From: Ujagar Bhachu
To: Williams, Gary E
Date: 3/1/03 12:05PM
Subject: February 26, 2003, Petition Review Board Meeting - DVA MML 10 CFR 2.206 Petition

Mr. Salsbury, the DVA MML 10 CFR 2.206 petitioner recommended during his presentation to the NRC Pettiton Review Board on February 26, 2003, that the NRC as a part of its evaluation of the petition review the copies of the following NHPP inspection reports.

- VA Kansas City. (the petitioner believes that two inspectors, Joe Wissing and Mike Simmons conducted
  these inspections in a very short time frame between the two reports).

- VACHCS report for 2002.

- VA Hines inspection report (the petitioner believes they
  had two missed administrations in one year)

The information provided by the petitioner is sketchy, however, could you please e-mail or overnight a copy of the referenced NHPP inspection reports.

Ujagar S. Bhachu
(301) 415-7894

CC: Marissa Bailey

From: Ujagar Bhachu
To: Kevin Null
Date: 3/4/03 2:43PM
Subject: DVA MML 2.206-Follow UP

Mr. Salsbury, the DVA MML 10 CFR 2.206 petitioner recommended during his presentation to the NRC Pettiton Review Board on February 26, 2003, that the NRC as a part of its evaluation of the petition review the copies of the following NHPP inspection reports.

- VA Kansas City. (the petitioner believes that two inspectors, Joe Wissing and Mike Simmons conducted (these inspections in a very short time frame between the two reports).

- VACHCS report for 2002.

- VA Hines inspection report (the petitioner believes they (had two missed administrations in one year)

The information provided by the petitioner is sketchy.

I requested NHPP hree reports and the applicant has e-mailed the attached two reports.

The applicant has notified us that the applicant will mail the copies of inspection reports to NRC and petitioner via fedex.

(Note that only the 1999 Kansas City NHPP inspection conducted by M. Simmon has been sent. A 1996 KC audit was conducted by J. Wissing. Mr. Wissing's report was issued by the former VA regional office, not by NHPP).

Ujagar S. Bhachu

Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D C. 20555-0001

Request to deny license/rescind license per 10 CFR 2.206

1. I request that the **master** license, which the Veterans Administration (VA) has applied for, be denied/rescinded. The reasons are as follows:

a. Systemic management failure-

Aa. A September 2000 NRC inspection of VA Chicago Health Care System (VACHCS) by Deborah Piskura, noted that the RSO was reporting problems to the Radiation Safety Committee but management was failing to respond.

Ab. RSO's are being driven from service. The RSO from VA Indianapolis is believed to have been harassed, by NHPP inspectors, to such an extent that he moved to the RSO position for the Customs Service in Indianapolis. The RSO at VA Saint Louis maybe having the same problem. The RSO at VA Philadelphia (see NRC report on the RSO harassment and reinstatement by VA Philadelphia) and VACHCS were driven out. Apparently a nurse was also discriminated against at VA Philadelphia NHPP and the poor management attitude will destroy the radiation safety culture in the VA, "corporate memory", and continuing safety failures will occur.

Ac. The National Health Physics Program has prohibited contact (with unspecified threats) between the VA radiation safety community and the NRC. I believe that this is a violation of various parts of 10CFR which allow full access to the NRC and other safety related individuals.

Ad. The master license radiation safety committee appears to be dominated with physicians who typically have aligned their allegiance with management. The National Heath Physics Program (NHPP) also has aligned itself with management because it is 1-2 steps removed from the local program. One lone RSO representative, with no authority or clout or access, represents the entire VA RSO population This is another indication of the low regard the VA has for its safety programs

Ae VA federal budget problems are becoming sever. Budgeting issues are straining manpower, for instance see VA Saint Louis, VA Hines, VACHCS and possibly VA Milwaukee. Budgeting is impacting hiring, experience level at hire, and grade level. For instance, the RSO supporting VA North Chicago is out of VA Hines at a GS 9 level. The previous VA Hines RSO retired, as a GS-11 in December 2001, still no replacement. VA Hines apparently has one of the largest uses of radioactive material in the VA system. The latest moch JCAHO inspection of VACHCS scored 46ish points. The last full JCAHO inspection score was in the 90's.

Af. When VA Hines lost its Director, the acting Director told the employees at VA Hines not to expect a permanent Director soon. The VA is so short of qualified management candidates that positions (the Director and Associate Directors, VACHCS were not replaced for several years) may remain open for years. The two Associate Directors recently hired at VACHCS appear to be substantially less experienced than the people they replaced. Rotating managements poses great problems because no one holds responsibility for the safety programs. An acting Director is not going to fix the problems that are not crises, and any new Directors will have to be "brought up to speed". If the Acting Directors are rotating every 4-6 months, as they were at VACHSC, decision making stops. Support stops.

Ag. Veteran patient populations are falling rapidly. Local budgets are allocated based on patient load not on program needs. The various safety programs needed by the VA have not been separately funded. This is particularly a problem when consideration is given to the various terrorist threats currently present. In a downward spiraling federal and local budgets, inexperienced management may be driven to support medicine over safety. Budgeting and management problems are a recipe for chaos. Couple these issues with NHPP's reluctance to take management to task, and significant failures could occur.

Ah Money returned, to the local VA hospitals, from VA headquarters, to support the research programs (to include safety) is diverted to support patient care.

Ai. The VA does not have a proactive safety program. The U.S. Navy when a hiring freeze occurred would not freeze safety positions. The VA has not exempted safety positions from hiring freezes. For instance, the Safety Manager position at VACHCS (only one person) remained unfilled for approximately a year. The only reason it was finally filled was the fire detection system failed and admissions were closed (and the hospital almost evacuated of inpatients). The conversations within the VA RSO's "e-mail group" have ranged from a neutral position to a very, very concerned position about the master license and NHPP's implementation of the master license. VA VISN 12 (Northern Illinois) (Dr Joan Cummings) requires the Dr VanDrunen, Chief of the Imaging Product Line approve ALL radiation safety positions in the region prior to hire, grade level at hire, responsibilities, duties and duty location The Chief of the Imaging Product Line controls Nuclear Medicine, Radiology, apparently radiation safety and also sits on the VA master license board. This is clearly a conflict of interest.

Aj. The VA does not have a policy on where in the management structure radiation safety, safety, and industrial hygiene should be placed. Until recently many RSO's were part of Nuclear Medicine and were often treated as technicians. For a number of years VA headquarters required the radiation safety program to be under the Nuclear Medicine service. Can a VA RSO be supervised by Nuclear Medicine, the Chief of Research, the Chief of Medicine, the Chief of Staff. All of these individuals pose a conflict of interest to the radiation safety program. They are also significantly removed from management.

Ak. VA management is apparently does not have a performance rating on safety. In the other two master licenses (Navy and Air Force), a failure to take action on a known safety issue would typically end the career of that commanding officer. There is no indication that hospital Directors, VISN Heads,... are rated on there safety performance, nor that significant action will be taken for a safety failure. In fact, there was a news article showing magots in VA patient's nostrils; safety and patient safety is not emphasized.

b. Management denying responsibility for the radiation safety program-

The Secretary of the VA was requested to provide testimony in an on going MSPB radiation safety case. The VA Regional Counsel, Tim Morgan, VA Hines, has refused stating that the Secretary may not be called to answer questions. If management is not responsible for the safety program in the VA, then who is? Who is responsible for the master license?

c. The VA National Health Physics Program (NHPP) is inconsistent with its inspections and violates its own standards-

Aa. NHPP often takes weeks to perform the same inspection NRC performs in a day. September 2000 VACHCS; NRC 1 person day (Deborah Piskura, Region III), NHPP 4 person weeks+ with multiple independent inspections and NHPP follow-ups (Joe Wissing

and Ed Leidholdt). November 2001 VACHCS, NRC approximately 3 person days (Chris Martin, Region III), NHPP 2 person weeks with significant follow up and report forwarding (Ed Leidholdt). 1999 VACHCS, NRC inspection 1 person day (Darrel Weidman, Region III), NHPP approximately a year later 1-2 person weeks (Joe Wissing and Ed Leidholdt). The NRC will typically not find any items of non-compliance; NHPP will cite multiple items (typically all level IV). For instance, NHPP has cited the following items at VA Chicago Heath Care Systems (VACHCS) while the NRC inspectors have found problems only with management:

Aaa. Lack of an inventory of the radioactive waste program, yet no indication that the licensee has exceeded the license limits (see NHPP inspection of VACHCS in late 2000 Joe Wissing and Ed Leidholdt).

Aab. Citations that the training program must comply, not as is described in the license application but is as described in the NRC's Reg Guides, even though the Reg Guides are not referenced in the license application (see various NHPP inspections of VACHCS 1999-2002). Since the NRC Reg Guides are guidelines I believe that they cannot normally be cited against by an inspector.

Aac. Citations against an NRC license which had been combined with another license and had been terminated and inspected by Region III with no violations found (see Ed Leidholdt, NHPP inspection of VACHCS in February 2002 and NRC inspection by Chris Martin/Gary Sheer, NRC February 2002).

Aad. After a NRC inspection (Deborah Piskura, Region III September 2000) noting management failure at VACHCS; NHPP inspectors, essentially, dismissed the NRC finding and instead focused on perceived RSO failures. This allowed management to ignore its own failures and divert attention to the RSO The NRC inspector noted no other problems other than management's failure to support the RSO. See NRC inspection of VACHCS Lakeside September 2000.

d Joe Wissing, NHPP inspector told the VACHCS Chief of Nuclear Medicine that all orders of radioactive material do not have to be approved by the RSO. This is in conflict with 10CFR35.21 (see e-mail From: Dr Chandramouli, Acting Chair, Nuclear Medicine To: William Salsbury 19 April 2001 "Mr. Joe Wissing said that this matter (ordering of therapy doses through the RSO per 35.21) should be considered by the RSC before any decision is made. The RSO cannot override the RSC's decision".

e. NHPP is fearful of management. NHPP will not take management to task, instead they "create" citations on others which shield management from responsibility. My conversations with the previous RSO at VA Hines (retired) indicated that the VISN 12 Head told NHPP to "back off" during one inspection, which NHPP apparently did. Note that VA Hines, within the recent past, had 2 of 4 misadministrations reported for that year.

f. The range of inspector's attitudes is extreme. One inspector appears anti-RSO. One inspector performs inspections to the letter of the law while ignoring the "big picture". One inspector decided that the VACHCS license application, which had been transmitted to the NRC, was too uninspectable. He rewrote the license application and sent it to VACHCS with orders to "sign it or else". This license was sent to the RSO representative for the master license; who responded that this was a very prescriptive, difficult to implement and expensive license. I had already made that determination. VACHCS management signed the NHPP written license, over my objections A recent NHPP inspection of VACHCS apparently failed to identify the failure of VACHCS to implement these license renewal changes, which NHPP had placed in the renewal (see NHPP inspection of VACHCS in late 2002 and license renewal) There is a hint that NHPP has an intent to harass the VACHCS RSO from his position and once that was accomplished, to reduce

inspection over sight. This shields management from responsibility and reduces the likely hood that NHPP will have to act against management.

