

LA:EB:NB (12563)

JUL 26 1963

Commanding Officer
Pitkin County General Hospital
Boulder 40, Colorado

Dear Sir:

This refers to your application dated April 29, 1963.

The application requests the possession of 150 millicuries of Iridium and 150 millicuries of Tantalum. The physical form of these materials is not specified. If they are to be procured commercially, the manufacturer and model number should be specified. The application does not include the proposed use for these materials nor how they will be stored and handled.

The dosages for use of Iodinated Human Serum Albumin for brain tumor localization and heart scans and for use of Mercury 203 as chlormerodrin for brain scans are specified as 10 mc/Kg. This appears to be a typographical error. Please clarify.

Items 4(a) and 5(a)2. on page 1 of Form ABC-213(a) specify use of byproduct material for medical research. Any use of byproduct material must be specified in the license. Any research uses for byproduct material should be requested as license amendments.

Sections 4, 14, and 15 of the document dealing with the Radioisotope Committee refer to 10 CFR 150.20. This section of the Commission regulation 10 CFR 150 deals with reciprocity and recognition of State licenses. Government agencies continue to be licensed by the U.S. Atomic Energy Commission and are not subject to State licensing. Licenses are subject to the provisions of 10 CFR 20. These sections should be revised.

There is no indication as to the frequency at which the Radioisotope Committee will meet, the criteria for designation of physicians to independently use byproduct material, other duties and responsibilities of the Committee, and how the Committee will implement its duties and responsibilities.

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Commanding Officer

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Section 3.2. of the Regulations and Rules Pertaining to the Use of Radionuclides in the Radioisotope Section of the Radiology Service outline the responsibilities of the Supply Officer. No indication is given of the training and experience with radioactive materials of the Supply Officer nor any procedures for proper storage and handling of incoming shipments of radionuclides.

Sections 7, 8, 11 and 12 of the Regulations and Rules all have the qualifying phrase "insofar as is practicable". Please clarify the intent of this statement and the conditions for not following the specific instructions in these sections of the Regulations and Rules.

The list of instruments does not include an instrument with a range higher than 20 mr/hour. We shall require that you have an ionization chamber instrument for use in conjunction with the quantities of radioactive material specified in the application.

The application does not include instructions to personnel for care of patients containing Iridium and Tantalum. If these materials will be used, appropriate instructions should be prepared.

We shall continue review upon receipt of the information specified above, in duplicate.

Sincerely yours,

Nathan Kossin
Isotopes Branch
Division of Licensing
and Regulation

cc: Office of the Surgeon General

bcc: Region IV, Compliance

OFFICE ▶	LR:IB					
SURNAME ▶	MBARRA, PHA					
DATE ▶	7/24/63					