THE REGULATIONS FOR RADIONUCLIDES AND CHEMICALS IN THE ENVIRONMENT

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SUBJECT OF PRESENTATION

(1) Detailed information on current and proposed standards, recommendations, and guidances for limiting routine and accidental radiation exposures of the public.

(2) Review of certain laws and regulations intended primarily for limiting exposures of the public to non-radioactive hazardous materials.

Limits on risk to the public embodied in laws and regulations are emphasized.

Risk is only basis for comparing potential impacts from exposure to radionuclides and other hazardous materials.

PRINCIPAL LAWS GOVERNING PUBLIC EXPOSURES TO RADIONUCLIDES AND OTHER HAZARDOUS MATERIALS

(1) Atomic Energy Act; Uranium Mill Tailings Radiation Control Act

Basis for most (but not all) regulations limiting public exposures to radionuclides resulting from production or use of source, special nuclear, and byproduct materials.

Source material - (1) uranium or thorium or (2) ores containing these materials.

Special nuclear material - excluding source material, (1) plutonium or uranium enriched in isotopes 233 or 235 or (2) materials artificially enriched by these radionuclides.

Byproduct material - (1) any radioactive material, except special nuclear material, resulting from production or use of special nuclear material and (2) uranium or thorium mill tailings.

Regulations developed under Act apply only to exposures resulting directly or indirectly from use of defense production or civilian power reactors but not to exposures to naturally occurring radionuclides other than source material or radionuclides produced in an accelerator.

PRINCIPAL LAWS

(continued)

(2) Safe Drinking Water Act

Basis for regulations limiting public exposures to hazardous materials (including radionuclides) in drinking water at the tap.

Standards developed under Act also have been applied to protection and cleanup of groundwater and surface waters.

(3) Clean Air Act

Basis for regulations limiting airborne emissions of hazardous materials from wide variety of facilities.

Act declared radionuclides to be hazardous materials, which permits Federal regulation of environmental releases of radionuclides by any pathway under authority of laws intended primarily for limiting public exposures to other hazardous materials.

(4) Resource Conservation and Recovery Act

Basis for regulations governing generation, transport, treatment, storage, and disposal of hazardous waste, except for radioactive materials regulated under authority of Atomic Energy Act.

PRINCIPAL LAWS

(continued)

(5) Comprehensive Environmental Response, Compensation, and Liability Act ("Superfund")

Basis for regulations governing responses to unpermitted releases of hazardous materials to the environment and cleanup of old, abandoned waste disposal sites.

CERCLA is intended to address environmental contamination not regulated under other laws (e.g., Clean Air Act, Safe Drinking Water Act, RCRA, and Atomic Energy Act).

(6) Toxic Substances Control Act

Basis for future Federal regulation of radioactive wastes not subject to authority of Atomic Energy Act.

(7) Indoor Radon Abatement Act

Basis for current Federal program to reduce public exposures to indoor radon.

INSTITUTIONAL RESPONSIBILITIES FOR REGULATING PUBLIC EXPOSURES TO RADIONUCLIDES AND OTHER HAZARDOUS MATERIALS

(1) For radioactive materials regulated under authority of Atomic Energy Act -

- EPA establishes environmental standards that are enforced by NRC for all civilian activities and certain DOE activities or by DOE for most defense activities;
- NRC develops licensing criteria for civilian activities;
- DOE develops orders that apply only to DOE or contractor organizations;
- States may regulate civilian activities subject to NRC licensing authority by agreement with NRC.

(2) EPA establishes and enforces -

- environmental standards for radionuclides developed under authority of other laws (e.g., Safe Drinking Water Act, Clean Air Act, CERCLA);
- environmental standards for other hazardous materials developed under authority of any laws.

(3) States are responsible for regulating hazardous materials not explicitly regulated by Federal agencies.

