An Overview of the Changing U.S. NRC Regulations—10 CFR Part 20

The Nuclear Regulatory Commission (NRC) has proposed major revisions in Code of Federal Regulations Title 10, Part 20 (10CFR 20) since December, 1985, and it appears that the revised 10 CFR Part 20 will become law in 1990. The purpose of this paper is to review historical developments surrounding the 10 CFR Part 20 and discuss concepts and major changes in proposed regulations.

The federal guidance on radiation protection programs has been, by and large, consistent with the recommendations of the International Commission on Radiological Protection (ICRP) and the U.S. National Council on Radiation Protection and Measurements (NCRP). More specifically, present 10 CFR Part 20 is based on ICRP Report No. 2 (1960) and 10 (1968). Proposed 10 CFR Part 20 is based on ICRP Report No. 26 (1977) and 30 (1979). There exist, however, major philosophical differences between ICRP 2/10 (present 10 CFR 20) and ICRP 26/30 (proposed 10 CFR 20). Recent publications of NCRP Report No. 91 (1987) and EPA Federal Guidance Report No. 11 (1988), basically reflect this new philosophy based on ICRP Report Nos. 26 and 30.

Since the publication of ICRP 26 in 1977, many developed countries reevaluated their national codes and have, since then, adopted this new radiation protection philosophy. The United States, however, is one of the few nations that have not yet adopted the ICRP 26/30 recommendations. On January 9, 1986, NRC published proposed rules for 10 CFR 20 in the Federal Register. As of this writing (January 1990), 13 years after the publication of ICRP 26, the new 10 CFR 20 has not yet become law in the United States. It appears that adoption of new 10 CFR 20 has been hampered due to political reasons more than anything else, in light of the fact that many industrialized nations have adopted the philosophy of ICRP 26/30 for a long time.

A detailed comparison between ICRP 2 and ICRP 26 is beyond the scope of this paper. Instead, for practical reasons we will focus on the key differences between the two. It is suggested that the reader refer to the Federal Register Vol. 51, 1986 for proposed 10 CFR 20, as well as to ICRP 26/30 and NCRP Report 91 for the new radiation protection philosophy. From now on we will refer to ICRP 2 and existing 10 CFR Part 20 as old standards, and ICRP 26 and proposed 10 CFR 20 as new standards.

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The new standards employ the concept of risk. Radiation protection limits are expressed in terms of acceptable levels of risk which are comparable to other "safe" industries. For protection of radiation workers, an annual risk is estimated by the average annual effective dose equivalent (EDE) and the nominal value of lifetime risk of fatal cancer. The average annual risk for radiation workers is comparable to those of "safe" industries. "Safe" industries are defined as those having a one-in-ten-thousand average annual risk of accidental fatality. The old standards were simply based on the dose-effect relationship established by review of biologic data.

OVERVIEW OF OLD AND NEW STANDARDS

Differences between the two standards are shown in Table 1. Despite the differences in terminology used to express a given concept, one realizes a similarity of approach in setting a given standard. The concept of risk is described in terms of stochastic and nonstochastic effects in the new standards. For radiation exposure limit, an EDE is introduced in the new standards, while the corresponding concept in the old standards is a maximum permissible dose. A derived air concentration is the concentration in air and water in the new standards and maximum permissible concentration is the corresponding term in the old standards. There is no definition for the maximum amount in the body in the new standards. The rate of intake in the new standards is an annual limit on intake, whereas old standards do not define the rate of intake.

Basic Terms as Defined in ICRP 26 and 30

Stochastic Effects. Those effects for which the probability of the effect occurring, rather than its severity, is a function of dose without threshold. The limit is set at 5 rem per yr.

Nonstochastic Effects. Those effects for which the severity is a function of dose, and a threshold may exist. For example, the limit is set to 15 rem per yr. for the lens of the eye.

Committed Dose Equivalent. The dose averaged throughout tissue T over 50 yr after intake of the radioactive material, given by:

$$H_{50,T} = \int_{t}^{t+50} \dot{H}(t)\, dt.$$

Weighting Factor ω_T. The fraction of the total stochastic risk associated with the irradiation of tissue T (see Table 2).

Effective Dose Equivalent. The sum of the weighted dose equivalents for irradiated tissues or organs. This concept provides a means to equate nonuniform or partial body

TABLE 1. Comparison of New and Old Standards

Concept	New Standards (Proposed 10 CFR 20 ICRP 26/30 NCRP 91)	Old Standards (Current 10 CFR 20 ICRP 2/10 NCRP 22)
Risk	Stochastic and nonstochastic effects	—
Radiation exposure limit	Effective dose equivalent	MPD*
Maximum amount in body	—	MPBB†
Rate of intake	ALI‡	—
Concentration in air and water	DAC§	MPC**

* MPD = maximum permissible dose.

