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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUN 13 1980

TO ALL NRC MEDICAL LICENSEES

POOR
ORIGINAL

Dear Licensee:

On September 28, 1979 we sent you a letter about an ALARA program to be implemented by December 4, 1979. We subsequently informed you that the implementation date was being delayed until March 4, 1980 in order to revise the model ALARA program to take into account many comments we received. Enclosed is a revised program which should be implemented by August 15, 1980. Additional time is being allowed so that licensees can make appropriate adjustments in their programs. During the past two months we have sought and considered the opinions and comments of many professionals in all areas involving the use of radiation in medicine. These discussions have led us to modify several program elements and to clarify others. The revised program reduces the administrative burden on the licensee while still meeting the original goal; to provide management a tool for maintaining occupational exposures ALARA and to provide NRC with a basis for inspecting ALARA programs.

The original program provided for establishment of an Action Level which was misinterpreted as a lowering of the maximum permissible dose limits. This was not, and is not, the intention of the program. The revised program applies the concept of "Investigational Levels" as defined in ICRP Report No. 26 "Recommendations of the Commission on Radiological Protection," January 17, 1977. The Investigational Levels in the revised program are not new dose limits but, as noted in the ICRP report, serve as check points above which the results are considered sufficiently important to justify further investigations. Investigational Levels are tools to be used by those in your institution responsible for the management of radiation safety programs. In determining compliance with regulations, NRC will be concerned with whether a review and/or investigation has been carried out rather than whether the Investigational Level has been exceeded.

There was concern on the part of some licensees that improved measurements would be required to comply with the program. Current methods of recording personnel exposures for purposes of compliance with 10 CFR 20, §20.101 are also adequate for use in determining the need for a review or investigation in accordance with the ALARA program.

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The new program has been revised to considerably reduce the paperwork burden. Actions to be taken under the revised ALARA program will be included in, or covered by, documentation already required to be maintained by licensees. Results of personnel monitoring are already recorded at least quarterly on Form NRC-5 or an equivalent form as required by 10 CFR 20, §20.401. Results of investigations you make when an Investigational Level is exceeded should be made part of the Radiation Safety Committee minutes, thus eliminating the need for a separate record. A private practice nuclear medicine licensee would need to maintain review or investigation records but since the majority of these licensees employ few staff requiring personnel monitoring this obligation should create no undue burden.

In the original program, reference was made to guidance provided by U.S. Nuclear Regulatory Guides 8.10 and 8.18. Some interpreted this as a commitment for strict adherence to all aspects of these guides. The guidance given in these documents should be reviewed to determine if the benefits, in terms of additional dose reductions, are justified by the cost of those reductions. Both guides are now used by the NRC licensing staff as part of the basis for evaluating license applications and radiation safety programs. NRC will continue to consider equivalent alternative methods of complying with the principles contained in the guides and with specified portions of the Commission's regulations. You should be aware that these are only two of many sources of information available to guide you in maintaining occupational radiation exposures at medical institutions ALARA. Another good reference source available from NRC is NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures At Medical Institutions As Low As Reasonably Achievable." The model program applies only to the radiation exposure of personnel arising in whole or in part from NRC licensed byproduct materials. Expanding the program to cover other radiation workers in your institution is an option available to you.

The revised model of an ALARA program is provided as an enclosure to this letter. Your institution should adopt this program or develop an equivalent alternative program for review by NRC. After August 15, 1980 you will submit your program when you submit your next renewal or significant amendment application. If necessary for clarification or emphasis, you are encouraged to add explanatory text to the model program. If accepted, your program will be incorporated as a condition of your NRC license. There is no need to submit your ALARA program to NRC *until* such time as you amend or renew your license. However, you should implement the program within your institution as soon as possible, if you have not already done so. Those licensees who have already submitted programs in accordance with the original model or an equivalent alternative program may either resubmit a revised program or maintain the program as proposed unless notified otherwise by NRC.

Model Program for Maintaining Occupational
Radiation Exposures at Medical Institutions ALARA

(Licensee's Name)

(Date)

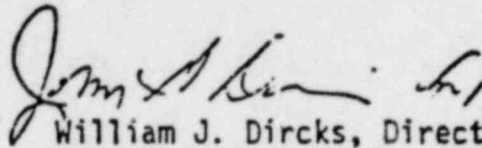
I. Management Commitment

- 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 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 judgement, 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.

¹ Private practice physician licenses do not include a RSC.

I would like to emphasize that the ALARA concept is not new and that most of the commitments in the enclosed formal program are already adhered to by those who maintain good radiation safety programs.

Sincerely,



William J. Dircks, Director
Office of Nuclear Material Safety
and Safeguards

Approved by GAO
B-180225 (R0658)
Expires 83-05-31

II. 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 assure 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 sponge 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 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.

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 I below are exceeded. The principle 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 paragraph VI).³

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

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.

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.

III. 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 paragraph VI 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 an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
2. The RSO will assure 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 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, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. 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 the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.
2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

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

VI. 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 Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

Table 1

	Investigational Levels - (mrems per calendar quarter)	
	<u>LEVEL I</u>	<u>LEVEL II</u>
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 is required by 10 CFR 20, §20.401. The following actions will be taken at the Investigational Levels as stated in Table 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 I 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. He will report the results of his 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, 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 Committee 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... Re-establishment of an individual occupational worker's Investigational Level II Above That Listed In Table I. ...

In cases where a worker's or a group of worker's 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 Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.

VII. Signature of Certifying Official⁴ ..

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

Signature

Name (print or type)

Title

Institution (or Private Practice) Name and Address:

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