g. Joe Wissing, NHPP inspector, decided that manpower was sufficient at VA Chicago Health Care Systems (VACHCS) and returned from his duty location to report his opinion to VACHCS management. The manpower determination was not discussed with the RSO nor was the RSO allowed to be present at the meeting with the Director. When the RSO discussed the inspector's actions with Gary Williams, NHPP, he said that Mr. Wissing's actions were contrary to NHPP policy and the inspector would be dealt with. To the best of my knowledge NHPP has not taken any action Mr. Wissing's report (November 2000) required VACHCS to perform a workload evaluation of VACHCS Lakeside Division (note that there are 2 hospitals; Lakeside Division and Westside Division). Mr. Wissing recommended Mr. Hensch, RSO Minneapolis VA. Mr. Hensch's report indicated one person could run VACHCS Lakeside Division. However, the VACHCS Westside Division is 5-25 times the size of the Lakeside Division and was not evaluated. Mr. Wissing had performed an inspection of the Westside Division on or about 1997. So Mr. Wissing knew the different sizes of the two facilities, yet only Mr. Wissing's actions shielded management from effective oversight and also acted to pervert the honest evaluation of manpower needs

h. NHPP inspectors are so poor:

aa. They are banned from certain VA hospitals and not allowed to perform inspections by NHPP's own management. Conversations with the previous RSO at VA Hines indicated that some inspector's citations were so outlandish that the Regional VA Director (VISN 12) banned the inspector from returning NHPP management may have taken this inspector to task by not allowing the inspector to perform inspections for a time (possibly up to 6 months and on more than one occasion). Another inspector is so prescriptive that he is, apparently, regularly chastised by NHPP management. NHPP management will use these inspectors on RSO's who have fallen from favor, possibly in a harrassive role.

Ab. comparison of the VACHCS inspections performed by NRC and NHPP are completely opposite from each other. Evaluation of the two NRC licenses held by VACHCS from 1998-2002 showed one citable event. NHPP evaluations showed multiple citations (possibly greater than a dozen) one a level III. Often these inspections are concurrent This is an indication of the harrassive role that NHPP has assumed.

Ac. A VACHCS report on a potential over exposure (9 November 2001, see Chris Martins inspection February 2002 of VACHCS) was approximately 20 pages when reviewed by an NRC inspector (with no comments), by the time NHPP was satisfied the report was approximately 1-1.25 inches thick.

2. The VA is not the agency which can handle internal regulation and the result will be a failed program and a danger to the public. The VA often has a relaxed attitude towards OSHA inspections because OSHA cannot (typically) fine the VA. If the master license is given to the VA a similar situation will result.

3. I request that I be allowed to update and enhance my request. I also request that names be removed whenever possible.

William Chuck Salsbury, MS, C.H.P.
320 N Wright St
Naperville, IL 60540
Salsbury_wcw@yahoo.com

DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: DEC 19 2002

From: Director, VHA National Health Physics Program (115HP/NLR)

Subj. Radiation Safety Program Inspection - Inspection Report 537-02-I02

To: Director (537/00), VA Chicago Health Care System, Chicago, Illinois

1. Paul L. Yurko, VHA National Health Physics Program, inspected the radiation safety program at the VA Chicago Health Care System, Chicago, Illinois, on November 20-21, 2002.

2. Attached to this memorandum is the inspection report. Within the scope of this inspection, we did not identify any deviations from Nuclear Regulatory Commission requirements for the use of byproduct radioactive materials.

3. You are not required to respond to this inspection report.

4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Yurko at (410) 642-2411, extension 6288, if you have any questions regarding the inspection or other related radiation safety issues.

E. Lynn McGuire

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 12 (10N12)

Attachment

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 537-02-I02
VA Chicago Health Care System, Chicago, Illinois
November 20-21, 2002

1. Introduction:

The VHA National Health Physics Program (NHPP) inspected the radiation safety program at the VA Chicago Health Care System, Lakeside and Westside Divisions, Chicago, Illinois, November 20-21, 2002. Paul L. Yurko performed the inspection. Mr. Yurko presented his preliminary findings at a meeting with key health care system staff on November 21, 2002.

2. Scope of inspection:

The inspection followed a pre-approved inspection plan. The inspection was a follow-up inspection to the NHPP inspection of January 16-18, 2002. A portion of the inspection was to evaluate security of radioactive materials with emphasis on sealed radioactive sources. The inspection consisted of an examination of the rooms and equipment of nuclear medicine and research at the Westside and Lakeside Divisions, sealed source inventory of sources greater than 100 microcuries, performance-based review of radiation safety practices, review of radiation safety records, comprehensive review of waste management, and interviews with health care system staff. The inspector completed spot-check radiation measurements in the nuclear medicine hot lab and imaging rooms and in the research areas. Corrective actions taken on the previous violations cited in the inspection of January 16–18, 2002, were a focus of the inspection. No reoccurrence of the previous violation could be found.

3. Findings and impressions:

a. The Nuclear Regulatory Commission (NRC) inspected the health care system on November 14, 2001. The NRC inspector cited no violations and closed out the concerns raised during the NRC inspection of August 1-2, 2000.

b. Security of radioactive materials is well maintained; all radioactive material including large sealed sources are stored and secure within nuclear medicine and research.

c. The following areas were reviewed with no deviations noted:

(1) Radiation Safety Committee (RSC) minutes and records for CYs 2001 and 2002 to date,

(2) CY 2001 radiation safety program reviews,

(3) Dose calibrator and survey instrument records for CYs 2001 and 2002 to date,

(4) ALARA program,

(5) Radioactive material security and general radiation safety practices,

(6) Radiation Safety Officer's files for training, spills/incidents, radioactive waste shipments, source inventories, leak tests, public dose assessments, and effluent release reports,

(7) Sealed source inventory with emphasis on sources greater than 100 microcuries,

(8) Personnel dosimetry radiation exposure records for CYs 2001 and 2002 to date, and

(9) Radioactive waste management.

4. Notice of Violation: In the areas inspected and within the scope of this inspection, no violations were identified.

VHA National Health Physics Program Inspection Record

Inspection report number: 537-02-I02

License number: 12-02642-06

Licensee (name/address):

Department of Veterans Affairs Chicago Health Care System
333 East Huron Street
Chicago, IL 60611

Locations of use on license being inspected: 333 East Huron Street, 820 South Damen Ave, 400 East Ontario

Licensee contact (name/telephone number): Bangaruswamy Chandramouli, M.D., (312) 569-6435

License priority: 2

License program code: 2110

Date of last inspection: November 14, 2001 (NRC) and January 16-18, 2002 (NHPP)

Date of this inspection: November 20-21, 2002

Type of inspection:

(X) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial

Next inspection date: November 2004

Summary of findings/actions:

(X) No violations cited, NHPP memorandum issued
( ) Non-cited violations
( ) Violation(s), NHPP memorandum and NOV issued
( ) Follow-up on previous violations

Inspector(s): original signed Date: December 9, 2002
Paul L. Yurko

Approved: E. Lynn McGuire Date: 12/19/02
E. Lynn McGuire, NHPP Director

Revised May 15, 2002, adapted from NRC Temporary Instruction 2800/033

VHA National Health Physics Program Inspection Record

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

1. AMENDMENTS AND PROGRAM CHANGES:

AMENDMENT #	DATE	SUBJECT
44	June 17, 2002	Renewal

2. INSPECTION AND ENFORCEMENT HISTORY:

This is a follow-up inspection to the NHPP inspection of January 16-18, 2002. The health care system was cited for three Level IV violations. Corrective actions for the previous violations were evaluated as part of this inspection. Completion of RSO orientation worksheet was part of this inspection. Health care system requested new RSO in letter dated September 19, 2002. New RSO is M.D.; therefore, allocation of time as physician authorized user and broad-scope RSO was evaluated.

The NRC inspection on November 14, 2001, cited no violations and was a follow-up on previous concerns.

NHPP inspection report number 537-01-I02 dated February 12, 2002, cited three Level IV violations. The inspector evaluated the licensee's corrective actions for each of the violations and found:

1. Training - a researcher who worked with radioactive material at the Westside Division did not receive the required training. The inspector reviewed the training records at both Westside and Lakeside, interviewed research employees at both Westside and Lakeside, and interviewed the Chairperson of the RSC and was satisfied adequate training is presently provided. The radiation safety manuals for Westside and Lakeside were revised to be consistent at both locations. Training on the new radiation safety manual was provided to all research employees who utilize radioactive material. This violation should be closed.

2. Spill reporting - a researcher did not report a spill that occurred on October 27, 2002, to the RSO until two weeks after contamination was found. The inspector interviewed a number of research employee including those from the laboratory involved and found each employee was now aware of proper procedures for reporting any incident to the RSO including spills. This violation should be closed.

3. Dosimetry - a research worker who utilized P-32 was not issued a proper dosimeter. The inspector reviewed the dosimetry records since the last NHPP inspection and observed employees and noted proper dosimetry is provided to the employees. This violation should be closed.

In addition, the issues raised by the previous RSO in a letter dated August 2, 2002, were discussed with the present RSO and licensee staff and all issues raised in the letter were closed as part of this inspection.

3. INCIDENT/EVENT HISTORY:

The health care system has not reported any incidents or medical events since the last NHPP inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The VA Chicago Health Care System has a medical broad scope license authorizing the use of byproduct material for diagnostic and therapeutic nuclear medicine and research at both the Chicago Westside and Chicago Lakeside locations.

The inspector determined the organization and scope of the radiation safety program were consistent with the license application, applicable regulations, type, quantity, and frequency of radioactive material uses. The RSC and RSO had adequate procedures and authority to direct safe work practices. Locations of radioactive material use were appropriately authorized, identified, and surveyed. The inspector site visited all areas of use at both the Chicago Westside and Lakeside locations.

The RSC is responsible for establishing policies regarding the safe use of radioactive material and for designating oversight of the facility's radiation safety program. Bangaruswamy Chandramouli, M.D., is the RSO for the license and David Barch, M.D., is the chairperson of the RSC. Om Kamaria is the Chief Nuclear Medicine Technologist at both the Chicago Westside and Lakeside locations and he handles the day-to-day duties in radiation safety for nuclear medicine. Ana Suboni is a contract physicist and she handles the day-to-day duties in research for both locations. The licensee has 15 authorized radioactive material principal investigators at Westside and 10 authorized radioactive material principal investigators at Lakeside; approximately six were active at Westside and four were active at Lakeside at the time of the inspection. The RSO stated there was no human use research being performed at this time. The inspection covered all areas of use in the license.

