



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
Southfield and Outer Drive
Allen Park MI 48101

March 29, 1994

In Reply Refer To: 553/00A3

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, IL 60532-4351

Dear Sir:

Enclosed is the proposed amendment to NRC License No. 21-04234-01 and the proposed amendment to the ALARA Program for VA Medical Center, Allen Park, Michigan.

Questions regarding these amendments may be addressed to Mr. Steven D. Conatser, Radiation Safety Officer, at (313) 562-6000, ext. 3444/3434.

Sincerely yours,

James H. Stephens
James H. Stephens
Director

Enclosures: 2

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PROPOSED AMENDMENTS TO NRC LICENSE NO. 21-04234-01

1. In the Medical Center's letter to the NRC dated September 26, 1991, modify paragraph 9 entitled, "Iodination", subparagraph (c)(2)(a)(2) to read as follows:

"9. (c) (2) (a) (2). For the therapeutic use of I-131, if the patient dose is equal to or greater than 30 milliCuries of I-131 and requires hospitalization of the patient, all employee participants of the dose-administration will be bioassayed no sooner than 6 hours, but no later than 72 hours."

2. In the Medical Center's letter to the NRC dated August 25, 1992 modify paragraph 9 entitled, "Iodination", subparagraph (c)(2)(a) through subparagraph (c)(2)(a)(1) to read as follows:

"9. (c) (2) (a). Routine bioassay. In keeping with the ALARA practice for diagnostic uses of Sodium Iodide-125, if the dosage (liquid or encapsulated) exceeds one hundred microCuries, thyroid uptake bioassays will be conducted."

"9. (c) (2) (a) (1). The imaging technologists of the Nuclear Medicine Section that use more than one hundred microCuries of Sodium Iodide-125 will be bioassayed quarterly."

3. In the Medical Center's letter to the NRC dated September 26, 1991, modify paragraph 6 entitled "Survey Program" to read as follows:

"6. Survey Program. The RSC has established the following policies and procedures to satisfy the requirements of 10 CFR 20.1501:

a. Types of survey.

(1) A GM meter is used only to screen an area/individual/clotting, etc. Such screening may be either routine or in the initial investigation of a suspected spill. In either case, meter readings above background levels will immediately be verified by performing a wipe test of the affected area.

(2) (a) Wipe-tests are routinely performed at specific locations within a working area, previously designated in the map (floorplan) developed jointly by the principal investigator and RSU and approved by the latter.

(b) Additional wipe-tests are accepted and encouraged, provided the source/location of those wipe-tests are clearly indicated.

(c) Wipe tests must be performed immediately to document decontamination following any kind of spill.

b. Frequency of survey.

(1) Day of radionuclide-use.

(a) Each laboratory and working area shall be monitored with a portable GM meter at the end of every working day in which radioactive material has been utilized. The only exception to this requirement is radionuclide usage that is limited to H-3 and/or C-14.

(b) A wipe-test and GM meter-monitoring shall be mandatory on each day of P-32 use.

(2) Weekly.

(a) If any laboratory or work area uses radioactive material at least once within a given week, then documentation of wipe-tests and GM meter-monitoring will be required.

(b) The facility's radioactive waste storage area shall be GM meter-monitored and wipe-tested as necessary.

(c) Research core-rooms where radioactive material is used or stored will be wipe-tested and GM meter-monitored every week.

(3) Quarterly. The RSO or his/her designee shall perform quarterly wipe tests and GM meter-monitoring in all areas approved for the use of radionuclides and elsewhere if he/she deems it necessary.

c. Assignment of responsibilities.

(1) The Chief, Nuclear Medicine Section is responsible for ensuring that his/her areas are surveyed as required in paragraph 6 (a) through 6 (b). He/she is also responsible for ensuring that wipe-tests taken are assayed and the results indicated in units of disintegrations per minutes per 100 square centimeters (DPM/100 cm²)

(2) A Principal Investigator of any research program approved for the use of radioactive material is responsible for ensuring that his/her areas are surveyed as required in paragraph 6 (a) through 6 (b). He/she is also responsible for ensuring that wipe-tests taken are assayed and the results indicated in units of DPM/100 cm².

