

30 Troy Road, Whippany, NJ 07981 USA: 800-526-0702, NJ: 201-386-0030 Telex: 136468 ClinSciWipy

October 20, 1986

U.S. Nuclear Regulatory Commission, Region 1
Nuclear Material Section B
631 Park Avenue
King of Prussia, PA 19406

Attention: Dr. John Glenn

Dear Dr. Glenn:

This letter is in regard to an oversight on a recent Material License application dated October 15, 1986, submitted to your office by Clinical Sciences, Inc.

On pages 2 and 15 of the supplemental information sheets, the symbol used to denote microcurie (μ) was inadvertently omitted. A space was left by the typist to allow us to handwrite the symbol since we did not have it on the typing element -- somehow we missed doing so.

I am forwarding corrected copies in duplicate to be attached to the original application.

Thank you for your kind attention in this matter.

Sincerely,

Marylou Panico

Marylou Panico
Manager, Regulatory Affairs

mp:pey .

Enclosure

8702120578 861113
REG1 LIC30
29-27872-01G PDR

41:1 WJ 82 100 9961

RECEIVED-REGION 1

106319

ML10

23 OCT 1986

"OFFICIAL RECORD COPY"

APPLICANT:
CLINICAL SCIENCES INC.
30 Troy Road
Whippany, NJ 07981

NRC FORM 313
Page 2

APPLICATION FOR MATERIAL LICENSE
SUPPLEMENTAL INFORMATION.

Item 5a,b, and c RADIOACTIVE MATERIAL

- a) Radionuclide: Iodine-125 (Maximum Activity/vial:
 approximately 6.6 μ Ci) (microcuries)
- b) Chemical form: 1) AUK-3 Kit: Antibody to Hepatitis B
 Surface Antigen 125 I (sheep)
 2) AB-COREK Kit: Antibody to Hepatitis B
 Core Antigen 125 I (human)
- c) Maximum amount possessed at any time: 25 millicuries or the
equivalent of approximately 1893 kits.

Item 6 PURPOSE(S) FOR WHICH LICENSED MATERIAL
 WILL BE USED

The AUK-3 and AB-COREK test kits are for in vitro use in the diagnosis of hepatitis B virus infection. None of the radioactive or non-radioactive components of either kit is for internal or external use in humans or animals. The kits are to be used by physicians, laboratories, or hospitals holding general licenses or specific licenses authorizing possession and use.

Item 7 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY
 PROGRAM AND THEIR TRAINING AND EXPERIENCE

William J. Vanjonack, Ph.D. is named the Radiation Safety Officer and will be responsible for the radiation safety program and the training of individuals working in and frequenting the restricted areas. Dr. William Vanjonack has 21 years of academic research and industry experience in nuclear medicine, radioisotope methodology and the manufacture of radiopharmaceuticals. Dr. Vanjonack's collateral area for his Doctor of Philosophy degree in Physiology is Nuclear Physics. The requirement for this collateral area was hands on work experience (including neutron activation analysis at the University of Missouri-Columbia Reactor) and the satisfactory completion of nine course hours at the graduate level which included but were not limited to:

- 1) radiation measurement, 2) intermediate errors in measurement,
- 3) radioactive decay, 4) properties of radiation and interaction with matter, 5) radiation detection based on ion collection, 6) scintillation techniques and nuclear emulsions, 7) radiochemical separation techniques, 8) nuclear analysis, 9) radioisotopes in chemistry, 10) isotopic tracers in biology, 11) radiation biology

23 OCT 1986

APPLICANT:
CLINICAL SCIENCES INC.
30 Troy Road
Whippany, NJ 07981

NRC FORM 313
Page 15

APPLICATION FOR MATERIAL LICENSE
SUPPLEMENTAL INFORMATION

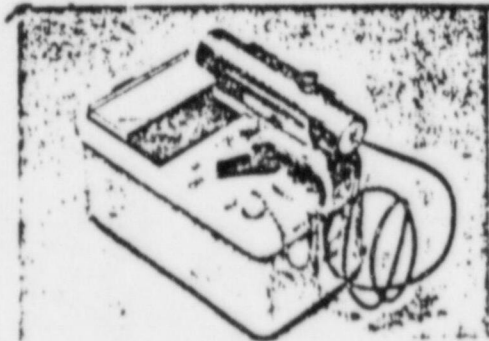
Item 10

RADIATION SAFETY PROGRAM

Radiation Safety Program will employ the use of Beta-Gamma survey meter manufactured by Atomic Products Corp., distributed by Lab Safety Supply of Janesville, Wisconsin, product no. D1567. The manufacturer provides calibration of instrument on an annual basis or more frequently if requested by CSI. See description and illustration below.

Survey meter will be used by Radiation Safety Officer or a trained employee to survey restricted radiation area before and after each shipment of kits is received to determine radiation levels. All surveys will be recorded and filed for review by NRC.

Trained authorized personnel working in or frequenting restricted area will be badged and monitored for radiation exposure as an extra precaution. Due to the low radiation levels of each kit (less than 13.2 μ Ci) and the small quantities of kits expected to be on hand, radiation levels are expected to be well below the permissible radiation dose standards for individuals in restricted areas pursuant to CFR 10 part 20 subpart 20.101.



Beta-Gamma Survey Meter

Portable, solid state survey meter detects radioactive contamination of instruments, personnel, work areas, food and clothing. Ideal for P^{32} , P^{33} and higher energy beta radiators. Optional headphones available for audio indication. The 3-range meter is graduated from 0.50 mR/hr. and 0.300 cpm. Range provides $\times 1$, $\times 10$ and $\times 100$ sensitivity. Meter includes sidewall, halogen quenched GM type probe with rotating metal shield to allow detection of gamma rays or beta rays above 175 KeV. Comes complete with meter, probe, batteries and operating manual. 7" L x 4" W x 7" H. 3 lbs.

D1567