Based on the exit meeting with the Chief of Staff and the ACOS for research, the inspector concluded management oversight was sufficient to provide the licensee radiation safety staff with adequate resources and authority to implement the radiation safety program. RSC membership is consistent with areas of use, license commitments, and regulatory requirements.

The RSO has adequate program knowledge to implement license commitments and regulatory requirements. The RSO was delegated, by management, authority to take corrective actions for any identified program deficiency. Audits and reviews, conducted primarily by the Chief Technologist in nuclear medicine and a contract physicist, were sufficient to evaluate radiation safety program practices and program implementation. The audit program was evaluated based on commitments made in item 10(a) of the licensee's renewal application dated May 29, 2002, and the inspector was satisfied that all commitments are being met. Results of audit are reported to the RSC as a standing agenda item. Only approved authorized users or staff, under the supervision of an authorized user, were utilizing licensed material.

The RSO is a physician and has other duties, but based on the support from the Chief Technologist in nuclear medicine and a contract physicist from RSSI, the program has adequate coverage. In addition, the Chief of Staff stated in the exit meeting the licensee was actively recruiting a full-time RSO.

2. INSPECTION SCOPE:

The inspector followed the inspection plan. The inspector completed an NHPP security worksheet and new RSO orientation worksheet as part of the inspection. The inspection consisted of a tour of the areas of use at both the Westside and Lakeside Divisions including the research building at 400 East Ontario, interviews with the licensee's staff, including reviews of laboratory radiation safety practices and

confirmatory radiation surveys. Interviews were conducted with all members of the research lab involved with a spill of Na-22, the Chairperson of the RSC who is also the ACOS for Research at the Lakeside Division, and the RSO.

Until September 2002, the Chicago Health Care System held two NRC Licenses, one at Westside and one at Lakeside. The health care system received license amendment dated September 28, 2001, designating the Westside Division as a location of use under NRC License Number 12-02642-06 and terminating NRC License Number 12-01403-01.

The licensee's research use is in decline. Only six of the sixteen authorized users at Westside were active and only four of the ten authorized users at Lakeside were active at the time of the inspection. The inspection was a follow-up inspection to the NHPP inspection number 537-01-I02. Three Level IV violations were cited as part of the inspection. The corrective actions taken by the licensee to address the violations cited were evaluated as part of this inspection and the actions were adequate to avoid a reoccurrence of the violations.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Surveys for radioactive contamination were made on surfaces of several areas during the inspection. In the hot lab at Chicago WS, Room 2483 - the areas survey was 0.04 mR/hr. In the hot lab at Chicago LS, Room 258 - the area survey was 0.06 mR/hr. In imaging, Room 2480 - the area survey was 0.02 mR/hr.

In research at the Chicago WS Lab 7-221 - the area survey was 0.02 mR/hr, and at the Chicago LS, Room 130 - the area survey was 0.02 mR/hr.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

In the areas inspected and within the scope of this inspection, no violations were cited.

5. PERSONNEL CONTACTED:

[2]Brian Schmitt, M.D., Chief of Staff
[2]Michael Clement, A/O Chief of Staff
[1,2,3]Bangaruswamy Chandramouli, M.D., Radiation Safety Officer
[1,2,3]Ana Suboni, Consultant Physicist
[1,2,3]Ompsakash Kamaria, CNMT, Chief Technologist
[2,3]David Barch, M.D., Chair Radiation Safety Committee
[3]Szpira Stopka, CNMT, Nuclear Medicine Technologist
[3]Pauline Berkebile, CNMT, Nuclear Medicine Technologist
[3]Waddah Alrefai, Research Lab Manager
[3]Kristin Keller, Research Specialist
[3]Terrie Kucgrda, Research Specialist
[3]Joseph DeSimone, M.D., Associate Chief of Staff
[3]Linda Lojo, CNMT, Nuclear Medicine Technologist
[3]Jean Gottstein, Research Specialist

1: Individual(s) present at entrance meeting
2: Individual(s) present at exit meeting
3: Individual(s) present or participating in site visit discussions

Workload Indicators

Licensee/date: Chicago WS V.A. Medical Center 11/21/02

Workload Indicator	Number	Time Period
Nuclear Medicine		
Technologists	7	At both locations
Diagnostic studies	17	Per Day
Diagnostic studies, (^{131}I, > 30 μCi)	3	2001
Ventilation studies (aerosols only)	0	2001
Therapies, ^{131}I, inpatient	0	2001
Therapies, ^{131}I, outpatient	4	2001
Therapies, ^{89}Sr	0	2001
Therapies, other (such as ^{153}Sm)	0	2001
Brachytherapy		
Remote afterloading procedures	NA	
Permanent implants - specify type	NA	
Temporary manual implants - specify type	NA	
Research -- Non-Human		
Protocol or project reviews	6	2001
Laboratory rooms	15	
Principal investigators	15	
Radiation workers or staff using radioactive materials	60	
Iodination approvals or procedures	0	Per Year
Packages or shipments received	1	Per week
Drums waste generated	30	2001
Drums waste shipped	30	2001
Animal research approvals	5	2001
Research - Human		
Protocol or project reviews	NA	
Active protocols	NA	
Protocols using approved radiopharmaceuticals as adjunct	0	
Protocols under manufacturer-sponsored IND	0	
Protocols under locally-sponsored IND	0	
Protocols approved by RDRC	0	
Protocols (other)	0	

(revised 5/2002)

Workload Indicators

Licensee/date: Chicago LS V.A. Medical Center 11/21/02

Workload Indicator	Number	Time Period
Nuclear Medicine		
Technologists	7	At both locations
Diagnostic studies	10	Per Day
Diagnostic studies, (^{131}I, > 30 μCi)	2	2001
Ventilation studies	1	Per Month
Therapies, ^{131}I, inpatient	0	2001
Therapies, ^{131}I, outpatient	2	2001
Therapies, ^{89}Sr	2	2001
Therapies, other (such as ^{153}Sm)	0	2001
Brachytherapy		
Remote afterloading procedures	NA	
Permanent implants - specify type	NA	
Temporary manual implants - specify type	NA	
Research -- Non-Human		
Protocol or project reviews	4	2001
Laboratory rooms	10	
Principal investigators	10	
Radiation workers or staff using radioactive materials	40	
Iodination approvals or procedures	0	
Packages or shipments received	1	Per Month
Drums waste generated	2	Per Year
Drums waste shipped	2	2001
Animal research approvals	0	
Research - Human		
Protocol or project reviews	NA	
Active protocols	NA	
Protocols using approved radiopharmaceuticals as adjunct	0	
Protocols under manufacturer-sponsored IND	0	
Protocols under locally-sponsored IND	0	
Protocols approved by RDRC	0	
Protocols (other)	0	

(revised 5/2002)

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date August 2, 1999

From: Director, VHA National Health Physics Program, Diagnostic Services SHG (115HP/NLR)

Subj: Inspection of Teletherapy Misadministration and Notice of Violation

To. Director (578/00), Edward Hines, Jr. VA Hospital

1. We conducted a reactive inspection of the radiation safety program at your facility on April 8 and 15, 1999. Joseph Wissing, Program Manager, Central Service Area, VHA National Health Physics Program completed the inspection. The inspection was to review the circumstances surrounding a ^{60}Co teletherapy misadministration that occurred on April 2, 1999.

2. The enclosed report details the inspection findings and lists four violations. The violations are deviations from Nuclear Regulatory Commission requirements for ^{60}Co teletherapy. We do not require you to respond to this memorandum, since you have taken appropriate measures to correct the four violations.

3. We appreciate the courtesy and cooperation extended during the inspection. Please contact Mr. Wissing at (734) 769-7100, extension 5021, if you have questions about the inspection.

E. Lynn McGuire

E. Lynn McGuire

Enclosure

cc: Chair, National Radiation Safety Committee
Network Director, VISN 12 (10N12)

Radiation Safety Program Reactive Inspection
Edward Hines, Jr. VA Hospital
April 8 and April 15, 1999

1. Summary

The NHPP completed a reactive inspection on April 8 and April 15, 1999, at the VA Hines, in Hines, Illinois. The inspection was to review the circumstances surrounding a reported ^{60}Co teletherapy misadministration that occurred on April 2, 1999. Joseph Wissing, Program Manager, Central Service Area, NHPP, completed the inspection. Mr. Wissing held a meeting with hospital management, Radiation Oncology Service staff, and the RSO on April 15, 1999, to discuss apparent violations, the root causes, and the corrective actions planned or taken.

John D. Jones, NRC, also completed a reactive inspection on April 8, 1999.

The NHPP determined that four violations of NRC requirements occurred. These violations are cited in the attached NOV. The circumstances related to the violations are described in detail in this report.

The NHPP agrees that the misadministration did not cause any significant adverse effects to the patient and that all required regulatory notifications were eventually made. However, the NHPP is concerned about the violations since, if allowed to continue, more serious consequences could potentially arise with future patient treatments.

The NHPP sent VA Hines a Confirmatory Action Letter on May 5, 1999. VA Hines responded on May 21, 1999. The NHPP has concluded that the VA Hines response adequately addressed the reason for the violations, that the actions taken and planned to correct the violations and prevent recurrence were sufficient, and that the date when full compliance will be achieved is acceptable. Therefore, VA Hines is not required to respond to this report unless the report does not accurately reflect the VA Hines corrective actions or understanding of the violations.

2. Purpose of the reactive inspection

The purpose of the reactive inspection was to review the circumstances surrounding a reported ^{60}Co teletherapy misadministration. The inspection included review of the circumstances of the misadministration, the root causes, and the VA Hines corrective actions. Since the use of the ^{60}Co teletherapy device at VA Hines is authorized under NRC Byproduct Materials License #12-01087-09, the inspection evaluated possible deviations from NRC requirements.

The misadministration occurred on April 2, 1999. VA Hines had identified the misadministration in which a patient received a 200 cGy treatment from a ^{60}Co teletherapy device, rather than from the intended treatment from a linear accelerator. The result was that a therapeutic radiation treatment from the ^{60}Co teletherapy device was delivered to the wrong patient.

