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IMPLEMENTATION OF REVISED 10 CFR PART 20

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INTRODUCTION

In January 1977, the International Commission on Radiological Protection (ICRP) approved new recommendations for radiation protection standards (1). These recommendations introduced significant changes to both the philosophy and the numerical limits for protecting both workers and the general public from ionizing radiation. The recommendations in ICRP-26 have been clarified and, in some cases, modified by statements issued by the ICRP since 1977 (2 - 8). Changes are being made or have already been made to national and international radiation protection standards in order to implement these recommendations.

The most significant new concepts that were introduced in ICRP-26 are shown in Table 1. Among the changes introduced by the ICRP are new concepts, new terms, and revised numerical dose limits. The concept of an "effective dose equivalent," whereby the internal radiation doses received by individual body organs are weighted and summed to produce a whole body risk equivalent dose, will require major changes in the way doses are calculated and recorded. The ability to equate and sum internal and external doses will also result in concomitant changes in recordkeeping and reporting requirements.

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TABLE 1.
SIGNIFICANT CONCEPTS INTRODUCED IN ICRP PUBLICATION NO. 26
(as modified by subsequent ICRP recommendations)

- Distinction between statistical (stochastic) latent health effects and nonstochastic effects as bases for standards
- Use of comparability of risks as a basis for standard-setting
- Summation of Risk-Weighted Organ Doses (Effective Dose Equivalent)
- Summation of Internal and External Dose Equivalents

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Associated with the issuance of ICRP-26 was an updating and revision of the metabolic and internal dosimetric models and parameters for radionuclides published in ICRP-30 (9) and its supplements. Modifications to the present limits on radionuclide intakes and concentrations are necessary to incorporate these revised values.

Actions in the United States to Implement ICRP-26

The Nuclear Regulatory Commission (NRC) formed a task group in 1978 to study the 1977 ICRP recommendations and to develop a plan to implement those changes. One of the principal products of this task group was a Advanced Notice of Proposed Rulemaking (ANPR) that was issued in 1980 (10). The ANPR discussed the ICRP recommendations and solicited public input on these and a number of related issues. The ANPR also asked for alternative methods for incorporating these issues in a revision of Part 20. Responses to the ANPR were factored into the development of a revised regulation and accompanying regulatory documents including revised and updated concentration limits. This effort culminated in the issuance of a proposed revision of 10 CFR Part 20 for public comment at the end of 1985 (11).

The public comment period on the proposed rule closed on October 31, 1986 and over 800 sets of comments were received. Since that time the NRC staff has been reviewing and catagorizing these comments, preparing a revised final rule, and updating the associated documents. As you know, the draft revised rule circulated for NRC division review was also distributed to the States for comment. Near the end of May we will be distributing the final rule and the statement of considerations for review concurrent with going out for NRC Office concurrence. Copies will also be provided at that time to the Advisory Committee on Reactor Safeguards and the Committee to Review Generic Requirements. The rulemaking package is scheduled to be transmitted to the Commission for approval by the end of June. The revised Part 20 rule would be issued in the Fall of 1988. An effective implementation date of January 1, 1991 is being considered as it would provide a period of five years from the issuance of the proposed rule in January 1986 and over two years from the anticipated publication of the final rule. A fixed implementation date at the beginning of a recordkeeping year is desired in order to avoid problems in mixed reporting of doses under both the existing "critical organ" approach and under the new "effective dose equivalent" system.

Revised guidance for Federal agencies on occupational radiation protection was approved by President Reagan and issued early in 1987 (12). The majority of the changes required to implement the Federal guidance had been incorporated in the proposed NRC rule. However, several changes did have to be made in Parts 19 and 20 in order to conform with specific wording of the final Federal guidance.

The essential elements of the ICRP system have also been endorsed by the National Council on Radiation Protection and Measurements (NRCP) in Report No. 91 (13) which was issued in mid-1987. However, the NCRP report also contains several additional recommendations including a lifetime dose limitation equal to 1 rem times the individual's age in years and a "negligible level of risk" of 1 millirem per year. Because these concepts were not available for public comment, they are not being incorporated into the Part 20 rule at this time.

PART 20 IMPLEMENTATION ISSUES

The new concepts and dose assessment methodology inherent in the adoption of the revised Part 20 will entail major changes in radiation protection practices. Some of the more significant changes are described below.

Use of New Dose Calculation Parameters

Because of the need for time to develop record systems and procedures consistent with the revised Part 20, there will be a two-year period in which the old Part 20 will continue to be effective. In order to ensure that a uniform methodology is used by all licensees, the NRC staff is recommending to its licensees that the new concept of an effective dose equivalent and the new Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) not be used prior to the effective date. Until that date, compliance will be measured against the current version of Part 20 and its Appendix B concentrations. Licensees may use the updated metabolic and dosimetric models and dose factors in ICRP-30 (and its supplements) to calculate internal doses from intakes, providing that organ doses rather than effective dose equivalents are calculated (the ICRP documents included dose/intake conversion factors for organ doses as well as the risk-weighted effective dose factors).

