GUIDELINES FOR RESEARCH INVOLVING EXPOSURE OF HUMAN SUBJECTS TO IONIZING RADIATION

[February 1998]

Ionizing radiation includes x-rays, beta-rays, gamma-rays, neutrons, and other high-speed particles.

The biological effect of radiation is measured in terms of “Roentgen equivalents in man”, or “rem”, which is a unit of uniform whole body exposure.

People are exposed to different amounts of natural “background” ionizing radiation, depending on where they live. Radon gas in homes is a problem of growing concern. The sources and respective average annual dosages of background radiation from each source are as follows: [1] Terrestrial (radiation from soil and rocks): 0.05 rem. [2] Cosmic (radiation from outer space): 0.05 rem. [3] Radioactivity normally found within human body: 0.025 rem. Depending on geographic and other factors, the range of cumulative annual dose of background radiation is 0.075 to 5.0 rem, with an average dose of 0.125 rem.

In addition to exposure from normal background radiation, medical procedures may contribute to the ionizing radiation dose people receive. Average dosages received by the bone marrow of persons undergoing various procedures involving ionizing radiation are as follows (variations by a factor of 2 above or below the average dosages are not unusual): [1] Chest roentgenogram: 0.01 rem. [2] Standard dental roentgenograms: 0.01 rem. [3] Roentgenograms of the rib cage: 0.14 rem. [4] Cholecystogram: 0.17 rem. [5] Barium enema large bowel examination: 0.5 rem. [6] Roentgenograms of the pelvis: 0.6 rem.

Regulations and guidelines of the US Nuclear Regulatory Commission (NRC) are based on the assumption that any amount of ionizing radiation, no matter how small, can have a harmful effect on an adult, child, or unborn child. This assumption is conservative, because there are no data showing ill effects from small dosages.

The NRC regulations (10 CFR 20; Standards for Protection Against Radiation; §101) have set the limit on dose of ionizing radiation that can be received on the job (i.e. by a radiation worker) as 1.25 rem per annual quarter, or 5.0 rem per year. Working minors (age <18 years) are limited to one-tenth the dose permissible for adults, or 0.125 rem per quarter and 0.5 rem per year. Amendment to 10 CFR 20, §1208 (1994) has set the limit on dose of radiation to an embryo/fetus of a “declared pregnant” woman radiation worker as 0.5 rem during the entire pregnancy.

For small doses of radiation exposure, estimates of the significance of risks are quite inaccurate. For doses less than 1 rem, the risk is too small to measure. For doses 1 to 5 rem, the risk may be similar to other every day risks, such as driving a car. On the other hand, for radiation exposure exceeding 5 rem, there is a measurable and significant increase in cancer risk; the magnitude of the risk varies widely, depending on the part of the body receiving the radiation. Thus, research involving radiation exposure of 5 or more rem would be justifiable only if there is strong likelihood that the subject will benefit from the exposure directly, an if the expected benefits clearly outweigh the risks.
In studies involving ionizing radiation, the informed consent document should contain meaningful and understandable information on the quantity of exposure, the risks of the exposure directly attributable to the dose received within the framework of the study, and the risks in terms of cumulative life-time exposure to ionizing radiation. The amounts of exposure are to be given in Roentgen equivalents in man (rem), and interpreted in relation to three other types of radiation exposure: [1] background radiation, [2] other medical radiological procedures, and [3] permissible radiation exposure limits for radiation workers. Assistance for radiation dosimetric analysis is available through IRBMED (irbmed@umich.edu).

Suggested text for inclusion in the “Risks” section of the informed consent document: “During the course of this study, as a result of procedures to be carried out for research reasons, you will be exposed to radiation in the form of <enter type of radiation exposure>. The biological effect of radiation is measured in terms of Roentgen equivalents in man, or “rem”, which is a unit of uniform whole body exposure. Radiation you will be exposed to in this study will amount to <enter the amount> rems. The effects on your body of this radiation exposure will be added to your overall life-time radiation risk. Your life-time radiation risk includes the background radiation you are exposed to naturally like everyone else living on this planet, which is on the average 0.3 rem per year; the radiation you will be exposed to in this study is about <x-tenth> or <x-hundredth> or <enter the amount> times (or <enter the amount>% of) the yearly background radiation. In terms of radiation a person may get exposed to during medical care, the amount you will receive in this study will be <enter the amount> times (or <enter the amount>% of) the amount of radiation received in routine dental x-rays or chest x-ray, which is 0.01 rem (or <enter type of a familiar diagnostic study> x-ray study). Federal Government requires that the amount of radiation exposure of radiation workers does not exceed 5 rems per year; the radiation you will be exposed to in this study is <x-tenth> or <x-hundredth> or <x-thousandth> that amount. Your life-time radiation risk also includes any radiation you may have received in the past for diagnosis or treatment, and any such radiation you may be exposed to in the future. Please tell us if you have had any major radiation exposure in the past, particularly in the past two years, such as treatment with x-rays or radioactivity, or diagnostic x-rays, CT-scans or nuclear medicine scans.” Depending on the radiation dose to be delivered in the study, additional summarizing statements may be included, to help the subject comprehend the magnitude of the risks involved; some examples follow: For doses less than 1 rem “The risk from radiation exposure of this amount is too small to estimate.” For doses 1 to 5 rem: “The risk from radiation exposure of this amount is considered to be similar to other every day risks, such as driving a car.” For doses more than 5 rem, there is a measurable increase in cancer risk, and the magnitude of the risk varies widely, dependent on what part of the body is being radiated. Thus, for exposure exceeding 5 rem, a summary statement would not be proper; rather, the subject should be given a clear assessment of the significance of the risk involved, weighed against direct benefits.