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

29 July 1982

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

Dear Mr. Olshinski,

This letter and accompanying documents are in response to your letter of 30 June 1982 concerning violations found during the routine safety inspection of licenses 47-01163-20 and 47-01163-22 conducted by R.A. Brown on 19 May 1982. Designations used are those of appendix A of your letter.

A. Teletherapy calibration. The interval between full calibrations did exceed one year. At the time of the inspection, a full calibration had already been scheduled for the weekend following the inspection. This was done in order to coincide with the installation of a new treatment planning system. This involved more extensive data than required by the annual calibration, but the personnel involved attempted to avoid duplication of effort and confusion in the records by using the same set of measurements for both purposes. These measurements were completed before the date of your letter. Repetition at annual intervals will be carried out, and we believe that this process has been simplified by the delay. We believe that full compliance has been achieved.

B. Linearity of Dose Calibrators. The failure to check the entire range of activities employed in Nuclear Medicine involved one or more errors of judgement on the part of the physicist assigned to this task. This check was completed prior to the date of your letter.

Our statement of 6 April 1979 concerning the frequency of checks of the linearity of the dose calibrator was by reference to Appendix D of Regulatory Guide 10.8 (unrevised). We had understood ourselves to have promised an annual linearity check, but cannot verify this because our copies of this guide have been replaced by Revision 1 (October 1980). Therefore, we have begun scheduling the linearity check quarterly. We believe that we are now in full compliance on this item.

C. Radioactive Cystography. As indicated, "studies were performed by administering by product material via catheter, a route of administration not listed on the product labeling."

Your suggestion that we apply to the FDA for approval of an IND exemption has been, at best, a source of confusion. Sources both within the University and within the FDA have given conflicting advice on the matter.

One does not apply for an IND exemption under 10 CRF 35.100 (c)(5) as you suggest, but under 21 CFR 312.1. This part does not concern itself with changes of routes of administration, but with shipment and delivery of new drugs. The only item dealing with an institution's filing of an IND appears to be 21 CFR 312.1 (b)(3) which is specific for imported drugs.

21 CFR 310.3 (h)(5) does allow for a definition of newness of a drug when the dosage, "method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug" is new. This, however, is not the case here. What we have is a case of a licensed physician using a drug in a manner other than the manner indicated on the label. This is routinely allowed by the FDA. One of the suggestions we had from a representative of the FDA was that it should be sufficient to have this use reviewed by our Institutional Review Board (Human Subjects Committee).

We have an additional problem with this violation. We have used a method of administration which involves a significantly lower dose to the patient than the approved alternatives. The ethical, legal and moral considerations involved in a rigid enforcement of your interpretation of the regulations are greater than can be encompassed by this correspondence.

Therefore, we have concluded that the intention of the regulation is not that we as the institution should file for an IND. We agree that we are in violation of 10 CFR 35.14 (b)(6), but we believe justifiably so, and we await your advice on how we may bring good medical practice and your regulations into conformity.

D. Radiation surveys in Nuclear Medicine. Surveys of the Nuclear Medicine area were not carried out with sufficient frequency as alleged. This problem has surfaced several times in the past in our own checks, and been corrected more than once. We now believe we have sufficient safeguards built into the quality assurance programs of both Nuclear Medicine and Radiation Safety to assure continued compliance. We believe that we are now in full compliance on this item.

The Notice of Deviation presents a different problem. On 22 April 1982 we applied for an amendment to license number 47-01163-20 to allow us to move our radioactive waste to leased space in a building formerly occupied by the Bailey Glass Company; a copy of this application is attached. After receiving your notice of deviation, we sought engineering advice on installing a CO_2 system in this location, which we thought more suitable than the present location. In addition, the weight of the waste has begun to cause structural damage to our present location, and the volume of waste has begun to made access to fire exits difficult. Therefore,

we took the liberty of telephoning the Materials Licensing Branch to seek advice on the handling of this problem. A copy of our confirming letter is attached.

We are now in the unenviable situation of not being able to implement what seems to us to be the best solution, or at least the one preferred to all others except finding a way to dispose of the waste, without action on the part of the Materials Licensing Branch. We, therefore, do not know when we will be in conformity with good practice on this item.

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

attachments

copy: E. Gordon Gee, President
J.W. Fisher, Executive Officer
C.A. Goodwin, M.D.

STS/tds