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DEPARTMENT OF VETERANS AFFAIRS
Medical Center
700 South 19th Street
Birmingham AL 35233

In Reply Refer To: 521/11D

Regional Administrator
United States Nuclear Regulatory Commission
Region II
101 Marietta Street, N.W.
Atlanta, Georgia 30323

Subject: NRC License 01-00643-02 Quarterly Audit

Dear Sir:

In your confirmatory order dated September 1993, you required that we have an outside consultant inspect our Radiation Safety Program at least quarterly for one year and semi-annually after that time for two years. Enclosed is a copy of the results of the first outside consultant inspection which occurred March 28-29, 1994.

If you have any questions, please contact our Radiation Safety Officer, Kathy Boyd, at (205) 933-8101, ext. 6610/6136.

Sincerely yours,

Linda L. Jeffrey

William A. Mountcastle
Director

Enclosure

IE35

Department of
Veterans Affairs

Memorandum

Date: April 14, 1994

From: Regional Director, Southern Region (133)

Subj: **NRC Mandated Quarterly Audit of Radiation Safety Program**

To: Medical Center Director (00)
Birmingham VA Medical Center

1. During March 28-29, 1994, Johnson D. Choppala, Ph.D., Regional Radiation Safety Program Manager, performed an audit of your facility's Radiation Safety Program, as required by Nuclear Regulatory Commission. This report is attached.

2. If you have any questions, please contact Dr. Choppala at 601-364-7863/7864.

for Richard P. Miller

Attachment

VA FORM
MAR 1989 2105

Radiation Safety Audit
Birmingham VA Medical Center

Dates: March 28-29, 1994

Auditor: Johnson D. Cioppala, Ph.D.
Regional Radiation Safety Program
Manager, Veterans Health Affairs
Southern Region
Jackson, Ms 39213

Scope of Audit:
This is the first of quarterly audits required by NRC. The audit included the following:

- Review of corrective actions taken and their effectiveness in response to previous NRC notice of violations and previous audit by Mr. F. Herbig (January 28, 1993).
- Review of records.
- Discussion with select members of Nuclear Medicine Oncology and Research Staff.
- Discussions with members of Management and Radiation Safety Staff.
- Review of minutes of RSC.
- Inspection of Nuclear Medicine area and Research Laboratories

Persons Contacted:
Management: Mr. Ramon Reevey, Medical Center Associate Director
Robert Roswel, M.D., Chief of Staff
Jerry Spenney, M.D., ACOS for Research

Paul Saunders, M.D., Chairman, RSC
Kathy Boyd,M.S., Radiation Safety Officer
Herbert Westmoreland, Radiation Safety Technician
Mike Barber, Chief Technologist, Nuclear Medicine

Evaluation Of responses to recommendations of previous audit by NAGORS:

1. Immediately issue an ALARA program statement detailing management commitment, RSO responsibility and authority; RSC responsibility and authority

   Action: This recommendation is implemented.

2. Re-issue hospital memorandum delegating authority to RSC and RSO and attach a revised radiation safety plan of regulation, policy and procedure.

   Action: This recommendation is implemented.

3. Meet with the full RSC to explain and reinforce responsibilities and expectations.

   Action: Done

4. Meet with full Research Service (PIs, technical and support staff; no exceptions, no excuses) to clearly communicate management commitment to the radiation safety effort, support for RSC and the RSO, and the expectations for improved performance.

   Action: The Medical Center Director and the RSO met with the entire Research Staff (who use the licensed radioactive materials) to communicate the management commitment.

5. Move as quickly as possible to install Ms. Boyd as the approved RSO.

   Action: Implemented.

6. Establish a clear supervisory/reporting path for the RSO to Management (COS).

   Action: The RSO reports to Medical Center Chief of Staff.

7. Permit frequent RSO-Management meetings (2-wk intervals) to access on going program effectiveness; frequency can be greatly reduced when full effectiveness is achieved.

   Action: Meetings between RSO and COS are presently taking place at 2-week intervals

8. Establish at least annual audit process for the RSC to evaluate fulfillment of specific regulatory requirements as well as effectiveness.

   Action: Annual audit plan is established

9. Arrange additional training for RSO:

   a. Health Physics Summer School, Atlanta
   b. Brief preceptor training, Philadelphia, Little Rock or St. Louis

   Action: 9.(a) Implemented. Ms. Boyd attended the HPS Summer School in Atlanta.
   9.(b) Has not been implemented. However, Ms. Boyd attended VA Southern Region Radiation Safety Workshop, Tampa, Fl., Nov 8-10, 1993. Since the recent NRC inspection did not result in any citations, the management is wondering if a preceptor training is warranted.