Weighting and Summation of Organ Doses

The concept of summing risk-weighted organ doses to arrive at an "effective dose equivalent" was generally accepted by the commenters on the proposed Part 20 rule. However, a number of commenters suggested that this procedure be extended to external doses in addition to internal comitted doses and include the embryo/fetus as well as internal organs.

A primary drawback to the use of external dose weighting factors is that the transmission and attenuation of the radiation would have to be estimated in order to properly calculate the doses to internal organs. This requires estimates of the photon energy spectrum and direction of the incident radiation. Personnel dosimeters and routine survey instruments do not currently provide quantitative data on energy spectra. Another issue is whether a single (or a few) personnel monitoring devices can provide sufficient coverage of the body to justify the use of this system.

Addition of Internal and External Doses

The public comments received on the proposed Part 20 indicated that there was considerable confusion regarding the requirements in §§ 20.204 and 20.502 of the proposed rule for adding internal and external doses. The proposed rule would have required that the internal and external doses (the committed effective dose equivalent and the deep dose equivalent, respectively) be added if they exceeded 10% of the dose limits for the external dose and 30% of the dose limits for the committed effective dose equivalent. Many commenters interpreted this to require monitoring sensitivities at the specified levels (10% and 30% of the limits) to demonstrate compliance. However, the intent of these requirements was to have external individual monitoring (personnel dosimetry) carried out if it is likely that the external dose to an individual would

exceed 10% of any of the external dose limits in § 20.202 (deep dose equivalent, eye dose equivalent, or shallow dose equivalent).

Similarly, the requirement to monitor intakes of radioactive materials depends upon whether intakes would be likely to exceed 10% of the dose limit (or 10 % of the Annual Limit on Intake (ALI) or 200 Derived Air Concentration-hours (DAC-hours)). For both internal and external doses, the estimate of the anticipated levels can be based upon previous monitoring histories or upon radiation surveys or ambient air monitoring data (occupational ingestion of radioactive materials in the form of contaminated liquids is not anticipated).

Protection of the Embryo/Fetus

A major new aspect of the revised Part 20 will be a limit on the dose received by a "declared pregnant woman." This limit of 0.5 rem to the embryo/fetus corresponds to the recommendations of the NCRP (13, 14) rather than the 1.5-rem limit proposed in ICRP-26 (1). This limit is available to any pregnant worker who formally declares her state of pregnancy to the her employer. The burden to take advantage of the lower dose limit is on the female worker to make this declaration. Licensees will not be required to provide additional protection for "undeclared pregnant workers." This somewhat awkward approach is a consequence of court rulings on the rights of the mother concerning the unborn child and the requirements of equal employment opportunity statutes.

Annual Limits on Intake and Revised Air Concentration Limits.

The majority of radionuclides will not pose any special implementation problems resulting from changes in intake or concentration limits (changes in calculation of organ doses generally resulted in higher derived air concentra - tions (DACs) for about 68% of the radionuclides listed compared with the present Part 20 concentration limits). There is a significant reduction by a factor of 60 in the concentration limit for thorium-232 from 3 x 10(-11) μCi/ml in the present Part 20 to 5 x 10(-13) μCi/ml in the revised Appendix B that will affect thorium processors. There is also a signficant change in the air concentration limit for insoluble uranium from 10(-10) μCi/ml to 2 x 10(-11) μCi/ml that will affect uranium mills, conversion and fuel fabrication facilities.

IMPLEMENTATION PLANS

Regulatory Guidance.

Additional guidance to licensees will be needed on the specific details of implementation. Areas where further guidance may be necessary are shown in Table 2. In addition to new guides, many existing guides will have to be revised; most guides will only require conforming citations of 10 CFR Part 20 to correspond to the revised rule. Several guides will require more extensive revisions to incorporate the new dose calculational methodologies and terms. We hope to this completed prior to the effective date of the revised rule.

Table 2

Areas Where Additional Regulatory Guidance May be Needed

- Content and recordkeeping for radiation protection programs (several guides for various classes of licensees may be needed)
- Alternative methods for estimating radionuclide intakes and internal doses
- Criteria for and procedures for summation of external and internal doses
- Methodology and parameters for calculating the dose to the embryo/fetus
- Format for reporting worker radiation doses via electronic media.
- Acceptable criteria, procedures and documentation for planned special exposures

Education and Training

It is recognized that the new approaches and concepts that are inherent in the revised Part 20 and the ICRP System of Dose Limitation will require the familiarization and education of personnel and management involved in radiation protection activities. There have been commercially-sponsored courses on the implementation of the proposed Part 20 and at least one video tape on this subject has been made and distributed commercially. The Health Physics Society is also preparing a series of lectures and manuals related to the implementation of the concepts underlying the ICRP dose limitation system and the Part 20 revision. Several Federal agencies, including the NRC, are supporting this effort.

CONCLUSIONS

The process of revising the NRC regulations to conform to the ICRP recommendations on radiation protection standards should reach its conclusion later this year. This effort has used considerable resources, not only on the part of the NRC staff, but also from the States, industry, labor unions, public intrest groups and members of the general public that took time to comment on the proposed rule and other drafts. The NRC staff hopes that this high degree of interest and continuing dialog will continue through the implementation period.

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