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RULEMAKING ISSUE

(Information)

SECY-82-168

April 21, 1982

For: The Commissioners

From: William J. Dircks
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Subject: REVISION OF 10 CFR PART 20: STANDARDS FOR PROTECTION AGAINST RADIATION

Purpose: To highlight the major features and changes being considered and to inform the Commissioners of the staff's efforts, including efforts to ascertain adverse technical and economic impacts on the NRC and licensees of the revised regulation.

Discussion: There are two primary reasons for considering a major revision of Part 20. Firstly, the radiation protection requirements have been amended many times since the regulation was made effective in 1957. These amendments have addressed essentially every feature of the existing Part 20 and have resulted in ambiguities and inconsistencies.

Secondly, and of much greater importance, is the need to revise Part 20 to reflect the use of health risks as a basis for radiation protection standards. This latter reason is consistent with the Commission's trend toward using, in the regulatory process, risk analyses involving probabilities of contaminating events and probabilities of health damage.

Since the late fifties, knowledge of the potential health damage from exposure to ionizing radiation has greatly expanded. The most recent of the several reviews and evaluations of this knowledge is the National Academy of Sciences' BEIR-III report published in 1980. Knowledgeable scientists from around the world are in general agreement on the magnitude of the health risk from ionizing radiation.

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As a result of this greater confidence in risk quantification, the fundamental approach to radiation protection has undergone a significant change. Quantification of risk has become an integral part of the analyses supporting radiation protection standards and estimates of risk are explicitly stated in documents supporting decisions. A particularly important example of this is found in Publication No. 26 of the International Commission on Radiological Protection (ICRP), published in 1977, in which the risk of fatal cancer is described and used in deriving recommendations on radiation protection.

By relating estimated risks of nonuniform irradiation to that from uniform total body irradiation, the ICRP has developed a method for adding the risks from internal emitters and the risks from external sources. It judges the "acceptability" of this total risk for occupational exposures by comparing it with industrial risks from non-radiation causes. The ICRP recommends that exposures should be controlled such that radiation risks would be at a level which would ensure that the total fatality rate would be low, and comparable to existing "safe" industries with rates below 100 deaths per million workers per year.

To facilitate this protection goal, the ICRP recommends a system of dose limitation which has the following three basic components:

1. Justification. No practice or operation involving exposure to radiation should be adopted unless its introduction produces a benefit.
2. Optimization. All exposures shall be kept as low as is reasonably achievable (ALARA), economic and social factors being taken into account.
3. Limits. The dose equivalent to individuals shall not exceed the limits selected for the appropriate circumstances.

A drafting group within the NRC and lead by RES is developing a revision of 10 CFR Part 20 to make the regulation consistent with these recent developments. This revision of Part 20 would treat the ICRP system, which is essentially a restatement of long-standing tenets of radiation protection, in the following way. The justification for the production and use of radiation and radioactive materials, as covered by the Atomic Energy Act, would be considered, when necessary, during the licensing process but not explicitly required in Part 20. Licensees would be required to establish a radiation protection program to ensure that exposures to radiation are kept as low as reasonably achievable. However, quantitative cost-benefit assessment of this optimization would not be required. Numerical dose limits would be provided.

Enclosed is a chart showing a comparison between the treatments of several important issues given by the existing 10 CFR Part 20 and a possible revision.

The ICRP method for summing internal and external exposure modes would be included in the revised 10 CFR Part 20, and the annual limit for occupational exposure from the combined modes would be set at 5 rems. The existing provision for dose-averaging under the formula $5(N-18)$ would be replaced with the ICRP-recommended provision for "planned special exposures." Under planned special exposures, a licensee could allow an adult worker to receive up to 10 rems during a single event, but not more than 25 rems for all such events during the worker's lifetime.

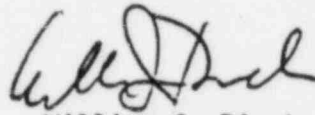
The draft revision would continue to impose the same dose limits on women and men except that planned special exposures would not be permitted for women of reproductive capacity. The rule would specify that a licensee shall ensure that any dose equivalent to an embryo or fetus due to occupational exposure of a declared expectant mother shall not exceed 0.5 rem during the entire gestation period.

The limit for members of the public would be 0.5 rem per year; in practice, no change from the current Part 20 requirement.

The question of impacts and practicality have been raised in connection with incorporating the ICRP recommendations into a revised Part 20. The drafting group has met with a number of people representing a broad spectrum of interests in the revision effort including industrial and medical licensees, members of Natural Council on Radiation Protection and Measurements, and a representative of the Natural Resources Defense Council. The intent of these meetings is to identify substantive issues that the present working draft must deal with prior to publishing a proposed revision, to identify areas where substantive impacts might be anticipated and, where possible, to quantify these impacts. These early discussions have been valuable in shaping the revision while it is in a formative stage. Responses to the draft revision have been generally favorable and the NRC effort has been welcomed as a meaningful and open outreach program. However, there remain some unresolved questions of cost and detailed implementation.

The present effort includes detailed revision of the draft prepared in November 1981; a concerted effort to resolve the practical problem of recording for the year of radionuclide intake the total 50-year dose commitment for long half-life materials such as

uranium; and an initial effort to obtain through contracting some information on cost of implementation. Our plan is to submit a Proposed Rule to the Commission by late 1982.



