received.

Following consultation with the Maryland Attorney General's office (memos attached) a letter (dated 8/1/96) was sent to the licensee outlining RHP concerns with JHMI's failure to obtain additional information regarding the two unauthorized visitors in the incident patient's room.

JHMI EXIT INTERVIEW BRACHYTHERAPY MISADMINISTRATION

On August 8, 1996 this inspector conducted an investigation exit interview at the licensee's address. The following individuals were in attendance:

Edward Bernacki, MD.	Executive Director for Health, Safety, and Environment
Stanley Siegelman, MD.	Chairman Radiation Safety Committee
Moody Wharam, MD.	Director of Oncology
Irene Gage, MD.	Patient's Attending Physician
Jennifer Bucholtz	Hospital Nursing Supervisor
Stanley Wadsworth	Radiation Safety Officer

The following concerns were discussed:

I. Details of information used to determine misadministration (dose to patient) is sketchy.

A. Unclear where the source was located.

B. Unclear how long the source was out of the container.

C. Unclear how the source got out of its container.

D. Since no reddening of the patients skin was determined, it appears that the patient may not have had the source beneath her for 44 hours.

Section D.1209 indicates the requirement for the licensee to report why the event occurred, the effect on the patient and what is required to prevent reoccurrence.

II. Root cause for the incident has not been established. Two possible scenarios appear possible. If a single root cause for incident can not be determined, JHMI must evaluate and address all possible causes as if they were the root cause. JHMI should indicate what systems/procedures are currently in place to prevent occurrences and evaluate what, if any additional systems/procedures should be added to prevent recurrence.

ROOT CAUSES

A. Source was dropped by physician during application.

1. Since it is a broad scope, authorized users are determined by licensee.

2. For other specific licenses, authorized users are determined by RHP.

3. Conduct an evaluation of the process used by JHMI for the qualification of MDs conducting brachytherapy implants.

4. If physician error was determined as the root cause, what specific actions would be taken by JHMI.

5. Has this incident been reviewed by an internal medical committee? If so, what were their findings and recommendations?

B. Source was removed from the applicator by the patient/visitor.

1. Evaluation of feasibility of patient tampering with source.

i. Has the patient been asked whether she tampered with the source? Has it been clearly indicated to the patient that there will be no legal ramifications for supplying information.

ii. If tampering occurred by patient, what is the potential for dose?

iii. What information is given to the patient regarding tampering with the source applicator? Is the therapy mechanism clearly explained to the patient?

2. If tampering occurred by an unauthorized visitor, what is potential for dose?

i. Have unauthorized visitors been asked whether they tampered with the source?

ii. JHMI responsibility to determine identity and dose of unauthorized individuals.

III. Unauthorized entry of the public into a restricted treatment area. JHMI failed to effectively restrict the area. At least two unauthorized individuals entered the treatment area during the two day period. Concerns of RHP are outlined in 8/5/96 letter.

A. Explain in detail JHMI mechanisms/procedures to restrict unauthorized entrance into patients therapy room.

B. What additional changes can be made to provide security?

C. Though a nurse determined that a visitor was in the room when she entered for patient care, his entrance was not observed. The female visitor's entrance and exit from the room was not observed by the nursing staff.

IV. Nursing training. Section G.42.

A. A nurse assigned to the patient indicated to RHP interviewer that she

what a brachytherapy source looks like.

B. A nurse assigned to the patient indicated that she does not always log the Xetex dose results into the nursing dose logbook. A review of the log book by a nursing supervisor showed no evidence that this individual ever logs in.

C. When a member of the nursing staff found the unauthorized person in the room she failed to get any identifying information, what and how long the individual was in the room, nor inform the RCU that an unauthorized person was found in the room. Under JHMI Manual Section 10.2 for notification of incidents: Each authorized user shall immediately notify the JHMI Radiation Control Unit of any incident involving any source of radiation which may have caused or threatens to cause a radiation exposure in excess of the applicable limits to any individual.

NOTE: Since nurses are using chirping Xetexs, they should be trained to recognize that an increase in the rate of chirp may indicate a dislodged source. Interviews with nursing personnel indicated that they did note an increase in the rate of chirping, but assumed this meant the unit was not functioning properly.

V. RCU actions:

A. RCU personnel were notified of a questionable Xetex at 1030 hours. This device, which was being used by nurses for whole body dosimetry, was not investigated/replaced until 1400 hours.

B. An immediate investigation with additional questions by the RCU inspector could have determined that the source was dislodged 3.5 hours earlier.

Summary of licensee statements:

1. Dr. Gage indicated that the patient's treatment followup is complete. At no time was there evidence of skin reaction due to radiation dose.

2. Dr. Gage stated that the patient was adamant about not wishing to speak to a RHP inspector regarding the incident.

3. Dr. Wharam suggested sending a certified letter to the patient from JHMI requesting how many visitors were in the room and their activities in the room. He suggested not asking the visitor's names. This inspector pointed out that

if estimates of dose received by members of the public exceeded 100 mRem or exceeds levels immediately hazardous to health, then JHMI may need to contact those individuals.

4. All JHMI staff present agreed with the multiple root cause analysis and the need to evaluate and respond to all possible potential root causes.

5. JHMI has already implemented some changes in their procedures resulting from the incident. These changes summarized are: Additional personnel observing Cs-137 source administrations; better security to the room; changes in nursing training and written procedures regarding RCU notification of incidents and identification of unauthorized visitors to the room.

ATTACHED DOCUMENTS TO THIS REPORT

-Initial licensee notification of incident to RHP

-MDE incident tracking sheet

-NRC PN of event

-Licensee's report pursuant to COMAR 26.12.01.01 Section D.1209(a)(ii)

-Brachytherapy plan without source being dislodged

-Brachytherapy plan with source being dislodged

-Oncology checklist for radioisotope procedure

-Oncology checklist for radioisotope procedure specific to incident patient

-Xetex dose results for nurses caring for incident patient

-Scope of nursing training program

-JHMI radiation safety guidelines for nurses

-6/14/96 telecon

-6/18/96 telecon

-6/20/96 telecon

-7/11/96 telecon

-7/11/96 RHP request for legal assistance

-7/16/96 AG response to request for assistance

-JHMI record for Xetex calibration

-JHMI dose rate evaluation for incident patient's room

-Inspector summary of RHP investigation concerns

-Pictures of relevant devices

10/9/96 Events
RIDS Dist.
SP04

EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT NO. __ - __ - __

DATE: September 24, 1996

TO:

Deputy Director
Office of State Programs

SUBJECT: MEDICAL EVENT AT JOHNS HOPKINS HOSPITAL, JUNE 3-5, 1996, INVOLVING A POTENTIAL BRACHYTHERAPY MISADMINISTRATION (INVESTIGATION REPORT)

STATE: MARYLAND

Signature and Title:

Carl Trump, DIRECTOR
RADIOACTIVE MATERIALS
LICENSING, COMPLIANCE, +
SAFEGUARDS DIVISION

160038

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