

Use of Effective Dose as an RDRC Research Study Limit

21 CFR 361.1(b)(3)(i) limits single organ and whole body dose to research subjects studied under RDRC control. The term “**whole body dose**” is an old quantity based upon the oversimplification that the entire radioactive decay energy of an administered radionuclide is uniformly distributed throughout all body organs and compartments, which is almost never true. It also ignores differences in organ and tissue radiation sensitivities.

ICRP publication 26 (1977) introduced the quantity “**effective dose equivalent**” for occupational absorbed dose. This approach employs tissue sensitivity weighting factors to produce a single value to measure stochastic risk to the radiation worker from non-uniform exposures. The NRC later (1994) adopted this approach into 10 CFR 20 occupational dose limits. ICRP 52 (1987) extended the use of effective dose equivalent to radiopharmaceuticals used in nuclear medicine, and published an extensive list of these in ICRP 53 (1988).

ICRP 60 (1991) updated tissue weighting factors based on the entire population (rather than just radiation workers) and the resulting quantity “**effective dose**” is now recognized as the most accurate measure of total potential detriment (induction of fatal and non-fatal cancer, serious hereditary defects, and life shortening) due to radiation exposure.

The NIH uses **effective dose** in medical radiation research consent forms, as spelled out in their brochure entitled “An Introduction to Radiation for NIH Research Subjects”, to inform subjects of actual risk. However, they, like others, are forced to revert to **whole body dose** for RDRC protocols, because this relic was never changed in the CFR. This leads to problems when trying to combine uniform radionuclide **whole body dose** with x-ray exposure **effective dose** to come up with a total radiation dose as required by 21 CFR 361.1.

Effective dose for radiopharmaceuticals, including many new research compounds, is listed in newer ICRP publications and other literature because it is the best measure of overall radiation risk. Similar data is available for most x-ray exams. The FDA should switch to effective dose in 20 CFR 361.1 to more accurately measure risk and to facilitate combining radionuclide with x-ray radiation doses.

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