I. THE REGULATIONS FOR RADIONUCLIDES

RECENT SUMMARIES OF RADIATION STANDARDS

W. A. Mills, D. S. Flack, F. J. Arsenault, and E. F. Conti, "A Compendium of Major U.S. Radiation Protection Standards and Guides: Legal and Technical Facts," ORAU 88/F-111, Oak Ridge Associated Universities (July 1988)

D. C. Kocher, "Review of Radiation Protection and Environmental Radiation Standards for the Public," Nucl. Saf. 29, 463 (1988)

TYPES OF STANDARDS FOR LIMITATION OF DOSE TO THE PUBLIC FROM ROUTINE RADIATION EXPOSURE

(1) Radiation protection standards specify limits on exposure regarded as necessary for protection of public health.

Radiation protection standards are generally applicable to all sources of exposure, exclusive of natural background radiation and deliberate medical practices.

Standards must be met, except in the case of accidents or emergencies, regardless of cost.

(2) Environmental radiation standards specify limits on exposure for particular practices or sources of exposure.

Most environmental radiation standards represent judgments regarding levels of public exposure from particular practices or sources that are reasonably achievable, rather than need for limitation of risk per se.

Standards for practices or sources involving man-made radionuclides provide practical basis for ensuring that radiation protection standards applicable to all sources of exposure will be met.

OUTLINE OF PRESENTATION ON RADIATION STANDARDS

(1) Radiation Exposures of U.S. Population

Data on exposures to natural and man-made sources.

(2) Radiation Protection Standards for the Public

Recommendations of national and international authorities on radiation protection, i.e., International Commission on Radiological Protection (ICRP) and National Council on Radiation Protection and Measurements (NCRP).

Current standards of NRC and DOE.

(3) Environmental Radiation Standards

Current and proposed standards or guidances of EPA, NRC, and DOE for limiting public exposures from specific practices or sources.

(4) De Minimis Dose, Exempt Levels of Radioactivity, Below Regulatory Concern (BRC)

(5) Protective Action Guides for Accidents

RADIATION EXPOSURES OF

U.S. POPULATION

ANNUAL EFFECTIVE DOSE EQUIVALENT EXPERIENCED BY U.S. POPULATION

Data in NCRP Report No. 93 (1987) on average annual effective dose equivalent in U.S. population (1 mSv = 100 mrem) -

Source	Dose (mSv)	Dose (mrem)
Natural sources		
Radon	2.0	200
Other	1.0	100
Nuclear fuel cycle	0.0005	0.05
Consumer products	0.1	10
Medical		
Diagnostic x rays	0.39	39
Nuclear medicine	0.14	14
Total	3.6	360

Other natural sources include cosmic rays, cosmogenic and terrestrial radionuclides, and radionuclides in the body.

Consumer products exclude tobacco; estimated annual dose equivalent to segment of bronchial epithelium from smoking is 0.16 Sv (16 rem).

RADIATION PROTECTION STANDARDS

FOR THE PUBLIC

PURPOSE OF RADIATION PROTECTION STANDARDS

Radiation protection standards for the public are concerned primarily with limitation of stochastic risk (risk of fatal cancers and genetic defects) from routine exposures.

Exposure limits in standards usually ensure prevention of non-stochastic (acute) radiation effects.

EARLY RECOMMENDATIONS OF ICRP

ICRP Publications 1 and 2 (1958, 1959), as amended in Publications 6 (1962) and 9 (1965), include recommended limits on annual dose equivalent to whole body or the critical organ for members of the public.

- Critical organ usually is organ receiving highest dose, and dose to critical organ often controlled permissible internal exposures involving non-uniform irradiations of whole body.

Concept of limiting dose to whole body or critical organ is still used in many environmental radiation standards for specific practices or sources developed by EPA and NRC.

ICRP SYSTEM OF DOSE LIMITATION

System of dose limitation recommended in ICRP Publication 26 (1977) -

(1) Justification of practice (positive net benefit);

(2) Reduction of exposures As Low As Reasonably Achievable (ALARA), i.e., optimization of collective (population) dose taking into account technical, economic, and social factors;

(3) Limitation of dose to individuals in critical groups of exposed population.

Use of ALARA principle is emphasized above limitation of dose to individuals; i.e., collective dose should be optimized even if all individual doses are below limits.

Dose limits for individuals are intended for application to average exposure situations for reference individuals in population groups receiving highest exposures, rather than single real individual receiving highest dose.