† MPBB = maximum permissible body burden.

‡ ALI = annual limit on intake; Federal Register Vol. 51 (1986) uses a term, annual limit *of* intake.

§ DAC = derived air concentration.

** MPC = maximum permissible concentration.

exposures to uniform whole body exposures. Weighting factors are derived from the risk factors which include mortality risks from cancer and the risk of severe hereditary effects in the first two generations associated with irradiation of different organs and tissues, given by:

$$H_E = \sum_T \omega_T H_{50,T}$$

Annual Limit on Intake (ALI). The activity of a radionuclide which, if taken in alone, would irradiate an individual to the limit set by the ICRP for each year of occupational exposure. Two points should be noted: (a) no considerations are placed on the instantaneous rate of intake, and (b) the intake limit is placed on the total intake in a single year. ALI applies to both stochastic (5 rem/yr) and nonstochastic limit (50 rem/yr).

stochastic:

$$ALI_{stochastic}\ (uCi/yr) \leq \frac{5\ rem/yr}{\omega_T\ H_{50,T}\ rem/uCi}$$

nonstochastic:

$$ALI_{nonstochastic}\ (uCi/yr) \leq \frac{50\ rem/yr}{H_{50,T}\ rem/uCi}$$

The approach is to calculate both the stochastic intake limit and the nonstochastic intake limit and choose the smaller of the two. Note that the organ with the highest committed dose equivalent is used to calculate $ALI_{nonstochastic}$.

TABLE 2. Weighting Factors

Tissue	Effect	Risk Coeff.	W_T
Gonads	Hereditary	40×10^{-6} rem^{-1}	0.25
Breast	Cancer	25×10^{-6} rem^{-1}	0.15
Lung	Cancer	20×10^{-6} rem^{-1}	0.12
RBM*	Leukemia	20×10^{-6} rem^{-1}	0.12
Thyroid	Cancer	5×10^{-6} rem^{-1}	0.03
Bone surfaces	Cancer	5×10^{-6} rem^{-1}	0.03
Remainder	Cancer	50×10^{-6} rem^{-1}	0.3
Total (WB)		165×10^{-6} rem^{-1}	1.0

* Red-bone marrow

Derived Air Concentration (DAC). That concentration of a radionuclide in air, which, if breathed for one working year, would result in an ALI by inhalation. DAC is given by:

$$DAC\ (uCi/ml) = \frac{ALI\ (uCi/yr)}{(2000\ hrs/yr)\ (60\ min/hr)\ (2 \times 10^4\ ml/min)}$$

$$= \frac{ALI\ (uCi/yr)}{2.4 \times 10^9\ (ml/yr)},$$

where 2000 hr/yr = (40 hr/wk at work) × (50 wk/yr), and a reference man inhales 2×10^4 ml/min at work.

Terms in The Old Standard—ICRP 2 (1960) and 10 (1968)

Maximum permissible dose (MPD). That dose accumulated over a long period of time or resulting from a single exposure, which, in the light of present knowledge, carries a negligible probability of severe somatic or genetic injuries.

Maximum permissible body burden (MPBB). The activity of a particular radionuclide which delivers a MPD to the whole body or one or more organs in the body.

Maximum permissible concentration (MPC). That concentration of material, in air or water, for which continuous exposure may occur without exceeding the maximum permissible dose.

Major Changes in 10 CFR 20

The major changes in 10 CFR 20 will be addressed in the same sequence as they appear in the Federal Register Vol. 51, 1986. It is suggested that the reader refer to the current 10 CFR 20, as well as to the proposed 10 CFR 20.

Occupational Dose Limits (Current 10 CFR 20.101 and Proposed 10 CFR 20.201 (see Table 3)). The cumulative lifetime dose limit of 5 (N-18) rem was dropped. The quarterly limits were dropped, except that the external dose is limited to 3 rems in any calendar quarter. In the old standard, no limit was set for internal dose. In the proposed standard, the 5-rem annual limit must include both external and internal committed EDEs.

Concentration in Air in Restricted Area (Current 10 CFR 20.103 and Proposed 10 CFR 20.204). The MPC concept was dropped and replaced with the DAC. In the current regulations, the internal dose was limited to 520 MPC-hours per

TABLE 3. Occupational Dose Limits

Old standards	**rem/calendar quarter**
Whole body, head and trunk, lens of eye, gonads	1.25
Hands and forearm, feet and ankle	18.75
Skin	7.50
Exposure of minors in restricted area	10% of the above
New standards	**rem/yr**
Whole body	5 (not more than 3 rem/quarter)
Skin	50
Extremities	50
Lens of the eye	15
Exposure of minors in restricted area	10% of the above

calendar quarter (40 hr/wk × 13 wk/quarter). In the proposed regulations, inhalation exposure shall not exceed 2,000 DAC-hours per year (40 hr/wk × 50 wk/yr = 2000 hr/yr).

