

September 19, 1980

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

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: Defective Medical Product

The subject line of Notice of Non-Routine Event No. 80-33 dated September 18, 1980 was titled "Medical Misadministrations". We have consulted with the Office of Standards Development who has advised that the event described would not constitute a misadministration as defined in 10 CFR 35.41, rather the event involves use of an improperly prepared radiopharmaceutical. The misadministration reporting requirements of 10 CFR 35 becomes effective November 10, 1980.

Contact: G. W. Kerr; J. R. McGrath, 492-7767

Distribution:  
Chairman Ahearne  
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Commissioner Bradford

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J. Sniezek, IE:Hq.  
J. O'Reilly, IE:II  
J. Keppler, IE:III

J. Fouchard, PA  
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Internal Distribution  
SA Staff  
Georgia file (yellow)  
Non-Routine Event file (Orig + 1cc)  
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OFFICE	SA	gsa			
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