EFFECTIVE DOSE EQUIVALENT DEVELOPED BY ICRP

Effective dose equivalent introduced in ICRP Publication 26 is defined as weighted sum of dose equivalents to different organs or tissues -

$$H_E = \sum_i w_i H_i, \quad i = \text{organ index}$$

Weighting factor w_i is proportion of stochastic risk resulting from ith organ to total risk, when whole body is irradiated uniformly.

Effective dose equivalent is used primarily to replace dose to critical organ from internal exposure and permits combining doses from external and internal exposure.*

Effective dose equivalent is intended to be proportional to stochastic risk for either uniform or non-uniform irradiations of whole body. Exposures with equal effective dose equivalents should correspond to equal risks regardless of distribution of dose among different organs or tissues.

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* "Effective dose equivalent" usually means sum of effective dose equivalent or dose equivalent to whole body from external exposure and 50-year committed effective dose equivalent from internal exposure.

EFFECTIVE DOSE EQUIVALENT

(continued)

Weighting factors (w_i) for different organs or tissues used by ICRP in defining effective dose equivalent -

Gonads	0.25
Breast	0.15
Red marrow	0.12
Lungs	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30
Sum	1.0

"Remainder" includes five other organs (excluding skin, lens of the eye, and body extremities) receiving highest doses, and each organ is assigned weighting factor of 0.06.

"Whole body" is not tissue at risk and is not included in remainder category; i.e., dose to whole body is no longer used in internal dosimetry.

Inclusion of dose to gonads in calculating effective dose equivalent means that total stochastic risk includes genetic effects as well as fatal cancers.

RISK FACTORS FROM RADIATION EXPOSURE RECOMMENDED BY ICRP

Total stochastic risk per unit dose equivalent from uniform whole-body irradiation, or risk per unit effective dose equivalent, recommended in ICRP Publication 26 -

$$\text{Risk factor} = 2 \times 10^{-2}\ \text{Sv}^{-1}\ (2 \times 10^{-4}\ \text{rem}^{-1}).$$

Risk factor for any organ is equal to product of risk factor from uniform whole-body irradiation and weighting factor for that organ.

Example 1 - For effective dose equivalent of 1 mSv per year received continuously over 70-year lifetime, total stochastic risk is -

$$\text{Risk} = (1 \times 10^{-3}\ \text{Sv/y})(2 \times 10^{-2}\ \text{Sv}^{-1})(70\ \text{y})$$
$$\simeq 1 \times 10^{-3}$$

Example 2 - For dose equivalent to thyroid of 0.75 mSv per year received continuously over 70-year lifetime, risk of fatal thyroid cancer is -

$$\text{Risk} = (7.5 \times 10^{-4}\ \text{Sv/y})(0.03)(2 \times 10^{-2}\ \text{Sv}^{-1})(70\ \text{y})$$
$$\simeq 3 \times 10^{-5}$$

CURRENT RECOMMENDATIONS OF ICRP

(continued)

Dose limits for individual members of the public in ICRP Publication 45 (1985) -

Principal limit on annual effective dose equivalent of 1 mSv (100 mrem);

Subsidiary limit on annual effective dose equivalent of 5 mSv (500 mrem) for some years, provided annual effective dose equivalent averaged over a lifetime does not exceed 1 mSv (100 mrem);

Limit on annual dose equivalent to skin and lens of the eye of 50 mSv (5 rem) (prevention of non-stochastic effects).

Limits on annual effective dose equivalent and weighting factors in definition of effective dose equivalent generally ensure that non-stochastic dose limit will be met for other organs and tissues (e.g., bone surfaces and thyroid).

Principal limit on annual effective dose equivalent of 1 mSv is based on assumed limit on acceptable lifetime risk from radiation exposure to all sources, except natural background and medical practices, of 10^{-3} and risk per unit effective dose equivalent of 2×10^{-2} Sv^{-1}.

CURRENT RECOMMENDATIONS OF NCRP

Dose limits for individual members of the public in NCRP Report No. 91 (1987) -

Limit on annual effective dose equivalent of 1 mSv (100 mrem) for continuous or repeated exposures;

Limit on annual effective dose equivalent of 5 mSv (500 mrem) for infrequent exposures;

Limit on annual dose equivalent to skin, lens of the eye, and extremities of 50 mSv (5 rem).

