

MINUTES OF THE MEDICAL ISOTOPES COMMITTEE

The Medical Isotopes Committee meeting scheduled for 28 September 1973 was cancelled since there was no new business to discuss and action had been closed or was still pending on old business. In lieu of a meeting, the Secretary will summarize the status of old business items.

1. Old Business:

a. Amendment to USAF Radioactive Material Permit No. 2-0002(D74) for Indium-111 DTPA for Cisternography. Hq USAF (SGPR) Ltr, dated 14 Aug 73, assigned file number 489 to this clinical investigation. The Surgeon General's Clinical Investigation Committee approved the proposal with the stipulation that the patient not be pregnant and be advised not to become pregnant during the course of the clinical study. Hq USAF (SGPR) also required compliance with the provisions of AFR 169-6 and AFR 169-8. The USAF Radioisotope Committee issued Amendment No. 6, dated 23 Aug 73, to USAF Radioactive Material Permit No. 2-0002(D74) authorizing possession and use of up to 2 millicuries of In-111 DTPA. Diagnostic Isotopes, Inc., Upper Saddle River, New Jersey, the manufacturer of In-111 DTPA, was sent a copy of Amendment No. 6 and associated documents on 28 Aug 73. Item closed.

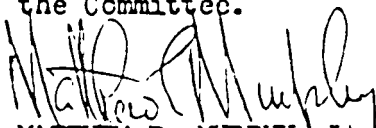
b. Amendment to USAF Radioactive Material Permit No. 2-0002(D74) for Gallium-67 Citrate for the Study of Malignant Neoplasms. Same comments in para. 1a except that Hq USAF (SGPR) assigned file number 488 to this clinical investigation, and Amendment No. 6 to subject Permit authorizes possession and use of up to 18 millicuries of Ga-67 Citrate. New England Nuclear, North Billerica, Mass., the manufacturer of Ga-67 Citrate, was sent a copy of Amendment No. 6 and associated documents on 28 Aug 73. Item closed.

c. Amendment to USAEC Byproduct Material License No. 34-04682-01 for Technetium-99m Stannous Polyphosphate for Skeletal Imaging. On 8 Aug 73, the USAEC issued Amendment No. 21 to subject license authorizing the possession and use of up to 100 millicuries of Technetium-99m Labeled Polyphosphates for Bone Imaging using either the New England Nuclear or Diagnostic Isotopes, Inc. kit. On 20 Aug 73, a copy of Amendment No. 21 and associated documents was sent to New England Nuclear, manufacturer of the Tc-99m Polyphosphate kit. In the license amendment application submitted to the USAEC on 30 April 1973, it was stated that certain conditions of a clinical investigation protocol were to be followed, part of which included consent of the patient and submission of periodic summary reports. The use of this radiopharmaceutical is now considered to be a "well-established diagnostic procedure" and as such, it is no longer considered to be under a clinical investigation. Hq USAF (SGPR) does not require compliance with AFR 169-6 and AFR 169-8, however, the USAEC may require submission of periodic reports since it was included as part of the original application. Action is to be taken by the Medical Center Radiation Protection Officer (Major Connolly) to delete the requirement for periodic submission of reports to the USAEC.

d. Amendment to USAEC Byproduct Material License No. 34-04682-01 for Increase in Possession Limits of Molybdenum-99/Technetium-99m Generators. On 8 Aug 73, the USAEC issued Amendment No. 21 to subject license authorizing the possession and use of up to 1500 millicuries of Mo-99/Tc-99m Generators, and included the use of several new models of generators. Item closed.

e. Selenium-75 Labeled Methionine for Pancreatic Imaging. Further action on this item is pending additional information on the special licensing criteria required by the USAEC and the presentation of a formal written report.

2. The next meeting will be at the call of the Chairman or the Secretary of the Committee.

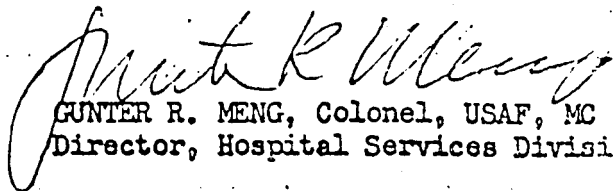


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