

DVA-VHA MML 10 CFR 2.206 PETITION
REVISED VERSION

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 I request that the master license, which the Veterans Administration (VA) has applied for, be denied/rescinded. I have revised my previous petition to include more specific information as requested by the NRC contact person. 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 Health 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 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 their safety performance, nor that significant action will be taken for a safety failure. In fact, there was a news article showing maggots 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 Health 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:

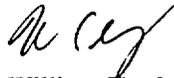
aa. They are banned from certain VA hospitals and not allowed to perform inspections by NHPP's own management. Conversations with the previous RSO at VA Hines indicated that some inspector's citations were so outlandish that the Regional VA Director (VISN 12) banned the inspector from returning. NHPP 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



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 15, 2000

Richard S. Citron, Director
Department of Veterans Affairs
Chicago Health Care Systems
Lakeside Division
333 East Huron Street
Chicago, IL 60611

SUBJECT: NRC INSPECTION

Dear Mr. Citron:

This refers to the inspection conducted on August 1-2, 2000, at the V.A. Lakeside Hospital. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you and members of your staff by telephone on August 4, 2000.

During the inspection period, your conduct of licensed activities was generally characterized by safety-conscious health physics operations and sound inventory controls. While no violations of regulatory requirements were identified during this inspection, we are concerned about the apparent lack of effective corrective actions associate with contamination events and conduct in radiologically controlled areas. Specifically, between July 9, 1999, and May 18, 2000, your Radiation Safety Officer (RSO) identified multiple radioactive contamination events in the nuclear medicine hot lab, treadmill room and hallway. Between May 10 and 17, 2000 alone, the department had four spills involving radioactive material; in one instance two spills occurred with contamination great enough that the cardiac stress lab had to be closed for 3 days. In addition to the contamination events, between September 30, 1999 and June 18, 2000, the RSO identified food, drink, and dishes in the nuclear medicine hot lab and the imaging rooms on 14 occasions.

We are concerned that while significant issues are being properly identified, corrective actions appear not to be effective in preventing their recurrence. We understand that the issues have been brought before V.A. Lakeside's radiation safety committee; however, the problems have continued. Because an effective corrective action program is very important in maintaining a quality radiation safety program, we request that you address our concerns within 30 days from the date of this letter. Your response should be specific and should reflect an assessment of current radiation safety activities, staff responsibilities, and the causal factors of the areas of concern. In addition, we have contacted the V.A. National Health Physics Program office and discussed our concerns with its management. It is our understanding that the V.A. National Health Physics Program office will review these issues with you at a later date.

EXH10

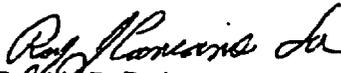
R. Citron

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and your response to this letter will be available electronically for public inspection in the NRC Public Document Room or from the *Publicly Available Records (PARS) component of the NRC's document system (ADAMS)*. ADAMS is accessible from the NRC Web site at <http://www/nrc.gov/NRC/ADAMS/index/html> (the Public Electronic Reading Room).

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

Sincerely,


Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

Docket No. 030-01435
License No. 12-02642-06

cc: William C. Salsbury, C.H.P.
Radiation Safety Officer

 E. Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
2200 Fort Roots Drive
North Little Rock, AR 72114

/ Salsbury

From: Rooney, Richard J.
Sent: Monday, April 23, 2001 7:26 AM
To: Chandramouli, B .; Hughes, Ronald J.; Kukreja, Subhash C.; Salsbury, William, Charles
Cc: Barch, David H.; Desai, Prakash N.; Schmitt, Brian P.; Citron, Richard
Subject: RE: Therapy doses

Ron, please add this to the list of justification for action.

-----Original Message-----

From: Chandramouli, B .
Sent: Monday, April 23, 2001 9:16 AM
To: Hughes, Ronald J.; Kukreja, Subhash C.; Salsbury, William, Charles
Cc: Barch, David H.; Desai, Prakash N.; Schmitt, Brian P.; Citron, Richard, Rooney, Richard J.
Subject: RE: Therapy doses

Please open the attached document
(NM service response to Mr.Hughes request, amended and expanded)
<< File: therapy3.doc >>

-----Original Message-----

From: Hughes, Ronald J
Sent: Friday, April 20, 2001 12:46 PM
To: Chandramouli, B .; Kukreja, Subhash C.; Salsbury, William, Charles
Cc: Barch, David H.; Desai, Prakash N.; Schmitt, Brian P.; Citron, Richard; Rooney, Richard J.
Subject: RE: Therapy doses
Importance: High

Dr. Desai, Dr. Schmitt, I am requesting you clinical input in order to resolve this situation discussed in this e-mail. As supervisor of the RSO, I would like to see this issue resolved as soon as possible, however, I am not a subject matter expert and can not render an opinion or decision. As a manager, I believe that this is a serious matter which require you clinical input. This matter has direct implications on patient care. I also believe that this situation should be resolve ASAP in order to minimize the impact on patient care.

Chuck, please provide a summary of your rational/justification for your recent decision concerning the ordering of Therapy doses

Dr. Kukreja, please summarize the impact of this decision on patient care and the day to day operation of Nuclear Medicine.

-----Original Message-----

From: Chandramouli, B .
Sent: Thursday, April 19, 2001 12:20 PM
To: Kukreja, Subhash C.; Salsbury, William, Charles
Cc: Hughes, Ronald J.; Barch, David H.
Subject: RE: Therapy doses

There seems to be no point in continuing this e-mail discussion. I think that RSO is confusing high dose therapy and regular outpatient I-131 therapy. I will not change anything until after the external review is completed. Mr Joe Wissing said that this matter should be considered by the RSC before any decision is made. The RSO cannot overide the RSC's decision

-----Original Message-----

From: Kukreja, Subhash C.
Sent: Thursday, April 19, 2001 12:15 PM
To: Salsbury, William, Charles; Chandramouli, B .
Cc: Hughes, Ronald J.; Barch, David H
Subject: RE: Therapy doses

Chuck, your comments regarding " the drop of a hat" are totally inappropriate.The therapy is

proscribed as needed in the best interest of the patient. You have not addressed my questions in my two previous messages to you(what was the problem that arose that prompted you to make this decision and what do we do when you are not here?).

We are spending time on this when there are basic things that need to be taken care of in the radiation safety program

-----Original Message-----

From: Salisbury, William, Charles
Sent: Thursday, April 19, 2001 11:06 AM
To: Chandramouli, B .
Cc: Hughes, Ronald J.; Kukreja, Subhash C.; Barch, David H.
Subject: RE: Therapy doses

The ordering process is at the discursion of the RSO. Since I-131 in multimilliCurie quantities can pose a significant contamination problem, and since Dr Kukreja wants to be able to perform therapies at the drop of a hat, I need to make sure that VACHCS is prepared for the therapy. Therefore, I need to insist on the therapy orders being signed off on by the RSO or someone in the RSO's office

How many therapies a year are we talking about

Note: since this is a specifically delegated responsibility of the-NRC, decisions of the RSC without the concurrence of the RSO will violate the NRC license conditions.

-----Original Message-----

From: Chandramouli, B .
Sent: Thursday, April 19, 2001 10:16 AM
To: Salisbury, William, Charles
Cc: Kukreja, Subhash C.; Barch, David H.; Hughes, Ronald J.
Subject: RE: Therapy doses
Importance: High

You have not given adequate explanation (rationale new approval requirement). I don't know what you mean by _And didn't I remove part of that blanket approval?: please explain.

I will bring this matter up at the LS RSC meeting.

-----Original Message-----

From: Salisbury, William, Charles
Sent: Wednesday, April 18, 2001 7:44 AM
To: Chandramouli, B .; Hughes, Ronald J.
Subject: RE Therapy doses

The RSO has already given blanket approval (list of doses etc authorized by you)

And didn't I remove part of that blanket approval?

This new approval you are proposing will disrupt ordering the therapy doses. Therapy dose is purely a clinical decision

This authority is SPECIFICALLY delegated to the RSO by the NRC. This is not a clinical decision. If you want a different policy you'll have to get NRC approval. Note LS did 2 therapies in 2000.

I will wait for approval by the RSC and clarification from NHK No changes will be made until then

NHK-not sure what this is RSC in this case is not part of the process, this authority is held directly by the RSO.

Signature approval of the RSO on all therapy doses is now required Note this

applies to both sites.

From: Chandramouli, B .
Sent: Monday, April 16, 2001 8:40 AM
To: Kukreja, Subhash C.; Salisbury, William, Charles; Kamaria, Omprakash B.; Hughes, Ronald J.
Subject: RE: Therapy doses

The RSO has already given blanket approval (list of doses etc authorized by you). This new approval you are proposing will disrupt ordering the therapy doses. Therapy dose is purely a clinical decision. I will wait for approval by the RSC and clarification from NHK. No changes will be made until then.

-----Original Message-----

From: Kukreja, Subhash C.
Sent: Monday, April 16, 2001 8:31 AM
To: Salisbury, William, Charles
Cc: Chandramouli, B .; Kamaria, Omprakash B ; Hughes, Ronald J
Subject: RE: Therapy doses

o Chuck, Please discuss this with Mouli and Om and settle this . Are you saying that you are designating Nuclear Medicine to order certain isotopes and not others. If so let us have that in writing. You are saying that you want to approve all therapy doses . What if you are not here, what if you don't read your email? How would this documentation occur? What purpose are we doing this for? For the Nuclear Medicine not to be able to order the therapy doses without the RSO approval we might be creating a unique situation. Let us discuss this at the next RSC.

-----Original Message-----

From: Salisbury, William, Charles
Sent: Monday, April 16, 2001 7:50 AM
To: Kukreja, Subhash C.
Cc: Chandramouli, B .; Kamaria, Omprakash B.; Hughes, Ronald J.
Subject: RE: Therapy doses

Per the Radiation Safety Manual WS, Ordering and Receiving Radioactive Materials (NM)

1. All orders for radioactive materials must be approved by the Radiation Safety Officer (RSO) or his designee....

Chuck

-----Original Message-----

From: Kukreja, Subhash C.
Sent: Friday, April 13, 2001 8:13 AM
To: Salisbury, William, Charles
Cc: Chandramouli, B .; Kamaria, Omprakash B.; Hughes, Ronald J.
Subject: RE: Therapy doses

What are the written policies and procedures on authorizing the purchase of byproduct materials?

-----Original Message-----

From: Salisbury, William, Charles
Sent: Thursday, April 12, 2001 4:06 PM
To: Kukreja, Subhash C.
Cc: Chandramouli, B .; Kamaria, Omprakash B.; Hughes, Ronald J.; Salisbury, William, Charles
Subject: Therapy doses

Per your request:

Sec. 35.21 Radiation Safety Officer. (a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. (b) The Radiation Safety Officer shall: (1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice, and implement corrective actions as necessary; (2) Establish, collect in one binder or file, and implement written policy and procedures for: (i) Authorizing the purchase of byproduct material; (ii) Receiving and opening packages of byproduct material; (iii) Storing byproduct material; (iv) Keeping an inventory record of byproduct material, (v) Using byproduct material safely; (vi) Taking emergency action if control of byproduct material is lost; (vii) Performing periodic radiation surveys; (viii) Performing checks of survey instruments and other safety equipment; (ix) Disposing of byproduct material; (x) Training personnel who work in or frequent areas where byproduct material is used or stored; (xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations. (3) Brief management once each year on the byproduct material program; (4) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure, (5) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence; (6) For medical use not at a medical institution, approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management; and (7) For medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

Sec. 35.22 Radiation Safety Committee. Each medical institution licensee shall establish a Radiation Safety [[Page 541]] Committee to oversee the use of byproduct material. (a) Each Committee must meet the following administrative requirements. (1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of

management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate. (2) The Committee must meet at least quarterly. (3) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative. (4) The minutes of each Radiation Safety Committee meeting must include: (i) The date of the meeting; (ii) Members present; (iii) Members absent; (iv) Summary of deliberations and discussions; (v) Recommended actions and the numerical results of all ballots; and (vi) ALARA program reviews described in Sec. 35.20(c). (5) The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license. (b) To oversee the use of licensed material, the Committee must: (1) Review recommendations on ways to maintain individual and collective doses ALARA; (2)(i) Review, on the basis of safety and with regard to the training and experience standards in subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; or (ii) Review, pursuant to Sec. 35.13 (b)(1) through (b)(4), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist; (3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under Sec. 35.31 of this part; (4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with byproduct material; (5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and (6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

-----Original Message-----

From: Salsbury, William, Charles
Sent: Wednesday, April 04, 2001 1:42 PM
To: Kamana, Omprakash B.
Cc: Chandramouli, B.
Subject: Therapy doses

Please note that all therapy doses need to be counter signed by me before the dose is ordered.

Chuck Salsbury, RSO

APPLICANT'S RESPONSE TO THE REVISED
DVA-VHA MML 10 CFR 2.206 PETITION

From: "McGuire, Lynn" <Lynn.McGuire@med.va.gov>
To: "Ujagar S. Bhachu (E-mail)" <usb@nrc.gov>
Date: 2/19/03 2:28PM
Subject: FW: response to second petition

Ujagar,

This provides a more detailed NHPP response to the 2nd petition. We request that our original response be included and considered as well, as it contains some more global responses.

Hard copies to be sent this afternoon.

-Lynn

<<response to second petition2.doc>>
<<response to second petition.doc>>

CC: "Gary Williams (E-mail)" <Gary.Williams3@med.va.gov>

Specific comments for undated petition under 10 CFR 2.206

1. Petition paragraph 1aAa.

- a. The petition statements refer to the results of a Nuclear Regulatory Commission (NRC) inspection.
- b. Contrary to the petition statement, the NRC inspection report of September 15, 2000, does not specifically identify executive management actions as an issue. The NRC did not cite the licensee for any violations.
- c. The NRC inspection record did have comments and statements related to a lack of executive management oversight.
- d. A subsequent National Health Physics Program (NHPP) inspection cited the licensee for a Severity Level III problem. One underlying violation was that "the medical center failed to provide management oversight..."

2. Petition paragraph 1aAb.

- a. The petition statements refer to the status of various VA Radiation Safety Officers.
- b. Contrary to the petition statement, the current Indianapolis Radiation Safety Officer is a long-term employee and held the position before formation of the NHPP.
- c. Contrary to the petition statement, the current St. Louis Radiation Safety Officer is a long-term employee and held the position before formation of the NHPP.
- d. Contrary to the petition statement, the NRC had purview for the regulatory actions related to Philadelphia. The NHPP did not have a specific role other than to benchmark to NRC actions.
- e. The NHPP has not received any radiation safety concerns or allegations related to the stated Radiation Safety Officer terminations or situations.
- f. The turnover for licensees who have full time VA Radiation Safety Officer positions is approximately 4% annually, as determined from a review of calendar years 2000 through 2003.
- g. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

3. Petition paragraph 1aAc.

- a. The petition statements refer to the VA communication policy for licensees.

b. Contrary to the petition statement, the VA communication policy for licensees is consistent with applicable regulations. The NRC required the VA to establish the policy to demonstrate a centrally controlled radiation control program and to demonstrate readiness for a master materials license.

c. The VA communication policy does not preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under 10 CFR 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.

d. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

4. Petition paragraph 1aAd.

a. The petition statements refer to the National Radiation Safety Committee.

b. The National Radiation Safety Committee has nine physician members out of the total membership of 15. The committee members represent the various disciplines and functional areas as are appropriate for executive management oversight of a regulatory compliance program. The NRC approved the committee membership.

c. Contrary to the petition statement, the National Radiation Safety Committee is proactive in taking actions to ensure regulatory compliance and direct NHPP efforts. The committee members who are part of the VA central office routinely provide oversight for VA activities within their functional areas.

d. Contrary to the petition statement, the committee member who represents the field Radiation Safety Officers has complete and frequent opportunity to raise issues. This committee member is routinely included in the annual program assessment process to ensure the Radiation Safety Officer perspective is considered in NHPP efforts. Also, the Radiation Safety Center for Inquiry (RSCI), a VA group that was formed to support the Radiation Safety Officer community consultation needs is represented on the National Radiation Safety Committee.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

5. Petition paragraph 1aAe.

a. The petition statements refer to federal budget issues and the Joint Committee on Accreditation of Healthcare Organizations (JCAHO) "mock" results for one licensee.

b. The NHPP does not address budget issues, though appreciates the usual federal

budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. The VA JCAHO scores, which include an evaluation of safety, are consistently higher than those of the private sector. In 2002, the VA average score was 95, nearly two points higher than the average for the private sector. The most recent score, in 2000, for the licensee where the petitioner was the Radiation Safety Officer was 96.

d. The petition does not identify any adverse outcomes or program deficiencies that might be associated with the "mock" score and that require a response. The JCAHO hospital accreditation system is nationally recognized by the health care industry as a major, independent review of health care. The JCAHO process includes an evaluation of safety programs. Hospitals often complete a "mock" JCAHO inspection to help prepare for upcoming formal JCAHO inspections. The score for a "mock" JCAHO inspection helps identify areas for improvement and includes a consolidated score for a range of clinical care, training, facility, and safety issues.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

6. Petition paragraph 1aAf.

a. The petition statements refer to turnover for executive management.

b. The NHPP does not provide staffing recommendations to licensees. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

7. Petition paragraph 1aAg.

a. The petition statements refer to federal budget issues.

b. The NHPP does not address budget issues, though appreciates the usual federal budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

8. Petition paragraph 1aAh.

- a. The petition statements refer to licensee budget issues.
- b. The NHPP does not address budget issues, though appreciates the usual federal budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.
- c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

9. Petition paragraph 1aAi.

- a. The petition statements refer to the status of VA safety programs, Radiation Safety Officer viewpoints, and how budgeting is completed for one organization.
- b. Contrary to the petition statement, the VA is quite proactive, and often recognized as a national leader, in patient safety initiatives and achievements. The VA commitment of resources and staff to patient safety including the master materials license effort belies the contrary statements in the petition.
- c. The NHPP completes permitting actions and inspections consistent with the master materials license application and NRC guidelines while providing focused information to assist permittees and Radiation Safety Officers. The Radiation Safety Officers are likely to have a diversity of opinions about the NHPP, the master materials license, and the relative success of each.
- d. The NHPP does not address budget issues, though appreciates the usual federal budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.
- e. Contrary to the petition statement, a conflict of interest is not apparent for a senior manager at a field facility both to make appropriate staffing and budgeting decisions at the field level and to represent VA-wide diagnostic radiology issues on the National Radiation Safety Committee.
- f. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

10. Petition paragraph 1aAj.

- a. The petition statements refer to the organizational structure for licensees and supervision for the Radiation Safety Officer.
- b. The NHPP does not provide staffing or organizational structure recommendations to

the licensees, other than those that are consistent with the organizational structure issues outlined in NUREG-1556, Volume 11. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

11. Petition paragraph 1aAk.

a. The petition statements refer to performance ratings for executive managers.

b. Contrary to the petition statement, VA Facility Director Performance Plans have under "Core Competencies" the comprehensive task of "Organizational Stewardship" with a specific task as "Operates an effective safety and occupational health program that meets VA, JCAHO, and OSHA standards."

c. Contrary to the petition statements, a Department of Labor occupational safety and health program evaluation of the VA concluded that "...management at all levels of the VHA participate in significant aspects of the safety and health program and are held accountable for supporting the goals of the program and promoting efforts to achieve expected results."

c. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

12. Petition paragraph 1b.

a. The petition statements refer to an ongoing Merit System Review Board case.

b. The NHPP does not have comments for an ongoing Merit System Review Board case.

c. The NHPP has not received any radiation safety concerns or allegations related to such a personnel action.

13. Petition paragraph 1cAa and 1cAaa through 1cAad.

a. The petition statements refer to NHPP inspections and compares NRC and NHPP inspection findings.

b. Contrary to the petition statements, the number of days onsite by NHPP inspectors did not exceed three days for any one inspection visit.

c. Contrary to the petition statements, the NHPP inspection reports cited violations that

represented well-documented deviations from regulatory requirements and license commitments.

d. The NRC completed a comprehensive readiness review for the VA in 2001 that resulted in a satisfactory report without any recommendations. The readiness review consisted of a thorough review of NHPP inspection and permitting (licensing) actions and staff performance and qualifications. The NRC has continued oversight of the VA centrally controlled radiation control program and ongoing efforts to function as if a master materials licensee.

e. One NHPP commitment is to complete inspections consistent with the master materials license application and NRC inspection guidelines. The readiness review discussed above did not identify any significant deficiencies in the NHPP inspection process or results. Annual external assessments by outside independent experts with master materials license experience have not identified any significant deficiencies in the NHPP inspection process or results.

f. The master materials licensees have historically cited more violations than NRC. In addition, a master materials licensee has broad authority to be more restrictive and prescriptive in radiation safety program requirements for their permittees. This includes completing inspections at a time and frequency deemed appropriate to the past enforcement history and requiring permitting actions to conform to specific guidelines deemed appropriate to the scope of use of radioactive materials and the past enforcement history.

g. NRC and master materials licensees inspections are separate and independent with limited expectation that inspections at a specific licensee (or permittee) in the same time period would necessarily identify the same violations. In addition, inspectors use different approaches within their professional discretion to inspect and to provide comments to licensee staff. Some inspectors provide "value-added" comments whereas other inspectors restrict their comments only to specific regulatory issues or violations.

h. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

14. Petition paragraph 1d.

a. The petition statements refer to an interpretation of 10 CFR 35.21 and Radiation Safety Officer authority.

b. Contrary to the petition statements, the interpretation is appropriate in that Radiation Safety Officers often delegate to clinical services authority to approve routine purchase of radioactive materials.

c. The petition does not identify any adverse outcomes, program deficiencies, or

regulatory noncompliance that requires corrective actions.