Dose limits are consistent with current ICRP recommendations.

CURRENT RECOMMENDATIONS OF NCRP

(continued)

Levels of exposure for individual members of the public for undertaking remedial action in NCRP Report No. 91 (1987) -

Average annual effective dose equivalent from external exposure, excluding medical practices but including naturally occurring sources, continuously exceeds 5 mSv (500 mrem);

Significant internal exposure from sources other than radon should be included in exposure assessment.

Annual average exposure to radon and its decay products exceeds 0.007 Jh/m^3 (2 WLM).

1 WLM (Working Level Month) = cumulative exposure equivalent to exposure to 1 Working Level (WL) for a working month (170 hours).

1 WL = 2.08×10^{-5} J of potential alpha-particle energy per m^3 of air (1.3×10^5 MeV/L) from short-lived radon decay products.

Remedial action levels take into account that natural sources enhanced by man-made radioactivity can result in annual effective dose equivalents greater than recommended limit of 1 mSv (100 mrem) for continuous exposure to man-made sources.

FEDERAL GUIDANCE ON RADIATION PROTECTION OF THE PUBLIC

Guidance on radiation protection of the public was developed by Federal Radiation Council (FRC) in 1960.

- Guidance included dose limits similar to recommendations in ICRP Publications 1 and 2.

Interagency committee headed by EPA is preparing new Federal guidance on radiation protection of the public.

CURRENT NRC RADIATION PROTECTION STANDARDS IN 10 CFR PART 20

Current NRC radiation protection standards for the public first developed in 1960 are legally binding on all NRC licensees and follow 1960 FRC guidance and recommendations in ICRP Publications 1 and 2, as amended.

Permissible levels of external radiation in unrestricted areas from licensee's operations and other sources -

Limit on annual dose equivalent to whole body of 500 mrem (5 mSv);

Limits on dose equivalent of 2 mrem (0.02 mSv) in any hour and 100 mrem (1 mSv) in any 7 consecutive days.

For control of internal exposures, maximum permissible concentrations (MPCs) of radionuclides in air and water above background at boundaries of unrestricted areas from licensee's operations.

MPCs are based on limits on annual committed dose equivalent of 0.5 rem (5 mSv) to whole body, gonads, or red marrow, 3 rem (30 mSv) to bone or thyroid, or 1.5 rem (15 mSv) to any other critical organ and internal dosimetry models in ICRP Publication 2, as amended.

Radiation exposures and releases to unrestricted areas should be maintained ALARA.

IMPENDING REVISIONS OF NRC RADIATION PROTECTION STANDARDS

In 1986, NRC published proposed revisions of radiation protection standards for the public in 10 CFR Part 20.

Impending final standards will differ somewhat from Proposed Rule but probably will include -

- requirement that doses shall be maintained ALARA;
- limit on annual effective dose equivalent to individuals of 100 mrem (1 mSv), excluding dose from permissible releases of radionuclides into sanitary sewerage;
- limit on effective dose equivalent in any unrestricted area of 2 mrem (0.02 mSv) in any hour;
- provision for permissible annual effective dose equivalent to individuals up to 500 mrem (5 mSv) with prior NRC authorization;
- concentration limits for radionuclides in air and water at boundaries of unrestricted areas based on limit on annual effective dose equivalent for adults of 50 mrem (0.5 mSv), to provide adequate protection of younger age groups for chronic exposures of the public, and internal dosimetry models in ICRP Publications 30 and 48.

DOE RADIATION PROTECTION STANDARDS FOR THE PUBLIC

Current radiation protection standards for the public from DOE operations in Order 5400.5 (1990) -

Limit on annual effective dose equivalent of 100 mrem (1 mSv);

If avoidance of higher exposures is impractical, temporary limit on annual effective dose equivalent not to exceed 500 mrem (5 mSv) may be authorized;

Limit on annual dose equivalent to any organ of 5 rem (50 mSv);

Concentration guides for radionuclides in air and water in uncontrolled areas based on limit on annual effective dose equivalent of 100 mrem (1 mSv) and internal dosimetry models in ICRP Publications 30 and 48 and concentration guides in air for limitation of external dose from noble gases and short-lived radionuclides;

Exposures of the public shall be maintained ALARA.

