No. 94-7 FOR IMEDIATE RELEASE
Tel. 301-504-2240 (Thursday, January 13, 1994)

NRC REVIEWS FILES TO IDENTIFY RADIATION EXPERIMENTS ON HUMAN BEINGS

The Nuclear Regulatory Commission is reviewing available files for certain licensees likely to have conducted medical or scientific radiation effects research on human beings before the Atomic Energy Commission was dissolved in 1975.

Purpose of the NRC review is to identify files containing information on experiments that deliberately exposed people to radiation. The agency will forward results of the review to the Department of Energy for inclusion in the Presidential task force on this subject.

The review, which includes both NRC headquarters and regional offices, will begin with readily available records and will focus initially on licenses that meet the following criteria:

(1) Military research facilities and affiliates,

(2) Military hospitals and medical centers, and

(3) Broad licenses issued before 1975 to land-grant universities and colleges, Department of Veterans Administration hospitals, and large state and private medical research and teaching facilities.

NRC has also asked the 29 Agreement States (which regulate most uses of nuclear material in their states, other than for nuclear power plants) to review their files and notify the NRC regarding files that contain information on similar experiments in which humans were deliberately exposed to radiation.

The NRC itself does not conduct or directly fund research on human beings.

NRC will grant licenses for research on human subjects if supervision is provided by an authorized physician and the licensee complies with the regulations of the Food and Drug

Administration or commits to review of research by an FDA-approved committee.

On June 17, 1993, the Commission proposed changes to its regulations to provide that in any research involving human subjects, licensees must not only follow the same regulatory requirements as for patients, but also must follow the Federal policy for the protection of human subjects.

The primary focus of NRC's review will be on old files of the Atomic Energy Commission. When the AEC was dissolved in 1975, the NRC became the regulator and custodian of AEC-issued licenses.

AEC also had broader responsibilities for licensee use of radioactive material for medical purposes than does NRC. Under a 1963 exemption from the Food and Drug Administration's investigational drug regulations, the AEC reviewed new radioactive drugs for safety and effectiveness. In 1975, FDA revoked this exemption. As a result, NRC took over, from the AEC, licensing responsibilities for the possession and use of radioactive materials, but did not assume the AEC's responsibility for the safety and effectiveness review of new radioactive drugs.

#