Exposure of Embryo/fetus (proposed 10 CFR 20.208). This is a new item in the proposed regulations. The current regulations do not address exposure of the embryo/fetus, except a recommendation found in the NRC Regulatory Guide 8.13. In the proposed regulations, specifics on the embryo/fetus exposure are stated:

1. Declaration of pregnancy must be made.
2. The dose limit to embryo/fetus of a declared pregnant woman is 0.5 rem during the entire pregnancy.

Practical Note: *Declaration of pregnancy must include estimated date of conception and must be in writing. The dose limit of 0.5 rem applies over the gestation period from the declaration of pregnancy. The licensee is not responsible for a woman (fetus) exposed to greater than 0.5 rem before her declaration of pregnancy. If she has exceeded the limit before the declaration of pregnancy, licensee is required to limit dose to 50 mrem for the remainder of gestation.*

Planned Special Exposures (Current 10 CFR 20.101 (b) and Proposed 10 CFR 20.206). This is a new item in the proposed regulations: This dose is allowed in addition to the annual limits specified. In the current regulations, 5(N-18) formula specified the dose limit. A planned special exposure must satisfy the following conditions:

1. A total lifetime dose from all planned special exposures, and all doses above the annual limits has a cap of five times the annual limit.
2. It requires a management (licensee) approval.

Practical Note: *Planned special exposure has lifetime limit of 25 rem and requires management approval.*

Exposure of the Public (Proposed 10 CFR 20.301 and 20.303). This is a new item; current regulations do not address this issue. The proposed regulation specifies:

1. The dose limit of any individual member of the public is 500 mrem/yr from all licensed and unlicensed sources and operations, except natural background and medical diagnosis and therapy.
2. The total dose calculation must include both the external exposures and internal dose.
3. Any single licensee cannot expose the public to more than 100 mrem/yr.

A Concept of de minimis (Proposed 20.304). This is a new item: current regulations do not address this issue. The term "de minimis" refers to a dose which is so low that the calculated risks are negligibly small. The de minimis level is specified as 1 mrem/yr to the individual members of the public.

Practical Note: *The de minimis concept enables the licensee to avoid an unwarranted commitment of resources for radiation safety operations at de minimis level.*

Personnel Monitoring (Current 10 CFR 20.202 and Proposed 10 CFR 20.502). In the current regulations, personnel monitoring is required if an individual is likely to receive a dose in any calendar quarter in excess of 25% of the limits. In the proposed regulations, the dose is lowered to 10% of the

TABLE 4. Warning Signs

Current standards	
1. CAUTION, RADIATION AREA	Area over 5 mrem in 1 hr or over 100 mrem in any 5 consecutive days
2. DANGER, HIGH RADIATION AREA	Area over 100 mrem in any 1 hr
3. CAUTION, RADIOACTIVE MATERIALS	Area containing more than 10 times Appendix C quantities
Proposed standards	
1. CAUTION, RADIATION AREA	Area over 5 mrem in 1 hr at 30 cm from a source or any surface
2. DANGER, HIGH RADIATION AREA	Area over 100 mrem in 1 hr at 30 cm from a source or any surface
3. DANGER, VERY HIGH RADIATION AREA	Area over 500 rads in 1 hr at 1 meter from a source or any surface
4. CAUTION, RADIOACTIVE MATERIALS	Area containing more than 10 times Appendix C quantities.

annual limits for external doses, and 30% of the ALI for internal doses. Personnel monitors must be processed by a processor accredited by the National Voluntary Laboratory Accreditation Program for Personnel Dosimetry Processors (NVLAP).

Warning Signs (Current 10 CFR 20.203 and Proposed 10 CFR 20.901 (see Table 4)). In this area, a new sign, "Danger, Very High Radiation Area", was introduced.

Practical Note. *The new standard defines distance for dose and dose equivalent rate measurements. This will help technologists in performing the area survey. The old standard does not define the distance.*

Package Pickup and Opening Guidelines (Current 10 CFR 20.205 and Proposed 10 CFR 20.905). The current regulation requires packages containing above Type A quantities (see current 10 CFR 20.205) to be wipe-tested no later than three hr after receipt during normal working hours, or 18 hr if received after normal working hours. The proposed regulation requires package containing above Type A_2 quantities to be wipe-tested no later than three hours after receipt during normal working hours, or not later than 3 hr from the beginning of the next working day if received after working hours.