DOE Order also contains requirements for control of public exposure from specific practices or sources.

REVISED RECOMMENDATIONS OF ICRP

ICRP will soon issue new recommendations on radiation protection to replace Publication 26.

Recommendations on radiation protection of the public are expected to include -

- increase in risk factor for uniform whole-body irradiation to about 8×10^{-2} Sv^{-1} (8×10^{-4} rem^{-1}) and inclusion of weighted non-fatal cancer incidence in risk factor;

- changes in organs/tissues and weighting factors used in calculating new "effective dose";

- limit on annual effective dose for individuals of 1 mSv (100 mrem), averaged over any five consecutive years;

- limits on annual "equivalent dose" of 15 mSv (1.5 rem) to lens of the eye and 50 mSv (5 rem) to skin or hands;

- remedial action levels for pre-existing exposure situations, e.g., radon and other natural sources, residual radioactivity, accidents and emergencies.

Decrease in dose limit for individuals will not be recommended, in spite of increase in risk factor, because of (1) widespread acceptance of present dose limit and increasing use of lower dose limits for specific practices or sources and (2) magnitude and variability of natural background.

ENVIRONMENTAL RADIATION STANDARDS FOR SPECIFIC PRACTICES OR SOURCES

BASIS FOR ENVIRONMENTAL RADIATION STANDARDS

Most environmental radiation standards for limiting public exposures from specific practices or sources are based primarily on -

- consideration of dose or release limits that are reasonably achievable using best-available effluent control technologies, particularly for standards that apply primarily to man-made radionuclides; or

- reduction of environmental radioactivity to levels near ambient background, particularly for standards that apply primarily to naturally occurring radionuclides.

Thus, most standards essentially result from application of ALARA principle to standard setting itself.

Exception is standards for airborne emissions of radionuclides developed under authority of Clean Air Act, which are based primarily on considerations of risk.

CATEGORIES OF REGULATED PRACTICES OR SOURCES

Current and proposed environmental radiation standards or guidances have been developed by EPA, NRC, and DOE under authority of several laws for -

- operations of uranium fuel-cycle facilities (Atomic Energy Act);
- radioactivity in drinking water (Safe Drinking Water Act);
- mill tailings and residual radioactivity (Uranium Mill Tailings Radiation Control Act, Atomic Energy Act);
- radioactive waste disposal (Atomic Energy Act, Toxic Substances Control Act);
- airborne radioactivity (Clean Air Act);
- indoor radon (Indoor Radon Abatement Act).

CURRENT RECOMMENDATIONS OF NCRP FOR CONTROL OF INDIVIDUAL SOURCES

Recommendation on control of individual sources of public exposure to man-made radionuclides in NCRP Report No. 91 (1987) -

> If member of the public could exceed 25% of annual effective dose equivalent limit from exposure to single source, then operator should ensure that annual effective dose equivalent to maximally exposed individual from all sources would not exceed 1 mSv (100 mrem) on continuous basis.

Recommendation assumes it is unlikely that individuals would receive significant exposure from more than four sources.

Recommendation essentially provides limit on annual effective dose equivalent of 0.25 mSv (25 mrem) per source.

Recommendation on control of individual sources is being considered by interagency committee preparing new Federal guidance on radiation protection of the public.

NRC STANDARDS IN 10 CFR PART 50

ALARA, DESIGN OBJECTIVES FOR NUCLEAR REACTORS (1975)

Standards specify that releases of radioactivity from civilian light-water-cooled nuclear power reactors shall be kept ALARA.

Appendix I - Numerical guides for design objectives and ALARA

Limits on annual dose equivalent or committed dose equivalent to whole body, skin, or any organ of 3-15 mrem (0.03-0.15 mSv) are <u>design objectives</u> for liquid and gaseous effluents and releases of iodine and particulates.