15. Petition paragraph 1e.

a. The petition statements refer to NHPP interactions with executive management and a Veterans Integrated Service Network (or VISN) office.

b. Contrary to the petition statements, the NHPP is a headquarters-level organization with strong executive management support for taking any appropriate enforcement actions including identifying failures by licensee executive management.

c. Contrary to the petition statements, the NHPP cited the licensee where the petitioner was the Radiation Safety Officer for a Severity Level III problem. One of the underlying violations was that, "the medical center failed to provide management oversight..." The inspection report extensively addressed the organizational issues that contributed to the violations.

d. Contrary to the petition statements, the NHPP has not received any comments or requests related to NHPP inspections from a VISN. The NHPP is a headquarters-level organization not subordinate to VISN offices.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

16. Petition paragraph 1f.

a. The petition statements refer to differences in and among inspectors for inspections and permit actions.

b. Both NRC and NHPP inspectors are individuals who might use different approaches within their professional discretion to inspect and provide comments to licensee staff. Some inspectors provide "value-added" comments whereas other inspectors restrict their comments only to specific regulatory issues or violations.

c. Inspections that are completed by different inspectors whether NRC or NHPP are separate and independent with limited expectation that inspections at a specific licensee in the same time period would necessarily identify the exact same violations. Inspections are performance-based and do not necessarily review in detail each separate radiation safety program elements during a specific inspection.

d. The master materials licensees have broad authority to be more restrictive and prescriptive in radiation safety program requirements for their permittees. This includes requiring permitting actions to conform to specific guidelines deemed appropriate to the scope of use of radioactive materials and the past enforcement history.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

17. Petition paragraph 1g.

a. The petition statements refer to staffing issues.

b. The NHPP does not provide staffing recommendations to licensees. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

c. Contrary to the petition statements about the scope of the radiation safety program at the license where the petitioner was formerly the Radiation Safety Officer, the recent NHPP inspection in 2002 determined the number of active researchers at the Westside Division was six and the number at the Lakeside Division was four. The NRC inspection report of 2000 stated the number of active researchers at the Lakeside Division was one. In addition, the nuclear medicine clinical programs at both divisions are modest and have similar workloads. Neither division completes brachytherapy procedures. The former Radiation Safety Officer (who is the petitioner) and the current Radiation Safety Officer had or now have health physics contract support to assist with radiation surveys, training, dosimetry, and waste management.

d. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

18. Petition paragraph 1h and 1hAa through 1hAc.

a. The petition statements refer to NHPP inspections and compares NRC and NHPP inspection results.

b. Contrary to the petition statements, the NHPP has not received any comments or requests related to NHPP inspections from a VISN. The NHPP is a headquarters-level organization not subordinate to VISN offices.

c. Contrary to the petition statements, the NHPP has not restricted any NHPP inspectors. The NHPP Director completes annual performance evaluations for NHPP inspectors with final approval by the National Radiation Safety Committee. Neither the National Radiation Safety Committee nor the NHPP Director has restricted an NHPP inspector from performing inspections. NHPP inspectors are assigned specific inspections and other tasks based on their previous training and experience and staff workload demands.

d. Contrary to the petition statements, differences between NRC and NHPP inspection results are expected. The master materials licensees have historically cited more violations than NRC. In addition, a master materials licensee has broad authority to be

more restrictive and prescriptive in radiation safety program requirements for their permittees. This includes completing inspections at a time and frequency deemed appropriate to the past enforcement history.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

19. Petition paragraph 2.

a. The petition statements refer to the VA organization culture related to safety and capability to management a regulatory compliance program.

b. Contrary to the petition statements, the VA is recognized as a leader in health care in reports from the New England Journal of Medicine (2000) and the Institute of Medicine (2002). The VA patient safety program has received international recognition, including an award from the American Medical Association in 2001. The current Department of Veterans Affairs Secretary has noted that the patient safety program has "helped to create a culture of safety in the VA by emphasizing prevention rather than punishment."

c. Contrary to the petition statements, the NRC staff has determined the VA master materials license application, the centrally controlled radiation safety program (including the professional staff), and the ongoing efforts to function as if a master materials licensee meet or exceed criteria in NUREG-1556, Volume 10.

d. Contrary to the petition statements, a Department of Labor occupational safety and health program evaluation of the VA concluded that "...management regards protection and promotion of employee safety and health as a fundamental value of the organization and applies its commitment to safety and health with as much vigor as to other organizational purpose."

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

permittees. This includes completing inspections at a time and frequency deemed appropriate to the past enforcement history.

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

19. Petition paragraph 2.

a. The petition statements refer to the VA organization culture related to safety and capability to management a regulatory compliance program.

b. Contrary to the petition statements, the VA is recognized as a leader in health care in reports from the New England Journal of Medicine (2000) and the Institute of Medicine (2002). The VA patient safety program has received international recognition, including an award from the American Medical Association in 2001. The current Department of Veterans Affairs Secretary has noted that the patient safety program has "helped to create a culture of safety in the VA by emphasizing prevention rather than punishment."

c. Contrary to the petition statements, the NRC staff has determined the VA master materials license application, the centrally controlled radiation safety program (including the professional staff), and the ongoing efforts to function as if a master materials licensee meet or exceed criteria in NUREG-1556, Volume 10.

d. Contrary to the petition statements, a Department of Labor occupational safety and health program evaluation of the VA concluded that "...management regards protection and promotion of employee safety and health as a fundamental value of the organization and applies its commitment to safety and health with as much vigor as to other organizational purpose."

e. The petition does not identify any adverse outcomes, program deficiencies, or regulatory noncompliance that requires corrective actions.

DVA-VHA MML 10 CFR 2.206 PETITION
ORIGINAL

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

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

Systemic management failure-

There are at least 2 RSO's alleging wrongful termination. One RSO (Philadelphia) has been upheld by an NRC investigation. The second is currently being investigated. Apparently a nurse was discriminated against at VA Philadelphia also.

Management denying responsibility for the radiation safety program-

The Secretary of the VA was requested to provide testimony in an ongoing MSRB radiation safety case. The VA Regional Counsel 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?

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

There are multiple incidences of the NRC performing an inspection and within several weeks the NHPP performing an inspection of the same licensee. The NHPP will typically spend 1-2 weeks inspecting the licensee vs. the 1-2 days the NRC inspects. The NRC will 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 Health Care Systems (VACHCS) while the NRC inspectors have found problems only with management:

Lack of an inventory of the radioactive waste program, yet no indication that the licensee has exceeded the license limits.

Citations that the training program must comply, not as is described in the license application but as is described in the NRC's Reg Guides, even though the Reg Guides are not referenced in the license application. Since the NRC Reg Guides are guidelines I believe that they cannot normally be cited against by an inspector.

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.

A recent NHPP inspection of VACHCS apparently failed to identify the failure of VACHCS to implement license application changes, which NHPP had placed in the application (over the objections of the RSO).

An 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 NHPP management they said that the inspector's actions were contrary to NHPP policy and the inspector would be dealt with. To the best of my knowledge they have not taken any action.

The range of inspectors 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 in Little Rock 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. I believe that this license application was intended to be narrative and punishing.

After a NRC inspection 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.

An NHPP inspector told a 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.

NHPP is fearful of management. NHPP will not take management to task, instead they "create" citations on others which shield management from responsibility.

VA budget problems are becoming sever. Budgeting issues are straining manpower, for instance see VA Saint Louis, VA Hines and VA Chicago. 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 person left in December 2001. The latest moch JCAHO inspection scored 46 points. The last full inspection was in the 90's.

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) requires the Chief of the Imaging Product Line approve al radiation safety positions 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.

RSO's are being driven from service. The RSO from VA Indianapolis stated that NHPP inspectors harassed the previous RSO to such an extent that he moved to a different job. The RSO at VA Saint Louis maybe having the same problem. The RSO at VA Philadelphia and VACHCS are being driven out. NHPP and the poor management attitude will destroy the radiation safety culture in the VA and continuing safety failures will occur.

NHPP inspectors are so poor 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 seems to have taken this inspector to task by not allowing the inspector to perform inspections for a time (possibly up to 6 months).

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.

I request that I be allowed to update and enhance my request.

William Cg 22 January 03
William Chuck Salsbury
320 N Wright St
Naperville, IL 60540

APPLICANT'S RESPONSE TO THE ORIGINAL
DVA-VHA MML 10 CFR 2.206 PETITION



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington, DC 20420

FEB 20 2003

In Reply Refer To: 598/115HP/NLR

Ujagar S. Bhachu
Nuclear Regulatory Commission (NRC)
Nuclear Materials Safety and Safeguards
Division of Industrial and Medical Nuclear Safety
Two White Flint North Building (Mail Stop: T-8F5)
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. Bhachu:

I am sending this letter in response to the 10 CFR 2.206 petition under Control Number 2003-00029.

The enclosed detailed comments are for the first version of the petition.

I look forward to providing any additional information required to resolve this issue. If you have any questions, please contact me at (501) 257-1571.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Lynn McGuire".

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

Enclosure to National Health Physics Program response on first petition

1. The Veterans Health Administration (VHA) is quite proactive, and often recognized as a national leader in patient safety initiatives and achievements. VHA commitment of resources and staff to patient safety, including the master materials license effort, belies contrary statements in the petition.

a. The VHA is recognized as a leader in health care in reports from the New England Journal of Medicine (2000) and the Institute of Medicine (2002). The VHA patient safety program has received international recognition, including an award from the American Medical Association in 2001. The current Department of Veterans Affairs Secretary has noted that the patient safety program has "helped to create a culture of safety in the VA by emphasizing prevention rather than punishment."

b. In 2002, VHA hospitals received average scores from Joint Commission on Accreditation of Healthcare Organizations (JCAHO) exceeding those of private sector counterparts. The JCAHO process includes an evaluation of safety programs. The JCAHO hospital accreditation system is nationally recognized by the health care industry as a major, independent review of health care.

c. The VHA invests significant resources to safety efforts, including radiation safety. This commitment to radiation safety is demonstrated by the master materials license effort and the continuing oversight at the headquarters level by the National Radiation Safety Committee (NRSC), with membership of senior executive managers.

d. The National Health Physics Program (NHPP), with a staff of 12 full-time equivalents, including six health physicists, is a highly proactive program. As an example, the NHPP recently completed a special project for security and developed specific frequently asked questions and other information to assist licensees with revised 10 CFR 35 implementation.

2. The Nuclear Regulatory Commission (NRC) staff has determined the VHA master materials license application, centrally controlled radiation safety program (including the professional staff), and ongoing efforts to function as if a master materials licensee meet or exceed criteria in NUREG-1556, Volume 10.

a. The NRC and VHA have invested significant time and effort in the master materials license, which is scheduled for issuance March 17, 2003. The VHA first applied for a master materials license in 1998 and has worked extensively with the NRC staff to ensure the application and centrally controlled radiation control program were consistent with regulatory guidelines.

b. The NRC completed a comprehensive readiness review for the VHA in 2001 that resulted in a satisfactory report without any recommendations for program improvements. The readiness review consisted of a thorough review of NHPP inspection and permitting (licensing) actions and staff performance and qualifications. The NRC has continued oversight of the VHA centrally controlled radiation control program and ongoing efforts to function as if a master materials licensee.

Enclosure to National Health Physics Program response on first petition

c. The master materials license transition steps initiated December 15, 2002, if curtailed, would result in a significant realignment of projected workload with NRC staff being tasked to complete more than 15 license renewals and a similar number of VA amendment requests. VHA would also fail to receive approximately \$560,000 in annual license fee refunds if the master materials license is issued after March 31, 2003, rather than on March 17, 2003, as projected.

3. Specific comments for statements in the 10 CFR 2.206 petition.

a. The comments below are limited to statements in the petition for which the NHPP has specific information and/or expertise.

(1) The petition has statements or assertions that are too vague in nature or have insufficient specific details to address.

(2) The NHPP does not provide staffing recommendations to licensees. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

(3) The NHPP does not provide personnel recommendations to licensees. The NHPP position is that radiation safety program deficiencies or cited violations, in and of themselves, have not been used historically as a basis for personnel actions (except, of course, for wrongdoing such as willful violations or gross negligence). Rather, the NHPP notes personnel actions should be within the context of the performance standards as for any other federal employee. The NHPP does require licensees not to preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under 10 CFR 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.

b. First paragraph. The NHPP does not have any information related to the stated Radiation Safety Officer terminations. The NHPP has not received any radiation safety concerns or allegations related to the stated Radiation Safety Officer terminations. The NRC has completed appropriate enforcement action related to Philadelphia.

c. Second paragraph. The NHPP does not have any information related to any personnel action currently under consideration by a Merit System Review Board. The NHPP has not received any radiation safety concerns or allegations related to such a personnel action.

d. Third paragraph. One NHPP commitment is to complete inspections consistent with the master materials license application and NRC inspection guidelines. The readiness review discussed in paragraph 2b above did not identify any significant deficiencies in the NHPP inspection process or results. Annual external assessments by outside independent experts with master materials license experience have not identified any significant deficiencies in the NHPP inspection process or results.

(1) The master materials licensees have historically cited more violations than NRC. In addition, a master materials licensee has broad authority to be more restrictive and prescriptive in radiation safety program requirements for their permittees. This includes completing inspections

Enclosure to National Health Physics Program response on first petition

at a time and frequency deemed appropriate to the past enforcement history and requiring permitting actions to conform to specific guidelines deemed appropriate to the scope of radioactive materials used and the past enforcement history.

(2) NRC and master materials licensees inspections are separate and independent with limited expectation that inspections at a specific licensee (or permittee) in the same time period would necessarily identify the exact same violations. In addition, inspectors use different approaches within their professional discretion to inspect and to provide comments to licensee staff. Some inspectors provide "value-added" comments whereas other inspectors restrict their comments only to specific regulatory issues or violations.

(3) Contrary to the assertion in this paragraph, the NHPP cited the licensee where the petitioner was the Radiation Safety Officer for a Severity Level III problem. One underlying violation was "the medical center failed to provide management oversight..." The NRC did not cite the licensee for a violation related to management oversight.

(4) The NHPP initially inspected the licensee where the petitioner was the Radiation Safety Officer in September 2000 based on an NRC request. Based on the Severity Level III problem, the NRSC directed the NHPP to complete a follow-up inspection at three months instead of the usual six months. The NHPP completed a second follow-up inspection in May 2001. The two subsequent inspections in November 2001 and January 2002 were in response and follow-up to a reported incident. The onsite time for each inspection was three days or less. The sequence of NRC and NHPP inspection reports for 2000, 2001, and 2002, are attached for additional information.

e. Fourth paragraph. The NHPP is a VHA headquarters-level staff with strong executive management support for taking appropriate enforcement actions including identifying failures by licensee executive management to oversee properly licensed activities. Contrary to the assertion in this paragraph, the NHPP cited the licensee where the petitioner was the Radiation Safety Officer for a Severity Level III problem. One of the underlying violations was "the medical center failed to provide management oversight..." The inspection report extensively addressed organizational issues considered to have contributed to the violations.

f. Fifth paragraph. The NHPP does not specifically address budget issues, though has an understanding of the usual federal budgetary challenges in the health care environment. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

g. Sixth paragraph. The VHA is quite proactive, and often recognized as a national leader in patient safety initiatives and achievements. See paragraph 1 above.

(1) The NHPP completes permitting actions and inspections consistent with the master materials license application and NRC guidelines while providing focused information to assist permittees and Radiation Safety Officers. The Radiation Safety Officers are likely to have a diversity of opinions about the NHPP, master materials license, and relative success of each.

Enclosure to National Health Physics Program response on first petition

(2) The NHPP does not specifically address the structure of VHA organizational entities during inspections and permitting, though understands a variety of methods are used to reach staffing and budgeting decisions. Rather, the NHPP evaluates radiation safety programs for performance and outcomes. This regulatory approach is consistent with that of the NRC.

h. Seventh paragraph. One NHPP commitment is to complete inspections consistent with the master materials license application and NRC inspection guidelines. The readiness review discussed in paragraph 2b above did not identify any significant deficiencies in the NHPP inspection process or results. Annual external assessments by outside independent experts with master materials license experience have not identified any significant deficiencies in the NHPP inspection process or results. Inspection accompaniments by NRC and the NHPP director for NHPP inspectors have not identified any significant deficiencies.

(1) The NHPP places emphasis on acceptable radiation safety program outcomes and follows common practices in root cause analysis that preclude a focus to individual performance or errors, except in the case of wrongdoing.

(2) The current Radiation Safety Officer at Indianapolis predates the formation of the NHPP.

i. Eighth paragraph. One NHPP commitment is to complete inspections consistent with the master materials license application and NRC inspection guidelines. Inspection accompaniments by NRC and the NHPP Director for NHPP inspectors have not identified any significant deficiencies.

(1) The NHPP is a VHA headquarters-level staff not subordinate to the Veterans Integrated Service Network (VISN) offices. The NHPP has not received any comments or requests related to NHPP inspections from a VISN.

(2) The NHPP Director completes annual performance evaluations for NHPP inspectors with final approval by the NRSC. Neither the NRSC nor the NHPP Director has restricted an NHPP inspector from performing inspections. NHPP inspectors are assigned specific inspections and other tasks based on their previous training and experience and staff workload demands.

j. Ninth paragraph. See paragraph 1 above.

Attachments:

NRC inspections

NHPP memorandum of September 19, 2000, with NRC report of September 15, 2000

NHPP letter of October 12, 2000, with response of October 10, 2000, to NRC report

NHPP memorandum of February 20, 2002, with NRC report of February 13, 2002

NHPP inspections

NHPP memorandum of October 31, 2000, with inspection report

VA Chicago Health Care System response letter of November 30, 2000

NHPP memorandum of March 2, 2001

NHPP memorandum of May 30, 2001, with inspection report

Enclosure to National Health Physics Program response on first petition

NHPP memorandum of February 12, 2002, with inspection report
VA Chicago Health Care System response letter of March 27, 2002

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date SEP 19 2000
From Director, VHA National Health Physics Program (115HP/NLR)
Subj Nuclear Regulatory Commission (NRC) Inspection
To Director (537A4/00), VA Chicago Health Care System, Lakeside Division, Chicago, Illinois

1. The NRC inspected the radiation safety program at the VA Chicago Health Care System, Lakeside Division, on August 1-2, 2000. Their inspection report, dated September 15, 2000, is attached for your action.
2. We must forward your response to the NRC within 30 days of the date of the NRC letter. That means we must receive your response no later than October 11 to comply with the due date. Our address is listed below:

National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, Arkansas 72114

3. If you have any questions, please contact Edward M. Leidholdt, Jr., Ph.D., VHA National Health Physics Program, at (707) 562-8374.

ELM

fm E. Lynn McGuire

Attachment

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



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

September 15, 2000

Richard S. Citron, Director
Department of Veterans Affairs
Chicago Health Care Systems
Lakeside Division
333 East Huron Street
Chicago, IL 60611

SUBJECT: NRC INSPECTION

Dear Mr. Citron:

This refers to the inspection conducted on August 1-2, 2000, at the V.A. Lakeside Hospital. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you and members of your staff by telephone on August 4, 2000.

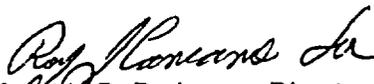
During the inspection period, your conduct of licensed activities was generally characterized by safety-conscious health physics operations and sound inventory controls. While no violations of regulatory requirements were identified during this inspection, we are concerned about the apparent lack of effective corrective actions associated with contamination events and conduct in radiologically controlled areas. Specifically, between July 9, 1999, and May 18, 2000, your Radiation Safety Officer (RSO) identified multiple radioactive contamination events in the nuclear medicine hot lab, treadmill room and hallway. Between May 10 and 17, 2000 alone, the department had four spills involving radioactive material; in one instance two spills occurred with contamination great enough that the cardiac stress lab had to be closed for 3 days. In addition to the contamination events, between September 30, 1999 and June 18, 2000, the RSO identified food, drink, and dishes in the nuclear medicine hot lab and the imaging rooms on 14 occasions.

