ADDITIONAL BACKGROUND MATERIALS

Major Revision of Part 20 in 1991 and ICRP 60

The last major revision of 10 CFR Part 20 was published in the Federal Register in May 1991. The purpose of the 1991 revision was to implement the 1987 Presidential guidance on occupational radiation exposure and to adopt the basic tenets of the ICRP system of dose limitation described in ICRP Publication 26, "Recommendations of the International Commission on Radiological Protection," published in 1977. The internal dosimetry aspects of the revised Part 20, such as the models and parameters used to calculate internal doses and to estimate intake limits, were based on a companion ICRP report, namely Publication 30, "Limits for Intakes of Radionuclides by Workers." Publication 30, which was published in 1978, was basically the application of the recommendations in Report 26 to the field of internal dosimetry.

Nearly coincidentally with publication of the revised Part 20 in the Federal Register in 1991, ICRP published Publication 60, "1990 Recommendations of the International Commission on Radiological Protection." The guidance in Publication 60 superceded the guidance provided in Publication 26, and the changes introduced in Publication 60 are discussed later in this attachment. Subsequently, the ICRP issued a series of publications dealing with various aspects of internal dose assessment, mainly the biological models that describe the routes of intake of radioactive materials into the body and its movement and elimination from the body. This series of reports substantially revised the models used to calculate internal doses, and also introduced age-dependence into the dose estimates. Most countries of the world, with the major exception of the United States, plan to adopt most or all of the recommendations in Publication 60 and use the internal dosimetry models and dose coefficients described in a series of ICRP publications.

Changes in Recommendations Between Publications 26 and 60

The main changes in the recommendations in ICRP Publication 60 from those in ICRP Publication 26, and hence from the bases of the current Part 20, are the following:

- The limit on the effective dose equivalent was lowered from 5 rem per year to a five-year average of 2 rem (20 mSv) per year, with the dose in any given year not to exceed 5 rem (50 mSv).
- The annual dose limit for members of the public was reduced from 500 mrem (5 mSv) in ICRP 26 to 100 mrem (1 mSv) in ICRP 60. This change has already been incorporated in Part 20.
- Part 20 limits exposure to an embryo/fetus during the gestation period to 500 mrem (5 mSv). ICRP 60 recommends 200 mrem (2 mSv) from external exposure and 1/20 of an Annual Limit on Intake (ALI) from internal exposure, or about a total of 450 mrem (4.5 mSv) for the gestation period.
- The dose limits for individual organs were eliminated, except for the skin and the lens of the eye, which were retained.
- Many of the quantities used in radiation protection were renamed, although most retained their original definitions with only subtle changes. For example, the dose equivalent was renamed the equivalent dose; the effective dose equivalent was renamed the effective dose; the quality factor used to convert dose to dose equivalent was renamed the radiation weighting factor; the organ weighting

factor was renamed the tissue weighting factor; and similar other name changes were made.

- The tissue weighting factors were changed both in magnitude for individual organs, and also in the number of organs specifically assigned weighting factors. In ICRP 26, six individual organs and tissues are given specific weighting factors, and five remainder organs share a weighting factor. In ICRP 60, 12 individual organs and tissues are given specific weighting factors, and the remainder organs include 10 named organs. The weighting factors for some organs and tissues changed significantly.
- The cancer mortality risk in ICRP 26 is 1.25×10^{-2} Sv^{-1} and applies to both sexes and all ages. The cancer mortality risk in ICRP 60 is 4×10^{-2} Sv^{-1} for adult workers and 5×10^{-2} Sv^{-1} for the general population.
- The risk of hereditary effects in ICRP 26 is 4×10^{-3} Sv^{-1}, and is 8×10^{-3} Sv^{-1} in ICRP 60 for the adult worker and 1.3×10^{-2} Sv^{-1} for the general population.
- ICRP 26 did not explicitly consider non-fatal cancers in its overall risk, whereas this was considered in the overall risk in ICRP 60. The risk of nonfatal cancer in ICRP 60 for workers is 8×10^{-3} Sv^{-1} and 1×10^{-2} Sv^{-1} for the general population.
- The total risk, including fatal and non-fatal cancer and hereditary effects in ICRP Publication 60 is 5.6×10^{-2} Sv^{-1} for adult workers and 7.3×10^{-2} Sv^{-1} for the general population.
- Although the dependence of a dose on age was not introduced explicitly in ICRP 60, it was introduced in subsequent reports.
- Although the default size for inhaled radioactive particulates was not changed in ICRP 60, it was changed to 5 µm for occupational exposures in subsequent reports. It remained unchanged at 1 µm for members of the general public.

Components of the ICRP 60 System of Radiological Protection

The system of radiation protection recommended in ICRP 60 and subsequent publications can be divided, for convenience, into two components: the dose limitation component and the dose assessment component. The dose limitation component is that part of the recommendations that establishes dose limits for the various exposed groups, such as workers, members of the public, minors, and pregnant workers, and also requires that these doses be maintained as low as is reasonably achievable (ALARA). This part of the system is based on current estimates of radiation risk per unit exposure. Obtaining this risk value involves several assessments and value judgements based mostly on epidemiological studies of exposed populations. These include estimates of the doses received by each member of the exposed population considered in the epidemiological studies (e.g., the DS86 dosimetry for the Japanese survivors); the models used to extrapolate the epidemiological data for cancer incidence and mortality as observed in an exposed population most of whose members are still alive, to a lifetime risk (e.g., use of the absolute or relative risk extrapolation models); transfer of the risk values from the exposed population to other, different populations (e.g., from risks for the Japanese population to risks to other populations); and allowances to account for the observation that low dose and dose rate exposures to penetrating radiation are less effective in inducing radiation injury than the high dose and dose rate exposures on which the Japanese A-bomb survivor data is based (e.g., use of the dose and dose rate effectiveness factor).

