West Virginia University | MEDICAL CENTER
MORGANTOWN, WEST VIRGINIA 26506

School of Medicine
Department of Radiology
Division of Medical Physics and Radiation Safety
Telephone: 304-293-3413

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John A. Olshinski, Director
Division of Engineering and Technical Programs
U.S.N.R.C., Region II
101 Marietta Street, N.W., Suite 3100
Atlanta, Georgia 30303

Dear Mr. Olshinski,

This is an addendum to our letter of 29 July 1982 concerning the inspection of licenses 47-01163-20 and 47-01163-22. The source of our confusion about item C, radioactive cystography studies, has begun to become visible.

It appeared to us that one of our options was to file a petition for rulemaking to have this use added to the schedules of 10 CFR 35.100. In preparation for this, we reviewed the petition of George V. Taplin, M.D. (deceased) dated 28 March 1979, and the resulting proposed rule (47 FR 15796) dated 8 April 1982. We quote from the latter

> NRC licenses institutions and individual physicians in private practice to use byproduct material on humans under the group medical license.
>
> The group medical license was designed to allow physicians and community hospitals wide access to nuclear medicine services. The "groups" in § 35.100 of 10 CFR Part 35 contain only radiopharmacenticals that are the subject of an FDA-approved "New Drug Application (NDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA.
>
> NRC regulations in § 35.14(b)(6) of 10 CFR Part 35, which apply to the group medical licensees, provide that when a physician uses a byproduct material for procedures other than those approved by FDA and specified in the product labeling (package insert), the physician must follow the product labeling regarding: (1) Chemical and physical form, (2) route of administration, and (3) dosage range.

These restrictions do not apply to the larger medical institutions possessing the NRC broad medical licenses where both the credentials of the physicians and all proposed uses of radioisotopes are reviewed by a specifically appointed Radiation Safety Committee (RSC) which has been approved by NRC.

It is our understanding that license 47-01163-20 is a specific license of broad scope, as delineated in 10 CFR Part 33, with its uses primarily in medicine and biomedical reseach. It is, therefore, our contention that it is sufficient to have proposed uses of otherwise approved radiopharmaceuticals reviewed by the appropriate institutional committee or committees.

We have proceeded on this basis in the past, and were not sure what our standing was when the regulations for group medical licensees were applied to us.

Sincerely,

Stephen T. Slack

Stephen T. Slack, Ph.D.
Radiation Safety Officer

William E. Collins

William E. Collins, Ph.D.
Vice President for Academic Affairs
and Chm., Radiological Safety
Committee

cc: E. Gordon Gee, President
J.W. Fisher, Executive Officer
Radiological Safety Committee

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