3. Event description

The following chronology of events is presented based on the results of interviews and record reviews made during the reactive inspection.

a. On Friday, April 2, 1999, Patient A, a 74-year-old white female with Graves ophthalmic disease, was scheduled for treatment at 10:30 a.m. on a 6 MV linear accelerator. The prescribed total dose for Patient A was 2000 cGy in 10 fractions of 200 cGy each. On this date, Patient A was to receive her ninth treatment of 200 cGy. The treatment for Patient A involved use of two parallel, opposed fields each lateral at 90 degrees to the vertical direction and directed to treat the eyes for Graves ophthalmic disease. The treatment involved the use of a white, plastic head immobilization mask, appropriately marked with the patient's name.

b. On this same date, (Friday, April 2, 1999), at 10:00 a.m., Patient B, a 66-year-old white female patient with a recurrent Merkel cell cancer of the right forehead and cheek, was scheduled for treatment on the Theratronics ^{60}Co teletherapy device. Patient B was to receive a prescribed dose of 200 cGy delivered with parallel, opposed left anterior field for 0.9 minutes and a right posterior oblique field for 0.76 minutes. This treatment also involved the use of a white, plastic head immobilization mask.

c. Patient A and Patient B have names that sound similar when pronounced by a person not familiar with the names. When the radiation therapist called the name of Patient B for treatment, the wrong patient (in this case, Patient A) responded. The radiation therapist asked Patient A if he had pronounced the name correctly. Patient A responded in the affirmative. The radiation therapist did not compare Patient A to the patient picture in the chart or ask for additional identification.

d. During verbal dialogue between the radiation therapist, operating the ^{60}Co teletherapy device and Patient A, the radiation therapist failed to realize that Patient A was the wrong patient. Appropriate facial photographs of each patient were in the patient charts, as well as their social security numbers. The radiation therapist did not verify the patient's identity using the photographs in the medical chart as prescribed by the VA Hines QMP.

e. The radiation therapist took the patient into the ^{60}Co treatment room and placed the white, plastic head immobilization mask on the patient. The radiation therapist noted to the patient that the mask didn't fit well. The radiation therapist did not consider that the fit of the mask was unusual, since the simulator technologist had just informed him that the patient's tumor had shrunk and that the patient was to be sent over for an immobilization mask refit. The radiation therapist delivered the treatment planned for Patient B to Patient A.

f. At the end of the treatment, during an additional dialogue with the patient and the patient's daughter, the patient's daughter noticed the treatment mask used did not have the correct name. The radiation therapist realized the wrong patient had been treated. The radiation therapist immediately reported the incident to Dr. Abayomi, the attending radiation oncology physician and acting authorized user. The prescribing radiation oncology physician, Dr. Emami, was on holiday at the time of the incident. Dr. Glasgow, Head, Physics Section, was also on holiday at

the time. Loyola University provided radiation therapy support under a contract. Since that Friday was a religious holiday for the Loyola University staff, the radiation therapist was covering for other staff who had previously treated the patients. Hence, the radiation therapist was not familiar with this particular patient.

g. Dr. Abayomi informed the patient on April 2, 1999. Dr. Abayomi decided to wait until Monday, April 5, 1999, to inform other staff, since the Radiation Oncology Service contract staff (Dr. Emami and Dr. Glasgow) was not at the hospital at the time of the misadministration. However, Dr. Abayomi did inform Dr. Emami on Sunday, April 4, 1999, regarding the misadministration.

h. Dr. Glasgow, Head, Physics Section, and Larry Case, RSO, VA Hines, were notified about the misadministration on Monday, April 5, 1999. On that same day, Dr. Glasgow and Dr. Emami confirmed that a misadministration had occurred on April 2, 1999. Upon confirmation that a misadministration had occurred, NRC was notified of the misadministration on April 5, 1999.

i. Additional discussions and counseling occurred between Patient A and the Radiation Oncology Service staff radiation oncology physicians on Monday, Tuesday, and Wednesday, April 5-7, 1999. Patient A received the prescribed treatments to complete her therapy.

4. Interviews with Radiation Oncology Service staff

The following Radiation Oncology Service staff were privately interviewed regarding the misadministration.

Robert Eady	Radiation therapist
Michele Reynolds	Radiation therapist
Kendra Hartman-Lock	Radiation therapist
Nancy Reichard	Radiation therapist

Additional interviews and discussions with Radiation Oncology Service staff included:

Dr. Glen Glasgow	Head, Physics Section, radiation physicist
Dr. Emami	Radiation oncology physician/authorized user
Dr. Abayomi	Radiation oncology physician/acting authorized user
Larry Case	RSO

As a result of the interviews and group discussions, the NHPP concluded that the staff was aware of QMP requirements to verify patient identity. The interviews revealed that staff knew to contact the radiation oncology physician in the event of a misadministration, as defined in the emergency call response list. The misadministration occurred as a result of the radiation therapist failing to follow procedures. Upon discovery of the misadministration, the radiation therapist contacted the radiation oncology physician on duty in a timely manner. Lack of adequate training regarding NRC and NHPP reporting requirements led to additional violations

5. QMP Review

The QMP was reviewed and discussed with Radiation Oncology Service staff and the RSO. Review of treatment records demonstrated that written directives, signed and dated by the authorized user, had been prepared prior to each therapeutic treatment. The written directives contained all required information. Interviews of selected Radiation Oncology Service staff revealed that they were knowledgeable of the QMP requirements for patient identification.

The radiation therapist administering the teletherapy treatments did not verify the patient's identity by at least two methods, as required by the VA Hines QMP, revised July 13, 1994, paragraph 2, Item IIIB. The radiation therapist did not compare the patient to be treated with the photograph of the patient's face prior to initiating treatment, resulting in the misadministration of a treatment to the wrong patient. This was a violation of 10 CFR 35.32(a) and 10 CFR 35.32(2), which require, in part, that the VA Hines establish and maintain a written QMP to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user; and that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

A review of training records demonstrated that VA Hines failed to adequately train all pertinent medical center staff in the QMP. Specifically, training records indicate that Dr. Abayomi did not receive QMP training from the licensee. This is a violation of 10 CFR 35.25(a)(1) and 10 CFR 35.25(a)(2), which require the VA Hines to:

a. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the VA Hines QMP; and

b. Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the VA Hines conditions with respect to the use of byproduct material.

VA Hines completed training for all Radiation Oncology Service staff on the VA Hines QMP and misadministration notification requirements. The training was completed on April 8 and April 22, 1999.

6. Reporting and notification

VA Hines failed to notify the NRC within 24 hours of a teletherapy misadministration. In addition, the NHPP was not notified within 24 hours. This is a violation of 10 CFR 35.33(a)(1), which requires that VA Hines shall notify by telephone the NRC Operations Center no later than the next calendar day after the discovery of the misadministration. Lack of communication and inadequate training are viewed as the root cause of this regulatory violation.

The patient was notified and counseled regarding the misadministration by the authorized user,

Dr. Emami, on April 5, 1999. The patient was advised that the incident was not detrimental to her planned therapy and involved no irradiation of any critical organs. She was also advised that the irradiation of tissue outside the planned target volume was of small consequence other than a small increased long-term risk of cancer in the irradiated tissue in the future. A written report was sent to the patient on May 5, 1999, 15 days beyond NRC requirements. This is a violation of NRC reporting requirements specified in 10 CFR 35.33(a)(4).

7. Dosimetry analysis

Dr. Glasgow reported that the 200 cGy treatment dose on April 2, 1999 resulted in only 20 to 25 cGy delivered to the planned target volume, rather than the prescribed 200 cGy. Additional radiation was delivered outside the planned target volume due to the beam arrangement. However, no critical organs, i.e., the eyes, were in the radiation beam. The additional radiation exposure was determined to pose a potential for only a small increase of cancer incidence over the natural incidence of cancer. The effects of the misadministration were communicated to the patient and the patient's family on April 5, 1999. The patient subsequently received the planned remaining treatment dose in two fractions on April 5, 1999 and April 7, 1999 to complete her therapy.

8. Actions taken to prevent reoccurrence

VA Hines held a QMP training session on April 8 and April 22, 1999 with all appropriate Radiation Oncology Service staff. The training was to review the incident, the root cause, and to stress the need to comply with the established operating procedures. The training session placed emphasis on these items: confirmation of patient identification by (a) asking the patient his/her full first and last names, (b) placement of the full face photographs in the chart immediately adjacent to the dose prescription sheets, and (c) placement of the photographs of the set-up, i.e., immediately adjacent to the dose prescription sheets. Supplemental written correspondence submitted on May 2, 1999, confirmed and detailed the revised procedures to verify patient identity.

9. Exit meeting

The NHPP held an interim exit meeting on April 8, 1999. The final exit meeting was held on April 15, 1999. During the meetings, the findings of the inspection were discussed, as well as VA Hines corrective actions. The following staff attended:

Larry Case, RSO, VA Hines
John Denardo, Director, VA Hines
Dahman Emami, M.D., authorized user, VA Hines
Glen Glasgow, Head, Physics Section, VA Hines
John D. Jones, Senior Radiation Specialist, NRC Region III
Pete Kelly, Alternate RSO, VA Hines
Teresita McCoo, Interim Manager for Radiation Therapy, VA Hines
Cynthia Peterson, Director, Division Nuclear Materials Safety, NRC Region III
Darlene Weisman, Chief, Safety Section, VA Hines

Joseph Wissing, NHPP, Program Manager, Central Service Area
Geoffrey C. Wright, Chief, Materials Inspection Branch, NRC Region III

10. Conclusions

The NHPP has concluded that four violations occurred. The violations are outlined in the attached Notice of Violation (Attachment A).

The NHPP has determined that the root cause of the misadministration was human error, in that the radiation therapist failed to follow patient identification procedures as prescribed in the QMP and the Radiation Oncology Service staff was not adequately familiar with the misadministration reporting regulations. Contributing factors to the misadministration include: similarity of last name pronunciation; failure of the radiation oncology physician to understand the difference between *calendar day* and *work day*; a misadministration occurring on a religious holiday (with coverage by staff members rotated from Loyola University who were not familiar with the specific patient); and, due to the clinic schedule falling behind, the 10:30 a.m. patient responding when the 10:00 a.m. patient's name was called (near the 10:30 a.m. patient's scheduled treatment time).

The NHPP concludes that appropriate actions have been taken to prevent recurrence.

11. VA Hines required action

The NHPP sent a Confirmatory Action Letter to VA Hines on May 5, 1999. VA Hines responded on May 21, 1999. The NHPP has concluded that the VA Hines response adequately addressed the reason for the violations, that the actions taken and planned to correct the violations and prevent recurrence were sufficient, and that the date when full compliance will be achieved is acceptable. Therefore, VA Hines is not required to respond to this report unless the report does not accurately reflect the VA Hines corrective actions or understanding of the violations.

12. Acronyms used

CFR	Code of Federal Regulations
cGy	S. I. unit of radiation dose, centiGray
Edward Hines, Jr. VA Hospital	VA Hines
NHPP	National Health Physics Program
QMP	Quality Management Program
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer

Attachment A to enclosure

Notice of Violation

VA Hines

NRC license 12-01087-09

1. 10 CFR 35.32(a) and 10 CFR 35.32(2) require a licensee to establish and maintain a written QMP such that radiation from byproduct material will be administered as directed by the authorized user; and that, prior to each administration, the patient's identity is verified by more than one method as being the individual named in the written directive.

Violation: Contrary to the above, on April 2, 1999, the radiation therapist did not verify the patient's identity by at least two methods as required by the VA Hines QMP, revised July 13, 1994, paragraph 2, Item IIIB. The result was a misadministration involving treatment of a wrong patient.

This is a Severity Level IV violation.