The dose assessment component is largely independent of the risks and dose limits established, and is the component that addresses the methods by which external and internal doses are assessed or estimated under different exposure conditions. These assessments use

a combination of instrumentation and mathematical models to estimate the external and internal doses received by workers and members of the general public. There have been substantial developments in this area since publication of Part 20 in 1991. These developments represent an increased understanding of the behavior of radioactive materials in the body, and also improved instrumentation for measuring external radiation fields and internally deposited radioactive materials, as well as much more sophisticated computational capabilities that permit even modestly equipped licensees to run complex mathematical dose calculations. Most of these models apply to internal dosimetry, and were described in the series of ICRP publications starting from Publication 56 in 1989 to ICRP Publication 72 in 1996. Developments in this area are expected to continue indefinitely. Parallel developments also occurred in the methods used to assess external doses, mainly by the use of tissue weighting factors for external exposures in a manner similar to that used for internal exposures, and by the use of multiple dosimetry to obtain better estimates of the effective dose from external exposures than is possible using a single dosimeter.

The two components noted above, namely dose limitation and dose assessment, are not completely independent. Tissue weighting factors are an important link between the two components. The tissue weighting factors are based on cancer mortality, account for years of life lost, and account for genetic and hereditary disorders. Changes in these factors will result in changes in the assessed effective doses. However, because they are based on relative rather than absolute risks, even a major change in the overall radiation risk coefficient need not necessarily lead to a change in the tissue weighting factors, and these factors are therefore much more robust than the absolute risk values.

Current Developments that May Affect Radiation Protection Practices

There are currently several major efforts underway that may have a significant impact on the dose limits recommended by national and international radiation protection advisory groups. These efforts include the following:

- A reassessment of the dosimetry for the survivors of Hiroshima and Nagasaki. Data now available suggest that the last such dosimetry assessment, called DS86, should be revised, and the new assessment, to be called DS02, is expected to be completed and published in 2002. A change in dosimetry may result in a change in the risk coefficients. This effort is critical because our knowledge of the radiation risk factors comes almost entirely from data on the Japanese survivors.
- The National Research Council was awarded a three-year grant in 1998 to conduct a reassessment of the health effect of low levels of ionizing radiation. The last such assessment, known as BEIR V (Committee on the Biological Effects of Ionizing Radiation) was published in 1990, and the new report will be BEIR VII. Because of the importance of the DS02 dosimetry in this type of reassessment, it is expected that the BEIR VII committee will not complete its work until mid- to late-2003
- The ICRP is also considering a complete review of its current recommendations, and the revised recommendations may differ substantially from the current ones. Because it is likely that ICRP will await completion of DS02 and publication of BEIR VII, the ICRP may publish revised recommendations in 2005 if not later.

Convention on Nuclear Safety

The Convention on Nuclear Safety was adopted on June 17, 1994, by a Diplomatic Conference convened by the International Atomic Energy Agency. By April 12, 1999, 50 states had ratified the Convention. The U.S. ratified the Convention on April 9, 1999. Under Article 15 of the Convention "each Contracting Party shall take the appropriate steps to ensure that in all operational states the radiation exposure to the workers and the public caused by a nuclear installation shall be kept as low as reasonably achievable and that no individual shall be exposed to radiation doses which exceed prescribed national dose limits." During the first review meeting of the Contracting parties, April 12-23, 1999, it was observed that "the ALARA principle (As Low As Reasonably Achievable) is implemented in all countries with regard to doses and releases. The Radiation Protection System recommended in ICRP 60 is already applied or is planned to be applied in all countries." The three elements of the radiation protection system being justification of a practice, optimization of protection and limitation of exposure and risk.

Although U.S. regulatory requirements are generally consistent with the recommendations of the ICRP, there are constraints that limit the extent to which the U.S. regulations coincide with the ICRP recommendations. One important consideration is the desire for regulatory stability; revising the regulations to reflect every new ICRP position would impose a serious burden on the licensees without a commensurate benefit. Furthermore, for nuclear power reactors, new requirements are constrained by the "backfit rule" (10 CFR Part 50.109) which in essence, requires that any increase in regulatory requirements be justified by a commensurate improvement in safety. Consequently, U.S. regulations often are based on older (rather than the most recent) recommendations of the ICRP.

It should also be noted that radiation protection rules promulgated by Federal agencies generally follow Presidential Guidance, which specifies the general outlines of the radiation protection system recommended for protecting workers and the general public against the hazards of radiation exposure. The Presidential Guidance has not been revised by EPA to reflect the ICRP 60 recommendations, and at this date there have been no recommendations to revise the guidance. To ensure coherence within the U.S. in formulating and implementing radiation protection regulations, it is important that the Presidential Guidance be revised prior to Federal agencies adopting new ICRP recommendations. To this end, the Federal agencies are discussing, and will continue to discuss, the possibility of changing the guidance, or parts of it, through ISCORS.