Radiation Safety Committee:

10. Establish a procedure for meetings through which the committee accepts and demonstrates full responsibility for its actions. Review suggests that the burden

of work and direction for actions is placed on the RSO. The RSO should advise the RSC but it should be clear that the RSC evaluates and acts. (This problem is common to RSCs and in no way unique to BVAMC)

Action: The Medical Center Associate Director discussed with RSO and RSC their respective responsibilities.

The chairman RSC needs to get more involved in the follow-up action process.

11. The numerical results of ballots must be documented.

    Action: Being done. The RSC minutes validate this action.

12. Develop and use an escalating table of sanctions for authorized users which relates failures in performance to restriction of activities,ie suspend ordering, removal of use privileges, recommended personnel actions, etc Give special attention to repeated violations.

    Action: An escalating table of sanctions is in place.

13. Require a report by the RSO in advance of meetings, which will serve as the basis for actions by the RSC. The report should include:

    - ALARA exposure evaluation; negative report required.
    - Special personnel/facility monitoring (pregnancy, bioassay, exposure potential
    - Incidents (spills, significant out of line) situation, actions, resolutions.
    - Summary of facility/user inspections (number of audits by user, current violations, last quarter, annual, number of repeat violations).
    - Recommendations of RSO to RSC for action.

The report should be appended to the minutes and should, in time, document progress in the program.

Action: Implemented

Operations:

14. RSO should develop a master calendar for rad safe activities to assure that required functions are not missed.

    Action: A wall calendar was purchased and is being used effectively.

15. Establish quarterly audits for all clinical and research programs.

    Action: Quarterly audits are being performed of all clinical and research programs.

16. Issue a prompt, concise written report to each user following audits.

    Action: Audit reports are posted at the entrance of each pertinent lab area, where it is clearly visible.

17. Require posting of the report (NOV) at the entrance to each facility; to remain until next audit.

Action: Being done.

18. Use previous audit as the first inspection item on the next audit.

    Action: This format is being followed.

19. Emphasize need for monitoring and swipe following every research procedure involving radio nuclides; protection against unwitting contamination spread.

    Action: This recommendation is incorporated as a requirement. Considerable unhappiness at being required to perform wipe testing 2 or 3 times a day, in some cases, was expressed by the ACOS for research.

    Recommendation: In consideration of the NRC confirmatory order modifying the license issued to BVAMC and the obvious need to assure NRC that licensed material will be used in accordance with regulatory requirements, no revision this requirement be attempted, at this time, until BVAMC, has demonstrated that it iscapable of complying with NRC regulations.

20. A brief, one page, s'' 'mary of regulatory requirements and policy (not procedures) should be prepared to assist the research staff; i.e., posting, ordering, receipt, accountability, survey type and frequency, monitoring, disposal.

    Action: A check list is being used. The effectiveness of this check list was no verified during this audit.

21. Assign routine sr veillance (records checks, surveys, etc.) to laboratory staff.

    Action: In nuclear medicine area, these functions are being performed by the new Chief tec nologist. My discussions with the new Chief technologist convinced me that he is capable and is doing an excellent job.

22. Examine all recording/reporting forms for completeness and attempt consolidation of information, in particular receipt, use, and disposed records.

    Action: During the quarterly audits all forms are examined for completeness. Format for consolidation of information appears to be acceptable.

23. Acquire additional PC and Software.

    Action: A PC and software are in place.

Pro_.am Needs:

24. There is no rest/eating area in the research area. Possibilities for providing this should be considered. The waste room should be renovated as recommended by the RSO.

    Action: Possibilities of providing a break area are being actively persued.

25. Need for technical/clerical assistance for the RSO should be evaluated.

    Action: A health physics technician is on board and performing remarkably well.

Equipment:

26. Radiation Safety Office has need of LSC beta counting equipment.

    Action: Beta counter is obtained.

27. There is a need to establish some long term goals for the program; principally amendment of the existing license and standardization of records.

    Action: A license application for renewal is completely rewritten and submitted.

Evaluation of corrective actions taken in response to deficiencies identified during NRC inspection June 8-10, 1993:

Four violations were identified. These were noncitable because they were self identified and corrective actions were taken or being taken. During this audit, the corrective actions were verified and all areas of concern are addressed.

Audit of the following areas were performed.

