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March 13, 1985

Regional Administrator
US NRC Region I
King of Prussia, PA 19406

Docket #030-01815
Cal No 84-21

Gentlemen:

Enclosed is a copy of my final report on the assessment of the Boston VA Medical Center Radiation Safety program as required in your letter dated 10/26/84.

This report was simultaneously submitted to officials at Boston VA Medical Center, who will respond, as required, within the prescribed 30 days.

Yours truly,

Frank Masse

Frank Masse, CHP

FXM/rd

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To: Boston VA Medical Center, Alan Robbins, MD

From: Frank Masse', CHP

Subject: Assessment report on BVAMC Radiation Safety Program

Date 2/25/85

As required by our current contractual arrangements and according to the directive in the NRC letter of 10/26/84 and repeated in the NRC Order of 12/26/84, we have completed our assessment of your radiation safety program. Following are our findings on the specific areas of interest as listed in our assessment plan of 11/19/84.

1. Review of organizational structure and procedures:

   a. Committee operation: The Medical Isotope Committee, under the chairmanship of Dr. Burrows, serves the primary role with respect to the administration of the NRC broad-coverage license issued to this institution. This committee does not meet on a regular schedule, but rather tends to call meetings on an as-needed basis. Consequently, meetings are often called on short notice, and are often attended by only those members who are physically present in the Nuclear Medicine Dept. Interaction between this committee and the medical center's Radiation Safety Committee (Chairman, Dr. Alan Robbins) consists primarily through liaison membership of Dr. Burrows and Mr. Cardarelli, RSO. Reports to the Radiation Safety Committee by the Medical Isotope Committee generally consist of a verbal "no problems" report at RSC meetings. Interaction with the Hospital Administration is via the Radiation Safety Committee. Thus interaction between the Medical Isotope Committee and the Administration is predictably sparse in light of the reporting practice. It is not apparent that this administration has denied support to either committee in recent years.

   b. Application Procedures: Project supervisors desiring to use radioactive materials apply to the Medical Isotope Committee via the RSO. Application includes little detail on the procedures to be followed in the proposed use. Application form asks for quantity in use and quantity to be used per year --- not required possession limit. No mechanism exists to readily determine that institutional possession limits are maintained. No application had been submitted or approved for Nuclear Medicine Department, the largest departmental user in the institution.

c. Review Procedures: Application review does not follow a prescribed protocol. Criteria for approval are not established in writing or standardized. Specific conditions of approval are not generally relayed back to the proposed user. There is no evidence that any request has been denied or delayed pending further information or due to lack of expertise or sufficient safety equipment.

d. Specific Requirements: Safe handing of radioactive materials is the responsibility of the project supevisor with only a non-specific reference to the BVAMC Radiation Safety Procedures Manual. No specific reference to applicable sections is made, no special precautions or instructions are included. The procedures manual is not consistent with the NRC application in that it does not closely follow the 10.8 Regulatory Guide referenced in the application. Therefore, the information provided to the user may be inconsistent with the terms and conditions of the license. Typical of this inconsistency are the laboratory survey requirements. Most research projects do not have a suitable survey instrument for monitoring of the work being conducted in the laboratory. Proper survey techniques would therefore require that research personnel borrow instrumentation from Nuclear Medicine on each day of radioactive materials use to comply with 10.8 requirements.

e. Renewals: Renewal procedures are less formal than initial application procedures. RSO determines when approval expires and submits listing of applications requiring renewal (extension) to the Medical Isotopes Committee often without input from the project supervisor. Action on such extensions or renewals are often not taken until long after the expiration date on the initial approval. Several applications had expired and had not been renewed or extended when this review was conducted.

f. Compliance: As indicated above, there is marginal compliance with the more general requirements of the Radiation Safety Procedures Manual in most laboratories, but less compliance with the more restrictive requirements of Regulatory Guide 10.8 which is also referenced in the license application. This is partly due to the ambiguity of the license application which stretches over a three year period and references documents which are inconsistent in their contents.

g. Recommendations: I recommend that the following procedures be instituted to correct the problems and deficiencies cited above:

1. Merge the responsibilites of the two existing committees into one appropriately constituted Committee based primarily on the current Radiation Safety Committee and satisfying the requirements of Regulatory Guide 10.8.

