AbstractID: 1114 Title: Human Research with Radioactive Drugs - FDA Radiation Dose Limits

In the U.S., conducting a clinical investigation with an investigational new drug requires submission of an Investigational New Drug Application (IND) (21 CFR 312). Radiation dose limits for human subjects do not exist for IND research, but are subject to approval by the local Institutional Review Board (IRB), a local panel of experts who balance the benefit with the risk. An IND is not required, however, when the investigation is considered basic research, meets pharmacologic and radiation dose standards, and is conducted under an FDA approved Radioactive Drug Research Committee (RDRC) (21 CFR 361.1). RDRC investigations have mandatory radiation dose limits and require IRB approval.

A review of the current regulations specifying radiation dose limits for research conducted under an RDRC, promulgated in 1975, will be compared with current annual radiation dose limits for members of the general public (1 mSv), occupational workers (50mSv) , and mammography (3 mGy) and fluoroscopy (10 R/m) equipment.

A review of radiation terminology will be made in an attempt to eliminate some of the confusion associated with the variety of terms currently in use. The International Council on Radiation Protection (ICRP) term “effective dose”, which allows partial body irradiations to be compared with whole body irradiations, along with current ICRP, National Council on Radiation Protection (NCRP), Nuclear Regulatory Commission (NRC), and FDA dose standards will be presented