We are concerned that while significant issues are being properly identified, corrective actions appear not to be effective in preventing their recurrence. We understand that the issues have been brought before V.A. Lakeside's radiation safety committee; however, the problems have continued. Because an effective corrective action program is very important in maintaining a quality radiation safety program, we request that you address our concerns within 30 days from the date of this letter. Your response should be specific and should reflect an assessment of current radiation safety activities, staff responsibilities, and the causal factors of the areas of concern. In addition, we have contacted the V.A. National Health Physics Program office and discussed our concerns with its management. It is our understanding that the V.A. National Health Physics Program office will review these issues with you at a later date.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and your response to this letter will be available **electronically** for public inspection in the NRC Public Document Room or from the *Publicly Available Records (PARS) component of the NRC's document system (ADAMS)*. ADAMS is accessible from the NRC Web site at <http://www/nrc.gov/INRC/ADAMS/index/html> (the Public Electronic Reading Room).

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

Sincerely,


Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

Docket No. 030-01435
License No. 12-02642-06

cc: William C. Salsbury, C.H.P.
Radiation Safety Officer

✓ E. Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
2200 Fort Roots Drive
North Little Rock, AR 72114



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

OCT 12 2000

In Reply Refer To: 598/115HP/NLR

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

We are forwarding the enclosed letter, dated October 10, 2000, from the Lakeside Division of the VA Chicago Health Care System, NRC License Number 12-02642-06. The letter is submitted in response to your letter, dated September 15, 2000, regarding a recent NRC inspection.

We have reviewed the letter from the licensee and found the information submitted to be responsive to your letter. Please note that the licensee's response also addresses related deficiencies discovered during a reactive inspection conducted by the VHA National Health Physics Program (NHPP) on September 6-8, 2000. We have kept NRC Region III informed, by several e-mail messages, of the NHPP inspection.

Please provide a copy of any correspondence regarding licensing or enforcement actions for this medical center to:

National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, Arkansas 72114

If you have any questions regarding this matter, please contact Edwin M. Leidholdt, Jr., Ph.D., at (707) 562-8374.

Sincerely,

A handwritten signature in cursive script, appearing to read "E. Lynn McGuire".

E. Lynn McGuire
Director, National Health Physics Program



**DEPARTMENT OF VETERANS AFFAIRS
VA Chicago Health Care System**

Lakeside Division
333 East Huron Street
Chicago IL 60611-3004

West Side Division
PO Box 8195
Chicago IL 60680-8195

Adam Benjamin, Jr. VA Outpatient Clinic
9330 Broadway
Crown Point IN 46307-8602

Community Based Outpatient Clinic
1502 East 63rd Street
Chicago IL 60637-2921

October 10, 2000

Lynn McGuire
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

The following information is provided in response to the September 15, 2000 letter from the NRC to the VA Chicago Health Care System concerning the August 1-2, 2000 NRC inspection of the VA Chicago-Lakeside Division.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard S. Citron".

Richard S. Citron
Director, VA Chicago Health Care System



DEPARTMENT OF VETERANS AFFAIRS
VA Chicago Health Care System

Lakeside Division
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Chicago IL 60637-2921

October 10, 2000

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety
Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

The following information is provided in response to the September 15, 2000 letter from the NRC to the VA Chicago Health Care System concerning the August 1-2, 2000 NRC inspection of the VA Chicago-Lakeside Division.

After the NRC inspection, the NRC contacted the VA National Health Physics Program and requested that the NHPP evaluate the medical center as related to the following issues:

- a. Numerous contamination events in nuclear medicine
- b. Use of food, drink, and utensils in restricted area.
- c. Training of nuclear medicine staff with emphasis on HAZMAT and package receipt.
- d. Orderly disposal of radioactive waste and
- e. Radiation Safety Officer authority and management support.

Following that conversation the NHPP program performed a reactive inspection of the VA Chicago-Lakeside Division on September 13-15, 2000. The "Agreed To Facts" (attachment #1) from that inspection stated that the medical center has committed four violations as listed below.

- a. Failure to have adequate management oversight of radiation safety program operations,
- b. Failure to perform adequate radiation safety program surveys and follow-up actions,
- c. Failure to provide radiation safety training and instruction, and
- d. Failure to inventory, manage, and dispose of radioactive waste.

Starting before the NHPP inspection the medical center also initiated an internal review of the radiation safety program and the issues identified by the NRC. This ongoing review has confirmed the findings of the NRC and identified many of the finding later listed in the "Agreed To Facts" from the NHPP. A comprehensive program of recommended actions to respond to these issues was prepared by the Lakeside Division Associate Chief of Staff for Research and these were presented to the presented to the Medical Center Director on September 22, 2000 (attachment #2). These recommendations were reviewed and extensively discussed by the Director, Associate Director, Chief of Staff-Lakeside Division, Chief of Staff-Westside Division, Associate Chief of Staff for Research-Lakeside Division, the RSO, and the Chief of Medicine-Westside Division (previously Chief of Nuclear Medicine Westside Division). The Lakeside Chief of Nuclear Medicine was not included in these discussions, as she had tendered her resignation after the NHPP inspection. The Director approved all of these recommendations and charged the Radiation Safety Committee, the RSO, the Associate Director, and the Associate Chief of Staff for Research to carryout these recommendations.

The Radiation Safety Committee held a special meeting on October 4, 2000 to review the findings of the NRC inspection and the NHPP inspection (Agenda; attachment #3). During this 2½ hour meeting the committee was instructed on their authority and responsibilities as they relate to the NRC Broad Scope License awarded to the Lakeside Division. The Radiation Safety Committee then reviewed the major issues raised by the NRC and the NHPP, discussed the causal factors, and reviewed the recommended actions prepared by the Associate Chief of Staff for Research, who was asked to chair the special Radiation Safety Committee meeting. The Radiation Safety Committee then discussed the plans and actions taken to date in response to the NRC and NHPP issues. The committee then discussed whether the planned actions were sufficient, and whether the target dates for completion and the milestones of completion were adequate.

The remainder of this letter will describe the specific action plans developed to address the NRC and NHPP issues listed above, the results to date of our implementation of these action plans, and the Radiation Safety Committee's comments and additional action plans.

Numerous contamination events in nuclear medicine.

Following the spills in the nuclear medicine labs in May of 2000, the Chief of Nuclear Medicine reevaluated the policies and procedures in the nuclear medicine area and in the stress test laboratory. At that time it was determined that a number of causal factors had contributed to the spills in the laboratory. It was determined that in May, the laboratory had run out of Leur lock syringes and the one of the spills was due to use of a non-Leur lock syringe. Another spill appeared to be caused by cardiology personnel removing IVs from patients after nuclear medicine injections and contaminated material dripping on the floor. Other problems were identified with patient volume and personnel flow through the stress test laboratory. These findings lead to changes in policy in the stress test laboratory stating that only Leur lock syringes may be used for nuclear medicine injections and that only nuclear medicine staff are allowed to remove and dispose of IV tubing used for nuclear medicine injections in the stress lab. These changes in procedure were reported to the Radiation Safety Committee at their July meeting and there have not been any additional spills in the Stress Laboratory since the implementation of these new procedures.

There were also long standing issues expressed by the RSO concerning the inconsistent performance of the Lakeside nuclear medicine technicians. The RSO was not satisfied with the oversight provided by the previous Chief of Nuclear Medicine. After the resignation of the previous Chief, the medical center has appointed the lead nuclear medicine physician from the Westside Division as the Acting Chief of Nuclear Medicine for VA Chicago. He and his nuclear medicine supervisor are now in charge of the Lakeside program. The new Chief and his supervisor were clearly tasked with their staff responsibilities and they understand the need to more closely supervise and appropriately discipline the nuclear medicine technicians. The new nuclear medicine team has been working with the Lakeside technicians to address compliance with procedures and emphasize the importance of careful technique in the nuclear medicine labs. The RSO has also brought in a consultant to review protocols and provide additional training at the Lakeside Division. Following these actions the RSO has stated that he feels the performance of the Lakeside nuclear medicine technicians has improved.

In response to the NHPP inspection the medical center has also agreed to (1) Obtain an external review of contamination control procedures in Nuclear Medicine Service by an outside expert, not currently employed or contracted by the medical center, within 60 days of the date of the NHPP inspection report, and (2) Obtain a review of the effectiveness of corrective actions by an outside expert, not currently employed or contracted by the medical center, within six months of the date of the NHPP inspection report.

The Radiation Safety Committee discussed these issues at their October 4th meeting. The committee felt that the causal factors were the lack of disciplinary action by the previous Chief of Nuclear Medicine and the lack of disciplinary action of the Chief of Cardiology. The Committee discussed the corrective actions that had been implemented. Their assessment of the current radiation safety activities was that these actions were sufficient as the technicians had received counseling, additional training, and additional supervision, and there had not been any additional spills since the change in procedures in May 2000.

Use of food, drink, and utensils in restricted area.

Numerous instances of food drink and utensils in restricted areas have been reported to the Radiation Safety Committee and one observed at the NRC inspection. The medical center had not previously address these issues with enough force to stop these repeated violations. A number of causal factors and root causes were identified including; lack of supervisory follow through by the previous Chief of Nuclear Medicine and the current Chief of Cardiology, inadequate instructional materials for new employees, lack of a clear disciplinary policy for salaried VA employees who did not follow radiation safety procedures, lack of any disciplinary policy for trainees not salaried by the VA who did not follow VA radiation safety procedures, lack of a convenient break room for nuclear medicine staff.

The Previous Chief of Nuclear Medicine and the current Chief of Cardiology (cardiology/nuclear medicine stress test lab) were tasked to review their policies and training of trainees and staff, and to correct deficiencies. The previous Chief of Nuclear Medicine noted that the previous policy sheet given to staff and trainees did not specifically address food and drink in the restricted areas. She corrected this oversight and had all current employees and trainees signed off that they had received and understood the new policy. She and the Chief of Cardiology then prepared a new statement clearly defining the importance of these rules and stated that employees would be disciplined according to the medical center human resources policies, up to and including possible termination, if they did not follow the rules (attachment #4). This memo also described the new disciplinary policy for trainees who did not follow the radiation safety rules. Each employee was also presented a copy of this disciplinary memo. This appeared to have a significant effect as the NHPP inspectors reported that one of the nuclear medicine technicians expressed to him how sorry she was for her past actions and how she finally understood the importance of these rules. The Chief of Cardiology also met with his staff and trainees and reviewed the nuclear medicine policies for the stress test laboratory. He also presented the disciplinary policy to his trainees, which states that a first infraction of the radiation safety rules would lead to a written warning and that a second infraction would result in a formal letter being placed in the trainee's University Training File (attachment #4). The cardiology fellow observed with a coffee cup in the stress lab has received counseling concerning that event (attachment #4). All trainees working in the stress test laboratory are now given a copy of both the radiation safety rules and a copy of the disciplinary policy. Since the implementation of this policy, one instance of a cardiology employee removing an IV from a patient in the stress lab was observed. This was a break in the policy that only nuclear medicine staff may remove these IVs. This employee has been formally reprimanded and this reprimand has been recorded in her personnel record as prescribed by our Human Resources Service.

In addition to these changes in policy and training, one of the unused nuclear medicine rooms was decommissioned and converted into a break room for the nuclear medicine staff. They now have an appropriate place to store their food and wash their utensils.

The Radiation Safety Committee agreed with the causal factors and assessed the current Radiation Safety Activities in this area at their October 4th meeting. The committee and felt that the implementation of new disciplinary policies, coupled with the active enforcement of these policies had resulted in appropriate corrective action.

Training of nuclear medicine staff with emphasis on HAZMAT and package receipt.

Deficiencies in training of medical center personnel were identified in multiple areas including; lack of HAZMAT training for individuals preparing return shipments of radioactive packages, lack of annual training of housekeeping staff that work in the nuclear medicine areas, and lack of understanding of the proper ordering and receipt of radioactive packages. The Radiation Safety Committee had previously discussed the receipt of radioactive packages for research. At that meeting the committee had approved the use of a computer based approval system to provide authorization numbers for radioactive orders in research and to also record the results of the surveys of incoming packages to document the correct receipt and survey of all incoming radioactive packages. The committee tasked the RSO to follow through on the purchase and installation of this system and to arrange for training of the research personnel who would be receiving the packages. The Software arrived last month but the system has not yet been implemented and the formal training of research personnel has not yet occurred. Until this system was installed the medical center was to continue to use the existing protocols described in the medical center radiation safety manual. These instructions were not clearly explained to those parties responsible for the ordering and receipt of

these packages. Research was not sure whether to ship to nuclear medicine or the RSO's office, and the nuclear medicine technicians did not understand that they were responsible for receiving and surveying radioactive packages for research. The Radiation Safety Committee was not satisfied with the training of staff involved in the ordering and receipt of packages and tasked the RSO to clearly review the policies with all involved. The Committee then discussed the issue of staffing in nuclear medicine and the concerns of the Acting Chief of Nuclear Medicine that his technicians did not have the time to be receiving research packages. The Committee then instructed the RSO to train some of the research personnel to receive the research packages delivered to nuclear medicine and to train them to perform the required wipe tests and document the activity of packages received. Approval for shipment of packages directly to research was again postponed until after the computer system was installed and the remainder of the ordering and receiving training was completed. The Radiation Safety Committee did not define a completion date for the computer system, but the Associate Director has instructed the RSO to have the system completely implemented before the end of December 2000.

Concerning the other training deficiencies, the Radiation Safety Committee was unaware of the requirement for HAZMAT training for technicians preparing radioactive packages for shipment and unaware of the requirement for annual training of housekeeping personnel who work in restricted areas. The Radiation Safety Committee tasked the RSO to schedule and complete the training of the housekeeping personnel before the next Radiation Safety Meeting, scheduled for October 25, 2000 and tasked the RSO to determine before the next Radiation Safety Committee meeting which of the nuclear medicine technicians should receive the HAZMAT training and to make the arrangements for their training. To date the RSO has presented a plan for completion of this training (attachment 5)

Orderly disposal of radioactive waste

The Radiation Safety Committee tasked the RSO to complete an inventory of all radioactive waste in the medical center and present that inventory to the committee at the October 25, 2000 Radiation Safety Committee meeting. The Radiation Safety Committee listened to the RSO's explanation that retaining radioactive waste on site was not in itself a violation, but still tasked the RSO to present a plan for the removal of the existing radioactive waste from the medical center. The Radiation Safety Committee also tasked the RSO to review all of the materials currently stored in the radioactive waste storage rooms and determine whether the items were in fact waste or potentially contaminated equipment. For items which need to be in the waste rooms the RSO was tasked to label them as supplies used in waste disposal, potentially contaminated equipment, contaminated equipment, or waste. All other items need to be removed from these areas. The Radiation Safety Committee also tasked the RSO to present a timetable at the October 25th Radiation Safety Committee meeting, defining by when he will survey the potentially contaminated equipment to determine if it needs to be decontaminated or disposed of as radioactive waste. To date the RSO has completed the inventory of our radioactive waste in Jugs, Animal Carcasses, and Drum Waste (inventory; attachment 6).

Radiation Safety Officer authority and management support.

During the external inspections and through our internal review it became clear that the members of the radiation safety team did not understand all of their authority and all of their responsibilities. In addition it was clear that radiation safety issues were not being effectively presented to management. Because of this, recurrent problems were not addressed and root causes were not resolved. This was exacerbated by the changes in the reporting structure of the Radiation Safety Committee through the Environment of Care Committee and by the transfer of the RSO from the Chief of Staff's Office to the Engineering Service. After these changes the representative from the Radiation Safety Committee did not attend the Environment of Care Committee meetings and the Radiation Safety Committee minutes were not forwarded to the Director. In addition the management representative on the Radiation Safety Committee did not understand his responsibility to bring issues directly forward to management and the RSO felt that he should report to the Chief of Engineering as opposed to directly to management. The chairman of the Radiation Safety Committee was sending a copy of the minutes to the Chief of Staff but these minutes were not shared with the Director. 11

Following these inspections, it was clear that this system was not working. The first question was whether the system should be changed or whether retraining all of the individuals responsible for each part of the system could solve the problem. It was noted that the same system has been used effectively at other VAs and management decided to maintain the current reporting structure while at the same time clearly delineating the duties and responsibilities of all the members of the Radiation Safety team.

Training was then implemented to instruct the Radiation Safety Committee of their responsibility and authority to shut down any program that was not addressing its radiation safety issues and the responsibility of the RSO (Associate Director email; attachment 7) and the management representative to take significant issues directly to management. These issues could be presented at the morning management meetings or presented directly to management at any time. The RSO and management representative were also tasked to document these communications with a written report of contact and to send documentation of these communications to the Director and to the Radiation Safety Committee (Section 8. of the Medical Center Memorandum defining duties and responsibilities of the Radiation Safety Committee; attachment 8).

The Chiefs of Cardiology, Nuclear Medicine and Research were also instructed on their responsibilities to resolve issues and to communicate these issues to the RSO, the Radiation Safety Committee and to Management.

In addition to this training, additional personnel changes were made to strengthen the program. The previous Chief of Nuclear Medicine resigned and a new Acting Chief of Nuclear Medicine was named. The medical center has assigned a new nuclear medicine supervisor to the Lakeside Division (the supervisor of the Westside Division Nuclear Medicine program has taken on the supervision of the Lakeside technicians). The previous Chairperson of the Radiation Safety Committee will be replaced with the appointment of the Associate Chief of Staff for Research as the new Chairperson. The medical center memorandum redefining the Chairperson of the Radiation Safety Committee is attached (attachment #8) and we have included a copy of the new chairperson's C.V. (David H. Barch, M.D. ACOS for Research and Development; attachment #9). We are including this information as our notification to the NRC of the change in our Radiation Safety Committee Membership and the change in the Chair of the Radiation Safety Committee. The Associate Chief of Staff for Research also has direct access to the Medical Center Management team. Because of these committee changes and the change in the reporting structure of the RSO, the medical center is currently preparing a formal license amendment request. This amendment will be submitted to the NRC within 30 days.

NHPP citations and issues

Failure to have adequate management oversight of radiation safety program operations,

As described above the medical center has educated our staff as to their roles in the Radiation Safety Program. The reporting structure has been clarified and a number of key individuals have been replaced in the Radiation Safety Program.

Failure to perform adequate radiation safety program surveys and follow-up actions,

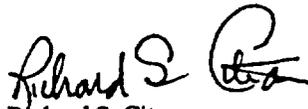
The Radiation Safety Committee was not aware that the surveys and documentation prepared by the RSO were not adequate. The Radiation Safety Committee tasked the RSO to design and implement a program to address these deficiencies by the October 25, 2000 RSC meeting and to report on the program at the October 25th Meeting.

Failure to provide radiation safety training and instruction, and Failure to inventory, manage, and dispose of radioactive waste.

These issues have already been discussed above and the Radiation Safety Committee has tasked the RSO to resolve or present a plan to resolve these issues by the October 25, 2000 Radiation Safety Committee Meeting.

In summary, the medical center understands that we have not effectively or responsibly managed our Radiation Safety Program. We understand that even our current efforts will not be adequate without continuous vigilance to maintain an ongoing program directed at attention to detail and prompt resolution of problems. We appreciate the time invested into our program by the NRC and the NHPP. We believe that the lessons we have learned will lead to a strongly committed Radiation Safety Program at VA Chicago, and that such a program will benefit our patients and employees.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard S. Citron".

Richard S. Citron
Director, VA Chicago Health Care System

September 25, 2000

**Agreed To Facts
VA Chicago Health Care System - Lakeside Division**

1. NRC routine inspections in 1999 and 2000

a. NRC routine inspection of May 25-26, 1999

(1) The inspector found contamination at several locations in Nuclear Medicine Service and on a technologist's hands.

(2) The inspector's shoes were contaminated.

(3) The NRC cited a severity level IV violation for failure to maintain security for a small vial of radioactive materials.

(4) The NRC discussed inspection findings with executive management.

b. NRC routine inspection of August 1-2, 2000

(1) The NRC did not cite any violations in the inspection report of September 15, 2000.

(2) The NRC did express concern about the "apparent lack of effective corrective actions associated with contamination events and conduct in radiologically controlled areas."

(3) The NRC requested that the medical center respond to the NRC concerns with an assessment of current radiation safety activities, staff responsibilities, and the causal factors of the areas of concern.

(4) The NRC discussed inspection findings with executive management.

c. NRC telephone contact with the NHPP

(1) The NRC contacted the NHPP on August 17, 2000, to discuss the most recent NRC inspection.

(2) The NRC later requested the NHPP to evaluate the medical center as related to the following issues.

(a) Numerous contamination events in nuclear medicine,

(b) Use of food, drink, and utensils in restricted areas,

(c) Training of nuclear medicine staff with emphasis on HAZMAT and package receipt,

- (d) Orderly disposal of radioactive waste, and
- (e) Radiation Safety Officer authority and management support.

2. Management oversight

a. Organizational structure and communications with executive management

(1) Before 1998, the Radiation Safety Officer reported to the Chief of Staff and the Radiation Safety Committee reported directly to executive management.

(2) In early 1998, the Radiation Safety Officer began reporting to the Chief, Engineering Service, and the Radiation Safety Committee to the Hazardous Materials Committee, which in turn reported to the Environment of Care Committee. The medical center did not submit an amendment request to approve the organizational change.

