



September 5, 1985

U.S. Nuclear Regulatory Commission  
Region III  
Attn: Evelyn R. Matson  
Materials Licensing Section  
799 Roosevelt Road  
Glen Ellyn, IL 60137

Re: Control # 19084

Dear Ms. Matson:

The following information is provided in support of our application dated June 29, 1985 as requested in your letter of August 8, 1985. Response is made per item number in your letter.

Item # 1 -Calibration of survey meter(s) will be performed by James E. Durlacher who is qualified to render this service per his license # 13-07215-01.

Item # 2 -We have ordered the following radionuclide standards:

57 - 5mci  $\pm 2.4\%$   
137<sup>Co</sup> - 100 $\mu$ ci  $\pm 2.9\%$   
133<sup>Cs</sup> - 250 $\mu$ ci  $\pm 2.7\%$   
Ba

Radioactive materials will be ordered on a daily basis by the technician. Quantities are dictated by the number of patients scheduled for the following day.

Item # 3 -Delivery of radioactive materials will be made directly to a Nuclear Medicine Technician. Materials will be stored in the Hot Lab which will be kept locked when the Nuclear Medicine Technician is not on duty.

The technician will verify that the proper materials have been delivered and that the activity does not exceed the possession limit as stated in the license.

Quantities received will be shielded until used and radiation levels in unrestricted areas will not exceed the limits specified in Section 20.105 of CFR Part 20.

Item # 4 -No deliveries will be accepted by anyone except the Nuclear Medicine Technician. Any deliveries made on off-hours will not be accepted. Since our supplier, Syncor, is about to

St. Vincent

CARMEL HOSPITAL

a Daughters of Charity Hospital

13500 North Meridian Street - Post Office Box 1903 - Carmel, Indiana 46032-4903 - (317) 843-2355

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13-23543-01

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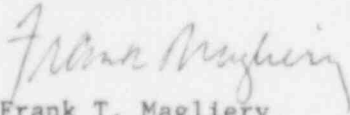
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minutes away, we do not anticipate any problem with this commitment.

- Item # 5 -We failed to indicate that Appendix F Procedures will be followed. They will be.
- Item # 6 -The Medical Isotopes Committee has been expanded to include a representative of the nursing staff. She is Paula West, R.N. from Surgery.
- Item # 7 Find enclosed two copies of the Model ALARA program which we will adopt.
- Item # 8 -All new employees will undergo orientation lectures at the beginning of their employment. These lectures will include coverage of the hospital program for use of radioactive materials and the nature of radiation hazards and the steps the hospital has taken to insure safety to all employees. This will confirm that there will be annual review of the nature of radiation hazards with the appropriate precautions to be taken.
- Item # 9 -This will confirm that the ventilation systems for Xenon-133 will be checked at least semiannually to measure airflow rates and to assure that the system performance meets the specifications stated in our application.
- Item # 10-Once a month we will test the efficiency of the Xenon trap by placing a plastic bag over the exhaust tube and check the contents for Xenon-133. We will permit 20% accumulation; any amount in excess will indicate the need for replacement of the trap.

We trust the above information is sufficient to support our application.

Sincerely,



Frank T. Magliery  
Administrator

FTM:dd

Enclosure

Model Program for Maintaining Occupational  
Radiation Exposures at Medical Institutions ALARA

St. Vincent Carmel Hospital  
(Licensee's Name)

9/5/85  
(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)<sup>1</sup> 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.

<sup>1</sup> Private practice physician licenses do not include a RSC.

## II. Radiation Safety Committee (RSC)<sup>2</sup>

### 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 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 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).<sup>3</sup>

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<sup>2</sup>The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section II

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<sup>3</sup>The 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 Official<sup>4</sup>

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

Frank Magliery  
Signature

Frank Magliery  
Name (print or type)

Administrator  
Title

Institution (or Private Practice) Name and Address:

<sup>4</sup> 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 licensee physician.