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Enclosure: Comparison of Salient
Issues in Existing 10 CFR Part 20
with Possible Alternatives"

Comparison of Salient Issues in Existing 10 CFR Part 20
With Possible Alternatives

Issue	Current 10 CFR Part 20	Possible Alternative
ALARA	Recommended	ALARA program required.
LIMITS		
Occupational	<p>External</p> <p>1.25 rems/quarter, or 3 rems/quarter with lifetime occupational exposure history and within 5(N-18) dose-averaging formula.</p> <p>Internal</p> <p>Intake equivalent to 520 MPC-hours per quarter. No summation required.</p>	<p>5 rems/year</p> <p>Includes summation of external dose and (internal) committed effective dose equivalent. (See Internal Dosimetric Methodology, below.)</p> <p>Planned special exposure. (Replaces 5(N-18).) 10 rems/event, up to 25 rems/lifetime.</p>
Embryo/Fetus	Not addressed	0.5 rem/entire gestation period due to occupational exposure of the "declared" expectant mother.
Basis for limits	Biological damage or health effects would not be clinically observable.	"Acceptable" risk based on estimated incidence of fatal cancers and serious hereditary disorders. Upper organ limits set to avoid nonstochastic (threshold) effects such as cataracts.
Internal dosimetric methodology		
Irradiation	Dose to the most irradiated organ, e.g., "critical organ," used to limit intake via "Maximum Permissible Concentrations." Dose to other organs ignored.	Dose to each organ is calculated, weighted by a factor equating risk from dose to that organ to risk from 5 rems of whole-body irradiation, then the products are summed. Values for Annual Limit of Intake (ALI) and Derived Air Concentration (DAC) have been calculated for each radionuclide.

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Issue	Current 10 CFR Part 20	Possible Alternative
Internal dosimetric methodology (con't)		
	Doses from radionuclides deposited in non-critical organs are ignored.	Doses to organs from radionuclides deposited anywhere in the body are summed.
Lung model	1959 ICRP-2 model used.	Improved 1966 model of ICRP Task Group on Lung Dynamics used.
Retention in lung	Aerosols ranked "Soluble" or "Insoluble." No consideration given for aerosol aerodynamic properties.	Aerosols ranked by translocation and elimination rates, e.g., D (days), W (weeks), Y (years). Assumes a 1 μ m AMAD. Adjustments for other aerosol size distributions, physical and chemical properties are possible.
Translocation	Based on 1959 biological data.	Based on 1978 biological data from ICRP-30.
Public	Inferred limit of 0.5 rem/year for individual. No summation of external and internal dose. No consideration of food pathways.	Explicit limit of 0.5 rem/year for individuals from all sources. Includes summation of external and internal dose and food pathways.
Reference levels	None	0.1 rem/year as action level for licensee. 0.025 rem/year as reporting level for licensee.
De minimis level	None	0.0001 rem/year used to truncate insignificant exposures to individuals in calculating doses to general population.
MONITORING		
Adult	Required at 25% of the basic quarterly limit (0.312 rem).	Required at 30% of the annual limit (1.5 rems).
Minor	Required at 5% of the basic quarterly limit (0.0625 rem).	Required at 5% of the annual limit (0.25 rem).

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Issue	Current 10 CFR Part 20	Possible Alternative
SEWER DISPOSAL	Concentration limits equivalent to 5 rems/year.	Concentration limits equivalent to 0.5 rem/year.
RECORDS		
Determination of prior dose	Occupational exposure history required as provision of 3 rems per quarter and 5(N-18). Signed statements of dose during last quarter required upon employment.	Occupational exposure history required for all individuals likely to receive more than 30% of the annual limit.
Current exposure records	Form NRC-5 includes only external dose. Includes items for calculating status under 5(N-18).	Form NRC-5 includes external dose, internal dose, summation, doses received during planned special exposures and as overexposures, and lifetime total occupational dose.
Effluent releases	Inferred under survey requirement.	Explicitly required.
REPORTS		
Criteria for immediate notification of incidents	20 times the basic quarterly dose limits. Property damage \$200,000.	5 times the new annual dose limits. Property damage \$300,000.
Overexposures of public	Required if limits for short-term radiation levels or annual effluent releases to unrestricted areas are exceeded.	Required if any individual in unrestricted area exceeds 0.5 rem from all sources
Planned special exposures	No provisions	Permitted
Exceeding reference levels	No provisions	Explicitly covered
Individual monitoring reports	Not required	Required.

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Issue	Current 10 CFR Part 20	Possible Alternative
REPORTS (con't)		
Individual monitoring reports	Annual statistical summary report required of 4 categories of licensees.	Annual report of annual and lifetime doses required of all licensees for each specifically identified individual for whom monitoring is required.
	Termination report required of same 4 categories of licensees.	Not required.
Reports to individuals	Required for any information reported to NRC. Applies only to overexposures and termination reports.	Required for any information reported to NRC. Note that the change in annual reporting requirements would require licensee to inform each individual of annual and lifetime dose each year.
Notification of intent to vacate premises.	Not required.	Required.