(3) The Chief, Nuclear Medicine Service is a member of both the Radiation Safety Committee and the Environment of Care Committee, for the purpose of maintaining liaison between the two committees.

(4) The Chairman, Environment of Care Committee has not received minutes from the Radiation Safety Committee since before September 1999. The committee has not discussed any radiation safety issues, except a proposed merger of the Lakeside and Westside Radiation Safety Committees.

(5) The Administrative Officer to the Chief of Staff attends Radiation Safety Committee meetings for the Chief of Staff, who is the management representative as submitted in the license application. The Administrative Officer to the Chief of Staff concluded that the committee had not identified a pattern of problems in Nuclear Medicine Service.

(6) The Chief of the Radiation Oncology Section of Radiology Service has served as the Chairman, Radiation Safety Committee since 1986. The chair routinely sends a copy of the committee minutes to the Chief of Staff.

(7) The Chief of Staff recently retired. Copies of recent Radiation Safety Committee minutes had been initialed by the former Chief of Staff.

(8) The Radiation Safety Officer presented the annual radiation safety program review to the Radiation Safety Committee once each year. The most recent presentation was on April 20, 2000.

(9) The Radiation Safety Officer did not present an annual briefing to executive management. The Radiation Safety Officer and committee chair considered attendance of the management representative alternate at the committee meetings and submission of the minutes to the Chief of Staff as adequate to brief executive management.

b. Radiation Safety Committee oversight

(1) The Radiation Safety Committee discussed ongoing problems in the Nuclear Medicine Service regarding radioactive contamination and food, beverages, and utensils in restricted areas on July 21, 1999, October 15, 1999, January 19, 2000, and April 20, 2000.

(a) The RSO identified 16 incidents in 1999 involving food, beverages, or utensils in restricted areas of Nuclear Medicine Service.

(b) The RSO identified four incidents in early 2000: one in January, two in February, and one in April.

(c) The committee relied on the Chief, Nuclear Medicine Service, to take corrective actions and did not elevate the issue to executive management.

(2) The committee minutes of the July 19, 2000, meeting were not yet prepared as of September 6, 2000. The committee chair expressed concern over a failure to submit committee minutes in a timely fashion in an e-mail message of April 27, 2000.

(3) The Administrative Officer to the Chief of Staff who attends committee meetings for the Chief of Staff was not fully aware of the role and responsibilities for the management representative.

3. Radiation surveys and follow-up actions

a. Weekly wipe surveys are performed in the Nuclear Medicine Service. However, the results are often not recorded in units of dpm per 100 cm².

b. A single wipe test is performed of all areas in the radiopharmacy. Positive wipe test results are not investigated to determine the exact location of contamination.

c. Wipe survey results do not document corrective action, if contamination is found.

d. A wipe survey result for the week of February 7, 2000, indicated 14,700 dpm per 100 cm² that exceeded the action level of 2000 dpm per 100 cm². However, the Radiation Safety Officer was not notified.

e. The Nuclear Medicine Service does not perform wipe tests of internal source containers during receipt surveys of radioactive packages.

f. The Radiation Safety Officer does not follow standards of practice and 10 CFR Part 35.21 to perform adequate surveys, evaluations, and investigations for spills and contamination in the Nuclear Medicine Service. The Radiation Safety Officer reported that the only documentation for spills was in the in the Radiation Safety Committee minutes. The reports in the committee minutes are inadequate to:

(1) Identify the radionuclides and estimated activities,

- (2) Determine the causes of the spill and contamination, and,
- (3) Recommend corrective action.

g. The Radiation Safety Committee and Radiation Safety Officer have not developed and implemented adequate contamination control procedures based upon repeated wipe survey results that indicate contamination within the Nuclear Medicine Service.

4. Radiation safety training and instruction

a. The instruction sheet used to train new cardiology fellows does not address the issue of eating and drinking in radioactive materials use areas.

b. HAZMAT training is not provided to nuclear medicine technologists who prepare shipments of radioactive materials for return to a commercial radiopharmacy.

c. Basic radiation safety training is not provided to housekeeping staff, at least annually.

d. Two radioactive material packages were not properly received.

(1) A commercial carrier attempted to deliver a radioactive materials package with 250 uCi ^3H to the radiopharmacy on July 27, 2000. A staff member refused to accept the package

(2) A radioactive materials package with 500 uCi ^{32}P was mistakenly addressed to the Radiation Safety Officer's office by Research Service, following instructions from the previous Radiation Safety Officer. The Research Service was not informed of the new delivery location in the Nuclear Medicine Service.

5. Waste management

a. Various types of non-radiation safety program equipment and medical center supplies are stored in the radioactive waste storage rooms.

b. The total activity and types of radioactive materials in the radioactive waste storage rooms is not known since an adequate inventory is not maintained. Radiation Safety Committee minutes do not include an inventory of radioactive materials currently in possession.

c. Nuclear medicine related radioactive waste is routinely disposed of per license conditions.

d. Other radioactive waste is not routinely disposed in a timely fashion consistent with standards of practice as in NRC Information Notice 90-09.

6. Medical center actions

a. Management oversight

(1) Executive management tasked the Radiation Safety Officer with responsibility to bring significant radiation safety issues directly to executive management and to prepare a report of contact for documentation.

(2) Executive management planned to clarify reporting for the Radiation Safety Officer through the Chief of Engineering in a meeting scheduled for September 13, 2000.

(3) Executive management provided clarification to the Administrative Officer to the Chief of Staff for the role of the management representative on the Radiation Safety Committee.

b. Radiation surveys and follow-up actions

(1) The Nuclear Medicine Service implemented a procedure to use only Luer-lock syringes for all injections of radiopharmaceuticals, to place an absorbent pad under each patient's arm during administrations for pharmacological stress myocardial perfusion studies, and to allow only nuclear medicine technologists to administer radiopharmaceuticals and remove and dispose of IV tubing from patients undergoing myocardial perfusion studies.

(2) The Nuclear Medicine Service is surveying the cardiac treadmill room at midday, in addition to the end-of-the-day surveys.

(3) A consultant provided training to the nuclear medicine technologists on contamination control procedures on September 5, 2000.

c. Radiation safety training and instruction

(1) Research Service was informed of the correct delivery location for radioactive materials packages. Research Service was tasked to notify Nuclear Medicine Service of research package orders.

(2) The Nuclear Medicine Service staff and cardiology fellows were provided instructions regarding food, beverages, and utensils in radioactive material use areas and possible disciplinary action for future infractions.

(3) Training materials for new cardiology fellows were modified.

d. Waste management: Executive management tasked the Radiation Safety Officer to prepare a plan to dispose of the accumulated waste.

7. NHPP conclusions

a. The medical center has committed four violations as listed below:

(1) Failure to have adequate management oversight of radiation safety program operations,

- (2) Failure to perform adequate radiation safety program surveys and follow-up actions,
- (3) Failure to provide radiation safety training and instruction, and
- (4) Failure to inventory, manage, and dispose of radioactive waste.

b. The root causes for the violations were as follows:

- (1) Failure to establish and implement accountability and reporting procedures for the radiation safety program,
- (2) Failure to implement standards of practice for radiation safety surveys and evaluation of results,
- (3) Failure to establish and implement policy and procedures for training, surveys, waste management, and receipt of radioactive materials, and
- (4) Failure to provide adequate supervision for the Nuclear Medicine Service work center.

c. The contributing factors for the violations were as follows:

- (1) The organizational structure of the radiation safety program hindered prompt and effective communication of significant radiation safety issues from either the Radiation Safety Committee or the Radiation Safety Officer to executive management.
- (2) The Radiation Safety Officer failed to identify root causes of incidents and recommend appropriate corrective actions to the Radiation Safety Committee.
- (3) The minutes of the Radiation Safety Committee minutes have not always been distributed in a timely manner.
- (4) The nuclear medicine technologists have not followed adequate contamination control practices while handling radioactive materials. In particular, they have not performed sufficiently frequent surveys of their hands.
- (5) There was a careless disregard of policy regarding food, beverages, and eating and drinking utensils in restricted areas by the nuclear medicine staff.
- (6) The management representative on the Radiation Safety Committee was not fully aware of his role.
- (7) The licensee did not dispose of radioactive waste promptly per NRC Information Notice 90-09.
- (8) The Radiation Safety Officer did not follow standards of practice to review and evaluate radiation safety survey results.

8. NHPP actions

- a. Hold conference call with executive management to review agreed to facts.
- b. Issue inspection report with requirement for written response within 30 days.
- c. Task medical center to do the following:
 - (1) Obtain an external review of contamination control procedures in Nuclear Medicine Service by an outside expert, not currently employed or contracted by the medical center, within 60 days of the date of the NHPP inspection report, and
 - (2) Obtain a review of the effectiveness of corrective actions by an outside expert, not currently employed or contracted by the medical center, within six months of the date of the NHPP inspection report.

Department of
Veterans Affairs

Memorandum

Date: September 22, 2000

From: ACOS R&D (537/151LS)

Subj: Response to NRC Letter of September 15, 2000

To: Director (00) *WLA*
Associate Director (01) *qu*

Thru: COS (11) *by 9/24/00*

1. The Nuclear Regulatory Commission (NRC) letter of September 15, 2000 requests that we reply to their concerns by Oct 15, 2000.
2. In the September 15th letter their concerns included; lack of corrective action associated with contamination events and conduct in radiologically controlled areas. They were also concerned that corrective actions that were taken appeared not to be effective in preventing recurrence.
3. My recommendations are that the Medical Center immediately take a number of corrective actions and that these actions are then described and documented in our response letter.
4. Recommended actions for the Director:
 - Appoint a new Chairperson for the Radiation Safety. Mr. Citron appears to have selected Dr. Barch. The VA NHPP surveyors also suggested Dr. Barch.
 - The Director personally communicate this change to the current Radiation Safety Committee (RSC) Chairman (Dr. Chang), personally thank him for his service, present Dr. Chang with a Letter of Appreciation or other such letter thanking him for his service as RSC chair, and request that he continue to serve on the RSC committee to be our institutional memory and to assist the new Chair.
 - That the reporting structure of the RSC be changed so that they report more directly to the Director (not through three other levels).
 - That the role of the Management representative on the RSC be clearly defined to include that this individual is responsible for bring issues of importance directly to upper management in addition to the committee reports to management through the committee structure.
 - That the reporting structure and responsibilities of the Radiation Safety Officer (RSO) be clarified so that the RSO clearly understands his responsibility to bring important issues directly to upper management and that he is responsible for documenting these communications, including the plans and outcomes of proposed resolutions to these issues.
5. Recommended Actions for the Radiation Safety Committee.
 - That the committee members be educated as to their role and responsibilities under a broad scope NRC license.
 - That an emergency meeting of the RSC be called to review and address the issues identified by the NRC, NHPP, and our own internal evaluation.
 - At this meeting the committee review the issue of spills, food in the radiation areas, receipt of radioactive packages into the Medical Center, onsite storage of radioactive waste, and the problems with the previous reporting of issues to Central Management. For each of these issues the committee needs to review the issues, review the new policies implemented, review the effectiveness of these policies since implemented and then determine if additional

The RSC also needs to review and approve any new Radiation users such as any Nuclear Medicine staff from Hines and approve the new or acting Chief of Nuclear Med to document that we are aware and approve of such changes following the resignation of Dr. Wojowics.

The RSC needs to hold the Chief of Nuc Med and the Chief of Cardiology responsible for the activities which occur in these areas and the RSC must be willing to revoke privileges of employees, physicians, residents and fellows who do not follow our rules and policies.

6. Recommended Actions for the Radiation Safety Officer.

The RSO needs to review the new reporting structure of the RSC and RSO and document that he understands these systems and feels that these will be effective communication systems.

The RSO needs to present a clear system for acceptance and control of radioactive packages for Research (preferably including the computerized system for Research ordering and direct shipment to research). This system needs to be approved by the RSC and disseminated to all users, the mailroom and receiving.

The RSO needs to present a plan and completion dates concerning waste removal.

7. If you have any additional questions, please contact me at ext #4310.



David H. Barch, M.D.

Man message for BARCH,DAVID ACOS R&D
 Printed at CHICAGO-WEST.VA.GOV 08 Oct 00 17:29
 Subj: Radiation Safety Committee Meeting Announcement [#14697401] 27 Sep 00 15:51 11 lines
 From: CHANG,SUNG KIL 1 of 1 response read. In 'IN' basket. Page 1

 An Emergency RSC Meeting is scheduled for Wednesday, 10/4/00 at 11:00 a.m. in room 2SB-06. Dr. D. Barch will be the acting chairman. As you may know already, the main agenda will be the response to and action on the result of the NRC and the NHPP inspections. All the members are requested to attend the meeting.

Mr. Salsbury, please have the last meeting (7/19/00) minutes ready for the discussion and approval at the meeting. I will be away on leave next week as I was excused by Dr. Barch. You may contact Dr. Barch if you have any questions or need more information.

Thank you, all, for your special consideration in and cooperation with this matter in advance.

1) BARCH,DAVID 28 Sep 00 12:59 29 lines

Agenda: Radiation Safety Committee October 4, 2000.
 11:00 AM in the Radiation Oncology Conference Room, 2nd Sub-basement.

Review and approval of Minutes of Previous Radiation Safety Committee meeting.

Review of the Medical Center Directors Recommendation for a New Chairman of the Radiation Safety Committee and revised Medical Center Memorandum for the Radiation Safety Committee.

Review of the Correspondence from the recent NRC inspection and the recent NHPP inspection of the Nuclear Medicine and Radiation Safety Program at VA Chicago Health Care System-Lakeside Division.

Issues:

Spills in Nuclear Medicine
 Food in Labeled Radiation Areas
 Receipt of Radiation package shipments
 Management of Radioactive Waste
 Communication between Radiation Safety Committee, RSO, and Medical Center Management

Review of New Radiation Safety Users

Nuclear Medicine; Dr. Nicholas Friedman M.D. and Dr. Leo Ackerman M.D. as Nuclear Medicine Physicians. Dr. Bangaruswamy Chandramouli, M.D. as the Acting Chief of Nuclear Medicine, VA Chicago.

Research Service: Dr. Barch's request for license for 32P, 35S in MSB rooms 237A and 237B.
 Dr. Richard Green's request for license for 32P, 35S, 3H, 14C in MSB rooms 300 and 112.

Local Message-ID: 14697401@CHICAGO-WEST.VA.GOV (15 recipients)

This message was addressed as follows:

BARCH,DAVID
 BORENSZTAJN,JAYME
 BRACKEN,KATHLEEN
 CHANDRAMOULI,BANGARUSWAMY
 CHANG,SUNG KIL
 CLEMENT,MICHAEL D
 CURRY,JAMES W
 EASTES,ERICK
 FLOWERS,CALVIN
 HUGHES,RONALD J
 KAMARIA,OMPRAKASH R
 LABADIE,KAREN S

.Subj: Radiation Safety Committee Meeting Announcement [#14697401] Page 2

SALSBURY, WILLIAM CHARLES
SCHMITT, BRIAN P
SPEER, BEVERLY L

**Department of
Veterans Affairs****Memorandum**

Date September 5, 2000

From James E. Rosenthal, M.D.; Chief, Cardiology Section, VA Chicago-Lakeside Division 

Subj Stress Lab rules

To David Barch, M.D.
Acting Chief of Staff

1. With respect to our conversation this morning, I was aware of the fact that on August 1, 2000 Dr. Allison Kean, one of our cardiology fellows, brought a cup of coffee into the cardiology stress laboratory, which is a room marked as a radiation area. This incident occurred on the first day of her month's long rotation in the laboratory.
2. On August 2, 2000, after I found out about the incident, I counseled Dr. Kean. To the best of my knowledge, she committed no further violations of radiation safety policy.
3. Dr. Constance Wojtowicz, Chief of Nuclear Medicine, and I have prepared a set of written rules with regard to conduct in rooms marked as radiation safety areas (attached). These documents are entitled:
 - (a) *Conduct in the nuclear stress laboratory*, dated September 5, 2000
 - (b) *Cardiology stress lab rules-Lakeside*, dated September 5, 2000
 - (c) *Policy regarding food and drink for all staff working in radiation areas*, dated September 5, 2000
4. We shall document, by means of signatures, that cardiology fellows and Heart Station employees assigned to the stress lab have received these rules and agree to comply with them.

Enclosures

Copies: Radiation Safety Committee Chairman through Chief of Staff
Dr. Brian Schmitt
Dr. Constance Wojtowicz

**VA CHICAGO HEALTH CARE SYSTEM
LAKESIDE DIVISION
Departments of Medicine (Cardiology Section) and Nuclear Medicine**

CONDUCT IN THE NUCLEAR STRESS LABORATORY

1. This policy applies to all members of the Department of Medicine and/or the Cardiology Section who are assigned to work in the stress laboratory or in other rooms marked as radiation areas in Nuclear Medicine. Such personnel include Heart Station technologists, cardiology fellows, and internal medicine residents.
2. Personnel will follow all rules and policies of the Nuclear Medicine section with regard to radiation safety, including those listed in the following documents:
 - (a) *Cardiology stress lab rules-Lakeside*, dated September 5, 2000
 - (b) *Policy regarding food and drink for all staff working in radiation areas*, dated September 5, 2000
3. Cardiology fellows and Heart Station technologists will indicate with their signature that they have reviewed the above policies. The document containing these signatures will be maintained by the director of Nuclear Medicine.
4. Violation of these rules and policies will result in formal counseling and disciplinary measures consistent with VHA HRMS policy. For cardiology fellows, a second violation will result in the generation by the Chief of Cardiology at the Lakeside Division of a memo to the Chief of the Division of Cardiology and the Director of the cardiology fellowship program at Northwestern University Medical School for filing with the fellow's permanent personnel folder. For medical residents, the aforementioned memo for a second violation will be sent to the Director of the internal medicine residency program at Northwestern University Medical School.

September 5, 2000

SEPT 5, 2000

CARDIOLOGY STRESS LAB RULES- LAKESIDE

RSO: William "Chuck" Salsbury x3000; Pager: 312 389 6901

POLICIES:

- 1. Fellows will attend radiation safety training at NMH.**
- 2. Film badges will be supplied by NMH and worn while conducting stress tests.**
- 3. Personnel must have alternate pair of shoes available in case of spill-contamination.**
- 4. Booties must be worn to cover shoes to minimize likelihood of shoe contamination.**
- 5. Only nuclear medicine technologists will handle radiopharmaceutical injection.**
- 6. Nuclear medicine technologists will remove and dispose of IVs.**
- 7. PREGNANCY: please notify radiation safety if you are or might be pregnant.**
- 8. No food or drink at any time in the stress lab.**

9/5/2000

Policy regarding food and drink for all staff working in radiation areas..

1. **No food, drink or associated containers are to be taken into any room marked as a radiation area.**
2. **Currently, in the nuclear medicine area such rooms are 254, 255, 257 258, and 260.**
3. **Violation of this policy will result in formal counseling and disciplinary measures consistent with VHA HRMS policy.**

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-
VA CHICAGO HEALTH CARE SYSTEM
LAKESIDE DIVISION
Departments of Medicine (Cardiology Section) and Nuclear Medicine

I have received copies of the following documents pertaining to rules of conduct in the nuclear stress laboratory:

- (a) *Conduct in the nuclear stress laboratory*, dated September 5, 2000
- (b) *Cardiology stress lab rules-Lakeside*, dated September 5, 2000
- (c) *Policy regarding food and drink for all staff working in radiation areas*, dated September 5, 2000

I understand these rules and agree to comply with them.

ATTACHMENT 5

Training will be performed as required, i.e. the janitorial and security services will have the required training by the end of October. Hazardous materials training, for those individuals requiring this training, will be completed by the end of November.

The RSO will evaluate the surveys being performed for compliance with NRC mandated requirements. Those not meeting NRC requirements will be corrected to bring them into compliance. The health physics software package, currently being installed, will help in prompting surveyors to enter the necessary information. Special attention will be paid to determine the isotope, cause of the spill and corrective actions recommended.

The RSO has been tasked with talking directly with management concerning those issues which pose a significant safety issue. This may occur through the Environment of Care Committee or through direct contact.

