

JUN 29 1970

Roger Williams General Hospital
825 Chalkstone Avenue
Providence, Rhode Island 02908

Attention: Dr. William S. Klutz

Gentlemen:

In support of your application for a broad specific byproduct material license, you should submit the following information:

1. A copy of the administrative procedures establishing control and enforcement by the Medical Isotope Committee over the use of radioisotopes within the institution. The administrative procedures should include the following:
 - a. The authority and responsibilities of the Committee.
 - b. The frequency at which the full Committee meets to discuss and act upon problems relating to the use of radioisotopes.
 - c. The criteria used in determining whether a physician is qualified to use radioisotopes clinically or experimentally in the institution.
 - d. Guidelines to the use of radioisotopes in nonroutine or investigational procedures. These should include requirements for conducting animal studies prior to initiating clinical research proposals, the type of information to be submitted in a research protocol, methods limiting the duration of the study, and the types of information to be submitted and the reports on such studies.
 - e. Detailed procedures for procuring radiosotopes, maintaining inventories, and controlling possession limits.
 - f. Methods employed for maintaining records of the Committee's procedures.

2. A copy of the formal set of rules, recommendations, and procedures for procurement and safe handling of radioisotopes within the Roger Williams General Hospital at Providence, Rhode Island. Your procedures should clearly define the following.
 - a. Radiation and contamination control.
 - b. Special equipment, facilities, and procedures for handling radioisotopes in the solid, liquid, or gas form.
 - c. Restriction of radiation areas from all unauthorized entrance.
 - d. Sealed source leak testing procedures.
 - e. Methods of waste disposal.
 - f. Transportation requirements.
 - g. Record keeping requirements.
 - h. Emergency procedures in case of accidents, spills, and over exposures.
3. Please state the responsibility and the authority of the radiation safety officer for insuring radiological safety in your radioisotope program.
4. State the procedure which will be followed for reaching a decision regarding authorization for nonroutine human use when the decision of the members of the Medical Isotope Committee or a subcommittee, thereof, are not unanimous.
5. Describe the quality control procedures for assuring the assay, identity, the quality, sterility, purity and nonpyrogenicity of radiopharmaceuticals when the materials are not obtained in a ready-to-administer form from a pharmaceutical supplier. Also describe the line of administrative and technical responsibilities of individuals filling key positions and the capabilities of the equipment used for this work. A discussion of the preparation of colloidal material and evaluation of nonsealed and sealed generators should be included.

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When this information is received, review of your application will continue.

Sincerely,

JUN 25 1970

Original Signed by
John E. Bowyer

John E. Bowyer
Materials Branch
Division of Materials Licensing

Enclosures:

1. List of Medical Uses for
Statement of Dosage Ranges
2. AEC Licensing Guide --
Medical Programs
3. 10 CFR Part 35
4. RC 19
5. Form AEC-313

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RADIATION DETECTION INSTRUMENTS - USAMRNL

TYPE OF INSTRUMENTS	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE(mr/hr)	ADDITIONAL INFORMATION	USE
				WINDOW THICKNESS (mg/cm ²)	
1. Packard Mod. 314EX Liquid Scintillation Counting System	1	Alpha, Beta	N/A	N/A	measuring
2. Packard Mod. 3375 Liquid Scintillation Counting System	1	Alpha, Beta	N/A	N/A	measuring
3. Packard Mod. 314E Auto-Gamma Scintillation Counting System	1	Gamma	N/A	N/A	measuring
4. Nuclear-Chicago Mod. 6801 Liquid Scintillation Counting System	1	Alpha, Beta	N/A	N/A	measuring
5. Nuclear-Chicago Mod. Mark I Liquid Scintillation Counting System	1	Alpha, Beta	N/A	N/A	measuring
6. Tracerlab Versa matic V Scaler with GM tube or Sodium Iodide Crystal	1	Beta, Gamma	N/A	150mg/cm ²	measuring
7. Atomic Ass. Chromatograph Plate Scanner	1	Beta	N/A	N/A	measuring
8. Nuclear-Chicago Survey Meter Mod. 2612	1	Beta, Gamma	0-200mr/hr	1.4mg/cm ²	surveying
9. IM-154/PDR-54 with Beta Probe Mod. AC-21B	1	Beta	N/A	0.85mg/cm ²	surveying
10. Nuclear-Chicago Labitron Mod. 1619A	2	Beta, Gamma	N/A	100mg/cm ²	surveying
11. Nuclear-Chicago Mod. 4351 Tobar Gamma Counting System	1	Gamma	N/A	N/A	measuring

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TYPE OF INSTRUMENTS	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm ²)	USE
12. Beckman Low Beta II	1	Alpha, Beta	N/A	80 ug/cm ²	measuring
13. Eberline Mod. PAC Mod. AC-2B	1	Beta	N/A	0.85mg/cm ²	surveying
14. Thyac III Victoreen GM-Scintillation Survey Meter Model 490 with GM Probe Model 489-4	1	Beta, Gamma	0-800,000cpm & 0-200mr/hr	30mg/cm ²	surveying
15. Packard Mod. 331A Tri-Carb Liquid Scintillation Spectrometer System	1	Alpha, Beta	N/A	N/A	measuring
16. Packard, Liquid Scintillation, Spectrometer, Mod. 3380	2	Alpha, Beta	N/A	N/A	measuring
17. Dosimeter, Tracer-lab, Pocket Chamber Mod. K-112	2	X-ray, Gamma	1-200mr/hr	N/A	measuring
18. Nuclear-Chicago Mod. 722. Liquid Scintillation Counting System	1	Alpha, Beta	N/A	N/A	measuring
19. Radiation Monitor Model RM-14 Eberline with Hand Probe Model HP-190	2	Alpha, Beta & Gamma	0-50,000cpm	1.4 to 2mg/cm ²	monitoring & surveying
20. Nuclear-Chicago Scintillation System, Model 4420	1	Gamma	N/A	N/A	measuring
21. Whole Body Shadow Shield Counter, W/sodium-iodide crystal and multi channel analyzer	1	Gamma	N/A	N/A	measuring