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MEMORANDUM

TO: RICHARD L. BANGART, Director
Office of State Programs

FROM: GRETA J. DICUS, Director
Division of Radiation Control & Emergency Management

DATE: January 18, 1994

RE: RESPONSE TO SP-94-011 REGARDING AUTHORIZATION FOR HUMAN USE

In response to the NRC's request we have reviewed the files of the two licensees that would meet the criteria suggested in the memo. Those licensees are the University of Arkansas for Medical Sciences and the University of Arkansas at Fayetteville.

The University of Arkansas at Fayetteville's license file indicates that none of the research projects involved human exposures for experimental purposes.

The University of Arkansas for Medical Sciences' license file indicates that research projects did involve human exposures but all of these projects appear to be associated with radiopharmaceutical research and were not bioeffects studies. However, each one is listed below and additional information will be provided if necessary. Unless we hear differently from you, this will be our only information transfer to you on this subject.

Date	Authorizing Body	Description of Study
1959-1963 (Approx)	Atomic Energy Commission	I-131 was administered to newborns in a study regarding birth trauma. The Medical School has classified this as radiopharmaceutical research not bioeffects. They have a hotline and have been responding to calls from individuals born at University Hospital between 1961 & 1963. Our files have the license amendment regarding medical research and a

		letter to the AEC in response to a visit from the AEC during which there was some question regarding "the criteria the Isotope Committee will use for the evaluation of request for unusual diagnostic or therapeutic uses" in human research. The letter is dated 5-12-59.
Dec., 1968	Arkansas Department of Health	Decision by the Radioisotope Committee at the Medical School to allow the use of I-125 as Iodothalamate in renal studies. The decision was not unanimous because one committee member believed that because the "human volunteers" would be used, the study should be evaluated under different guidelines.
1972+	Arkansas Department of Health	Medical Research involving a Pu-238 powered pacemaker. Purpose of the study was to reduce the number of pacemaker "changeouts" the Medical School was preforming. Patients were carefully selected: expected to live at least 15 years and would come back often for followup exams.

Since the mid-70's it appears that any investigational use of a radiopharmaceutical required a specific license amendment and had to be done as an Investgational New Drug study.