The waste inventory has been located and is enclosed. The recent Nuclear Medicine waste and approximately 2 drums from research are not on the inventory. These will be added by the end of November

W C Salsbury 10 OCT 00
William C Salsbury, Radiation Safety Officer Date

VA CHICAGO - WAREHOUSE
 INVENTORY 10-10-2000
 OF RADIOACTIVE WASTE

Jugs Inventory
 Activities in mCi

ATTACHMENT 6

Waste ID#	Storage Date	H-3	C-14	P-32	S-35	Co-57	I-125	##	H-3	C-14	P-32	S-35	Co-57	I-125
5	4/11/80		0.2						0	0.1996	0	0	0	0
2092b	9/6/95	0.001	0.01						0.0009	0.01	0	0	0	0
2104	8/6/93	0.0012							0.0009	0	0	0	0	0
2114	6/11/96	0.1							0.0903	0	0	0	0	0
2359	8/29/95		0.002						0	0.002	0	0	0	0
2379	3/26/96	0.1							0.0892	0	0	0	0	0
2383	4/20/96					0.015	0.05		0	0	0	0	0.0024	1E-05
2395	4/26/96					0.015	0.05		0	0	0	0	0.0025	1E-05
2396	8/9/96					0.015	0.05		0	0	0	0	0.0032	5E-05
2397	4/26/96					0.015	0.05		0	0	0	0	0.0025	1E-05
2398	4/26/96					0.015	0.05		0	0	0	0	0.0025	1E-05
2403	7/12/96	0.1							0.0907	0	0	0	0	0
2406	8/9/96					0.015	0.05		0	0	0	0	0.0032	5E-05
2407	8/9/96					0.015	0.05		0	0	0	0	0.0032	5E-05
2408	8/9/96					0.015	0.05		0	0	0	0	0.0032	5E-05
2409	8/9/96					0.015	0.05		0	0	0	0	0.0032	5E-05
2417	8/30/96	0.05							0.0457	0	0	0	0	0
2422	10/10/96					0.015	0.05		0	0	0	0	0.0038	0.0001
2423	10/10/96					0.015	0.05		0	0	0	0	0.0038	0.0001
2424	10/10/96					0.015	0.05		0	0	0	0	0.0038	0.0001
2425	10/10/96					0.015	0.05		0	0	0	0	0.0038	0.0001
2427	9/6/93	0.1	0.01						0.0772	0.01	0	0	0	0
2432	1/24/97					0.015	0.05		0	0	0	0	0.0049	0.0003
2433	1/24/97					0.015	0.05		0	0	0	0	0.0049	0.0003
2434	3/7/97						0.05		0	0	0	0	0	0.0006
2435	1/24/97					0.015	0.05		0	0	0	0	0.0049	0.0003
2442	3/7/97						0.05		0	0	0	0	0	0.0006
2443	3/7/97						0.05		0	0	0	0	0	0.0006
2444	4/18/97						0.035		0	0	0	0	0	0.0006
2445	4/18/97						0.035		0	0	0	0	0	0.0006
2452	10/15/97						0.035		0	0	0	0	0	0.0051
2553	10/15/97						0.035		0	0	0	0	0	0.0051
2454	4/18/97						0.035		0	0	0	0	0	0.0006
2462	10/15/97						0.035		0	0	0	0	0	0.0051
2463	10/15/97						0.035		0	0	0	0	0	0.0051

Waste ID#	(Container) Form	Lab location Placed	Date Placed	Date Removed	W. Log Isotopes	Activity mCi	Date to 10 half-lives	Date Disposed	Method of Disposal	By
2491	Jug	716		10/15/97	I-125	0.035				
2492	Drum	257	11/19/97	1/12/98	Tc-99m TI-201	0.030 0.010	2/12/98			
2493	Drum	258	11/19/97	2/19/98	Tc-99m TI-201	0.030 0.015	3/19/98			
2494	Bag	MSB-305		11/21/97	H-3	0.030				
2495	Vials	MSB-305		11/21/97	H-3	0.015	deregulated			
2496	Vials	MSB-305		11/21/97	H-3	0.015	deregulated			
2497	Drum	257	1/12/98	2/19/98	Tc-99m Xe-133 TI-201	0.030 0.015 0.020	4/19/98			
2498	Drum	809	2/3/98							
2499	Jug	809	2/3/98							
2500	Drum	258	2/18/98	3/25/98	Tc-99m TI-201	0.015 0.010	4/25/98			
2501	Drum	257	2/19/98	3/25/98	Tc-99m Xe-133 TI-201	0.030 0.015 0.010	5/25/98			
2502	Drum	258	3/25/98							
2503	Drum	257	3/25/98							
2504	Drum	258	6/24/98		Tc-99m TI-201 Xe-133					
2505	Drum	257	6/26/98		Tc-99m TI-201 Xe-133					
2506	Drum	258	6/26/98	8/21/98	Tc-99m TI-201 Ca-67					
2507	Drum	257	6/26/98	8/21/98						
2508	Drum	257	8/21/98							
2509	Drum	258	9/19/98	9/24/98	Tc-99m TI-201					
2510	Jug	300 MSB	8/19/98							
2511	Drum	258	9/24/98		Tc-99m TI-201					

Barch, David H.

From: Kuchyak, Jacqueline
Sent: Wednesday, October 04, 2000 9:21 AM
To: Barch, David H.
Cc: Citron, Richard; Hughes, Ronald J.; Salsbury, William, Charles; Schmitt, Brian P.; Desai, Prakash N.
Subject: MEMO of October 3, 2000

I am in receipt of your memo dated October 3, 2000. It will not be possible to provide all that you have requested for today's meeting.

I have met with Radiation Safety Officer (RSO) and the Chief of Engineering together and separately on numerous occasions since the NRC and NHPP visits. It is clear to RSO and Chief of Engineering that although he reports to the Chief of Engineering, he is to bring violation to the Associate Director and/or Director immediately. He is also aware that recurring problems should be brought directly to the Associate Director as well. We discussed that we will continue to use the morning meeting as a vehicle to bring issues to the entire leadership team. It is clear to the RSO that the Associate Director has an open door for him.

The RSO is being added as a member of the Environment of Care Committee and the Associate Director recently took over as the chair. We discussed the minutes and they have been reformatted to more clearly define issues and follow the issues to completion. At the last meeting, it was made clear that the committee needed to document problems to resolution. Please note that the Chair of the Radiation Safety Committees have not been attending the EOC meeting over the past year.

I will ask via this message that the RSO bring the minutes from the last meeting to your meeting today. I will meet with the RSO to provide deadlines for the other information requested. Action plans will be finalized now that we had the call with NHPP. Plans will be sent to leadership before being sent to the committee.

Please call me if you would like to discuss further.

VA Chicago Health Care System
Chicago, Illinois

MEMORANDUM NO.00-21
Appendix F-LS
October 10, 2000

Lakeside Division Radiation Safety Committee

1. PURPOSE: The purpose of this policy memorandum is to define the functions and responsibilities of the Lakeside Division Radiation Safety Committee (RSC) and its role in the ALARA program. The VA Chicago Health Care System has separate Radiation Licenses for the Lakeside and Westside Divisions. Each Division maintains its own independent Radiation Safety Committee. The ALARA program is a program established to ensure that to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public are "as low as is reasonably achievable" (ALARA).

2. POLICY: The Lakeside Division Radiation Safety Committee provides guidelines for the medical and research use of all forms of ionizing radiation at the Lakeside Division of the VA Chicago Health Care System. The Lakeside Division Radiation Safety Program is defined by the Lakeside Division Radiation Safety Committee and its established procedures through the regulations prescribed by the United States Nuclear Regulatory Commission and other associated regulatory agencies

3. DEFINITIONS:

a. **ABJOPC-** Adam Benjamin Jr Out Patient Clinic (Crown Point)

b. **Abbreviated Radiation Safety Committee-** A two person (RSO and Radiation Safety Committee Chairperson) Committee who may act for the Radiation Safety Committee in limited circumstances. See Abbreviated Radiation Safety Committee under PROCEDURES.

c. **ACOS-** Associate Chief of Staff

d. **ALARA-** as low as reasonably achievable

e. **AUTHORIZATION-** also user **AUTHORIZATION-** the process and paperwork that allows principal investigators to buy, possess and use radioactive material. Normally issued for radioactive materials only. Principle investigators submit appropriate user **AUTHORIZATION** forms and paperwork to the Committee, the Committee reviews the application and approves/disapproves the application. If approved the principle investigator will receive an approval notification which will also detail the isotope, amount, form, etc. of radioactive material that the principle investigator may buy, use, and/or possess.

f. **CFR-**Code of Federal Regulations

g. **Chairperson-** see Radiation Safety Committee Chairperson

h. **DOT-**Department of Transportation

i. **FDA-**Food and Drug Administration

j. **JCAHO-Joint Commission on Accreditation of Hospitals Organization**

k. **National Health Physics Program-the VA's initiative to combine all NRC licenses in the VA under one Master License.**

l. **NRC-Nuclear Regulatory Commission**

m. **OSHA-Occupational Safety and Health Administration**

n. **Lakeside Division Radiation Safety Committee- The primary Committee reviewing the use of radiation devices, radioactive materials, and the control of those materials at the Lakeside Division of the VA Chicago Health Care System. Has the authority of the Director, VA Chicago Health Care System with respect to all Lakeside Division radiation issues. Any member may meet with any employee of VACHCS (to include the Director, VACHCS) in order to discuss radiation safety issues. Normally, the Committee will report to the Director, VACHCS through the Environment of Care Committee.**

o. **Radiation Safety Committee Chairperson- over sees and supervises the Radiation Safety Committee.**

p. **RSO-Radiation Safety Officer- the person or persons tasked with the day to day radiation safety overview responsibilities. The RSO has a dual roll, to act as a member of the Radiation Safety Committee and to act as the Director's representative in dealing with radiation safety issues. Has the authority of the Director, VA Chicago Health Care System with respect to all unsafe radiation issues (has immediate authority to stop all unsafe uses of radiation producing devices or radioactive materials). Normally reports to the RSSC but has the authority to talk to any employee of VACHCS including the Director.**

q. **Summary Report-An NRC mandated report discussing ALARA, status of program, personnel exposures, changes to license(s), and recommendations for the radiation safety program.**

r. **VA-Department of Veterans Affairs**

s. **VACHCS- VA Chicago Health Care System**

4. **MEMBERSHIP: The following individuals (or their designates) are appointed as members of the Lakeside Division Radiation Safety Committee (RSC):**

**ACOS for Research (Lakeside Division), Radiation Safety Committee Chairperson
Chief, Nuclear Medicine Service
Chief, Radiology Service
Dental Service Representative
Chief, Medical Service
Chief, Nursing Service
Radiation Safety Officer, Radiation Safety Committee Secretary
Director's Management Representative (Administrative Assistant to the Chief of Staff/Lakeside Division)
Chief, Engineering Services**

The following individuals (or their designates) are appointed as members of the Abbreviated Radiation Safety Committee,

**Chairperson, Radiation Safety Committee
Radiation Safety Officer**

5. RESPONSIBILITIES:

a. The Radiation Safety Committee will:

1. Be familiar with all pertinent NRC, OSHA, JCAHO, and FDA regulations; and the NRC license applications, licenses and amendments.
2. Ensure that all individuals who work with or in the vicinity of radioactive materials or ionizing radiation, have sufficient training and experience to enable them to perform their duties safely and in accordance with Nuclear Regulatory Commission (NRC) regulations, the conditions of this medical center's NRC materials license, and the radiation safety policies described in the Radiation Safety Manual.
3. Ensure that all use of radioactive material and ionizing radiation is conducted in a safe manner and in accordance with NRC regulations, the conditions of this medical center's NRC materials license, and the radiation safety policies described in the Radiation Safety Manual.
4. Determine whether current radiation safety procedures are maintaining ionizing radiation exposures "as low as reasonably achievable" (ALARA) through a table of investigational levels for both workers and members of the public.
5. Ensure that licensed radioactive material will be used safely. This includes the review as necessary of training programs, equipment, facility supplies and procedures.
6. Review on the basis of safety and approve or deny all requests for **AUTHORIZATION** to use radioactive materials within the Lakeside Division of the Medical Center, consistent with the limitations of the regulations, the NRC license, and the ALARA philosophy.
7. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
8. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radiation or radioactive materials are used are appropriately instructed as required in 10CFR19.12 and 29CFR1910.96(i).
9. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
10. Ensure that the NRC licenses are amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

b: The Radiation Safety Officer (RSO) will:

1. Perform Annual and Quarterly Reviews.

- (a) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Review of specific methods of use may be conducted on a more frequent basis.

(b) Quarterly review of occupational exposures with special attention to pregnant personnel. The RSO will review at least quarterly radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(c) Quarterly review of records of radiation area surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

2. Carry Out the Education Responsibilities for the ALARA Program.

(a) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(b) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

(c) The RSO will inform pregnant workers of their dose limits and provide additional monitoring or protective devices if warranted based on the type of work the individual performs.

3. Review Instances of Deviation from Good ALARA Practices. The RSO will investigate all known instances of deviation from good ALARA practices (including overexposures, accidents spills, losses, thefts, unauthorized receipts, uses transfers, disposals, misadministrations, and other deviations from approved radiation safety practices) and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Establish and oversee implementation of written policies and procedures for:

- (a) Authorizing the purchase of radioactive material;
- (b) Receiving and opening packages containing radioactive material;
- (c) Storage of radioactive material;
- (d) Inventorying radioactive material;
- (e) Ensuring the safe use of sources of radiation;
- (f) Taking emergency action if control of radioactive material is lost;
- (g) Performing periodic radiation surveys;
- (h) Calibration of survey instruments and other safety equipment;
- (i) Disposal of radioactive waste;

(j) Training personnel who work in or frequent areas where sources of radiation are used or stored;

(k) Keeping copies of all records and reports required by NRC/NHPP regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations;

5. Brief management at least once a year on the radiation protection program:

6. Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

7. Approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety and the subsequent approval by the Radiation Safety Committee;

8. Consult with users and advising management on radiation safety principles and practices to minimize exposure to radiation;

9. Assist the Radiation Safety Committee in the performance of its duties.

6. PROCEDURES:

a. The Radiation Safety Committee will:

1. Quarterly

(a) Review the Summary Report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.

(b) Review the report of inspections of radiation producing equipment, noting needs for repair.

(c) Review the report of radiation surveys, inspections, incidents, and notices of violation issued by the Radiation Safety staff.

2. Annually (generally the first meeting of the year)

(a) Review the Summary Report of the entire safety program to determine that all activities are being conducted safely, in accordance with NRC, OSHA, FDA, etc. regulations and the requirements of the byproduct materials license, and are consistent with the ALARA program and philosophy. The review should include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system.

(b) Review the records of radioisotope usage in nuclear medicine and radiation research involving human subjects.

3. At any meeting

(a) Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the byproduct materials license, and the ALARA philosophy, all requests for AUTHORIZATIONS to use radioactive material. The minimum review will include:

an estimate of the maximum dose anticipated for any individual involved in the experiment

ALARA considerations

the amount of radioactive material to be used and the (chemical) compound or form

the training and experience level of proposed users of radioactive material

any special requirements for this authorization (bioassay, physical examinations of users, special instrumentation or film badges)

any emergency response issues

any waste disposal issues

any environmental or offsite issues

any other safety issues (i.e. fire, toxicity...)

The AUTHORIZATIONS are good for a period of one year unless the Committee approves a longer time.

b. The Abbreviated Radiation Safety Committee (ARSC):

The Chairperson may sign for the Committee (but not the Radiation Safety Officer) for AUTHORIZATIONS that:

The ARSC acts for the RSC between regularly scheduled meetings and may approve AUTHORIZATIONS which must be approved between Radiation Safety Committee meetings AND that the Chairperson believes to be low risk and/or having been reviewed and approved earlier (i.e. AUTHORIZATION's for experiments that are substantially identical to ongoing or previously approved AUTHORIZATIONS). If the Chairperson feels that the full Radiation Safety Committee needs to be involved, they may call a meeting of the Radiation Safety Committee at any time. Approval of the ARSC requires approval of both the Chairperson and the RSO

Any AUTHORIZATIONS, approved by only the Abbreviated Radiation Safety Committee, must be presented to the Committee at its next meeting.

c. The Radiation Safety Committee and/or (if within the limited scope of) The Abbreviated Radiation Safety Committee will:

1. Review, on the basis of safety, and recommend approval or disapproval, with the advice and consent of the Radiation Safety Officer changes in radiation safety procedures, manuals, NRC licenses....
2. Ensure that the NRC radioactive materials license is complied with or amended prior to any changes in facilities, equipment, policies, procedures and personnel.

3. Ensure that all persons whose duties may require them to work in or frequent areas where radioactive material or radiation is used are appropriately instructed as required in 10CFR19.12 and 29CFR1910.96(i)

4. Ensure that all radiation exposures are ALARA and that the risks and benefits are weighed in any approval for use of radioactive material or radiation producing device.

5. Review and recommend approval or disapproval, with regard to the training and experience of the incumbent Radiation Safety Officer (RSO) and future applicants for the position. Selection and appointment of applicants for this position is by approval of the Director following review by the Radiation Safety Committee.

d. Authorized Users of Radioactive Material:

1. New Methods of Use Involving Potential Radiation Doses

(a) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(b) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs of new uses will be encouraged.

2. Authorized User's Responsibility to Supervised Individuals.

(a) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(b) The authorized user will also ensure that pregnant workers are informed of the ALARA concept as it pertains to pregnant workers.

(c) The authorized user will inform the Radiation Safety Officer in the event of any declared pregnant worker.

(d) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

7. **MEETINGS:** The Radiation Safety Committee will meet at least quarterly, or as called by the Chairperson. To establish a quorum, at least one half of the Committees membership; including the Chair, RSO, Nursing representative, one radioactive material user and a management representative; must be present.

8. **MINUTES:** Written minutes of all Committee meetings; including dates, attendance, discussions, actions, recommendations, decisions, and approvals; will be recorded, approved by the RSC, and forwarded to the Director through the Environment of Care Committee for review. Serious safety issues may be immediately communicated to Management (the Director, Associate Director, or Chief of Staff-Lakeside Division) with written correspondence provided to the Director and to the Radiation Safety Committee to document such correspondence.

9. **REFERENCES:** 10CFR (NRC), 29CFR1910.96 (OSHA), 21CFR (FDA), 49CFR (DOT), various NRC licenses.


Richard S. Citron
Director

Distribution: A
Members

Curriculum Vitae

David H. Barch, M.D.

Office Address: VA Chicago Health Care System-Lakeside Division
Research Service (151)
400 East Ontario
Chicago, Illinois 60611

Date and Place of Birth: [REDACTED]

Education:

Fellow in Gastroenterology, Northwestern University, Chicago, IL. 1982-1984
Medical Resident, Northwestern University, Chicago, IL. 1979-1982
M.D. with Distinction from Wayne State University, Detroit, MI. 1979
B.S. with High Honors in Biochemistry, Michigan State University, East Lansing, MI. 1975

Appointments:

Associate Chief of Staff for Research and Development, VA Chicago Health Care System-Lakeside, Chicago, IL. Nov 26, 1995 to present
Director-Robert H. Lurie Cancer Center Central Facilities/Media Prep, Northwestern University Lurie Cancer Center, Chicago, IL. Nov 1, 1990 to present
Associate Professor of Medicine, Department of Medicine, Northwestern University, Chicago, IL. July 1, 1990 to present.
Staff Physician, Department of Medicine, Lakeside Veterans Affairs Medical Center, Chicago, IL. July 1, 1990 to present
Chief, Section of Gastroenterology, Dept of Medicine, Lakeside Veterans Administration Hospital, Chicago, IL. Jan 1, 1992 to Nov 25, 1995 and Acting Chief June 1999 to July 2000
Assistant Chief of Staff for Quality Assurance, Westside Veterans Administration Hospital, Chicago, IL. February 1989-June 1990
Assistant Professor of Medicine, Department of Medicine, University of Illinois at Chicago, Chicago, IL. Sept 1986-June 1990
Staff Physician, Department of Medicine, Westside Veterans Administration Hospital, Chicago, IL. July 1984-June 1990
Instructor, Department of Medicine, University of Illinois at Chicago, Chicago, IL. July 1984-August 1986
Instructor, Department of Medicine, Northwestern University, Chicago, IL. July 1983-June 1984

Honors:

Alpha Omega Alpha
M.D. with Distinction, Wayne State University
B.S. with High Honors, Michigan State University

Specialty Certification:

Diplomat of the American Board of Internal Medicine 1982
Diplomat in the Subspecialty of Gastroenterology 1987

Licensure: Illinois Physician and Surgeon #36-61569

David H. Barch, M.D.