Dose limits are <u>not</u> an environmental radiation standard for operating reactors licensed by NRC, but NRC requires reporting of releases and remedial action plans if design objectives are exceeded.

ALARA - As interim measure, additional effluent controls shall be used if cost is less than $1,000 per person-rem ($100,000 per person-Sv) avoided to whole body or thyroid for population within 50 miles.

Numerical guide for ALARA quantifies optimization of collective dose based on cost-benefit analysis, but only for design of reactors.

EPA STANDARDS IN 40 CFR PART 190

OPERATIONS OF URANIUM FUEL CYCLE (1977)

Standards apply to normal operations in milling of uranium ore, chemical conversion, fuel fabrication, electricity generation in nuclear power plants, and fuel reprocessing but not to mining, waste disposal operations, transportation, and reuse of recovered special nuclear and byproduct materials.

Limits on annual dose equivalent from all radionuclides except radon and its daughters -

- 25 mrem (0.25 mSv) to whole body;
- 75 mrem (0.75 mSv) to thyroid;
- 25 mrem (0.25 mSv) to any other organ.

Limits on releases per GW-year of electrical energy produced -

- 50,000 Ci (2 PBq) for ^{85}Kr;
- 5 mCi (0.2 GBq) for ^{129}I;
- 0.5 mCi (0.02 GBq) for ^{239}Pu plus other alpha-emitting transuranic radionuclides with half-lives greater than 1 year.

Dose and release limits were regarded by EPA as reasonably achievable using best-available effluent control technologies.

EPA STANDARDS IN 40 CFR PART 141

RADIOACTIVITY IN COMMUNITY DRINKING WATER SYSTEMS (1976)

Interim standards developed under authority of Safe Drinking Water Act apply (1) to public or private water systems with at least 15 service connections or serving at least 25 persons and (2) at the tap rather than at the source.

Limits on concentrations of radionuclides -

- 5 pCi/L (0.2 Bq/L) for ^{226}Ra plus ^{228}Ra;
- 15 pCi/L (0.6 Bq/L) for gross alpha-particle activity, including ^{226}Ra but excluding radon and uranium.

Limit on annual dose equivalent to whole body or any organ of 4 mrem (0.04 mSv) from man-made, beta/gamma-emitting radionuclides.

Standards for radium and gross alpha-particle activity were based on analyses of costs of reducing ambient levels in community drinking water systems in relation to health risks averted (application of ALARA principle).

For ingestion of 2 liters of water per day, concentration limit for radium corresponds to annual effective dose equivalent of about 5 mrem (0.05 mSv).

Standard for beta/gamma-emitting radionuclides was based on maximum levels of ^{90}Sr and ^{137}Cs from fallout in water, and EPA anticipated no additional cost in meeting standard.

EPA STANDARDS IN 40 CFR PART 141

RADIOACTIVITY IN COMMUNITY DRINKING WATER SYSTEMS

(continued)

Impending proposed revisions of drinking water standards may include -

- revised cost-benefit analyses for reduction of ambient levels of radioactivity in community water systems;
- separate concentration limits for ^{228}Ra and ^{226}Ra;
- concentration limit for uranium somewhat greater than present limit for radium to provide similar limit on annual effective dose equivalent (i.e., risk);
- concentration limit for radon about two orders of magnitude greater than present limit for radium;
- use of concentration limit for gross alpha-particle activity only as screening tool in monitoring requirements;
- alternative of single limit on annual effective dose equivalent from all radionuclides.

Drinking water standards are increasingly being applied to radioactivity in potential sources of drinking water that may be contaminated by past or future practices (e.g., radioactive waste disposal).

DOE STANDARDS FOR RADIOACTIVITY IN DRINKING WATER

Requirements in DOE Order 5400.5 (1990) -

Limit on annual effective dose equivalent from drinking water supplies operated by or for DOE of 4 mrem (0.04 mSv), excluding naturally occurring radionuclides;

Liquid effluents from DOE activities will not cause private or public drinking water systems downstream of facility discharge to exceed concentration and dose limits in EPA drinking water standards (40 CFR Part 141).