2. 10 CFR 35.33(a)(1) requires that the licensee shall notify the NRC Operations Center by telephone no later than the next calendar day after the discovery of the misadministration.

Violation: Contrary to the above, VA Hines failed to notify the NRC and the NHPP within 24 hours of a teletherapy misadministration.

This is a Severity Level IV violation.

3. 10 CFR 35.25(a)(1) and 10 CFR 35.25(a)(2) require the licensee to instruct the supervised individual in radiation safety and the licensee's written QMP and require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and QMP, and comply with the regulations and NRC license conditions.

Violation: Contrary to the above, VA Hines failed to adequately train pertinent medical center staff in the QMP. VA Hines did not have evidence that training was performed for all Radiation Oncology Service staff in the QMP and misadministration notification requirements.

This is a Severity Level IV violation.

4. 10 CFR 35.33(a)(4) requires that if the patient is notified verbally, the licensee shall also furnish a written report to the patient within 15 days after discovery of the misadministration.

Violation: Contrary to the above, VA Hines failed to provide a written report to the patient within 15 days after discovery of the misadministration. The VA Hines Radiation Oncology Service staff was aware of the requirement as discussed on April 8, 1999.

This is a Severity Level IV violation.

DEPARTMENT OF
Memorandum
VETERANS AFFAIRS

Date: January 25, 1999

From Director, VHA National Health Physics Program (115HP/NLR)

Subj Radiation Safety Program Inspection

To Director (589/00) VAMC Kansas City

Thru VISN Director (10N15)

1. A routine inspection of the radiation safety program of your facility was conducted, on January 20-21,1999 by Michael C. Simmons, Program Manager, Northwestern Service Area, VHA National Health Physics Program. The attached report includes an overview of the radiation safety program and an assessment of program strengths and weaknesses. This report should be reviewed by all personnel responsible for the radiation safety program and presented at the next meeting of the Radiation Safety Committee.

2. During this inspection, no violations of U.S. Nuclear Regulatory Commission regulations were identified.

3. A customer satisfaction survey form is also enclosed. Timely return of the form will assist us in refining medical center audit methodology and will enable the National Health Physics Program to focus on issues of greatest importance to your facility. Please fax the completed form to (501) 688-1605.

4. Thank you for the courtesy, cooperation, and assistance extended during the inspection. Please call Mr. Simmons at (206) 768-5311 should you have questions regarding the inspection or any other issues involving radiation safety.

E. Lynn McGuire

E. Lynn McGuire

Attachments

Attachment A

INSPECTION OF THE RADIATION SAFETY PROGRAM
KANSAS CITY VA MEDICAL CENTER
JANUARY 25, 1999

1. INTRODUCTION

The Radiation Safety Program of the Veterans Affairs Medical Center in Kansas City, Missouri, was audited by Michael C. Simmons, Program Manager, Northwestern Service Area, VHA National Health Physics Program, on January 20-21, 1999. Mr. Simmons presented his preliminary impressions at a meeting on the afternoon of January 20, attended by Hugh Doran, Medical Center Director; Reginald W. Dusing, M.D., Chairman, Radiation Safety Committee, and Chief, Nuclear Medicine Service; Richard W. Trullinger, Ph.D., Director, DRC; Robert A. Stoker, Industrial Hygienist; and Richard T. Whitman, M.S., Radiation Safety Officer.

2. SCOPE OF AUDIT

The audit consisted of interviews with persons such as the Radiation Safety Officer (RSO), research staff, nuclear medicine technologists, and Chairman, Radiation Safety Committee; a tour of all radioactive materials laboratories with a thorough scrutiny of security. The audit also included a review of the minutes of the Radiation Safety Committee (RSC); a review of the records of the Radiation Safety Office; the observation of work practices and a review of a sample of records in the Nuclear Medicine Service; and the observation of practices and a review of records in the radioactive materials laboratories of Research Service.

3. RADIATION SAFETY PROGRAM, VA MEDICAL CENTER, KANSAS CITY

The Kansas City VA Medical Center conducts a radiation safety program under a U.S. Nuclear Regulatory Commission (NRC) license of limited scope. The medical center is affiliated with Kansas University.

The nuclear medicine program encompasses both diagnostic and therapeutic nuclear medicine. Technetium-99m is obtained as unit dosages from a local commercial radiopharmacy. Lung ventilation studies are performed with xenon-133 gas. Thirty-two radiopharmaceutical administrations requiring written directives were performed during 1998, two of which required patient hospitalization. Brachytherapy is permitted by the license, but has not been performed since the last NRC inspection. External beam radiation therapy is not performed at the medical center.

There are eight laboratories authorized to use radioactive material for biomedical research; two of these laboratories are active with minimal use of radioactive materials.

A medical center's Radiation Safety Committee is responsible for establishing policies regarding and for oversight of the facility's radiation safety program. In a license of limited scope, the NRC delegates some of its powers to the Committee such as personnel radiation exposure control, radiation safety training programs, radioactive materials inventory control, and radioactive waste management. In addition, the NRC expects the Radiation Safety Committee, in lieu of the NRC, to carefully review the qualifications of the users and the procedures for each proposed use of radioactive material and to approve or disapprove the proposed users and experiments prior to NRC review. The Radiation Safety Committee is led by Reginald W. Dusing, M.D., Chief,

Nuclear Medicine Service. A review of the minutes and interviews with Dr. Dusing indicate the RSC meets regulatory expectations for radiation safety program control.

A Radiation Safety Officer (RSO) is responsible for the operational aspects of a radiation safety program, such as ensuring that all required tests and monitoring are performed in a timely fashion; training radioactive materials users and ancillary personnel; providing technical advice regarding the safe use of radioactive material; auditing the research and nuclear medicine laboratories for compliance with regulations of regulatory agencies and the medical center's radiation safety committee; and informing the committee of all incidents and violations. The Radiation Safety Officer is Richard T. Whitman, M.S., who has held this position for about six years. He is assisted by a volunteer who works approximately eight hours per month.

4. FINDINGS AND IMPRESSIONS

A considerable portion of the audit was devoted to Nuclear Medicine. Nuclear Medicine is part of Diagnostic and Rehabilitation Service, which is led by Richard W. Trullinger, Ph.D. The nuclear medicine technologists are well trained, adhere to established radiation safety procedures and demonstrated knowledge of ALARA principles. No significant violations were identified.

All research laboratories using radioactive material were visited and a focused inspection of both work practices and records-keeping was performed in Dr. Festoff's laboratory. A high degree of compliance with regulatory requirements and good radiation safety practices was observed in this laboratory. The security of radioactive materials was very closely reviewed. Security precautions are in place to prevent unauthorized removal of licensed materials. No significant violations were identified.

Mr. Whitman has implemented all required safety monitoring procedures; however, several minor violations could be mitigated by improving the documentation contained in the monitoring reports. Mr. Simmons and Mr. Whitman jointly developed a list of program improvements that, when implemented, will verify regulatory compliance matters and assure continued radiation safety program quality improvement and performance.

Mr. Simmons extends his gratitude for the courteous assistance shown to him during the audit by Drs. Citron and Dusing, Mr. Whitman and Mr. Max Cram, CNMT.

5. ACTION

The list referred to above should be presented to the Radiation Safety Committee for review of actions taken and consideration for use as future radiation safety program performance indicators.

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

Customer Feedback Form

Please help the National Health Physics Program (NHPP) improve its medical center audit program. The NHPP needs your feedback on your recent audit. Rate the NHPP audit and auditor by circling numbers from 1 to 4 to the right of this form. Thank you in advance for assisting the NHPP.

Not at all Satisfied 1 2 3 4 **Extremely Satisfied**

NHPP Auditor Name_____

Initial Contact	The scope of the audit was clearly communicated.	1 2 3 4 or N/A
	The expected duration of the audit was clearly communicated.	1 2 3 4 or N/A
	Previous items of noncompliance were specifically discussed.	1 2 3 4 or N/A
Audit	The scope of the audit was appropriate to your program.	1 2 3 4 or N/A
	Assistance was provided to correct program deficiencies.	1 2 3 4 or N/A
Closing Contact	Preliminary findings of the audit were provided to your satisfaction.	1 2 3 4 or N/A
	Radiation safety related issues were addressed to your satisfaction.	1 2 3 4 or N/A
Auditor	Auditor's knowledge of radiation safety standards satisfied your needs.	1 2 3 4 or N/A
	Auditor was clear when requesting records for review.	1 2 3 4 or N/A
	Auditor was professional during all phases of the audit process.	1 2 3 4 or N/A
	Auditor was courteous during all phases of the audit process.	1 2 3 4 or N/A
	Auditor addressed your questions and concerns to your satisfaction.	1 2 3 4 or N/A
Overall	We were satisfied by the audit service.	1 2 3 4 or N/A

How might the NHPP improve its medical center radiation safety program audit procedures?

Any additional comments or concerns?

DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date November 15, 1999

From Director, VHA National Health Physics Program (115HP/NLR)

Subj Radiation Safety Program Inspection and Notice of Violation - Inspection Report 578-99-I03

To Director (578/00), Edward Hines Jr. VA Hospital, Hines, IL

1. Michael C. Simmons, Program Manager, Northwestern Service Area, VHA National Health Physics Program, performed a reactive inspection of the radiation therapy program at the Edward Hines Jr. VA Hospital, Hines, IL, on September 27, 1999. Mr. John D. Jones, Senior Health Physicist, Nuclear Regulatory Commission, Region III, accompanied Mr. Simmons.

2. The attachments to this memorandum include a narrative of the events surrounding the misadministration, a notice of violation, and the points of agreement concerning the misadministration facts. Based on information developed during the inspection and the information provided during the telephone conference held on October 19, 1999, between NHPP and Hines VA Hospital staff, NHPP has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Attachment B).

3. The National Radiation Safety Committee requires Hines VA Hospital to obtain an external Quality Management Program evaluation that will include all radiotherapy modalities. The objectives of the external review are to identify any generic issues arising from the September 23, 1999 misadministration and to evaluate the overall effectiveness of the Hines VA Hospital Quality Management Program.

4. The Hines VA Hospital is required to respond to the Notice of Violation within 30 days of the date of this memorandum. Specific response instructions are included in Attachment A.

5. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Simmons at (206) 768-5311 if you have any questions regarding the inspection report or other related radiation safety issues.

E. Lynn McGuire

Attachments

cc: Chair, National Radiation Safety Committee
Network Director, VISN 12 (10N12)

REACTIVE INSPECTION
Inspection Report Number 578-99-I03
Edward Hines Jr. VA Hospital, Hines, Illinois
September 27, 1999

1. Introduction

The National Health Physics Program (NHPP) performed a special announced reactive inspection of the radiation therapy program at the Edward Hines Jr. Veterans Affairs (VA) Hospital, Hines, Illinois, on September 27, 1999. Michael C. Simmons, Program Manager, Northwest Service Area, NHPP completed the inspection. Mr. Simmons informed hospital executive staff of the NHPP role in performing the reactive inspection at an entrance briefing, and presented preliminary findings at an exit briefing at the conclusion of the inspection on September 27, 1999.