2. Formalize the organizational structure and operating procedures of that surviving committee, using Regulatory Guide 10.8 as a reference.

3. Improve the application form and review process, including more specific information on safety related aspects of radionuclide use. Authorize possession limits as subunits of the institutional possession limits.

4. Formalize the review process to include professional review of the application before committee deliberation. Review should involve interaction between RSO and laboratory personnel to enhance understanding of requirements and establish ALARA considerations. Final committee authorization should include specific conditions of approval that become required conditions of the departmental license.

5. Renewal process must be initiated by the applicant who desires renewal or extension of this departmental license. This opportunity to review practices and procedures and operational performance should be utilized to maximum advantage by the RSO.

2. Review of training, experience and duties of radioactive materials management personnel:

a. Radiation Safety Officer:. Althouth the RSO has a master's degree in physics, he has not had specific training and/or experience in radiaton protection under the supervision of a qualified health physicist. Further, while many people in similar circumstances have been able to "pull themselves up by the bootstraps", the divided responsibilities in this position have always been such that the primary concern has not been for radiation safety. Presently the RSO estimates that he specnd 80% of his time in Nuclear Medicine, 20% as RSO.

b. Committee Members: As mentioned in 1a above, the Medical Isotopes Committee members who are also members of the Nuclear Medicine Dept. are the most active members of that committee, partly because of

the way the committee operates. While these members are all clearly qualified by training and experience to serve as committee members, the committee is overloaded with representatives of Nuclear Medicine and does not involve adequate representation from other users within the hospital. Also the operating history of the committee does not include active participation of the administration or of the nursing department. As mentioned before, there appears to be better representation in the Radiation Safety Committee.

c. Recommendations:

RSO: I recommend that the present RSO be allowed to return to his full-time nuclear medicine assignment from which he was drafted for RSO duties several years ago, and that a full-time RSO with formal training in radiation protection be recruited. I recommend that this full-time position be created at the senior staff level and be adequately funded and supported with clerical help as appropriate.

Committee: I recommend (as mentioned before) that the two committees be merged with the Radiation Safety Committee established as the surviving committee. The new committee should be expanded to include all the requirements of Regulatory Guide 10.8, including representation of all using departments and nursing. As mentioned before, I recommend that the organizatonal procedures of the committee be formalized.

3. Training:

a. Supervisors: Applicants for supervisor of new projects involving radioactive materials are generally authorized to conduct the program requested without adequate review of prior experience and/or training since there is no established criteria for acceptance.

b. Users: there is no training/experience requirement at BVAMC for new users. In fact, only those users who are handling materials requiring the wearing of a film badge are listed with the RSO as radioactive materials users.

c. Training Program: The current program includes no formal mechanism for a supervisor to obtain additional training and/or expetience either by working under the supervision of another established supervisor or by direct RSO training. Even if the applicant's previous experience is adequate for the proposed tasks, there is no formal procedure for assuring that he is adequately informed of the requirements of the BVAMC license.

Similarly, there is no formal program for the training and indoctrination of users of radioctive materials at BVAMC, not all users of radioactive materials are formally identified. Total dependence for training is placed on the laboratory supervisor, who, as mentioned earlier, has not been properly informed of the policies and procedures at BVAMC, and whose own credentials have not been subject to formal RSO or Committee review.

Retraining: Similarly, there is no formal mechanism for retraining of workers who wish to continue work with radioactive materials. No formal refresher course exists within the institution and past attempts to send workers outside for retraining proved unsuccessful and were discontinued several years ago.

e. Recommendations:

Supervisors: I recommend that a formal mechanism for assuring the adequacy of training and experience of supervisors be established as follows:

1. Supervisor should have, as a minimum, training as described in 10 CFR33.15(b).

2. Specific training on the requirements of BVAMC Radiation Safety Committee and the contents of BVAMC's NRC license should be provided by the RSO.