EPA STANDARDS IN 40 CFR PART 440

MINING EFFLUENT LIMITS FOR U AND RA (1982)

Standards developed under authority of Clean Water Act apply to liquid discharges from mines or mills used to produce or process uranium, radium, and vanadium ores.

Limits on concentrations in effluents for any day -

- 10 pCi/L (0.4 Bq/L) for dissolved ^{226}Ra;
- 30 pCi/L (1 Bq/L) for total ^{226}Ra;
- 4 mg/L for uranium.

Limits on average concentrations in daily effluents for 30 consecutive days -

- 3 pCi/L (0.1 Bq/L) for dissolved ^{226}Ra;
- 10 pCi/L (0.4 Bq/L) for total ^{226}Ra;
- 2 mg/L for uranium.

Standards are based on best-available effluent control technologies rather than consideration of health risks from ingestion of contaminated water.

EPA STANDARDS IN 40 CFR PART 192
URANIUM AND THORIUM MILL TAILINGS (1983)

Standards for (1) control and cleanup of residual radioactive materials at inactive uranium processing sites or (2) management of uranium and thorium byproduct materials at active processing sites -

Limit on annual average release rate of ^{222}Rn to atmosphere of 20 pCi/m^2s (0.7 Bq/m^2s) or annual average concentration of ^{222}Rn in air above background outside disposal site of 0.5 pCi/L (0.02 Bq/L);

Limits on ^{226}Ra concentration in soil above background of 5 pCi/g (0.2 Bq/g) averaged over first 15 cm below surface and 15 pCi/g (0.6 Bq/g) averaged over 15-cm thick layers more than 15 cm below surface;

Limit on radon decay-product concentration (including background) in any occupied or habitable building of 0.03 WL (6×10^{-7} J/m^3), with objective for remedial action of 0.02 WL (4×10^{-7} J/m^3);

Limit on gamma radiation level above background in any occupied or habitable building of 20 μR (5 pC/kg) per hour;

To convert exposure in air to effective dose equivalent, 1 R (2.58×10^{-4} C/kg) $\simeq$ 0.7 rem (7 mSv).

EPA STANDARDS IN 40 CFR PART 192

URANIUM AND THORIUM MILL TAILINGS

(continued)

- Standards (continued) -

Limits on concentrations of ^{226}Ra plus ^{228}Ra and gross alpha-particle activity, excluding radon and uranium, in groundwater as given in EPA drinking water standards (40 CFR Part 141);

Limits on annual dose equivalent from thorium processing operations of 25 mrem (0.25 mSv) to whole body, 75 mrem (0.75 mSv) to thyroid, or 25 mrem (0.25 mSv) to any other organ;

Limits for uranium, ^{222}Rn, and ^{226}Ra also apply to thorium, ^{220}Rn, and ^{228}Ra, respectively;

Standards for control of radon emissions shall be effective for up to 1,000 years, to extent reasonably achievable, and in any case for at least 200 years.

EPA STANDARDS IN 40 CFR PART 192

URANIUM AND THORIUM MILL TAILINGS

(continued)

Estimates of limits on annual effective dose equivalent corresponding to different limits in mill tailings standards -

Outdoor ^{222}Rn concentration of 0.5 pCi/L (0.02 Bq/L) - 26 mrem (0.26 mSv), based on mean annual effective dose equivalent per unit concentration for outdoor residence time of 15% recommended in ICRP Publication 50;

^{226}Ra concentrations in soil - 60 mrem (0.6 mSv), assuming continuous external exposure, all ^{226}Ra decay products present in equilibrium, indoor and outdoor residence times of 85% and 15%, and dose reduction factor indoors due to building shielding of 0.7;

Indoor ^{222}Rn decay-product concentration of 0.03 WL (6×10^{-7} J/m^3) - 800 mrem (8 mSv), based on mean annual effective dose equivalent per unit exposure for indoor residence time of 85% recommended in ICRP Publication 50;

Indoor gamma radiation level of 20 μR (5 pC/kg) per hour - 100 mrem (1 mSv), assuming indoor residence time of 85%;

^{226}Ra concentration in groundwater of 5 pCi/L (0.2 Bq/L) - 5 mrem (0.05 mSv), assuming ingestion of 2 liters of water per day.