2. Scope of inspection

This was a reactive announced inspection to review the circumstances, causes, and corrective actions regarding a reported misadministration that occurred on September 23, 1999 at Edward Hines Jr. VA Hospital. The inspection was conducted according to a pre-approved inspection plan. The inspection was coordinated with Mr. John D. Jones, Nuclear Regulatory Commission (NRC), Region III. Mr. Simmons served as the lead investigator at the request of Mr. Jones. The inspection consisted of interviews with Hines VA radiation therapy staff involved with the misadministration event, a review of patient records and records concerning the Quality Management Program (QMP), radiation therapy staff training records, and a performance based review of the computer set-up and operation of the High Dose Rate (HDR) Gamma Med IIi remote afterloading brachytherapy unit.

3. Findings and impressions

a. A QMP was written and implemented in January 1993. The QMP was modified on July 14, 1994, to formalize certain radiation therapy practices and procedures. The QMP describes radiation therapy treatment procedures for each radiation therapy treatment modality. Patient identification and HDR therapy plan verification procedures are described in the QMP; however, exact instructions concerning the HDR treatment plan verification sequence are not specified in the QMP.

b. HDR operators must receive specialized training and complete specific training modules prior to participating in HDR treatments. The radiotherapist and the physicist involved in the misadministration had completed this training during 1998. The radiotherapist and the physicist had never participated in a HDR procedure that included a "step" programming sequence. Radiation therapy staff had received QMP annual refresher training in April 1999.

c. The misadministration occurred as a result of a failure by a radiotherapist to correctly enter the treatment plan parameters that included a 60 mm "step" sequence into the HDR remote afterloading device computer control console. A second failure occurred when a physicist did not verify that the treatment parameters displayed on the computer console were consistent with the instructions contained in the written directive prior to executing the treatment plan. As a consequence, the HDR radioactive source was not positioned correctly at the beginning of the treatment and a therapeutic dose of radiation was delivered to an area that was 60 mm below the intended starting point.

d. The patient was not positively identified by more than one method prior to treatment by the radiotherapist according to a specific procedure contained in the facility QMP.

4. **Notice of Violation (NOV) and required action**

a. Two violations of NRC requirements are listed in the NOV (Attachment B).

b. The Hines VA Hospital must take prompt action to correct the violations listed in the NOV and ensure that they do not reoccur.

c. The Hines VA Hospital must obtain an external program review to determine the effectiveness of the Quality Management Program for all radiotherapy modalities. The objectives are to identify any generic issues arising from the September 23, 1999, misadministration and to evaluate the overall effectiveness of the Hines VA Hospital Quality Management Program. The external program review must be completed within six months of the date of the memorandum transmitting this NOV.

d. The Hines VA Hospital must submit a written statement to the NHPP within 30 days of the date of the memorandum transmitting this NOV. For each violation, the Hospital response must describe the:

(1) Reason for the violation, or, if contested, the basis for disputing the violation or severity level.

(2) Corrective action that has been taken and the results achieved.

(3) Corrective actions that will be taken to avoid further violations.

(4) Date when full compliance will be achieved.

e. Where good cause is shown, the NHPP will consider extending the response time. The Hospital should use the following notice to assist in preparing the response: NRC Information Notice 96-28, "*Suggested Guidance Relating to Development and Implementation of Corrective Action*". This notice was faxed to Larry Case, Hospital RSO, and is also available on the NHPP intranet web site at http://nhpp.med.va.gov.

Notice of Violation
Inspection Report Number 578-99-I03

Edward Hines Jr. VA Hospital, Hines, IL **NRC license #12-01087-07**

1. Quality Management Program (QMP) – 10 CFR 35.32 (a) requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

a. The Edward Hines Jr. VA QMP requires that "...Technologists, dosimetrists, or physicists entering treatment planning parameters into the operating console of a remotely controlled afterloading device will have their computer entries verified and documented by signature or initial, by a second technologist, dosimetrist, or physicist before commencing therapy." The verification procedure used by the radiation therapy staff involves three data comparisons. The procedure does not provide an explanation of the treatment plan data verification sequence to ensure the treatment plan printed on the simulated treatment record agrees with the authorized user instructions contained in the written directive.

b. Violation: Contrary to the above, on September 23, 1999, the treatment plan parameters that were entered into the operating console of the Gamma Med Ili remotely controlled afterloading device were not verified by a second technologist, dosimetrist, or physicist as being consistent with the treatment plan contained in the written directive prior to commencing therapy. As a result, the patient received a brachytherapy radiation dose to the wrong treatment site.

This is a Severity Level IV violation.

2. Patient Identification – 10 CFR 35.32(a)(2) requires that prior to administration, the patient's identity be verified by more than one method as the individual named in the written directive.

a. The Edward Hines Jr. VA Hospital submitted a notification to NRC dated April 28, 1999, to change and improve the patient identification procedure. The amended procedure requires radiation therapy staff to ask the patient to state his/her full name and date of birth. Full-face photographs are present in the front of the patient's chart. The procedure states the radiotherapist will use this photograph to visually confirm that the patient to be treated matches the photograph.

b. Violation: Contrary to the above, the radiotherapist stated this procedure was not followed and consequently the patient was not identified by more than one method.

This is a repeat Severity Level IV violation.

Points of Agreement
Reactive Inspection 578-99-I03
Edward Hines Jr. VA Hospital
October 19, 1999, Teleconference Call

1. Written Directive and Treatment Plan

a. The Radiation Therapy Service follows a particular sequence of events before a patient receives an HDR treatment. First, the physician authorized user must complete the "HDR Brachytherapy Planning and Treatment Record" identifying the patient, specifying the dose, the source distance from the treatment area, and the dose fractions. The information completed by the physician authorized user is the written directive. Other blocks on the "HDR Brachytherapy Planning and Treatment Record" provide for the treatment plan.

b. The medical physicist uses the written directive to create a treatment plan that specifies how the dose will be delivered. The treatment plan is described in the appropriate section of the "HDR Brachytherapy Planning and Treatment Record."

c. A second medical physicist reviews the "HDR Brachytherapy Planning and Treatment Record" to evaluate whether the treatment plan will result in a dose to the treatment area that is consistent with the written directive.

d. The radiotherapist enters the treatment plan data into the HDR computer console by taking that data from the "HDR Brachytherapy Planning and Treatment Record." The treatment plan data displayed on the HDR computer monitor is compared with the treatment plan data contained on the "HDR Brachytherapy Planning and Treatment Record" by a staff member other than the radiotherapist who originally entered the data.

e. A simulated treatment record is printed and compared to the data displayed on the HDR computer monitor by the medical physicist. The treatment is administered after the medical physicist verifies that the treatment plan data that is printed on the simulated treatment record agrees with the treatment plan data that is displayed on the HDR computer monitor. Each step of this process is documented in the blocks or spaces provided on the "HDR Brachytherapy Planning and Treatment Record."

2. Quality Management Program (QMP)

a. The QMP outlines specific steps to follow for a HDR treatment. These steps are used to verify that the treatment plan is consistent with the written directive. As noted above, both the written directive and treatment plan is specified on the "HDR

Brachytherapy Planning and Treatment Record." Two steps to check consistency are as follows:

(1) The treatment plan data displayed on the HDR computer console is compared to the treatment plan data specified on the "HDR Brachytherapy Planning and Treatment Record."

(2) The treatment plan data displayed on the HDR computer console is compared with the treatment plan data printed on the simulated treatment record.

b. The treatment data printed on the simulated treatment record is not compared to the treatment plan data on the "HDR Brachytherapy Planning and Treatment Record." This possible third verification might identify errors that could result in a misadministration.

c. Other possible issues related to the QMP include:

(1) The use of the "HDR Brachytherapy Planning and Treatment Record" is not defined as to when the signatures or initials of the staff member(s) confirming data entry should be made.

(2) The use of the "HDR Brachytherapy Planning and Treatment Record" is not clear since terminology on the "HDR Brachytherapy Planning and Treatment Record" to define treatment parameters is different from the HDR computer software language, ("skip and step" vs. "dist").

(3) The "HDR User Instructions" of February 8, 1995, and the "HDR Brachytherapy Planning and Treatment Record" do not specify which data parameters must be confirmed immediately before the therapy treatment commences. The Hines VA Hospital, as reported by the chief physicist, had assumed that the information would be confirmed as part of normal practice.

(4) The QMP of July 13, 1994, does not specify how the treatment plan data entered into the HDR computer console is verified.

d. The Hines VA Hospital considered the QMP to be adequate, though not consistently followed for this patient. The VA Hospital Hines has drafted a change to the "HDR Brachytherapy Planning and Treatment Record" with signature lines and a two page set of detailed instructions to be followed. These changes will be submitted as a notification of change to the QMP and evaluated separately.

Hines VA Hospital
October 19, 1999 Teleconference Call
Points of Agreement

3. **Event Chronology**

a. The reported misadministration involved the Gamma Med IIi HDR remote afterloading brachytherapy device. The brachytherapy source was approximately 3.8 Ci of ^{192}Ir.

b. The Hines VA event report provides factual information related to the misadministration.

c. The patient was scheduled to undergo a HDR treatment to the esophagus in two fractional doses of 5 Gy each for a total of 10 Gy. The first treatment was to be administered on September 23, 1999.

d. The brachytherapy treatment was in addition to external beam radiation therapy. The physician authorized user prescribed the dose as a written directive on the "HDR Brachytherapy Planning and Treatment Record." A radiograph was used to document the position of dummy (or non-radioactive) sources in the treatment area.

e. The physician authorized user indicated in writing on the scout film that the first treatment site was 60 mm from the end of the catheter containing the dummy sources. The treatment method was referred to as a "skip."

f. The medical physicist noted the dummy source position and developed a treatment plan that specified a 60 mm "skip" distance. The plan provided for full extension of the ^{192}Ir source into the end of the catheter. Upon full extension, the source was to retract 60 mm from the end of the catheter to the first treatment site.

g. The treatment plan was consistent with the written directive approved by the physician authorized user. Both the treatment plan and the written directive were specified on the "HDR Brachytherapy Planning and Treatment Record." The 5 Gy treatment fraction would be delivered using various exposure times ranging from 14 to 25 seconds to a total of eleven treatment sites. The treatment sites were located 10 mm apart. The treatment plan was reviewed and verified as correct by a second medical physicist.

h. The radiotherapist used the treatment plan data on the "HDR Brachytherapy Planning and Treatment Record" to enter the treatment parameters into the HDR computer console. The "skip" portion of the treatment was omitted by mistake during this data entry.