1. Nuclear Medicine Service:

   An examination of records revealed that required daily records are being maintained accurately. Discussions with the Chief Technologist indicated that he is constantly checking to assure that required tasks are performed and records are maintained. Compliance with QM Rule was verified and found to be in total compliance. Chief, Nuclear Medicine Service was unavailable for discussions

2. Research Service:

   Scheduled discussions were held separately with the Associate Chief of Staff for Research and Chairman, Radiation Safety Committee. During the discussions both expressed concern over the methods of strict enforcement of regulations. Some investigators (authorized users) have expressed desire to leave VA and perform their investigation in University of Alabama at Birmingham (UAB). They have complained that requirements for monitoring and surveying of areas after completion of each research procedure sometimes required monitoring 3 times in a day. They felt it was an "overkill" if not excessive. Another complaint was regarding the requirement that records must be kept for daily hand and foot monitoring. A recent violation involved a research lab assistant who created records of hand and foot monitoring. The ACOS for Research indicated that the lab assistant had performed the required monitoring but neglected to record. When the RSO asked for the records, he panicked and created records to satisfy the RSO. On the other hand, the RSO is charged with relentless pursuit of compliance, as the medical center Director had indicated to NRC and the requirement for documenting hand and foot surveys is a license condition as it is indicated as a procedure in the license application. During this audit it was pointed out that procedural requirements may be revised periodically as required and approved by RSC and the Director and submitted as amendment to license only after the research staff had demonstrated total compliance with current license?regulatory requirements. This auditor is not convinced that the state of full compliance both in terms of attitude towards regulatory requirements and performance of tasks as required is achieved. For example, while in the RSO's office a phone call from one of the lab assistants caused concern. The caller was informing the RSO that she had moved an equipment, containing a plastic shield contaminated with p-32,

from VA to UBA.

Only a few days earlier, the RSO had gone over the procedures for transferring radioactive material from VA to UBA and vice/versa. The young lady had totally disregarded the instruction and called only after the transfer had taken place.

This incident indicates that the process of sensitizing some of the research staff to regulatory compliance is not yet completed. Therefore no regulatory requirement should be relaxed at this time. The RSO should continue to require total compliance to all requirements.

A select number of research laborites were inspected (3R9, 3R13, 3R26, 5R31 and 2R29). Discussions were held with Research assistants and authorized users. Except for cases cited in previous narrative, the research staff in general are cooperating with administration's efforts to achieve total compliance and supporting the efforts of RSO and her assistant.

A confirmatory survey in room 5R31 revealed hot spots. It was evident that the research assistant needed a demonstration in correct methods of monitoring with a survey meter. The RSO had demonstrated and instructed the research assistant in the proper method which identified the hot spots.

Inspection Closeout:

Members Present:

- Mr. Ramon Reevey, Associate Medical Center Director
- Dr. Robert Roswell, Chief of Staff
- Ms. Kathy Boyd, Radiation Safety Officer
- Dr. Johnson D. Choppala, Regional Radiation Safety Program Manager
- Herbert Westmoreland, Radiation Safety Technician

Recommendations:

1. Security of Licensed Material:

   Explore the possibility of installing push-button locks at main entrances to the research area. Consult with fire & safety for compliance with OSHA regulations.

2. Unannounced Audits:

   Although there are some complaints about unannounced audits, continuation of the practice is recommended.

3. Unauthorized transfers of licensed material between VA and UAB.

   Develop clear, mutually acceptable and regulatorily sound, verifiable and enforceable policy.

4. Creating records constitutes willful misconduct and treated as a serious offense by NRC.

   If a task is not performed, just indicate that it was not done.

5. The RSO is the custodian of all licensed radioactive material in licensee's possession, therefore, should have ready access to all areas where radioactive material is present.

   Provide the RSO with a master key.

6. RSO should be relieved of clerical/typing tasks especially typing RSC minutes. She should have more time to devote to RSO duties.

   Therefore, please provide secretarial assistance.

General Comments:

- In general the radiation safety program at Birmingham VAMC is in excellent state.
- The RSO is receiving full support from the management.
- The Chief of Staff expressed concern that the negative reaction from the investigators was mainly due to the method of enforcing the regulations more than the regulations themselves. He says "sugar coat it".
- The RSO and the health physics technician are doing an excellent job in staying on top of the program. Present level of management support & commitment should contin to assure compliance with regulations.

Johnson D.Choppala. Ph.D.
Regional Radiation Safety Program Manager
VHA Southern Region
Jackson, MS 39213

Distribution:

Francis Herbig, Deputy Director
National Health Physics Program