Committees:

- Department of Veterans Affairs, Medical Research Merit Review Council,
June 1997 to Present.
- Department of Veterans Affairs, Medical Research Merit Review Appeals Committee,
October 1996 to June 1999.
- Department of Veterans Affairs, Research and Development National Biosafety Taskforce.
February 1997 to June 1998.
- National Cancer Institute-Member of the RFA Review Committee "Translational Investigations
in Cancer Prevention and Control" December 1996, Bethesda MD
- National Cancer Institute-Member of the RFA Review Committee "Dietary Exposure and
Effects of Plant Food Constituents" July 1996, Bethesda MD
- National Cancer Institute-Ad Hoc Member of the Path B Study Section,
National Institutes of Health, January 1992.
- National Cancer Institute-Member of the RFA Review Committee "Mechanisms of Tobacco
and Alcohol in Carcinogenesis" August 1988, Bethesda MD
- Chairman-University Chemical and Biological Safety Committee, Northwestern University.
1995 to Present (Committee Member 1993-1995)
- Member-Northwestern University Institutional Review Board (IRB) Advisory Committee,
August 1999 to Present.
- Member-Northwestern University Medical Problem Based Learning Steering Committee,
November 1999 to Present.
- Member-Northwestern University Medical School Research Committee, Northwestern
University. 1996 to 1998
- Member-Medical School Medical Scientist Training Program (MSTP) Steering Committee.
1995 to Present
- Member-Developmental Research Committee, Robert H. Lurie Cancer Center,
Northwestern University. 1993 to Present
- Member-Research and Development Committee, VA Chicago Health Care System-
Lakeside Division. 1994 to Present
- Member-Institutional Research Grant Committee, Illinois Cancer Center.
1990 to 1992.
- Member-Scientific Advisory Committee of the Carol Fisher Chapter, National Foundation for
Ileitis and Colitis. 1987 to 1991.
- Member-College of Medicine Committee on Research (BSRG Review Committee),
University of Illinois. 1986 to 1990.
- Chairman-Clinical Quality Assurance Committee, West Side Veterans Administration
Medical Center. 1986 to 1990.
- Member-University of Illinois Hospital Committee on Medical Records. University of Illinois.
1986 to 1990.
- Ad Hoc Reviewer-Veterans Administration Merit Review
- Ad Hoc Reviewer-University of Illinois Campus Research Board
- Ad Hoc Reviewer-Cancer Research, Carcinogenesis, Gastroenterology, New England Journal
of Medicine, Biochemical Pharmacology, Nutrition and Cancer, Journal of Laboratory and
Clinical Medicine, The Cancer Journal, Cancer.

Invited Lectures:

- National Cancer Institute Symposium: Role of Essential Nutrients in Carcinogenesis.
February 1, 1985, Bethesda, MD.
- American College of Nutrition Symposium: Nutrition and GI Cancer
September 22, 1987, Pheasant Run, IL.
- Medizinische Universitätsklinik, Schwerpunkt Gastroenterologie
January 12, 1988, Heidelberg, West Germany
- Nutrition Seminar Series, Department of Preventive Medicine, Univ. of Texas
Medical Branch at Galveston April 3 1989 Galveston TX.

David H. Barch, M.D.

Cancer Center Conference, Fred Hutchinson Cancer Research Center,
September 7, 1989, Seattle, WA.

Grand Rounds, Medical College of Ohio, December 17, 1990, Toledo, OH.

National Cancer Institute and Univ. of Texas M.D. Anderson Cancer Center

Symposium: Environmental Carcinogenesis and Its Prevention:

The Head and Neck Cancer Model. October 7, 1991, Hershey, PA.

Chairman, Esophageal Cancer-American Gastroenterological Association

Research Forum, Digestive Disease Week, May 18, 1993, Boston, MA.

Chairman, Gastroenterology Research Forum, Annual Meeting of the Central

Society for Clinical Research, Sept 17, 1994, Chicago, IL.

Environmental Toxicology Seminar Series, University of Illinois

October 27, 1995, Urbana-Champaign, IL.

Research Support:

1999-(2002) Department of Veterans Affairs Merit Review Grant

\$234,000. Mechanisms of the Anticarcinogenic Actions of Ellagic
Acid. Principal Investigator D.H. Barch, M.D.

1993-(2001) National Institutes of Health, National Cancer Institute

Cancer Center Core Grant P30-CA60553, \$6,250/yr in Salary Support as
Director of Central Facilities of the Northwestern University

Lurie Cancer Center. Principal Investigator S.T. Rosen, M.D.

1995-(1998) Department of Veterans Affairs Merit Review Grant

\$206,400. Mechanisms of the Anticarcinogenic Actions of Ellagic
Acid. Principal Investigator D.H. Barch, M.D.

1995-1997 American Institute for Cancer Research

\$99,895. Induction of Carcinogen Detoxifying Enzymes by the Dietary
Anticarcinogen Ellagic Acid. Principal Investigator D.H. Barch, M.D.

1990-1994 Veterans Administration Merit Review Grant

\$295,200. Mechanisms of the Anticarcinogenic Actions of Ellagic
Acid. Principal Investigator D.H. Barch, M.D.

1988-1992 National Institutes of Health, National Cancer Institute

RO1-CA40487 \$231,082. Role of Zinc and Ethanol in Esophageal
Carcinogenesis. Principal Investigator D.H. Barch, M.D.

1987-1990 Veterans Administration Merit Review Grant

\$136,900. Effects of Ellagic Acid on Nitrosamine Induced
Esophageal Carcinoma. Principal Investigator D.H. Barch, M.D.

1988-1989 American Cancer Society-Illinois Division

\$25,116. Mechanisms of Oncogene Activation in Esophageal
Carcinogenesis. Principal Investigator D.H. Barch, M.D.

1988-1989 Biomedical Research Support Grant BRSG S07 RR 05369

\$21,140. Ultracentrifuge for Research in the Department
of Medicine. Principal Investigator D.H. Barch, M.D.

1985-1988 National Institutes of Health: New Investigator Research Award

R23-CA40487 \$107,473. Role of Zinc and Ethanol in Esophageal
Carcinogenesis. Principal Investigator D.H. Barch, M.D.

1985-1986 Veterans Administration Research Activities Grant

\$24,180. Effects of Dietary Ethanol on Nitrosamine Induced
Esophageal Carcinoma. Principal Investigator D.H. Barch, M.D.

1984-1985 Campus Research Board Grant #975 University of

Illinois at Chicago, Health Sciences Center. \$11,992.
Esophageal Metabolism of N-Nitrosomethylbenzylamine.

Principal Investigator D.H. Barch, M.D.

1984-1985 American Cancer Society Grant IN-159 \$7439.

Zinc Deficiency and Methylation of Esophageal DNA

David H. Barch, M.D.

Principal Investigator D.H. Barch, M.D.

1983-1984 Northwestern University Biomedical Research Support
Grant RR05370 Award #8379. \$5000. Effects of Zinc Deficiency
on Nitrosamine Induced Esophageal Carcinogenesis.
Principal Investigator D.H. Barch, M.D.

Membership in Professional Societies:

Alpha Omega Alpha
American Association for Cancer Research
Fellow of the American College of Physicians
American Gastroenterological Association
American Society for Cell Biology
Chicago Society of Gastroenterology
Eastern Cooperative Oncology Group (ECOG)
Midwest Gut Club

Publications/Articles:

Barch, D.H., Kuemmerle, S.C., Hollenberg, P.F. and Iannaccone, P.M. Esophageal Microsomal Metabolism of N-Nitroso-Methylbenzylamine in the Zinc Deficient Rat. Cancer Research 44:5629-5633, 1984.

Kim, Y.D., Nolan, J., Malkin, A., Barch, D. and Tomita, J.T.
A Qualitative Agar Gel Immunoprecipitin (IP) Test for Detection of Fecal Occult Human Hemoglobin. Clinica Chimica Acta 154:175-184, 1985.

Barch, D.H., Walloch, J., Hidvegi, D. and Iannaccone, P.M. The Histopathology of Methylbenzyl nitrosamine-Induced Esophageal Carcinoma in the Rat: A Comparison with Cytomorphology. Journal of the National Cancer Institute 77:1145-1153, 1986.

Barch, D.H., Iannaccone, P.M. Role of Zinc Deficiency in Carcinogenesis. In: Essential Nutrients in Carcinogenesis (L. Poirier, P. Newberne, and M. Pariza, eds) pp. 517-527, Plenum Press, New York, 1986 (Advances in Experimental Medicine and Biology, Volume 206).

Barch, D.H., Mobarhan, S. Vitamin Deficiencies In the Alcoholic Patient. Nutrition and the MD 13:1-3, 1987.

Barch, D.H., Fox, C.C., Mobarhan, S. Effects of Chronic Disease on Nutrition. Nutrition International 3:79-86, 1987.

Barch, D.H., Fox, C.C., Bennett, B.T. A Simple System of Feeding Bottles for the Study of Zinc Deficiency and Ethanol Consumption in the Rat. Laboratory Animal Science 37:504-506, 1987.

Barch, D.H., Fox, C.C. Dietary Zinc Deficiency Increases the Methylbenzyl nitrosamine-Induced Formation of O-6-Methylguanine in the Esophageal DNA of the Rat. Carcinogenesis 8:1461-1464, 1987.

Boron, B., Hupert, J., Barch, D.H., Fox, C.C., Friedman, H., Layden, T.J., Mobarhan S. Effect of Zinc Deficiency on Hepatic Enzymes Regulating Vitamin A Status. Journal of Nutrition 118:995-1001, 1988.

Diamond, K.L., Fox, C.C., Barch, D.H. The Role of Cecal pH in Intestinal Oxalate Absorption in the Rat. J Lab Clin Med 112:352-356 1988.

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Barch, D.H., Fox, C.C. Selective Inhibition of Methylbenzyl nitrosamine Induced Formation of Esophageal O⁶Methylguanine by Dietary Ellagic Acid in Rats. Cancer Research 48:7088-7092, 1988.

Mobarhan, S., Barch, D.H. Nutritional Management of Patients with Deglutition Disorders, Transfer Dysphagia and Esophageal Carcinoma. Diseases of the Esophagus 2:15-22, 1989.

Roxe, D.M., Mistovich, M., Barch, D.H. Phosphate Binding Effects of Sucralfate in Patients with Chronic Renal Failure. American Journal of Kidney Diseases 13:194-199, 1989.

Andrianopoulos, G.D., Nelson, R.L., Barch, D.H., and Nyhus, L.M. Sulfasalazine Alters the Character of Dimethylhydrazine-Induced Colorectal Carcinoma in Rats. Anticancer Research 9:1725-1728, 1989.

Barch, D.H. Esophageal Cancer and Microelements. Journal of the American College of Nutrition 8:99-107, 1989.

Barch, D.H., Fox, C.C. Dietary Ellagic Acid Reduces the Esophageal Microsomal Metabolism of Methylbenzyl nitrosamine. Cancer Letter 44:39-44, 1989.

Andrianopoulos, G.D., Nelson, R.L., Barch, D.H., Bombeck, C.T., and Nyhus, L.M. The Effect of Mild Stress on 1,2-Dimethylhydrazine Induced Colorectal Cancer. Cancer Detection and Prevention 14:577-581, 1990.

Shapiro, A.B., Barch, D.H. Constipation. In: Conn's Current Therapy, R.E. Rakel, M.D. (ed) W.B Saunders Co., New York. 14-17, 1991.

Barch, D.H., Jacoby, R.F., Brasitus, T.A., Radosevich, J.A., Camey, W.P. and Iannaccone, P.I. Incidence of Harvey-ras Oncogene Point Mutations and Their Expression in Methylbenzyl nitrosamine-Induced Esophageal Tumorigenesis. Carcinogenesis 12:2373-2377, 1991.

Klygis, L.M. and Barch, D.H. The Role of Ethanol in Esophageal Carcinogenesis. In: Alcohol and Cancer (R. R. Watson, Ph.D., ed) pp. 73-89, CRC Press, Boca Raton, 1992.

Mobarhan, S., Greenberg, B., Mehta, R., Friedman, H., and Barch, D. Zinc Deficiency Reduces Hepatic Cellular Retinol-Binding Protein in Rats. International Journal for Vitamin and Nutrition Research 62:148-154, 1992.

Barch, D.H., Fox, C.C., Rosche, W.A., Rundhaugen, L.M. and Wrighton, S.A. Inhibition of Rat Methylbenzyl nitrosamine Metabolism by Dietary Zinc and Zinc *in vitro*. Gastroenterology 103:800-806, 1992.

Barch, D.H., Rundhaugen, L.M., Thomas, P.E., Pillay, N.S. and Kardos, P. Dietary Ellagic Acid Inhibits the Enzymatic Activity of CYP1A1 Without Altering Hepatic Concentrations of CYP1A1 or CYP1A1 mRNA. Biochemical and Biophysical Research Communications 201:1477-1482, 1994.

Barch, D.H., Rundhaugen, L.M. Ellagic Acid Induces NAD(P)H:Quinone Reductase Through Activation of the Antioxidant Regulatory Element of the Rat NAD(P)H:Quinone Reductase Gene. Carcinogenesis 15:2065-2068, 1994.

Barch, D.H., Rundhaugen, L.M., Pillay, N.S. Ellagic Acid Induces Transcription of the Rat Glutathione S-Transferase Ya Gene. Carcinogenesis 15:665-668, 1994.

David H. Barch, M.D.

Siglin, J.C., Barch, D.H., Stoner, G.D. Effects of Phenethyl Isothiocyanate, Ellagic Acid, Sulindac and Supplemental Dietary Calcium on the Induction and Progression of N-Nitrosomethylbenzylamine-Induced Esophageal Carcinogenesis. Carcinogenesis 16:1101-1106, 1995.

Barch, D.H. Dietary Ellagic Acid Induces Transcription of the Phase II Detoxification Enzyme Glutathione S-Transferase Ya. Journal of the Robert H. Lurie Cancer Center 4:76-82, 1995.

Kawamata, H., Kameyama, S., Kawai, K., Nan, L., Barch, D.H., Steller-Stevenson, W.G. & Oyasu, R. Marked Acceleration of the Metastatic Phenotype of a Rat Bladder Carcinoma Cell Line by the Expression of Human Gelatinase A. Int. J. Cancer 63:568-575, 1995.

McBride, M.A., Vanagunas, A.A., Breshnahan, J.P. & Barch, D.H. Combined Endoscopic Thermal Electrocoagulation with High Dose Omeprazole Therapy in Complicated Heterotopic Gastric Mucosa of the Esophagus. Am. J. Gastro. 90:2029-2031, 1995.

Barch, D.H., Rundhaugen, L.M., Stoner, G.D., Pillay, S. and Rosche', W.A. Structure-Function Relationships of the Dietary Anticarcinogen Ellagic Acid. Carcinogenesis 17:265-269, 1996.

Rosenberg-Ben-Dror, K., Barch, D.H., Rooney, R. and Borensztajn, J. Developing a Pharmacist Managed Helicobacter pylori Clinic. Federal Practitioner 14(7):7-19, 1997.

Di Renzo, A., Fisk, B., Barch, D.H., Haines, K. Heterogeneity of Microsatellite Mutations Within and Between Loci, and Implications for Human Demographic Histories. Genetics 148:1269-1284, 1998.

Publications/Abstracts:

Wilson, J., Barch, D. Heterogeneity of Rat Brain Mitochondria. Federation Proceedings 30:1139 Abstr, 1971.

Barch, D.H., Pandey, R.N., Kuemmerle, S.C., Hollenberg, P.F., Iannaccone, P.M. Effects of Dietary Zinc Deficiency on Esophageal Microsomal Metabolism of Methylbenzyl nitrosamine. Proceedings of the American Association for Cancer Research 25:133, 1984. Presented at: 1984 Annual Meeting of the American Association for Cancer Research.

Barch, D.H., Iannaccone, P., Hidvegi, D., Walloch, J. Effects of Zinc Deficiency on the Cytology of the Rat Esophagus. Acta Cytologica 28:660, 1984. Presented at: 1984 Annual Meeting of the American Society of Cytology.

Barch, D.H. Zinc Induced Inhibition of the Esophageal Microsomal Metabolism of Methylbenzyl nitrosamine (MBN). Proceedings of the American Association for Cancer Research 26:A416, 1985. Presented at: 1985 Annual Meeting of the American Association for Cancer Research.

Barch, D.H. Noncompetitive Inhibition of the Esophageal Microsomal Metabolism of Methylbenzyl nitrosamine by Zinc In Vitro. Gastroenterology 88:1315, 1985. Presented at: 1985 Annual Meeting of the American Gastroenterological Association.

Barch, D.H. Zinc In Vitro Noncompetitively Inhibits the Hepatic Microsomal Metabolism of Methylbenzyl nitrosamine. Clinical Research 33:A319 1985

David H. Barch, M.D.

Barch, D.H. Zinc Deficiency Increases Methylbenzyl Nitrosamine Induced Formation of O-6-Methylguanine in the Rat Esophagus. Clinical Research 34:A951, 1986. Presented at: 1986 Annual Meeting of the Central Society for Clinical Research-Midwest Section.

Barch, D.H., Fox, C.C. Dietary Ethanol and Total Caloric Restriction Both Increase the Esophageal Microsomal Metabolism of Methylbenzyl Nitrosamine. Gastroenterology 90:1336, 1986. Presented at: 1986 Annual Meeting of the American Gastroenterological Association.

Barch, D.H., Fox, C.C. Noncompetitive Inhibition of the Hepatic Microsomal Metabolism of Dimethylnitrosamine (DMN) by Dietary Zinc and Zinc In Vitro. Proceedings of the American Association for Cancer Research 27:118, 1986. Presented at: 1986 Annual Meeting of the American Association for Cancer Research.

Boron, B., Hupert, J., Fox, C., Barch, D., Freidman, H., Layden, T.J., Mobarhan, S. Effect of Zinc Deficiency on Hepatic Enzymes Regulating Vitamin A Status. Federation Proceedings 47:1011, 1987. Presented at: 1987 Annual Meeting of FASEB.

Diamond, K.L., Fox, C.C., Barch, D.H. The Effect of Lactulose on Cecal pH and Intestinal Oxalate Absorption in the Rat. Clinical Research 35:886A, 1987. Presented at: 1987 Annual Meeting of the Central Society for Clinical Research-Midwest Section.

Barch, D.H., Fox, C.C. Dietary Zinc Deficiency Increases the Formation of Methylbenzyl Nitrosamine Induced O-6-Methylguanine in the Rat Esophagus. Proceedings of the American Association for Cancer Research 28: 1987. Presented at: 1987 Annual Meeting of the American Association for Cancer Research.

Barch, D.H., Radosevich, J., Carney, W.P., and Iannaccone, P.M. Evidence Supporting a G->A Transition at Position 34 in H-ras-1 in Methylbenzyl Nitrosamine Esophageal Tumorigenesis. Journal of Cell Biology A591, 1987. Presented at: 27th Annual Meeting of the American Society for Cell Biology.

Barch, D.H. Esophageal Cancer and Micronutrients. Journal of the American College of Nutrition 6:427, 1987. Presented at: 28th Annual Meeting of the American College of Nutrition.

Barch, D.H., Fox, C.C. Dietary Ellagic Acid Inhibits the Cytochrome P-450 Dependent Esophageal Microsomal Metabolism of Methylbenzyl Nitrosamine. Clinical Research 36: 1988. Presented at: 1988 AAP/ASCI/AFRC Meeting.

Barch, D.H., Fox, C.C. Different Cytochrome P-450 Enzymes are Responsible for the Activation of Hepatic and Esophageal Specific Nitrosamines. Clinical Research 36:871A, 1988. Presented at: 1988 Annual Meeting of the Central Society for Clinical Research-Midwest Section.

Barch, D.H., Fox, C.C. Dietary Ellagic Acid Selectively Blocks Methylbenzyl Nitrosamine Induced Formation of Esophageal O⁶Methylguanine Without Altering the Formation of ⁷Methylguanine. Proceedings of the American Association for Cancer Research 29:A515, 1988. Presented at: 1988 Annual Meeting of the American Association for Cancer Research.

Andrianopoulos, G.D., Nelson, R.L., Barch, D.H., Carvalho, P., and Nyhus, L.M. The Effect of Sulfasalazine on 1,2-Dimethylhydrazine- Induced Colorectal Carcinogenesis. Anticancer Research 8:1055-1056, 1988. Presented at: Second International Conference of Anticancer Research, October 1988, Saronis Greece.

David H. Barch, M.D.

Barch, D.H., Fox, C.C. Effects of Acute Ethanol Administration on Methylbenzyl nitrosamine (MBN) Induced Methylation of Esophageal DNA in the Rat. Gastroenterology 94:A21, 1988. Presented at: 1988 Annual Meeting of the American Gastroenterological Association.

Barch, D.H., Fox, C.C., Koop, D.R. Different Cytochrome P-450 Enzymes are Responsible for the Activation of Hepatic and Esophageal Specific Nitrosamines. Hepatology 8:1278, 1988. Presented at the 1988 Annual Meeting of the American Association for the Study of Liver Diseases.

Barch, D.H., Farrell L.C., Fox C.C., Rosche W.A. Inhibition of Methyl nitrosourea (MNU)-Induced formation of O-6-Methylguanine (O6mGua) by Gallic Acid (GA). Proceedings of the American Association for Cancer Research 30:A676, 1989. Presented at: 1989 Annual Meeting of the American Association for Cancer Research

Mobarhan, S., Greenberg, B., Mehta, S., Friedman, H., Barch, D., & Layden, T.J. Zinc deficiency reduces cellular retinol binding protein. FASEB Journal 4:A659, 1990.

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David H. Barch, M.D.

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**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date FEB 20 2002

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

Subj: Nuclear Regulatory Commission (NRC) Inspection

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

1. The NRC inspected the radiation safety program at the VA Chicago Health Care System on November 14, 2001.
2. The attached NRC, Region III, inspection report of February 13, 2002, does not cite any violations. You are not required to respond to the NRC or this memorandum.
3. If you have any questions, please contact Gary E. Williams, VHA National Health Physics Program, at (501) 257-1572.


