

SEP 16 1980

Department 10, 1980

NOTICE OF NON-ROUTINE EVENT INVOLVING AGREEMENT STATE OR AGREEMENT MATERIALS - 80-33

This NOTICE constitutes an early report of events occurring in an Agreement State of possible safety or public interest significance. The information presented is as initially received without verification or evaluation and is basically all that is known by State Agreements Program staff as of this date.

AGREEMENT STATE: Georgia

FACILITY: Medical Research Foundation, Inc., Atlanta

SUBJECT: Medical Misadministrations

Personnel of the State Agreements Program, OSP were notified by SD of an inquiry from FDA headquarters. The facts of the case are as follows. Medical Research Foundation, Inc. (MRF) of Atlanta has an IND from FDA for the distribution of microspheres tagged with yttrium-90. The yttrium microspheres are for the treatment of liver cancer. The microspheres are manufactured for MRF by Georgia Tech. Georgia Tech has no other customers for this product.

On September 3, 1980, MRF shipped 4 vials of microspheres to various customers (participants in the IND studies). On September 5 MRF was notified by one customer of an apparent tagging problem. Free yttrium (untagged to microspheres) would deliver a higher radiation dose to the patient. In these cases the estimated dose to the patients was around 200 rad whole body. A total of 8 patients were treated with the 4 vials of microspheres shipped on September 3. 1 vial which was kept by MRF was not used. Apparently the September 3 shipments are the only ones effected. On September 16, 1980 MRF met with the State and FDA and MRF agreed to hold further shipments until they completed an investigation into why the incident occurred. Georgia will confirm this in writing with the licensee. Georgia will not authorize renewed shipments until they receive written verification that FDA has renewed distribution of the IND product.

IE and NMSS have been informed of the facts concerning two customers in non-Agreement State. SP has notified two affected Agreement States.

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