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i. The medical physicist who originally developed the treatment plan verified that the printed record of the simulated treatment parameters agreed with the treatment plan data displayed on the computer monitor.

j. The patient was connected to the HDR unit. Treatment commenced at 12:36 PM on September 23, 1999. After the treatment, the HDR unit printed a post-treatment record of the treatment positions, elapsed times, and distances. This record was attached to the "HDR Brachytherapy Planning and Treatment Record" per standard operating procedure.

k. The medical physicist then signed the "HDR Brachytherapy Planning and Treatment Record" in the space immediately below the statement "To Within 10%, This Treatment Plan Was Delivered, As Planned." The medical physicist stated the signature was entered to indicate that the medical physicist was present during the treatment.

l. Coincident with signature noted above in paragraph 3k, the medical physicist discovered the treatment error while comparing the post-treatment printed record with the treatment plan contained on the "HDR Brachytherapy Planning and Treatment Record." The medical physicist brought the treatment error to the attention of a senior medical physicist. That senior medical physicist had previously reviewed and approved the treatment plan.

m. The treatment error was reported to the chief medical physicist on September 24, 1999, at approximately 8:00 AM. The chief medical physicist contacted the physician authorized user. They jointly reviewed the patient record, concluded that the treatment was not completed as planned, and that a medical misadministration had occurred.

n. The chief medical physicist notified the Radiation Safety Officer at approximately 9:00 AM. The Radiation Safety Officer subsequently notified VA Hines Hospital management, the Nuclear Regulatory Commission, and the NHPP.

o. The referring physician and the patient were notified by telephone later that afternoon.

p. The chief medical physicist confirmed the HDR unit was working correctly by successfully performing a pseudo-treatment with a planned 60 mm skip late in the afternoon of September 24, 1999.

q. The NHPP received a written notification of the misadministration as required by 10 CFR 35.33 on October 4, 1999. The NHPP forwarded the notification to the Nuclear Regulatory Commission on October 5, 1999.

Hines VA Hospital
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Points of Agreement

r. The Radiation Safety Officer indicated to the NHPP that the Hines VA sent the patient written notification on October 8, 1999. This patient notification was provided within 15 days as required by 10 CFR 35.33.

4. **QMP Patient Identification Procedures**

a. The Hines VA modified the QMP on April 28, 1999, to specify methods for patient identification.

b. The modified QMP requires the Radiation Therapy Service staff member administering a treatment to use the full-face patient photographs to visually identify the patient. The staff then confirms that the patient matches the photograph by asking the patient to state their full name – first name and last name, as well as their date of birth.

c. The radiotherapists interviewed by Mr. John D. Jones, NRC, Region III, on October 7, 1999, indicated that they routinely follow the above procedure for patient identification.

d. The radiotherapist involved in the misadministration reported that he did not follow the patient identification procedure in the modified QMP.

5. **Actions Taken**

a. The Hines VA notification report of October 5, 1999, lists initial actions taken to prevent recurrence of the misadministration.

b. The initial actions included:

(1) Modification of the HDR unit instructions to require a skip treatment to be programmed and completed as part of equipment checks on the day of treatment. The radiotherapists complete this equipment check. This change was communicated in writing on October 1, 1999, to staff members. The retraining was given to the therapist involved in the misadministration. Retraining for other staff members is pending.

(2) Adding a similar skip sequence to the monthly HDR quality control procedures. The dosimetrists and medical physicists complete the quality control procedures. The quality control procedure will be completed using the identical method of skip treatment used with patients.

Hines VA Hospital
October 19, 1999 Teleconference Call
Points of Agreement

6. **NHPP Conclusions**

a. A misadministration occurred since the wrong patient site was treated.

b. The HDR unit was properly functioning before and immediately after the misadministration.

c. The misadministration most likely occurred as a result of inadequate verification procedures. The QMP and other Radiation Therapy Service procedures did not ensure that the HDR treatment was administered as directed by a physician authorized user.

d. Factors contributing to the misadministration include:

(1) Human error in failing to enter treatment plan data correctly into the HDR unit.

(2) The various treatment team members inconsistently applied the treatment plan verification procedure. Therefore, there was a lack of a uniform procedural verification method to ensure that staff members always and consistently reviewed and compared the treatment plan data, the data displayed on the HDR computer console, and the treatment plan data printed on the simulated treatment record.

(3) Training - Although the radiotherapist had completed HDR step training and was an experienced staff member, the radiotherapist failed to correctly enter the treatment plan data into the HDR computer indicating a lack of effective training.

(4) Experience - The radiotherapist has seven years of experience. The medical physicist has less than one year of experience. The radiotherapist and the medical physicist had never participated in a HDR administration that included a step treatment.

e. The radiotherapist failed to identify the patient involved in the misadministration before treatment by more than one method as required by 10 CFR 35.32 and the QMP.

f. The notification report did not fully address actions to prevent recurrence such as identifying the root cause for the misadministration.

g. Hines VA Hospital executive management must complete an external program evaluation with emphasis on generic issues related to other therapy treatment modalities.

Hines VA Hospital
October 19, 1999 Teleconference Call
Points of Agreement

h. The NHPP will report the misadministration to the NRSC and the National Patient Safety Improvement Oversight Committee. The NRSC member for radiation oncology will review the medical effects related to the misadministration.

i. Hines VA Hospital must make any appropriate reports related to the misadministration for patient safety or risk management.

VA Medical Center, Hines
Reactive Inspection Plan
September 27, 1999

1. Coordinate with NRC representatives, as needed.

2. Ensure that medical center management understands the NHPP role in performing a reactive inspection separate from any NRC inspection.

3. Interview medical center staff and review records to establish the chronological sequence of events related to the reported misadministration including notification procedures.

4. Evaluate implementation of, and compliance with, the medical center Quality Management Program with emphasis on the HDR unit.

5. Evaluate training records as related to the Quality Management Program with emphasis on the HDR unit.

6. Determine the root cause for the reported misadministration with emphasis on procedural steps for entering an irradiation sequence and any required reviews or checks to be conducted before patient treatment.

7. Review, as needed, any other regulatory compliance, medical physics, or health physics issues related to medical center compliance with their NRC license.

Submitted by: Michael Simmons Date: September 24, 1999

Approved by: E. Lynn McGuire Date: September 24, 1999

VA Medical Center, Hines
Reactive Inspection Plan
September 27, 1999

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Submitted by: Michael Simmons

Approved by: E. Lynn McGuire [redacted]

DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: November 9, 1999

From: Director, VHA National Health Physics Program (115HP/NLR)

Subj: Radiation Safety Program Inspection and Notice of Violation - Inspection Report 578-99-I03

To: Director (578/00), Edward Hines Jr. VA Hospital, Hines, IL

accomp

1. Michael C. Simmons, Program Manager, Northwestern Service Area, VHA National Health Physics Program, performed a reactive inspection of the radiation therapy program at the Edward Hines Jr. VA Hospital, Hines, IL, on September 27, 1999. Mr. Simmons was assisted by Mr. John D. Jones, Senior Health Physicist, Nuclear Regulatory Commission, Region III.

2. The attachments to this memorandum include a narrative of the events surrounding the misadministration, a notice of violation, and the points of agreement concerning the misadministration facts. Based on information developed during the inspection and the information provided during the telephone conference held on October 19, 1999, between NHPP and Hines VA Hospital staff, NHPP has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Attachment B).

3. The National Radiation Safety Committee requires Hines VA Hospital to obtain an external Quality Management Program evaluation that will include all radiotherapy modalities. The objectives of the external review are to identify any generic issues arising from the September 23, 1999 misadministration and to evaluate the overall effectiveness of the Hines VA Hospital Quality Management Program.

4. The Hines VA Hospital is required to respond to the Notice of Violation within 30 days of the date of this memorandum. Specific response instructions are included in Attachment A.

5. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Simmons at (206) 768-5311 if you have any questions regarding the inspection report or other related radiation safety issues.

E. Lynn McGuire

Attachments

cc: Chair, National Radiation Safety Committee
Network Director, VISN 12 (10N12)

REACTIVE INSPECTION
Inspection Report Number 578-99-I03
Edward Hines Jr. VA Hospital, Hines, Illinois
September 27, 1999

1. Introduction

The National Health Physics Program (NHPP) performed a special announced reactive inspection of the radiation therapy program at the Edward Hines Jr. Veterans Affairs (VA) Hospital, Hines, Illinois, on September 27, 1999. Michael C. Simmons, Program Manager, Northwest Service Area, NHPP completed the inspection. Mr. Simmons informed hospital executive staff of the NHPP role in performing the reactive inspection at an entrance briefing, and presented preliminary findings at an exit briefing at the conclusion of the inspection on September 27, 1999.

2. Scope of inspection

This was a reactive announced inspection to review the circumstances, causes, and corrective actions regarding a reported misadministration that occurred on September 23, 1999 at Edward Hines Jr. VA Hospital. The inspection was conducted according to a pre-approved inspection plan. The inspection was coordinated with Mr. John D. Jones, Nuclear Regulatory Commission (NRC), Region III. Mr. Simmons served as the lead investigator at the request of Mr. Jones. The inspection consisted of interviews with Hines VA radiation therapy staff involved with the misadministration event, a review of patient records and records concerning the Quality Management Program (QMP), radiation therapy staff training records, and a performance based review of the computer set-up and operation of the High Dose Rate (HDR) Gamma Med IIi remote afterloading brachytherapy unit.

3. Findings and impressions

a. A QMP was written and implemented in January 1993. The QMP was modified on July 14, 1994 to formalize certain radiation therapy practices and procedures. The QMP describes radiation therapy treatment procedures for each radiation therapy treatment modality. Patient identification and HDR therapy plan verification procedures are described in the QMP; however, exact instructions concerning the HDR treatment plan verification sequence are not specified in the QMP.

b. HDR operators must receive specialized training and complete specific training modules prior to participating in HDR treatments. The radiotherapist and the physicist involved in the misadministration had completed this training during 1998. The radiotherapist and the physicist had never participated in a HDR procedure that included a "step" programming sequence. Radiation therapy staff

had received QMP annual refresher training in April 1999.

c. The misadministration occurred as a result of a failure by a radiotherapist to correctly enter the treatment plan parameters that included a 60 mm "step" sequence into the HDR remote afterloading device computer control console. A second failure occurred when a physicist did not verify that the treatment parameters displayed on the computer console were consistent with the instructions contained in the written directive prior to executing the treatment plan. As a consequence, the HDR radioactive source was not positioned correctly at the beginning of the treatment and a therapeutic dose of radiation was delivered to an area that was 60 mm below the intended starting point.

d. The patient was not positively identified by more than one method prior to treatment by the radiotherapist according to a specific procedure contained in the facility QMP.