E. Lynn McGuire

Attachment

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



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

February 13, 2002

Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NRC INSPECTION (IR 03001435/2001001(DNMS) &
03001435/2001002(DNMS)) DEPARTMENT OF VETERANS AFFAIRS,
VA CHICAGO HEALTH CARE SYSTEM

Dear Mr. McGuire:

This refers to the routine inspection conducted at the VA Chicago Health Care System Lakeside and the VA Chicago Health Care System West Side from November 14, 2001 through January 16, 2002. The objective of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The inspection involved an examination of activities conducted under the VA Chicago Health Care System license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. At the conclusion of the inspection, the findings were discussed with VA Chicago Health Care System representatives. In addition, the findings were discussed with you by telephone on January 30, 2002.

The inspection included a review of the circumstances related to a spill of approximately 200 nanocuries of sodium-22 at the West Side facility. The radiation safety officer reported the event to the NRC on November 10, 2001 due to the potential that a researcher may have received an occupational dose to the skin in excess of the NRC's regulatory limit of 50 rems shallow-dose-equivalent. Sodium-22 is not byproduct material, and, therefore, its possession and use is not subject to NRC jurisdiction. However, 10 CFR 20.1003 defines occupational dose, in part, as dose received in the course of employment from both NRC-licensed materials and materials not subject to NRC jurisdiction. Since the researcher involved in the spill of sodium-22 also received exposure from byproduct materials, any dose that she may have received from her use of sodium-22 that could have resulted in her occupational dose exceeding any of the NRC's regulatory limits is subject to our review.

During the inspection period, the VA Chicago Health Care System staff's conduct of licensed activities was generally characterized by safety-conscious health physics operations. Specifically, the inspector concluded that the staff's response to and proposed corrective actions for the sodium-22 event were adequate. VA Chicago Health Care System staff determined that the dose to the researcher from the spill of sodium-22 was 3.6 rem shallow-dose-equivalent, a dose substantially below the regulatory limit of 50 rems shallow-dose-equivalent. Our review of the calculations determined that the assumptions used were reasonable and valid. No violations of regulatory requirements were identified during the inspection.

L. McGuire

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure(s) will be available electronically for public inspection in the NRC Public Document Room or from the *Publicly Available Records (PARS) component of NRC's document system (ADAMS)*. *ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).*

Sincerely,


Gary L. Shear, Chief
Material Inspection Branch

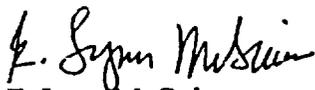
Docket No. 030-01435
License No. 12-02642-06

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date: OCT 31 2000
From: Director, VHA National Health Physics Program (115HP/NLR)
Subj: Radiation Safety Program Inspection and Notice of Violation - Inspection Report 537A4-00-I01
To: Director (537A4/00), VA Chicago Health Care System, Lakeside Division, Chicago, Illinois

1. Joseph R. Wissing and Edwin M. Leidholdt, Jr., Ph.D., VHA National Health Physics Program, performed an announced reactive inspection at the VA Chicago Health Care System, Lakeside Division. The inspection was in response to concerns raised by the Nuclear Regulatory Commission after their August 1-2, 2000, inspection. The on-site portion of the inspection was conducted during September 6-8, 2000. The inspection was closed on October 2, 2000.
2. Attachment A is the inspection report. Attachment B is a Notice of Violation that cites four violations. The violations represent a Severity Level III problem. You must respond to the Notice of Violation within 30 days of the date of this memorandum. You must follow the instructions in Attachment B in preparing the response.
3. You also must complete the following actions listed in the agreed-to facts in Attachment C:
 - a. Obtain an external review of contamination control procedures in Nuclear Medicine Service by an outside expert within 60 days of the date of this memorandum.
 - b. Obtain a external review of the effectiveness of corrective actions within six months of the date of this memorandum.
4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Wissing at (734) 761-7906 if you have any questions regarding the inspection 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 537A4-00-I01
VA Chicago Health Care System, Lakeside Division
September 6-8, 2000

1. Introduction

a. The VHA National Health Physics Program (NHPP) performed an announced reactive inspection at the VA Chicago Health Care System, Lakeside Division. The on-site portion of the inspection was conducted September 6-8, 2000, with continuing review through October 2, 2000, when the inspection was closed.

b. The inspection was in response to concerns raised by the Nuclear Regulatory Commission (NRC) after their August 1-2, 2000, inspection. Joseph R. Wissing and Edwin M. Leidholdt, Jr., Ph.D., NHPP, performed the inspection. Mr. Wissing and Dr. Leidholdt presented preliminary findings at a meeting with key medical center staff on September 8, 2000.

c. An exit interview was conducted by teleconference on October 2, 2000, to discuss the agreed-to facts. Lakeside Division executive management concurred with the agreed-to facts in Attachment C.

2. Scope of inspection

The inspection followed a pre-approved inspection plan focusing on five areas of concern raised by the NRC:

- a. Numerous contamination incidents in nuclear medicine.
- b. Repeated findings of food, beverages, and utensils in restricted areas of nuclear medicine.
- c. Training of nuclear medicine staff with emphasis on HAZMAT and package receipt.
- d. Disposal of radioactive waste, including decay-in-storage materials and sealed sources.
- e. Radiation Safety Officer (RSO) authority and management support.

During the inspection, NHPP inspectors interviewed medical center personnel and reviewed radiation safety program records. The inspectors performed surveys for radioactive contamination and radiation exposure rates in Nuclear Medicine Service. The daily operations of Nuclear Medicine Service were observed on two mornings. The inspectors reviewed staff performance in the handling of radioactive materials and receipt surveys of radioactive packages delivered to the radiopharmacy. One inspector inspected the radioactive waste storage rooms. The organizational structure of the radiation safety program, with an emphasis on the functioning of the Radiation Safety Committee (RSC) and communication of significant radiation safety issues to executive management, was reviewed.

**Radiation Safety Program Inspection
VA Chicago Health Care System, Lakeside Division – September 6-8, 2000**

3. Findings and impressions

a. Recent NRC and NHPP inspections:

(1) The NRC conducted a routine inspection on May 25-26, 1999, with continuing in-office review through June 23, 1999. At the conclusion of the inspection, the findings were discussed with medical center executive management during an exit briefing on May 26, 1999. During this inspection, the NRC inspector found contamination at several locations in Nuclear Medicine Service and on a technologist's hands. Analysis indicated that the dose to the technician's hands (estimated at 3.2 millirem) was well below regulatory limits. During the inspection, the NRC inspector's shoes were found to have minor contamination. A Notice of Violation was issued to the medical center on June 29, 1999, citing one Severity Level IV violation. The medical center had not secured from unauthorized removal or limited access to, as required by 10 CFR 20.1801, 200 microcuries of ^{32}P stored in an unlocked refrigerator located in an unrestricted area. Due to the medical center's action taken to correct the violation and prevent recurrence, the NRC did not require a response.

(2) The NRC conducted a routine inspection on August 1-2, 2000. The findings were discussed with medical center executive management by telephone on August 4, 2000, and described in a letter, dated September 15, 2000. No violations of regulatory requirements were cited. However, the NRC expressed concern about the "apparent lack of effective corrective actions associated with contamination events and conduct in radiologically controlled areas." Specifically, between July 9, 1999, and May 18, 2000, the RSO had identified multiple radioactive contamination events in the nuclear medicine hot lab, treadmill room, and hallway. Between May 10 and 17, 2000 alone, the department had four spills involving radioactive material. In one instance, two spills occurred with contamination great enough that the cardiac stress lab had to be closed for 3 days. In addition to the contamination events, between September 30, 1999, and June 18, 2000, the RSO had identified food, drink, or dishes in the nuclear medicine hot lab and the imaging rooms on 14 occasions. The NRC expressed concern that, while significant issues are being properly identified, corrective actions appeared to be ineffective in preventing their recurrence. The issues had been brought before the medical center's RSC; however, the problems had continued. Because an effective corrective action program is very important to radiation safety, the NRC requested that the medical center respond to the identified items within 30 days from the date of the NRC's letter. The NRC requested that the response be specific and reflect an assessment of current radiation safety activities, staff responsibilities, and the causal factors of the areas of concern.

(3) The NRC contacted the NHPP on August 17, 2000, and raised concern regarding five areas. In response, the NHPP performed a reactive inspection on September 6-8, 2000, focusing on the five areas. Preliminary findings were discussed with the medical center executive management on September 8, 2000.

Radiation Safety Program Inspection

VA Chicago Health Care System, Lakeside Division – September 6-8, 2000

b. Management oversight of the radiation safety program:

(1) *Organizational structure of the radiation safety program and communications with medical center executive management:* Prior to 1998, the RSO reported to the Chief of Staff, and the RSC, in effect, reported directly to executive management. In early 1998, the radiation safety program was reorganized, with the RSO reporting to the Chief, Engineering Service, who reports to the Associate Medical Center Director, and the RSC reporting to the Hazardous Materials Committee, which, in turn, reports to the Environment of Care Committee. The RSO meets daily with the Chief, Engineering Service. The Chief, Nuclear Medicine Service, is a member of both the RSC and the Environment of Care Committee, apparently for the purpose of maintaining liaison between the two committees. Since about September 1999, the Chairman, Environment of Care Committee, has been the Deputy Chief Engineer. He stated that the Environment of Care Committee has not received minutes from the RSC, and that he does not recall any radiation safety issues, with the exception of a proposed merger of the Lakeside Division and Westside Division RSCs, being brought to the attention of the Environment of Care Committee. In the NRC license application, the Chief of Staff is listed as a member of the RSC. However, the Administrative Officer to the Chief of Staff (AO) attends the meetings instead of the Chief of Staff and serves as the management representative on the committee. (The application states that delegates may attend in lieu of members.) The AO stated that he kept the minutes sent to him as his personal copies and mentioned more significant events to the Chief of Staff. The AO further stated that he believed that the committee had not concluded that a pattern of problems existed in Nuclear Medicine Service. The Chief, Radiation Oncology Section, Radiology Service, has served as the Chairman, RSC since 1986. He stated that the Chief, Nuclear Medicine Service, serves as the RSC's liaison with the Environment of Care Committee and that copies of the minutes are routinely sent to the Chief of Staff, who has recently retired. Recent RSC minutes, which had been initialed by the now retired Chief of Staff, were found in the files.

(2) *Amendment to the NRC license before restructuring the radiation safety program:* Item 26 of the NRC license requires that the radiation safety program be conducted per statements, representations, and procedures in the documents listed in Item 26, including the license application, dated February 29, 1988. The license application, under "Authority and Duties of the Radiation Safety Officer," states that the RSO reports to the Chief of Staff. However, since early 1998, the RSO has reported to the Chief, Engineering Service. The medical center had not submitted a license amendment request to approve the restructuring.

(3) *Adequate annual briefing of medical center executive management on the radiation safety program:* 10 CFR Part 35.21(b)(3) and "Authority and Duties of the Radiation Safety Officer," included in the NRC license application and incorporated by reference in the NRC license, require the RSO to brief management annually on the radiation safety program. The RSO has

Radiation Safety Program Inspection

VA Chicago Health Care System, Lakeside Division – September 6-8, 2000

presented annual radiation safety program review during RSC meetings with the most recent on April 20, 2000. Since the AO functions as the management representative at the RSC meetings, the RSO does not perform a formal briefing to executive management. The RSO and Chairman, RSC, stated that the attendance of the management representative at the RSC meetings and submission of minutes to the Chief of Staff is the method by which executive management is briefed on the radiation safety program. Thus, neither the Director, the Associate Director, nor the Chief of Staff receives a direct briefing annually of the status of the radiation safety program.

(4) *Radiation Safety Committee*: The RSC meets quarterly, with the RSO, management representative, and a quorum of the membership present at each meeting. The ongoing problems in Nuclear Medicine Service regarding radioactive contamination and prohibition of food, beverages, and utensils in restricted areas were discussed in the minutes of meetings held on July 21, 1999; October 15, 1999; January 19, 2000; and April 20, 2000, and in the annual review of the radiation safety program, presented at the April, 2000, meeting. Minutes of the July 19, 2000, meeting were not yet prepared at the time of the NHPP inspection.

(5) *Promptly providing minutes of the RSC meetings to members*: 10 CFR Part 35.22 requires the committee to promptly provide each member with a copy of the minutes. However, the RSO confirmed that he had not prepared minutes of the July 19, 2000, meeting by the date of this NHPP inspection. The Chairman, RSC, in an e-mail message dated April 27, 2000, expressed concern over a failure to submit committee minutes in a timely fashion.

(6) *Management representative on the RSC awareness of responsibilities*: An interview with the AO, who functions as the management representative to the RSC, indicated that the AO had not received training in the role of the management representative at RSC meetings. The Associate Chief of Staff for Research and Development stated that executive management had identified this as a deficiency.

(7) *Multiple instances of food, beverages, and eating and drinking utensils found in restricted areas of Nuclear Medicine Service*: The "Basic Rules for Radionuclide (Hot) Lab Conduct," contained in the NRC license application and incorporated by reference in the NRC license, states that no eating, drinking, food storage, or food preparation is permitted in radionuclide laboratories. In 1999, the RSO identified 16 incidents involving food, beverages, or utensils in restricted areas of Nuclear Medicine Service. The RSO identified four incidents earlier in 2000: one in January, two in February, and one in April. Many of these incidents involved eating or drinking utensils being stored or washed. (Technically, these rules do not forbid the storage or washing of utensils in radionuclide laboratories. However, the storage or washing of utensils in radionuclide laboratories is not consistent with standards of practice.) These incidents appear to have been committed mainly by staff nuclear medicine technologists, a former contract nuclear medicine technologist, and the former nuclear medicine secretary. The NRC inspector found a

Radiation Safety Program Inspection

VA Chicago Health Care System, Lakeside Division – September 6-8, 2000

new cardiology fellow consuming a beverage in the treadmill room, a radionuclide use laboratory during the 2000 NRC inspection. The NHPP inspectors did not observe similar violations. The RSO repeatedly reported these ongoing incidents to the RSC. The Chief, Nuclear Medicine Service, who was made aware of the incidents by the RSO and at RSC meetings, apparently requested the staff to comply with the rules, a request that proved ineffective. The RSC was aware of the ongoing incidents, though relied on the Chief, Nuclear Medicine Service, to take action. The RSC did not elevate the issue to executive management when the issue was not resolved. The organizational structure of the radiation safety program, described in paragraph 3.b.(1) above, appears to have kept executive management informed about the incidents.

(8) *Violation:* The failure of management to provide management oversight of the radiation safety program is a violation listed in Attachment B.

c. Radiation surveys and follow-up actions:

(1) *Nuclear Medicine Service staff surveys:* 10 CFR 35.70(e) requires weekly surveys for removable contamination of all areas where radiopharmaceuticals are routinely prepared, administered, or stored. 10 CFR 35.70(h) requires that the removable contamination be recorded for each area in units of disintegrations per minute (dpm) per 100 cm². The NHPP inspectors confirmed that surveys are being completed weekly in the year 2000. However, results are often not recorded in units of dpm per 100 cm². Furthermore, a single wipe test of all areas surveyed in the radiopharmacy is being performed and, when contamination is found on this test, the results is recorded for all areas surveyed. The standard of practice is to perform additional tests to document which areas are contaminated and which are not. The records do not document corrective action when contamination is found.

(2) *Notification of the RSO by Nuclear Medicine Service staff when contamination exceeded the trigger level:* 10 CFR 35.70 (g) requires the individual performing a survey to notify the RSO if contamination exceeds the trigger level. On the week of February 7, 2000, removable contamination was recorded as being 14,700 dpm per 100 cm² exceeding the action or trigger level of 2000 dpm per 100 cm². (This survey appeared to have been performed by a student technologist.) However, the RSO was not notified by the technologist.

(3) *Wipe tests of internal source containers during receipt surveys of radioactive packages by Nuclear Medicine Service staff:* The "Instructions for Inspecting Packages," contained in the NRC license application and incorporated by reference in the NRC license, requires that wipe tests of the internal source containers be performed for receipt surveys of packages of radioactive materials. The Nuclear Medicine Service staff does not perform these tests.

Radiation Safety Program Inspection

VA Chicago Health Care System, Lakeside Division – September 6-8, 2000

(4) *Surveys for radioactive spills in Nuclear Medicine Service:* 10 CFR Part 35.21 and Draft Station Memorandum No. 11-18, incorporated by reference in the NRC license, require the RSO to investigate radioactive spills. 10 CFR Part 20.1501 requires each licensee to perform surveys that may be necessary to comply with the regulations of Part 20 and are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive material, and the potential radiological hazards that could be present. 10 CFR Part 20.1003 defines "survey" to mean an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. 10 CFR Part 20.2103 requires records of such surveys to be kept for three years. The RSO stated that the only documentation of spills was in the RSC minutes. No other reports are prepared for each spill. The NHPP inspectors found the limited assessments documented in the RSC minutes to be inadequate, by themselves, to fulfill regulatory requirements and standards of practice. For example, spectroscopy was not performed to identify radionuclides, an estimation of the spilled activity was not performed, and documentation of an analysis of the causes of the spill and recommended corrective action was not prepared.

(5) *Contamination control procedures based upon repeated radiation safety survey results that indicated frequent contamination within the nuclear medicine areas:* The NRC inspections in 1999 and 2000 raised this issue. Modifications to handling procedures in Nuclear Medicine Service, to reduce contamination events, were made and discussed during the RSC meeting on January 19, 2000. After four spills in Nuclear Medicine Service in May, 2000, additional precautions were implemented. These appear to have been effective in reducing the frequency of the more severe contamination events. However, relatively minor contamination is still being found.

(6) *Violation:* The failure of the medical center to complete adequate radiation surveys and follow-up actions is a violation listed in Attachment B.

d. Radiation safety training and instruction:

(1) *Initial instructions to new cardiology fellow:* During the 2000 NRC inspection, the inspector observed a new cardiology fellow drinking a beverage in the treadmill room, a radioactive material use area. The RSO stated that the cardiology fellow was working at a computer terminal, that no radioactive materials were present in the room at the time, and that no Nuclear Medicine staff were present. The Chief, Nuclear Medicine Service, has been providing training to all new cardiology fellows. However, the instruction sheet for cardiology fellows did not address the issue of eating and drinking.

Radiation Safety Program Inspection

VA Chicago Health Care System, Lakeside Division – September 6-8, 2000

(2) *HAZMAT training to Nuclear Medicine Service staff:* 49 CFR Part 172.704 requires that workers involved in the shipping of radioactive materials receive HAZMAT training within 90 days of assuming these duties and every three years thereafter. 49 CFR Part 172.704 also specifies required training records that must be maintained. Nuclear Medicine Service staff prepare shipments of radioactive material for return to a commercial radiopharmacy, though no records of HAZMAT training were available. The RSO stated that he had not given HAZMAT training to the staff.

(3) *Annual training to housekeeping workers:* Attachment 8 to the NRC license application, incorporated by reference in the NRC license, requires housekeeping workers to receive one hour of training annually in specified topics related to radiation safety. The RSO stated that housekeeping staff are not receiving training.

(4) *Procedures for receiving radioactive materials for research laboratories:* On July 27, 2000, and on August 28, 2000, radioactive materials packages for Research Service were not promptly accepted by the medical center when delivery was attempted by the carrier. Current procedures specify package delivery to the Nuclear Medicine Service radiopharmacy and acceptance by Nuclear Medicine Service staff. According to the RSO, a carrier attempted to deliver a package containing approximately 250 microcuries of ^3H to the radiopharmacy on July 27, 2000, and someone refused to accept the package. The Chief, Nuclear Medicine Service, stated that she queried her staff and all denied refusing to accept the package. In the second case, a package containing approximately 500 microcuries of ^{32}P was mistakenly addressed to the RSO's office by Research Service, following the practice under the previous RSO. No one was present when delivery was attempted. According to the Associate Chief of Staff for Research, the research office staff had not been informed of the new delivery location, the Nuclear Medicine Service radiopharmacy.

(5) *Violation:* The failure of the medical center to complete initial training for cardiology fellows, HAZMAT training, annual training to housekeeping workers, and provide instructions for radioactive materials packages delivery is a violation listed in Attachment B.

e. Waste management:

(1) *Inventory of radioactive waste materials:* The RSO did not maintain an inventory of radioactive waste. Draft Medical Center Policy 11-18, Appendix A, "Authority and Duties of the Radiation Safety Officer," incorporated by reference in the NRC license, requires that inventories of radioactive materials be maintained. In addition, 10 CFR 35.21(b)(2)(iv) requires that the RSO maintain an inventory of radioactive materials. An inventory did not exist of the quantity and specific radionuclides in storage. The RSC minutes do not include inventories or discussion of radioactive materials currently held by the medical center. The RSO stated that he had not performed an inventory of radioactive waste in storage.