(3) The Acting Chief of Staff for Research and Development is responsible for ensuring that research core-rooms where radioactive material is used or stored are wipe-tested and GM meter-monitored every week.

(4) The RSO is responsible for ensuring that the facility has no non-fixed beta/gamma contamination levels in excess of 200 DPM/100 cm². He/she will periodically audit documentation of wipe-tests and GM meter-monitoring of all areas where radioactive material is used, to ensure compliance of the survey program.

PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES
AS LOW AS REASONABLY ACHIEVABLE (ALARA)

VA MEDICAL CENTER
Allen Park, MI 48101
March 17, 1994

1. MANAGEMENT COMMITMENT:

a. We are committed to the radiation safety program in this document for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accordance with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policies, procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program including the ALARA considerations. This shall include reviews of operating procedures, past exposure records, inspections and consultation with the Radiation Safety Officer and/or outside consultants.

c. Modifications to operating procedures, equipment and facilities will be made for the purpose of reducing exposure to radiation unless the cost is considered to be unjustified. We will be able to demonstrate (if necessary) that improvements have been sought and implemented where reasonable. Where improvements have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining exposures ALARA to individuals, the average exposure (i.e., @individual exposures ÷ no. of individuals) of a given Service will also be maintained at the lowest practicable level.

2. RADIATION SAFETY COMMITTEE:

a. Review of proposed users and uses of radioactive material:

(1) The RSC will thoroughly review the qualifications of each applicant with respect to his/her proposed types, quantities and uses of radioactive material, to ensure that ALARA exposure levels are maintained.

(2) The RSC will ensure that the proposed user can justify his/her procedures and that ALARA exposures can be maintained during those procedures.

b. Delegation of authority:

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority.

(3) If the RSC overrules the RSO's recommendation for new procedures or corrective actions, the Committee minutes will reflect the reason for the RSC's decision to override the recommendation from the RSO.

c. Review of ALARA Program: Note: The term "annual" is defined as the period of time beginning on the first day of January and ending on the last day of December.

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to maintain the ALARA concept.

(2) The RSC will meet at least quarterly, and should convene during the months of February, May, August and November. The meeting will include the review of occupational exposures with particular attention to instances where an individual's exposure exceeds either of two thresholds ((ALARA Investigational Levels I and II). The description and required actions for the ALARA Levels follow:

(a) ALARA Investigational Level I: Individual exposures which exceed 10 percent (but less than 30 percent) of annual occupational exposure limits for adults as established by 10 CFR 20.1201. These exposures will be investigated by the RSO and reported to the RSC.

(b) ALARA Investigational Level II: Individual exposures which are equal to or greater than 30% percent of annual occupational exposure limits for adults as established by 10 CFR 20.1201. Level II exposures will be investigated by the RSO and reported to the RSC in writing, along with a summary of the individual's exposure history and comparison with the doses of others assigned to the same Service/Section as the individual in question.

(c) NOTE: If an individual or group of individuals is engaged in performing a procedure which habitually causes exposures in excess of the ALARA Investigational Levels, higher levels may be established by the RSC. Higher levels will only be approved by the RSC, based on the RSO's recommendations that the procedure, which results in an elevated occupational exposure, provides a significant benefit to outweigh the exposure received and that there are no alternate cost-effective means to reduce the occupational exposure. Any higher levels established by the RSC will be documented in the

Committee minutes, and will ensure that annual occupational exposure limits do not exceed those as established by 10 CFR 20.1201.

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users and management.

3. RADIATION SAFETY OFFICER:

a. Quarterly ALARA review: The RSO will notify the RSC of any unusual radiation exposure of individuals which, if routinely received, could exceed ALARA Investigational Levels that are based on the annual occupational exposure limits established by 10 CFR 20.1201.

b. Quarterly audits:

(1) Radiation level surveys: The RSO will conduct audits of laboratory surveys performed at our facility, to ensure the ALARA concept. This will include that surveys are being performed properly and at the required frequency as determined by the RSC.

