

**Veterans
Administration**

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APR 22 1985

In Reply Refer To: 520/115

Materials Licensing Branch
Division of Fuel Cycle & Material Safety
Office of Nuclear Material Safety & Safeguards
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

THRU: Director, Nuclear Medicine Service (115)
VA Central Office
Washington, D.C. 20420

Gentlemen:

Reference Renewal Application, License No. 23-12255-02,
Control No. 17807, and telephone request from Mr. Earl
Wright, Region II Compliance Office, Atlanta, GA on
April 19, 1985.

Data relating to Edward C. Kreckler, M.D. is supplied as
NRC Form 313M, Supplement A, per NRC letter dated February 5,
1985.

We have thus far been unable to obtain the requested
documentation relating to Henry A. Clarite, M.D. We there-
fore request that at this time you omit consideration with
respect to Dr. Clarite. We will submit the data on Dr.
Clarite in the form of a separate amendment request when it
becomes available in the future.

Request that the authorization for Group VI, 10CFR 35.100
be deleted from NRC Form 313M, Page 1, of the July 1984 re-
newal application. If a specific requirement exists in the
future we will submit an application for amendment.

Data relating to the institutional ALARA program is furnished
as an extract of Appendix O, Regulatory Guide 10.8 (October
1980).

Sincerely,

J. H. Caldwell, Jr.
J. H. CALDWELL, JR.
Center Director

Enclosures (2)

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REG2 LIC30
23-12255-02 PDR

FEE EXEMPT Official Copy
James J. Smith
JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420
4/25/85

TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

EDWARD C. KRECKER, M.D.

2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE

Kentucky, Indiana, Mississippi

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Pathology	Anatomic & Clinical Pathology	November 1977

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Laboratory Service VA Medical Center Louisville, Kentucky 9/74-10/74	12	80
b. RADIATION PROTECTION	same as a	4	2
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	same as a	4	2
d. RADIATION BIOLOGY	same as a	4	2
e. RADIOPHARMACEUTICAL CHEMISTRY	same as a	4	24

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-125	20 microcuries	Laboratory Service VA Medical Center Louisville, Kentucky	8 weeks	In-Vitro Testing
I-131	50 microcuries	same as above	8 weeks	In-Vivo Assay
Cr 51	50 microcuries	same as above	6 weeks	In-Vivo Assay

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

V. A. Medical Center, Biloxi, MS

(Licensee's Name)

April 19, 1985

(Date)

1. Management Commitment

- a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)¹ and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee (RSC)²

- a. Review of Proposed Users and Uses
 - (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
 - (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
 - (3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).
- b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

 - (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. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

¹Private practice physician licenses do not include an RSC.

²The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

c. Review of ALARA Program

- (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table O-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).³
- (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 workers as well as those of management.

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

- (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
- (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.
- (3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

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

- (2) 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. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

- (1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.
- (2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

- (1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.
- (2) The authorized user will ensure that persons under his/her supervision who are

³The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Persons Who Receive Occupational Radiation Exposure

- a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.
- b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table O-1 below. These levels apply to the exposure of individual workers.

Table O-1

	<i>Investigational Levels (mrems per calendar quarter)</i>	
	<i>Level I</i>	<i>Level II</i>
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

* Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table O-1:

- a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table O-1 values for the Investigational Level I.

- b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

- c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

- d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table O-1.

In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official⁴

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

⁴The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.

Signature

J. H. CALDWELL, JR.

Name (print or type)

Center Director

Title

Institution (or Private Practice) Name and Address:

V. A. MEDICAL CENTER

BILOXI, MS 39531

4/19/85

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME

☒ A.M.

☐ P.M.

☐ INCOMING CALL

☒ OUTGOING CALL

☐ VISIT

PERSON CALLING

E. WRIGHT

OFFICE/ADDRESS

389-3195

PHONE NUMBER

EXTENSION

PERSON CALLED

Roy Woodward/Helen M

OFFICE/ADDRESS

VA B. loxi

PHONE NUMBER

EXTENSION

601-388-5341

CONVERSATION

X 484

SUBJECT

Renewal (July, 1984)

1780 7

SUMMARY

called to follow up on Candrea
McDonalds Ltr of Feb 5, 1985
info is in process of ~~being~~ being
mailed. He will also include
signed ALARA program.

E Wright

REFERRED TO:

ACTION REQUESTED

☐ ADVISE ME OF
ACTION TAKEN.

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE