

Consultants on Radioisotopes for the Medical Profession

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Reply To: St. Louis, Missouri June 7, 1963

> Mr. Richard Cunningham Division of Licensing & Regulations U. S. Atomic Energy Commission Washington 25, D.C.

Dear Mr. Cunningham:

By this letter I should like to request that our present byproduct material license No. 24-4206-1 be amended to allow us to possess and use certain byproduct materials at a second location.

If you will recall, we discussed this matter earlier this week during my visit to Washington, D.C. for the joint meeting of radiopharmaceutical manufacturers, the AEC and the FDA.

For the past six months NUCLEAR, the Pharmaceutical Division of Nuclear Consultants Corporation, has been preparing and offering for sale to the medical profession diagnostic kits containing generally licensed quantities of radioactive (I-131) Triiodothyronine tagged to ion exchange resin A technique developed by Dr. Scholer of Palo Altc, California and modified by our laboratories has proven to be one of the best thyroid diagnostic studies yet devised. Our sales of these kits have increased to such a point we are running into space problems within our present facilities. We are presently involved in purchasing land and constructing a new laboratory, which we plan to move into by this Fall. However, in the meantime, we have found it necessary to rent additional space.

The space in question is located at 9848 Manchester - just three doors away from our present facilities. It is a single room which had previously been used as a suite of rooms by a vet. The room is approximately 10 x 30 feet in size. It is equipped with a sink. It is located to the outside of a one story building and has a private entrance. The room immediately to the front of this room is unoccupied. The room to the rear is occupied by two consulting engineers who are in the office, it appears, about one fourth the time.

We wish to use this room only for the handling of already tagged T-3 resin. No liquid or other form of radioactivity will be handled in this room and no tagging, or other chemical reactions, will be carried out in the area. T-3 resin will be tagged in our present facilities. The bulk ,

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Mr. Richard Cunningham

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already tagged, dried resin would then be transported by our own personnel the few hundred feet from our present location to this new facility. Here the resin is dispensed into 4 ml vials (0.1 gm to each vial) counted, and packed (10 each) into our TBI Kits. It is most unlikely that we would ever have more than 5 mc of I-131 in the form of tagged resin, however, I should like to request a possession limit for 10 mc of I-131 in the form of tagged resin.

In addition to packaging the resin in kit form, we wish to use these same facilities to perform the TBI test. We are presently running some 200 tests a week to assist us in better understanding and improving the tagged resin, our synthetic TBI control serum and the test procedures.

My request, hence, is for an amendment to my present license, No. 24-4206-1, authorizing us to possess up to 10 mc of tagged (I-131) resin at 9848 Manchester for the purpose of packaging this material for sale and to perform the TBI tests.

Should you have any questions concerning this request please contact me at your earliest convenience.

Yours very truly,

NUCLEAR CONSULTANTS CORPORATION

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W. R. Konneker, Ph.D. President

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