

**Veterans
Administration**

July 15, 1982

In Reply Refer To: 662/115

Materials Licensing Branch
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20420

SUBJ: Amendment to License 04-00421-05

1. Attached please find a proposed amendment to our facility's license, number 04-00421-05, with an expiration date, September 30, 1984. This amendment describes the procedures by which the Isotope Committee will evaluate proposals for additions to the list of routine, or standard, diagnostic uses of radioactive materials. Our license, as it stands, does not specifically describe such an evaluation process for adding to the list of routine diagnostic procedures, although it does address the issue for research uses.
2. The Isotope Committee at its meeting of June 24, 1982, unanimously approved the submission of this proposed amendment to your office. We would appreciate your prompt attention to this matter.
3. In addition, we have enclosed the Curriculum Vitae of a new member of our Isotope Committee, Dr. Carl Grunfeld, who is expert in modern techniques of cell culture, particularly involving radioiodine-labeled hormones, in iodination of polypeptide hormones, and radioassay methods.

RALPH R. CAVALIERI, M.D.
Chairman, Isotope Committee

Enclosures

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PROPOSED AMENDMENT TO NRC LICENSE - 04-00421-05

Procedure for Evaluating Proposals for Alterations to List of Standard
(Routine) Clinical Diagnostic Uses of Radioisotopic Agents

- I. The following information must be included in any proposal.
 - A. Background and justification for the procedure as a routine clinical use (diagnostic).
 1. Citation of published data on efficacy.
 2. Advantages (vs. alternatives).
 3. Disadvantages and risks.
 - B. Description of Procedure.
 - C. Radiation Dosimetry.
 - D. Personnel Involved and Their Qualifications.
 - E. References to Literature.
- II. The Isotope Committee will consider the proposed addition, using the following criteria.
 - A. Need for the procedure for routine diagnostic use.
 1. Efficacy.
 2. Advantages over alternative methods in use.
 - B. Qualifications of personnel (including training and experience in similar applications).
 - C. Radiation Safety Aspects:
 1. Patient risks (radiation dosimetry, other)
 2. Other safety aspects (radiowaste disposal, etc.)