4. **Notice of Violation (NOV) and required action**

a. Two violations of NRC requirements are listed in the NOV (Attachment B).

b. The Hines VA Hospital must take prompt action to correct the violations listed in the NOV and ensure that they do not reoccur.

c. The Hines VA Hospital must obtain an external program review to determine the effectiveness of the Quality Management Program for all radiotherapy modalities. The objectives are to identify any generic issues arising from the September 23, 1999, misadministration and to evaluate the overall effectiveness of the Hines VA Hospital Quality Management Program. The external program review must be completed within six months of the date of the memorandum transmitting this NOV.

d. The Hines VA Hospital must submit a written statement to the NHPP within 30 days of the date of the memorandum transmitting this NOV. For each violation, the Hospital response must describe the:

(1) Reason for the violation, or, if contested, the basis for disputing the violation or severity level.

(2) Corrective action that has been taken and the results achieved.

(3) Corrective actions that will be taken to avoid further violations.

(4) Date when full compliance will be achieved.

e. Where good cause is shown, the NHPP will consider extending the response time. The Hospital should use the following notice to assist in preparing the response: NRC Information Notice 96-28, "*Suggested Guidance Relating to Development and Implementation of Corrective Action*". This notice was faxed to Larry Case, Hospital RSO, and is also available on the NHPP web site at http://nhpp.med.va.gov.

Intranet

Notice of Violation
Inspection Report Number 578-99-I03

Edward Hines Jr. VA Hospital, Hines, IL **NRC license #12-01087-07**

1. Quality Management Program (QMP) – 10 CFR 35.32 (a) requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

a. The Edward Hines Jr. VA QMP requires that "...Technologists, dosimetrists, or physicists entering treatment planning parameters into the operating console of a remotely controlled afterloading device will have their computer entries verified and documented by signature or initial, by a second technologist, dosimetrist, or physicist before commencing therapy." The verification procedure used by the radiation therapy staff involves three data comparisons. The procedure does not provide an explanation of the treatment plan data verification sequence to ensure the treatment plan printed on the simulated treatment record agrees with the authorized user instructions contained in the written directive.

b. Violation: Contrary to the above, on September 23, 1999, the treatment plan parameters that were entered into the operating console of the Gamma Med IIi remotely controlled afterloading device were not verified by a second technologist, dosimetrist, or physicist as being consistent with the treatment plan contained in the written directive prior to commencing therapy. As a result, the patient received a brachytherapy radiation dose to the wrong treatment site.

This is a Severity Level IV violation.

2. Patient Identification – 10 CFR 35.32(a)(2) requires that prior to administration, the patient's identity be verified by more than one method as the individual named in the written directive.

a. The Edward Hines Jr. VA Hospital submitted a notification to NRC dated April 28, 1999, to change and improve the patient identification procedure. The amended procedure requires radiation therapy staff to ask the patient to state his/her full name and date of birth. Full-face photographs are present in the front of the patient's chart. The procedure states the radiotherapist will use this photograph to visually confirm that the patient to be treated matches the photograph.

b. Violation: Contrary to the above, the radiotherapist stated this procedure was not followed and consequently the patient was not identified by more than one method.

This is a repeat Severity Level IV violation.

Points of Agreement
Reactive Inspection 578-99-I03
Edward Hines Jr. VA Hospital
October 19, 1999, Teleconference Call

1. **Written Directive and Treatment Plan**

a. The Radiation Therapy Service follows a particular sequence of events before a patient receives an HDR treatment. First, the physician authorized user must complete the "HDR Brachytherapy Planning and Treatment Record" identifying the patient, specifying the dose, the source distance from the treatment area, and the dose fractions. The information completed by the physician authorized user is the written directive. Other blocks on the "HDR Brachytherapy Planning and Treatment Record" provide for the treatment plan.

b. The medical physicist uses the written directive to create a treatment plan that specifies how the dose will be delivered. The treatment plan is described in the appropriate section of the "HDR Brachytherapy Planning and Treatment Record."

c. A second medical physicist reviews the "HDR Brachytherapy Planning and Treatment Record" to evaluate whether the treatment plan will result in a dose to the treatment area that is consistent with the written directive.

d. The radiotherapist enters the treatment plan data into the HDR computer console by taking that data from the "HDR Brachytherapy Planning and Treatment Record." The treatment plan data displayed on the HDR computer monitor is compared with the treatment plan data contained on the "HDR Brachytherapy Planning and Treatment Record" by a staff member other than the radiotherapist who originally entered the data.

e. A simulated treatment record is printed and compared to the data displayed on the HDR computer monitor by the medical physicist. The treatment is administered after the medical physicist verifies that the treatment plan data that is printed on the simulated treatment record agrees with the treatment plan data that is displayed on the HDR computer monitor. Each step of this process is documented in the blocks or spaces provided on the "HDR Brachytherapy Planning and Treatment Record."

2. **Quality Management Program (QMP)**

a. The QMP outlines specific steps to follow for a HDR treatment. These steps are used to verify that the treatment plan is consistent with the written directive. As noted above, both the written directive and treatment plan is specified on the "HDR

Brachytherapy Planning and Treatment Record." Two steps to check consistency are as follows:

(1) The treatment plan data displayed on the HDR computer console is compared to the treatment plan data specified on the "HDR Brachytherapy Planning and Treatment Record."

(2) The treatment plan data displayed on the HDR computer console is compared with the treatment plan data printed on the simulated treatment record.

b. The treatment data printed on the simulated treatment record is not compared to the treatment plan data on the "HDR Brachytherapy Planning and Treatment Record." This possible third verification might identify errors that could result in a misadministration.

c. Other possible issues related to the QMP include:

(1) The use of the "HDR Brachytherapy Planning and Treatment Record" is not defined as to when the signatures or initials of the staff member(s) confirming data entry should be made.

(2) The use of the "HDR Brachytherapy Planning and Treatment Record" is not clear since terminology on the "HDR Brachytherapy Planning and Treatment Record" to define treatment parameters is different from the HDR computer software language, ("skip and step" vs. "dist").

(3) The "HDR User Instructions" of February 8, 1995, and the "HDR Brachytherapy Planning and Treatment Record" do not specify which data parameters must be confirmed immediately before the therapy treatment commences. The Hines VA Hospital, as reported by the chief physicist, had assumed that the information would be confirmed as part of normal practice.

(4) The QMP of July 13, 1994, does not specify how the treatment plan data entered into the HDR computer console is verified.

d. The Hines VA Hospital considered the QMP to be adequate, though not consistently followed for this patient. The VA Hospital Hines has drafted a change to the "HDR Brachytherapy Planning and Treatment Record" with signature lines and a two page set of detailed instructions to be followed. These changes will be submitted as a notification of change to the QMP and evaluated separately.

C-3

Hines VA Hospital
October 19, 1999 Teleconference Call
Points of Agreement

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a. The reported misadministration involved the Gamma Med IIi HDR remote afterloading brachytherapy device. The brachytherapy source was approximately 3.8 Ci of ^{192}Ir.

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c. The patient was scheduled to undergo a HDR treatment to the esophagus in two fractional doses of 5 Gy each for a total of 10 Gy. The first treatment was to be administered on September 23, 1999.

d. The brachytherapy treatment was in addition to external beam radiation therapy. The physician authorized user prescribed the dose as a written directive on the "HDR Brachytherapy Planning and Treatment Record." A radiograph was used to document the position of dummy (or non-radioactive) sources in the treatment area.

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h. The radiotherapist used the treatment plan data on the "HDR Brachytherapy Planning and Treatment Record" to enter the treatment parameters into the HDR computer console. The "skip" portion of the treatment was omitted by mistake during this data entry.

Hines VA Hospital
October 19, 1999 Teleconference Call
Points of Agreement

i. The medical physicist who originally developed the treatment plan verified that the printed record of the simulated treatment parameters agreed with the treatment plan data displayed on the computer monitor.

j. The patient was connected to the HDR unit. Treatment commenced at 12:36 PM on September 23, 1999. After the treatment, the HDR unit printed a post-treatment record of the treatment positions, elapsed times, and distances. This record was attached to the "HDR Brachytherapy Planning and Treatment Record" per standard operating procedure.

k. The medical physicist then signed the "HDR Brachytherapy Planning and Treatment Record" in the space immediately below the statement "To Within 10%, This Treatment Plan Was Delivered, As Planned." The medical physicist stated the signature was entered to indicate that the medical physicist was present during the treatment.

l. Coincident with signature noted above in paragraph 3k, the medical physicist discovered the treatment error while comparing the post-treatment printed record with the treatment plan contained on the "HDR Brachytherapy Planning and Treatment Record." The medical physicist brought the treatment error to the attention of a senior medical physicist. That senior medical physicist had previously reviewed and approved the treatment plan.

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Hines VA Hospital
October 19, 1999 Teleconference Call
Points of Agreement

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c. The radiotherapists interviewed by Mr. John D. Jones, NRC, Region III, on October 7, 1999, indicated that they routinely follow the above procedure for patient identification.

d. The radiotherapist involved in the misadministration reported that he did not follow the patient identification procedure in the modified QMP.

5. **Actions Taken**

a. The Hines VA notification report of October 5, 1999, lists initial actions taken to prevent recurrence of the misadministration.

b. The initial actions included:

(1) Modification of the HDR unit instructions to require a skip treatment to be programmed and completed as part of equipment checks on the day of treatment. The radiotherapists complete this equipment check. This change was communicated in writing on October 1, 1999, to staff members. The retraining was given to the therapist involved in the misadministration. Retraining for other staff members is pending.

(2) Adding a similar skip sequence to the monthly HDR quality control procedures. The dosimetrists and medical physicists complete the quality control procedures. The quality control procedure will be completed using the identical method of skip treatment used with patients.

Hines VA Hospital
October 19, 1999 Teleconference Call
Points of Agreement

6. **NHPP Conclusions**

a. A misadministration occurred since the wrong patient site was treated.

b. The HDR unit was properly functioning before and immediately after the misadministration.

c. The misadministration most likely occurred as a result of inadequate verification procedures. The QMP and other Radiation Therapy Service procedures did not ensure that the HDR treatment was administered as directed by a physician authorized user.

d. Factors contributing to the misadministration include:

(1) Human error in failing to enter treatment plan data correctly into the HDR unit.

(2) The various treatment team members inconsistently applied the treatment plan verification procedure. Therefore, there was a lack of a uniform procedural verification method to ensure that staff members always and consistently reviewed and compared the treatment plan data, the data displayed on the HDR computer console, and the treatment plan data printed on the simulated treatment record.

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e. The radiotherapist failed to identify the patient involved in the misadministration before treatment by more than one method as required by 10 CFR 35.32 and the QMP.

f. The notification report did not fully address actions to prevent recurrence such as identifying the root cause for the misadministration.

g. Hines VA Hospital executive management must ~~consider~~ complete~~ing~~ an external program evaluation with emphasis on generic issues related to other therapy treatment modalities.

Hines VA Hospital
October 19, 1999 Teleconference Call
Points of Agreement

h. The NHPP will report the misadministration to the NRSC and the National Patient Safety Improvement Oversight Committee. The NRSC member for radiation oncology will review the medical effects related to the misadministration.

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