3. A written exam designed to assure adequate knowledge of radiation protection appropriate to the proposed use should be successfully completed by the prospective supervisor prior to his assuming responsibility for radioactive materials supervision.

4. For medical use, the requirements for medical use specified in Regulatory Guide 10.8 should be required.

5. The written exam may be waived only for persons previously specifically named in an NRC or agreement state license or Board Certified in Nuclear Medicine.

Users: A training and retraining program should be established in which the RSO trains all users in the basics of radiation safety and the specifics of the BVAMC program, including the license contents. This should include, but not be restricted to:

1. periodic (e.g. monthly) training sessions to include all new workers assigned to radionuclide use within the BVAMC.

2. periodic retraining of all workers at intervals not to exceed two years, possibly in project groups in conjunction with the renewal of applications.

3. periodic (e.g. annual) training of individuals whose duties may require them to work in the vicinity of licensed material.

4. Review of ongoing program

a. Radionuclide purchases: The current program requires that the RSO purchase all radionuclides. However, since the established control mechanism does not include an automatic possession limit control, adherence to the license possession limits is not easily established. Further, laboratory visits in conjunction with this assessment program uncovered a history of transfers of radionuclides into BVAMC from surrounding institutions, for which the RSO had no record and no knowledge. Also there are indications that most radionuclides are purchased by phone with the RSO notified after the fact.

b. Incoming shipments: The current standard practice includes receipt of all incoming shipments by the RSO, who notifies the prospective user of a shipment's arrival and stores it for pickup by the user. Further, the location of the stored shipments awaiting pickup by the user is common with the central storage of larger quantities of radionuclides for Nuclear Medicine, the walk-in refrigerator in the entrance corridor to Nuclear Medicine. This refrigerator is left open and accessible to anyone entering the area, and there is no mechanism for obtaining signed receipts for people who come in to pick up their shipments. We have recommended that the security in this area be improved and the materials be better controlled.

c. Departmental Inventory Control: Since no departmental possession limits are issued, the departmental users do not feel obliged to maintain inventory records of materials in their possession. Rather, they consider the annual purchase limts in their application as the controlling factor. Upon, inspection we found an appreciable quanitity of old radionuclides in storage that are not likely to be used. We recommended a house-cleaning in this regard, and suggested the issuance of departmental possession limits as mentioned above.

d. Radiation Survey Program: The survey practice by users is generally far below the frequency recommended in Regulatory Guide 10.8, and is rarely if ever supported by documentation. The lack of adequate instrumentaton mentioned before resulting in the requirement that most users arrange to borrow a survey instrument from Nuclear Medicine to conduct such surveys clearly contributes to this deficiency. We have recommended the purchase of several additional instruments to rectify this situation and management quickly complied with the recommendation. Nuclear Medicine is the only department conducting any routine wipe-testing, which was begun after the August, September 1984 inspection. Only two other labs have submitted wipe-test samples or data to the RSO, these submitted at irregular frequencies. Part of the confusion on survey requirements is due to the ambiguity between the requirements in Regulatory Guide 10.8, which is referenced in the license application, and those in the BVAMC Radiation Safety Manual, which was circulated to the users.

e. Personnel Monitoring: The current practice is for project supervisors to determine when badges should be issued, arrange for badges through departmental contracts, and supply a report copy to the RSO. There is no central RSO file on badge wearers or other radioactive materials users for whom the project supervisor has not requested badges. Bioassays (primarily thyroid monitoring) are performed by the RSO upon request from the laboratory supervisor.

f & g. RSO surveys and audits: The current practice is for the RSO to perform monthly GM survey meter surveys of the radionuclide laboratories throughout the institution. This is the only time the RSO visits these laboratories, and constitutes the entire audit program. The RSO does not check on the frequency or results of the monitoring or audit program within the department, hence virtually no program exists. Further, we found that no RSO surveys were performed from October to December, 1984, due to the confusion following the NRC notification of violations. We have recommended that the RSO frequency of visits be elevated to weekly in laboratories handling mCi quantities and that they include auditing of departmental activities pending resolution of the overall program.

