

HUMAN USE DOSE CONSIDERATIONS ADOPTED BY COMMITTEE I -

Rev. November 4 1998

That research studies involving the administration of radiation to human subjects and which do not fall under the jurisdiction of the RDRC shall meet the following requirements:

- ? The study shall be designed so that the subject receives the smallest radiation dose with which it is practical to perform the study.
 - ? The study shall be designed to use the smallest number of subjects necessary to achieve the desired result.
 - ? The study shall be terminated when the desired result is achieved, or when the hypothesis is determined to have failed.
 - ? The study shall limit the radiation dose to normal control subjects to less than or equal to :
 - 3.75 rem to any organ per 24 hours
 - 10 rem to any organ per year
 - 3 rem to the whole body per 24 hours
 - 5 rem to the whole body per year
 - ? The study shall limit the radiation dose to persons affected by the disease under study to less than or equal to *:
 - 5 rem to any organ per 24 hours
 - 15 rem to any organ per year
 - 3 rem to the whole body per 24 hours
 - 5 rem to the whole body per year
- *Exclusions:
- a. All Therapeutic applications
 - b. Protocols which use routine Nuclear Medicine studies for research purposes rather than clinical purposes and which exceed the above limits will be evaluated on a case-by-case basis.
- ? Minors shall not be considered as candidates for human subjects unless the disease under study principally afflicts minors.

- ? The Committee recognizes that the ICRP recommends radiation dose to minors be limited to 50 percent of the adult radiation dose limits, and that the FDA recommends radiation dose to minors be limited to 10 percent of the adult radiation dose limits. Dose limits to minors will be considered by the Committee if the need arises.
- ? Pregnant women shall not participate as human subjects. Women of child-bearing age or potential shall not participate as human subjects unless a pregnancy test has been performed within 24 hours of the study, and the result of the pregnancy test is negative.
- ? A consent form shall be used which describes the relative risk of the radiation exposure received due to participation in the study *from radioisotopes (11/98)*. Attachment 1* is representative of the items which shall be included in the consent form.
 - *Exclusion: Attachment 1 provisions are not applicable to therapeutic protocols. (5/96)
- ? The researcher shall report to the Committee, via Radiation Safety, semiannually (5/96), the status of his study.

The report shall include for the study :

The study title, *the study status (11/98)*, the investigator, the radionuclide, the compound, *the representative dosage (11/98)*, the maximum radiation dose to the whole body and to the significantly exposed organs received by a representative subject, the number of subjects studied in the reporting period, and any adverse events. (11/98)

A form for providing this information is available from the Radiation Safety Office.