Comments about packaging and transportation (see Table 5). Three federal agencies are identified in connection with radioactive transportation in the U.S.: The U.S. Department of Transportation (DOT), U.S. NRC and U.S. Postal Service (USPS). The following is the relationship between NRC and DOT: The NRC assists and advises DOT in the establishment of both national and international safety standards and in the review and evaluation of packaging designs. The NRC inspects its licensees for compliance with DOT regulations applicable to shippers.

"Special Form" radioactive material refers to massive solid material or high integrity encapsulation as a sealed source. "Normal Form" may be solid, liquid, or gaseous and include any material which has not been quantified as Special Form.

TABLE 5. Transport Activity Spectrum

Classification	Quantities
1. Not regulated in transport (not considered as radioactive material)	<0.002 μCi/g
2. Limited quantities and excepted articles	≥0.002 μCi/g <10^{-3} A_1 and 10^{-3} A_2 (solids) <10^{-4} A_2 (liquids)
3. Type A quantities	≥10^{-3} A_1 and 10^{-3} A_2 (solids) ≥10^{-4} A_2 (liquids) <A_1 or A_2
4. Type B quantities	≥A_1 or A_2 <3000 A_1 or 3000 A_2 *or* 30,000 Ci (whichever is least)
5. Highway route-controlled-quantity	≥3000 A_1 or 3000 A_2 *or* 30,000 Ci

TABLE 6. Notification of Incidents

Item	Current	Proposed
Immediate notification		
Whole body	≥25 rems	≥25 rems
Skin	≥150 rems	≥250 rads
Extremities	≥375 rems	≥250 rads
Lens of the eye	—	≥75 rems
24-hr notification		
Whole body	≥5 rems	≥5 rems
Skin	≥30 rems	≥50 rems
Extremities	≥75 rems	≥50 rems
Lens of the eye	—	≥15 rems

The A_1 value is the number of curies of a particular radionuclide when in Special Form. The A_2 value is the number of curies of a particular radionuclide when in Normal Form.

The current regulations use A_1 (for special form) and A_2 (for normal form) values as points of reference for quantity limitations for every radionuclide. This system replaces the former Transport Group system that was used to identify limitations when the radioactive materials were in normal form. Table 5 summarizes the transport activity classifications.

Waste Disposal by Sewer (Current 10 CFR 20.303 and Proposed 10 CFR 20.1003). The current regulation specifies the daily and monthly average soluble waste limits. In addition, the gross quantity released, except hydrogen-3 (^{3}H) and carbon-14 (^{14}C) cannot exceed 1 Ci/yr. The quantities of ^{3}H and ^{14}C must be <5 Ci/yr and 1 Ci/yr, respectively. The proposed regulation specifies the monthly average soluble waste limits. In addition, the gross quantities released must be <5 Ci of ^{3}H, 1 Ci of ^{14}C, and 1 Ci of all others.

Records (Current 10 CFR 20.401 and Proposed 10 CFR 20.1102-20.1108). The current regulation requires licensees to maintain records about personnel doses, monitoring surveys, and waste disposal. The proposed regulation requires the licensee to maintain records about the as low as reasonably achievable (ALARA) program, personnel doses, planned special exposures, overexposures, monitoring surveys, waste disposal, and effluent releases.

Practical Note: *In the proposed regulations, the development and implementation of the ALARA program is required.*

Notification of Incidents (Current 10 CFR 20.403 and Proposed 10 CFR 20.1202). Changes are noted in exposure levels as shown in Table 6. In addition, the proposed regulations deleted the reporting criteria involving property damage and loss of facility use.

CONCLUSION

Significant changes in radiation regulatory standards are under way in U.S. agencies, including the EPA, NRC, and DOE. It is expected that the state regulatory agencies will follow suit in the near future. For individual NRC licensees, it is important to recognize this national trend of change and

prepare for the upcoming new regulations. Readers are suggested to obtain copies of Federal Register Vol. 51 (proposed 10 CFR 20), p. 1123, January 9, 1986, ICRP Report 26 (1977) and NCRP Report 91 (1987). We recommend that readers take the following steps to be familiarized with new standards:

1. Using suggested references (*1–20*), compare old and new 10 CFR 20.
2. Understand significant changes in underlining philosophy of the new standards. New standards employ the concept of risk in establishing radiation protection limits.
3. Learn new terms. Once familiarized with the new language, the reader may find that radiation protection practice to be more or less same as under the old standards.

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