Radiation Safety Program Inspection

VA Chicago Health Care System, Lakeside Division – September 6-8, 2000

(2) *Storage of radioactive waste materials:* The volume of radioactive material stored in the rooms did not appear outside normal radiation safety program operations. Radioactive waste stored included approximately 20 containers of various sizes containing long-lived radioactive waste from Research Service. A few containers of radioactive waste from the clinical RIA lab, which has decayed to background levels, were present. One freezer had a small number of radioactive animal carcasses. Various decayed sealed sources (^{198}Au , ^{57}Co) and sealed sources with exempt quantities of byproduct material no longer in use were stored. Approximately 20 empty drums that had previously contained radioactive waste, which have not been assayed for residual radioactive material content, were stored. However, because of the lack of an inventory, discussed above, the total activity could not be determined.

(3) *NRC Information Notice 90-09:* The RSO did not dispose of radioactive waste promptly per standards of practice in NRC Information Notice 90-09.

(4) *Cleanliness of radioactive waste storage areas:* The two rooms used for radioactive waste storage are in disarray. Large amounts of dust and debris exist. The concrete floor is not sealed to prevent spilled radioactive liquids from being absorbed into the flooring.

(5) *Security for radioactive waste storage areas:* The radioactive waste storage areas were secure from authorized access.

(6) *Nuclear Medicine Service radioactive waste materials:* Nuclear medicine waste held for decay had been routinely disposed of per license requirements.

(7) *Violation:* The failure of the medical center to properly manage radioactive waste and maintain an inventory is a violation listed in Attachment B.

f. Medical center actions taken prior to the NHPP inspection:

Actions taken by the date of the NHPP inspection are documented in a May 17, 2000, memorandum from the Chief, Nuclear Medicine Service, to the RSO, and in a September 6, 2000, memorandum from the Associate Chief of Staff for Research and Development to the NHPP inspection team.

(1) *Management oversight of radiation safety program:*

(a) On September 5, 2000, executive management informed the RSO that he was responsible for carrying information directly to executive management when significant problems occurred and for documenting such interactions with a Report of Contact. The mechanism of when the

Radiation Safety Program Inspection

VA Chicago Health Care System, Lakeside Division – September 6-8, 2000

RSO should report through his supervisor, the Chief of Engineering, instead of directly to the Director or Associate Director was to be clarified in a meeting scheduled to occur before Wednesday, September 13, 2000. In addition, the responsibility of the AO was reviewed, and he now understands that, as the management representative to the RSC, he should also present issues to the Chief of Staff if they cannot wait to go through the standard committee reporting mechanism.

(b) NHPP assessment of actions taken by date of NHPP inspection: The NHPP considers these actions taken to be a useful initial step in resolving these issues. However, the steps taken do not address the organizational placement of the RSC in a hierarchy of committees and the lack of effective flow of information through the hierarchy.

(2) *Radiation surveys and follow-up actions:* Follow-up actions for radioactive spills and contamination events in Nuclear Medicine Service were as follows:

(a) Actions taken by date of NHPP inspection: The actions included implementing procedures to use only Luer-lock syringes for all injections, placing an absorbent pad under each patient's arm during injections for pharmacological stress myocardial perfusion studies, and allowing only nuclear medicine technologists to administer radiopharmaceuticals and remove and dispose of IV tubing from patients undergoing myocardial perfusion studies. According to the Chief, Nuclear Medicine Service, informal meter surveys are being performed of the cardiac treadmill room at midday, in addition to the formal end-of-the-day surveys. Furthermore, a consultant provided training to the nuclear medicine technologists in contamination control on September 5, 2000.

(b) NHPP assessment of actions taken by date of NHPP inspection: The actions appear to be effective in reducing the frequency of spills. However, the NHPP inspectors found instances of work practices likely to spread contamination. For example, a nuclear medicine technologist was observed handling a contaminated vial shield and then pressing a button on the dose calibrator with the same hand. The technologist later picked up a syringe holder from the dose preparation area with an ungloved hand. Another technologist picked up the only set of forceps with an ungloved hand. However, the forceps had been recently used in the contaminated dose preparation area. Further corrective action is required to reduce potential contamination.

(3) *Radiation Safety training and instruction:*

(a) Receipt of radioactive packages

(1) Actions taken by date of NHPP inspection: These include informing Research Service of the delivery location in Nuclear Medicine Service and establishing a procedure whereby Research Service staff will notify Nuclear Medicine Service of research package orders so that nuclear medicine staff will be prepared to receive the packages.

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Radiation Safety Program Inspection

VA Chicago Health Care System, Lakeside Division – September 6-8, 2000

(2) NHPP assessment of actions taken by date of NHPP inspection: These actions appear to be adequate. The NHPP inspectors discovered an unrelated violation in that Nuclear Medicine Service technologists were not performing wipes tests of the internal source containers, as required by the NRC license. Corrective action is required for this issue.

(b) Food, beverages, and utensils in Nuclear Medicine Service restricted areas.

(1) Actions taken by date of NHPP inspection: Corrective actions included ensuring that all nuclear medicine and cardiology personnel using these rooms are aware of the policy forbidding food, beverages, and utensils and are aware that disciplinary action will follow future infractions. Training materials for new cardiology fellows were modified to describe the prohibition.

(2) NHPP assessment of actions taken by date of NHPP inspection: The actions appear to be adequate, provided that they are consistently enforced.

(4) *Waste management:*

(a) Actions taken by date of NHPP inspection: Executive management directed the RSO to determine the resources necessary to dispose of stored radioactive waste.

(b) NHPP assessment of actions taken by date of NHPP inspection: The actions are a necessary initial step.

4. NHPP conclusions

a. Four violations of NRC regulatory requirements have been identified and are listed in Attachment B. Because of extent and nature of the violations, the violations represent a Severity Level III problem.

b. The violations do not pose an actual risk to the health and safety of staff, patients, or members of the public.

5. Further actions required

a. The medical center must respond to the Notice of Violation in Attachment B.

b. The medical center must complete the following:

(1) Obtain an external review of contamination control procedures in Nuclear Medicine Service by an outside expert not currently employed or contracted by the medical center within 60 days of the date of the NHPP inspection report

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(2) Obtain a review of the effectiveness of corrective actions by an outside expert, not currently employed or contracted by the medical center, within six months of the date of the NHPP inspection report.

6. Root and contributing causes

a. The NHPP identified the following root causes for the violations:

- (1) Lack of radiation safety program oversight by the RSC.
- (2) Ineffective audits of radiation safety program operations by the RSO.
- (3) Inadequate communications with executive management.
- (4) Inadequate radiation safety training.

(5) Inadequate supervision of nuclear medicine staff by the Chief, Nuclear Medicine Service in that no effective action was taken to stop the staff of Nuclear Medicine Service from taking food, beverages, and utensils into restricted areas.

b. The NHPP identified the following contributing factors:

(1) The organizational structure of the radiation safety program hindered prompt and effective communication of significant radiation safety issues from either the RSC or the RSO to senior medical center management.

(2) The RSO failed to identify root causes of incidents and recommend appropriate corrective actions to the RSC.

(3) The minutes of the RSC minutes have not always been distributed in a timely manner.

(4) The nuclear medicine technologists have not followed adequate contamination control practices while handling radioactive materials. In particular, they have not performed sufficiently frequent surveys of their hands.

(5) There was a careless disregard of policy regarding food, beverages, and eating and drinking utensils in restricted areas by the nuclear medicine staff.

(6) The management representative on the RSC was not fully aware of his role.

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(7) The licensee did not dispose of radioactive waste promptly per NRC Information Notice 90-09.

(8) The RSO did not follow standards of practice to review and evaluate radiation safety survey results.

7. Personnel contacted

Richard Citron, Medical Center Director ^{1,4}
Jacqueline Kuchyak, Acting Associate Director ^{1,2,3,4}
David H. Barch, M.D., Associate Chief of Staff for Research ^{1,3,4}
William Salsbury, RSO ^{2,3,4}
William Spaar, Deputy Chief Engineer and Chairman, Environment of Care Committee ²
Michael Clement, Management representative to the RSC ²
Constance Wojtowicz, M.D., Chief, Nuclear Medicine Service ²
Grace DiServio, Nuclear Medicine Technologist ²
Ermalinda Lojo, Nuclear Medicine Technologist ²
Sung Chang, M.D., Chief, Therapeutic Radiology Section, and Chair, RSC ^{2,3}
Brian Schmitt, M.D., Acting Chief of Staff ³
Ronald Hughes, Chief, Engineering Service ³
William Mudd, Process Improvement Coordinator ³

E. Lynn McGuire, Director, National Health Physics Program ⁴
Joseph Wissing, Program Manager, National Health Physics Program ^{1,2,3,4}
Edwin M. Leidholdt, Jr., Ph.D., Program Manager, National Health Physics Program ^{1,2,3,4}

Attendees for meetings:

¹Participated in entrance meeting on September 6, 2000

²Other contacts

³Participated in preliminary exit meeting on September 8, 2000

⁴Participated in final exit meeting on October 2, 2000

8. Notice of violation: Attachment B is a Notice of Violation that cites four violations. The violations represent a Severity Level III problem.

9. Agreed-to facts: Attachment C is the agreed-to facts.

**Notice of Violation
Inspection Report Number 537A4-00-I01**

VA Chicago Health Care System, Lakeside Division NRC License Number 12-02642-06

1. Management oversight of the radiation safety program – The medical center is required to ensure compliance with NRC regulations and license conditions.

Violation: Contrary to the above, the medical center failed to provide management oversight of the radiation safety program in that the Radiation Safety Officer (RSO) position was realigned without submitting an amendment request, the RSO failed to brief executive management annually, Radiation Safety Committee (RSC) minutes were not promptly distributed, the management representative to the RSC was not aware of responsibilities, and radiation safety practices in the Nuclear Medicine Service were not enforced.

2. Radiation surveys and follow-up actions – The medical center is required to perform adequate radiation surveys and take appropriate follow-up actions.

Violation: Contrary to the above, the medical center failed to complete adequate radiation surveys and follow-up actions in that weekly survey results were not recorded in appropriate units, the RSO was not notified when a survey result exceeded trigger levels, incoming packages were not properly checked, and the RSO did not complete adequate investigations of spills and possible contamination events.

3. Radiation safety training and instruction – The medical center is required to complete HAZMAT training for workers and annual training for housekeeping staff.

Violation: Contrary to the above, the medical center failed to complete radiation safety instruction and training in that training was not completed for a new cardiology fellow, workers shipping radioactive materials, and housekeeping staff, and procedures for radioactive materials package receipt were not effective.

4. Waste management – The medical center is required to inventory, maintain, and dispose of radioactive waste.

Violation: Contrary to the above, the medical center failed to properly manage radioactive wastes in that a waste inventory was not maintained.

These four violations represent a Severity Level III problem.

Required action:

a. The medical center must take prompt action to correct the violations listed in the NOV and ensure that they do not reoccur.

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Notice of Violation

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b. The medical center must submit a written statement to the NHPP within 30 days of the date of the memorandum transmitting this NOV. For each violation, the medical center 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 action that will be taken to avoid further violations.
- (4) Date when full compliance will be achieved.

c. Where good cause is shown, the NHPP will consider extending the response time. The medical center must use the following notice in preparing the response: NRC Information Notice 96-28, *Suggested Guidance Relating to Development and Implementation of Corrective Action*. The notice is available on the NHPP intranet web site at <http://nhpp.med.va.gov>.

**Agreed-To Facts
Inspection Report Number 537A4-00-I01**

VA Chicago Health Care System, Lakeside Division NRC License Number 12-02642-06

1. NRC routine inspections in 1999 and 2000

a. NRC routine inspection of May 25-26, 1999

(1) The inspector found contamination at several locations in Nuclear Medicine Service and on a technologist's hands.

(2) The inspector's shoes were contaminated.

(3) The NRC cited a severity level IV violation for failure to maintain security for a small vial of radioactive materials.

(4) The NRC discussed inspection findings with executive management.

b. NRC routine inspection of August 1-2, 2000

(1) The NRC did not cite any violations in the inspection report of September 15, 2000.

(2) The NRC did express concern about the "apparent lack of effective corrective actions associated with contamination events and conduct in radiologically controlled areas."

(3) The NRC requested that the medical center respond to the NRC concerns with an assessment of current radiation safety activities, staff responsibilities, and the causal factors of the areas of concern.

(4) The NRC discussed inspection findings with executive management.

c. NRC telephone contact with the NHPP

(1) The NRC contacted the NHPP on August 17, 2000, to discuss the most recent NRC inspection.

(2) The NRC later requested the NHPP to evaluate the medical center as related to the following issues:

(a) Numerous contamination events in nuclear medicine,

(b) Use of food, drink, and utensils in restricted areas,

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- (c) Training of nuclear medicine staff with emphasis on HAZMAT and package receipt,
- (d) Orderly disposal of radioactive waste, and
- (e) Radiation Safety Officer (RSO) authority and management support.

2. Management oversight

a. Organizational structure and communications with executive management

(1) Before 1998, the RSO reported to the Chief of Staff and the Radiation Safety Committee (RSC) reported directly to executive management.

(2) In early 1998, the RSO began reporting to the Chief, Engineering Service, and the RSC to the Hazardous Materials Committee, which in turn reported to the Environment of Care Committee. The medical center did not submit an amendment request to approve the organizational change.

(3) The Chief, Nuclear Medicine Service is a member of both the RSC and the Environment of Care Committee, for the purpose of maintaining liaison between the two committees.

(4) The Chairman, Environment of Care Committee has not received minutes from the RSC since before September 1999. The committee has not discussed any radiation safety issues, except a proposed merger of the Lakeside and Westside RSCs.

(5) The Administrative Officer to the Chief of Staff attends RSC meetings for the Chief of Staff, who is the management representative as submitted in the license application. The Administrative Officer to the Chief of Staff concluded that the committee had not identified a pattern of problems in Nuclear Medicine Service.

(6) The Chief of the Radiation Oncology Section of Radiology Service has served as the Chairman, RSC since 1986. The chair routinely sends a copy of the committee minutes to the Chief of Staff.

(7) The Chief of Staff recently retired. Copies of recent RSC minutes had been initialed by the former Chief of Staff.

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(8) The RSO presented the annual radiation safety program review to the RSC once each year. The most recent presentation was on April 20, 2000.

(9) The RSO did not present an annual briefing to executive management. The RSO and committee chair considered attendance of the management representative alternate at the committee meetings and submission of the minutes to the Chief of Staff as adequate to brief executive management.

b. RSC oversight

(1) The RSC discussed ongoing problems in the Nuclear Medicine Service regarding radioactive contamination and food, beverages, and utensils in restricted areas on July 21, 1999, October 15, 1999, January 19, 2000, and April 20, 2000.

(a) The RSO identified 16 incidents in 1999 involving food, beverages, or utensils in restricted areas of Nuclear Medicine Service.

(b) The RSO identified four incidents in early 2000: one in January, two in February, and one in April.

(c) The committee relied on the Chief, Nuclear Medicine Service, to take corrective actions and did not elevate the issue to executive management.

(2) The committee minutes of the July 19, 2000, meeting were not yet prepared as of September 6, 2000. The committee chair expressed concern over a failure to submit committee minutes in a timely fashion in an e-mail message of April 27, 2000.

(3) The Administrative Officer to the Chief of Staff, who attends committee meetings for the Chief of Staff, was not fully aware of the role and responsibilities for the management representative.

3. Radiation surveys and follow-up actions

a. Weekly wipe surveys are performed in the Nuclear Medicine Service. However, the results are often not recorded in units of dpm per 100 cm².

b. A single wipe test is performed of all areas in the radiopharmacy. Positive wipe test results are not investigated to determine the exact location of contamination.

c. Wipe survey results do not document corrective action if contamination is found.

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d. A wipe survey result for the week of February 7, 2000, indicated 14,700 dpm per 100 cm² that exceeded the action level of 2000 dpm per 100 cm². However, the RSO was not notified.

e. The Nuclear Medicine Service does not perform wipe tests of internal source containers during receipt surveys of radioactive packages.

f. The RSO does not follow standards of practice and 10 CFR Part 35.21 to perform adequate surveys, evaluations, and investigations for spills and contamination in the Nuclear Medicine Service. The RSO reported that the only documentation for spills was in the in the RSC minutes. The reports in the committee minutes are inadequate to:

- (1) Identify the radionuclides and estimated activities,
- (2) Determine the causes of the spill and contamination, and,
- (3) Recommend corrective action.

g. The RSC and RSO have not developed and implemented adequate contamination control procedures based upon repeated wipe survey results that indicate contamination within the Nuclear Medicine Service.

4. Radiation safety training and instruction

a. The instruction sheet used to train new cardiology fellows does not address the issue of eating and drinking in radioactive materials use areas.

b. HAZMAT training is not provided to nuclear medicine technologists who prepare shipments of radioactive materials for return to a commercial radiopharmacy.

c. Basic radiation safety training is not provided to housekeeping staff at least annually.

d. Two radioactive material packages were not properly received.

(1) A commercial carrier attempted to deliver a radioactive materials package with 250 μCi ³H to the radiopharmacy on July 27, 2000. A staff member refused to accept the package.

(2) A radioactive materials package with 500 μCi ³²P was mistakenly addressed to the RSO's office by Research Service, following instructions from the previous RSO. The Research Service was not informed of the new delivery location in the Nuclear Medicine Service.

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5. Waste management

a. The total activity and types of radioactive materials in the radioactive waste storage rooms is not known since an adequate inventory is not maintained. RSC minutes do not include an inventory of radioactive materials currently in possession.

b. Nuclear medicine related radioactive waste is routinely disposed of per license conditions.

c. Other radioactive waste is not routinely disposed in a timely fashion consistent with standards of practice as in NRC Information Notice 90-09.

6. Medical center actions

a. Management oversight

(1) Executive management tasked the RSO with responsibility to bring significant radiation safety issues directly to executive management and to prepare a report of contact for documentation.

(2) Executive management planned to clarify reporting for the RSO through the Chief of Engineering in a meeting scheduled for September 13, 2000.

(3) Executive management provided clarification to the Administrative Officer to the Chief of Staff for the role of the management representative on the RSC.

b. Radiation surveys and follow-up actions

(1) The Nuclear Medicine Service implemented a procedure to use only Luer-lock syringes for all injections of radiopharmaceuticals, to place an absorbent pad under each patient's arm during administrations for pharmacological stress myocardial perfusion studies, and to allow only nuclear medicine technologists to administer radiopharmaceuticals and remove and dispose of IV tubing from patients undergoing myocardial perfusion studies.

(2) The Nuclear Medicine Service is surveying the cardiac treadmill room at midday, in addition to the end-of-the-day surveys.

(3) A consultant provided training to the nuclear medicine technologists on contamination control procedures on September 5, 2000.

c. Radiation safety training and instruction

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(1) Research Service was informed of the correct delivery location for radioactive materials packages. Research Service was tasked to notify Nuclear Medicine Service of research package orders.

(2) The Nuclear Medicine Service staff and cardiology fellows were provided instructions regarding food, beverages, and utensils in radioactive material use areas and possible disciplinary action for future infractions.

(3) Training materials for new cardiology fellows were modified.

d. Waste management: Executive management tasked the RSO to prepare a plan to dispose of the accumulated waste.

7. NHPP conclusions

a. The medical center has committed four violations as listed below:

(1) Failure to have adequate management oversight of radiation safety program operations,

(2) Failure to perform adequate radiation safety program surveys and follow-up actions,

(3) Failure to provide radiation safety training and instruction, and

(4) Failure to inventory, manage, and dispose of radioactive waste.

b. The root causes for the violations were as follows:

(1) Failure to establish and implement accountability and reporting procedures for the radiation safety program,

(2) Failure to implement standards of practice for radiation safety surveys and evaluation of results,

(3) Failure to establish and implement policy and procedures for training, surveys, waste management, and receipt of radioactive materials, and

(4) Failure to provide adequate supervision for the Nuclear Medicine Service work center.

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c. The contributing factors for the violations were as follows:

(1) The organizational structure of the radiation safety program hindered prompt and effective communication of significant radiation safety issues from either the RSC or the RSO to executive management.

(2) The RSO failed to identify root causes of incidents and recommend appropriate corrective actions to the RSC.

(3) The minutes of the RSC minutes have not always been distributed in a timely manner.

(4) The nuclear medicine technologists have not followed adequate contamination control practices while handling radioactive materials. In particular, they have not performed sufficiently frequent surveys of their hands.

(5) There was a careless disregard of policy regarding food, beverages, and eating and drinking utensils in restricted areas by the nuclear medicine staff.

(6) The management representative on the RSC was not fully aware of his role.

(7) The licensee did not dispose of radioactive waste promptly per NRC Information Notice 90-09.

(8) The RSO did not follow standards of practice to review and evaluate radiation safety survey results.

8. NHPP actions

a. Hold conference call with executive management to review agreed-to facts.

b. Issue inspection report with requirement for written response within 30 days.

c. Task medical center to do the following:

(1) Obtain an external review of contamination control procedures in Nuclear Medicine Service by an outside expert, not currently employed or contracted by the medical center, within 60 days of the date of the NHPP inspection report, and

(2) Obtain a review of the effectiveness of corrective actions by an outside expert, not currently employed or contracted by the medical center, within six months of the date of the NHPP inspection report.