(2) Inventories of radioactive material: The RSO will conduct audits of inventories performed by authorized users of radioactive material. The inventories must reflect that RSC-approved possession limits are not exceeded by authorized users, to maintain the ALARA concept.

c. Annual ALARA review: The RSO will perform an annual review of the Radiation Safety Program for adherence to the ALARA concept. Reviews of specific procedures may be conducted on a more frequent basis.

d. Education responsibilities: The RSO will schedule briefings and educational sessions to inform radiation workers of ALARA program efforts. The RSO will also ensure that authorized users and ancillary personnel who may be exposed to radiation are instructed in the ALARA philosophy.

e. Cooperative efforts for development of ALARA procedures: The RSO will be in close contact with all authorized users in order to develop ALARA procedures for working with radioactive material. This will include the evaluation of any suggestion made by individual workers that may improve radiation safety at our facility.

f. Reviewing instances of deviation from ALARA practices: The RSO will investigate all known departures from good ALARA practices. When the cause of such departures are determined, the RSO will recommend corrective action to the RSC. If departures from ALARA represent a serious safety hazard, the RSO will implement immediate corrective actions, followed by the retrospective review of the corrective actions by the RSC.

4. AUTHORIZED USERS:

a. Authorized users should consult with the RSO during the planning stage of a new procedure involving radioactive material. The user will not be allowed the use or storage of radioactive material without the approval of the RSC.

b. The authorized user will evaluate all procedures before using radioactive material to ensure that exposures are kept ALARA. This may be enhanced through the application of trial runs.

c. The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all individuals he/she is responsible for.

d. The authorized user will ensure that all individuals that he/she is responsible for are trained and educated in good health physics practices, in order to maintain exposures ALARA.

5. PERSONNEL DOSIMETRY PROGRAM:

a. The RSO will review and record the results of personnel exposure on Form NRC-5 or an equivalent form (e.g., dosimeter processor's report) not less than once per calendar quarter.

b. Only vendors that are currently accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology will be contracted with. Temporary use of a non-accredited service must be approved by the RSC, should a contracted service lose accreditation during the contract period. Should a contractor lose accreditation, the RSO will immediately notify the RSC for prompt action.

c. Dosimeters will be exchanged at least quarterly, unless either of the following apply:

(1) Any individual for whom a higher ALARA investigational level has been set by the RSC for any of the various types of dosimeters will have his/her respective dosimeter processed monthly.

(2) Any individual who receives over 5% of any of the various annual occupational exposure limits will have his/her respective dosimeter exchanged monthly. If the individual's exposure for three consecutive months reflect less than 5% allowed, his/her respective dosimeter may again be exchanged quarterly.

d. Personnel will be placed on the dosimetry program, based on the following criteria:

(1) Whole body dosimeters: All personnel who are regularly (and occupationally) exposed to ionizing photon radiation will be assigned a whole body dosimeter, if a possibility exists that they

will receive 10 percent of the annual occupational exposure limits for the adult whole body or skin.

(2) Extremity dosimeters:

(a) All personnel who regularly handle moderate to high energy gamma or x-ray emitters, with energies equal to or greater than 250 KeV will be assigned an extremity dosimeter, if a possibility exists that they will receive 10 percent of the annual occupational exposure limit for the adult extremities.

(b) All personnel who regularly handle radioactive material in amounts exceeding one milliCurie that fit any of the following will be considered for the issuance of an extremity dosimeter. Such a device will be issued if it is likely that 10 percent of the occupational exposure limit for the adult extremities will be exceeded:

(i) Beta particle emitters where the maximum beta energy is more than 500 KeV (e.g., P-32, I-131, etc.).

(ii) Low energy gamma or x-ray emitters where the energy is less than 250 KeV (e.g., I-125).

(iii) Low efficiency gamma emitters where the incidence of emission is less than 20% of the disintegration rate (e.g., Cr-51).

6. SIGNATURE OF CERTIFYING OFFICIAL: I hereby certify that this institution has implemented the ALARA Program set forth above.



JAMES H. STEPHENS

Director

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