

## **Guidance for use of Radiology Devices and Radioactive Materials in Research Protocols**

### **Definition of “generally recognized as safe and effective”:**

1. The amount of active ingredient or combination of active ingredients to be administered is known not to cause any clinically detectable pharmacological effect in human beings.
2. Under no circumstances does the radiation dose to an adult research subject (either from a single study or cumulatively from a number of studies conducted within 1 year) exceed limits specified by 21 CFR 361.1.
3. The amount of radioactive material to be administered is the smallest radiation dose the subject can practically receive to perform the study without jeopardizing the benefits to be obtained from the study.
4. All radioactive material included in the drug, either as essential material or as a significant contaminant or impurity, was included when total radiation doses and dose commitments were determined.
5. Radiation doses from x-ray procedures that are part of the research study (i.e., would not have occurred but for the study) and the possibility of follow-up studies were included in the dose calculations.
6. Numerical definitions of dose were based on an absorbed fraction method of radiation absorbed dose calculation, such as the system set forth by the Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine, or the stem set forth by the International Commission on Radiological Protection.
7. The radiation exposure is justified by the quality of the study and the importance of the information it seeks to obtain.

### **For radioisotope projects, investigators provide to Health Physics the following radiation- and safety-related information:**

- Identify the radionuclide, chemical form, FDA status, and route of administration.
- For each dosage, provide the amount in millicuries received, the amount administered, and the method of measurement.
- Describe the pharmacokinetics sufficiently to allow internal dosimetry calculations. Alternatively, dosimetry published by United States Pharmacopeial Forum Society of Nuclear Medicine, in a package insert, or in another peer reviewed format may be submitted.
- Describe preparation, handling, storage, administration, and waste disposal in sufficient detail to permit a radiological hazards evaluation of the proposal, including potential for radiation dose to other health care providers from external radiation or contamination.
- Describe safety measures and safety equipment that will be used.
- Identify the rooms where radioactivity will be handled and where research subjects will be used.

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### **For radiation machine projects, investigators provide to Health Physics the following information about diagnostic and therapeutic procedures:**

- For well-established radiographic procedures, identify the radiographic procedures and the number of times each will be performed on a single research subject. State whether the procedures are performed as a normal part of clinical management for the medical condition that is under study or whether they are being performed because the research subject is participating in this project.
- For each radiographic procedure, provide the setup and technique sufficient to permit dose modeling. The chief technologist can usually provide this information.
- For radiographic procedures that are not well-established, provide the FDA status of the machine, and information sufficient to permit dose modeling.
- For a well-established therapeutic procedure, identify the area treated, the dose per fraction, and the number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research subject's medical condition or whether it is being performed because the research subject is participating in this project.
- For a therapeutic procedure that is not well-established, provide the FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

Each applicant or user must have previously filed with Health Physics a complete and is providing radiation support services to an applicant who does not personally provide radiation medicine.) See <http://www.stanford.edu/dept/EHS> and click Health Physics, or telephone the Radiation Safety Office at (650) 725-1413 for assistance.