h. Radioactive waste management: The RSO is ultimately responsible for all offsite waste disposal. Individual researchers store animal carcasses containing radioactive materials in freezers for ultimate packaging by RSO. There is an inconsistency between a statement in the Radiaton Safety Manual which states that radioactive animal carcasses may be incinerated at BVAMC, and NRC correspondence which clearly states that such incineration is not allowed. Further, unauthorized incineration at a sister institution has been ongoing for several years. The 10CFR20.305 regulation allowing H-3 and C-14 animal incineration was not clearly understood, hence the hospital has not taken proper advantage of this possibility. There was also a contractual problem with the commercial waste broker named in the license application, hence no waste has been shipped for several months. Finally, it was determined that labelled organic fluids other than liquid scintillation fluid were being disposed of as chemical waste due to a further mis-interpretation of 10CFR20.305. These problems have been resolved through the course of this investigation as a stopgap until the final reorganizatonal program is established.

i. Recommendations: As part of the reorganization of this program, I recommend that the current procedures be changed to include the following:

1. All authorized users at BVAMC should be issued possession limits as subunits of the institutional possession limit. Laboratory supervisor should be responsible for maintaining possession limits subject to audit by RSO.

2. Purchase orders for additional radionuclides should be submitted through the RSO and should include a statement on the current inventory in the department. If telephone orders are necesary, they should be made by the RSO.

3. All incoming shipments should be processed in the same way, even those coming from a sister institution.

4. All incoming shipments should be received and inspected by RSO. Monitoring and package opening procedures should be standardized in this way.

5. Security on all radioactive materials, those in custody of the RSO, and those in final custody of the user, should be improved such that it is inaccessible to all but authorized users.

6. All radioactive material leaving the institution should be transferred via the RSO, including those being transferred to a sister institution.

7. Additional survey equipment should be purchased such that each laboratory has the necessary survey equipment in place (in progress). Laboratory supervisors should be informed of the monitoring requirements in Regulatory Guide 10.8, which they are obliged to follow.

8. Each laboratory should keep complete records of surveys subject to RSO audit. Independent RSO surveys should include wipe testing and audits of departmental monitoring and procedures.

9. Personel monitoring program should be under complete control of the RSO who should designate which users require badges, and which users require bioassays. Further, all users, whether or not personnel monitoring is necessary, should be on record with the RSO, who should maintain a central file, complete with training data on each individual.

10. The waste management program should be formalized under the RSO. License should be amended to include authorization for incineration of animal carcasses other than those containing C-14 and H-3. Waste separation to utilize storage-for- decay, and waste compaction should be incorporated into the program. Proper laboratory waste management should be included in the new RSO program for user training.

5. Current status of compliance:
As noted in the letter submitted by BVAMC in response to the "Notice of Violation" following the September inspection, all items of non-compliance identified in that Notice have been corrected and compliance with those issues is now in effect. However, as a result of this more thorough assessment, continuing non-compliance is noted in the following areas:

a. The current departmental licensing program is at variance with the license application in that it does not adequately control possession limits within the institution.

b. Training and retraining of supervisors and users is at variance with the license application and 10CFR19 in that it is virtually nonexistent.

c. Radionuclide purchasing is not controlled as

described in the license application. Most purchases are made by phone without the knowledge of the RSO. Purchases accomplished by telephone do not involve the transmittal of paper.

d. The laboratory survey program is not in compliance with Regulatory Guide 10.8 which was referenced in the license application. Ambiguity between the contents of the application and the Radiation Safety Manual distributed to the BVAMC users compound this problem. A lack of survey equipment has further complicated this issue.

e. Radiation worker documentation is not in compliance with 10CFR parts 19 and 20. Inadequate records of radioactive material use, particularly for non-film-badge-wearers, exists throughout the program.

While we have attempted to improve in each of the above areas to the extent possible throughout the assessment program, full compliance cannot be accomplished until the program is reorganized, a full-time RSO is hired, and the license is amended to change several aspects of the program as necessary. Hopefully, complete compliance with all NRC regulations through the proper operation of a thoroughly revamped program can be accomplished before the end of the 1985 calendar year, depending upon prompt action by NRC on the necessary license amendments to assist in the accomplishment of this task.