Medical Center

5th and Fort Streets
Boise, ID 83702

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Veterans Administration

September 28, 1984

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

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Thru: Chief, Nuclear Medicine Service (115)
Veterans Administration Central Office
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Subj: Revised Applications for Renewal (R.A.M. License No. 11-18311-01)

Dear Sir:

Enclosed please find application for modification of a license to use byproduct materials at VAMC, Boise, Idaho. We are presently operating under license # 11-18311-01 and its amendments, as authorized by your letter of September 21, 1983. Our intent in submitting this application is to update our radiation control program, organize our system to make it more manageable and nullify those older portions of our program which may no longer be appropriate. In short, we would like to have a document that would make it more efficient for us to operate, and for you to be able to evaluate our program with more complete information presented in an orderly fashion. We hope we have succeeded.

Heretofore the VAMC has had a Nuclear Medicine Service which has operated within the bounds of groups licensing. We feel that this continues to be an acceptable licensing arrangement for clinical use. However, with an anticipated increase in our research efforts, due to doubling of our research staff since our last submission, we find our old license to be too restrictive, and request certain changes related to investigative use of radionuclides. Although we are not asking for a broad license, we would like greater flexibility in the use of radioactive materials "in vitro" and for use in animals. We feel that we have established adequate controls for the latter uses through the mechanism of a large committee representing diverse backgrounds, but with adequate representation for radiation related sciences. We have increased the efforts of our consultant Radiation Safety Officer to one-half day per week to provide more direct support to the program. Although Mr. Stano is the only certified physicist in Idaho engaged in private practice, he is a resident of Boise, and spends more than 95% of his work time within the three hospitals in the city of Boise.

In Reply Refer To: 531/151

The only anticipated research in humans would involve those uses of radioactive materials where small quantities would be used in investigational studies designed to provide new knowledge about the physiology and/or distribution, or intermediary metabolism of a labeled compound; essentially, this involves those uses which were anticipated when the FDA generated the definitions of when a radiopharmaceutical is safe and effective for the purposes intended. You will note that our Radiation Protection Guide addresses this issue. We have submitted to the FDA the memberships of our proposed Radioactive Drug Research Committee. Please note that our committee, which we call the Radiation Control and Radioactive Drug Research Committee (RCRDRC), performs both those functions which are mandated by NRC licensing requirements for broad licensing and also those mandated by FDA for investigational use in humans. Our research scientists have faculty appointments at the University of Washington, Seattle, Washington, and the U. of W. Institutional Review Board (Human Subjects Review Committee) is the final authority in all research studies done in VA patient or volunteer subjects by U. of W. faculty.

Dr. Lawrence Knight and Dr. John Tweeten are the only authorized users listed on our current license. We request that the RCRDRC be empowered to authorize professional personnel of the VAMC to use radioactive materials in "in vitro" and in applications in animals where such individuals can demonstrate by previous training, experience, and education that they are capable of safely using such radioactive materials. We further request that supervised use of R.A.M. and training under the guidance of the RCRDRC lead to such local approval for investigators in non-human uses.

Requests for any additional information related to this application may be directed to Dr. Lawrence Knight, (FTS 554-7240), who is the Chairman of our Radiation Control and Radioactive Drug Research Committee and Director of Radiation Control for our Medical Center.

Sincerely,

JAMES A. GOFF
Medical Center Director

[illegible] SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420