EPA STANDARDS IN 40 CFR PART 192
URANIUM AND THORIUM MILL TAILINGS
(continued)

Mill tailings standards are based primarily on ambient levels of radioactivity in western U.S. where uranium and thorium ore deposits exist and residual materials are obtained.

Standards essentially require that, to extent reasonably achievable, control and cleanup of mill tailings should result in public health risks no greater than risks from unmined ore from which tailings were produced.

Total annual effective dose equivalent corresponding to mill tailings standards is an order of magnitude greater than limit of 100 mrem (1 mSv) in radiation protection standards for the public, but dose from mill tailings is due to naturally occurring radionuclides.

Proposed revision of standards (1987) -

Limit on concentration of ^{234}U plus ^{238}U in groundwater near inactive uranium processing sites of 30 pCi/L (1 Bq/L).

Limit is intended to provide risk from uranium in drinking water equivalent to risk associated with current limit of 5 pCi/L (0.2 Bq/L) for radium.

NRC STANDARDS IN 10 CFR PART 40, APPENDIX A
URANIUM MILL TAILINGS (1985)

NRC regulations conform in most respects to EPA standards in 40 CFR Part 192.

Remaining differences with EPA standards -

External photon exposures from tailings or wastes should be reduced to background levels;

Indoor concentrations of radon decay products are not addressed.

NRC regulations also include -

- technical criteria for siting and design of disposal facilities and protection of groundwater;
- requirement that airborne effluents from milling operations shall be ALARA.

DOE STANDARDS FOR RESIDUAL RADIOACTIVITY

Requirements for control of residual radioactive material at DOE sites in Order 5400.5 (1990) address -

- release of contaminated property for unrestricted use by the public;
- interim storage of residual radioactive material;
- long-term management of uranium, thorium, and their decay products.

Requirements do not apply to cleanup of inactive radioactive waste disposal sites.

Requirements involve hierarchy of -

- requirements for radiation protection of the public;
- guidelines (generic or derived) for acceptable levels of residual radioactivity that can be used if radiation protection requirements will be met;
- authorized limits on acceptable levels of residual radioactivity that are used if generic or derived guidelines would not ensure that radiation protection requirements are met.

DOE STANDARDS FOR RESIDUAL RADIOACTIVITY

(continued)

Requirements for radiation protection of the public -

Limit on annual effective dose equivalent from routine DOE activities and exposure to residual radioactive material of 100 mrem (1 mSv);

Higher doses from acute exposure are permitted, provided annual effective dose equivalent averaged over a lifetime is not expected to exceed 100 mrem (1 mSv).

Levels of residual radioactivity shall be reduced ALARA;

If residual radioactivity is not reduced to levels permitting unrestricted use by the public, controls should be used to reduce exposures ALARA.

Release of real property (i.e., land and structures) for unrestricted use by the public shall be governed by guidelines for residual radioactivity developed in Formerly Utilized Sites Remedial Action Program (FUSRAP) and remote Surplus Facilities Management Program (SFMP).

DOE STANDARDS FOR RESIDUAL RADIOACTIVITY

(continued)

Guidelines for residual radioactivity at FUSRAP and remote SFMP sites -

Limits on residual concentrations of radium and thorium in soil, airborne radon decay products in occupied or habitable structures on private property, and external gamma radiation inside buildings or habitable structures on a site as given in EPA mill tailings standards (40 CFR Part 192);

Limits on residual concentrations of other radionuclides in soil shall be derived from dose limits in radiation protection requirements using prescribed site-specific procedures and data.

Dose from residual radioactivity in soil and external gamma radiation (including exposure on open lands) shall comply with limits in radiation protection requirements.

Limits on residual radioactivity on surfaces of structures and equipment, based on NRC guidelines (1982) and NRC Regulatory Guide 1.86 (1974);

Limits on residual concentrations of radionuclides in air and water such that applicable Federal and State standards will be met.

DOE STANDARDS FOR RESIDUAL RADIOACTIVITY

(continued)

Authorized limits for residual radioactive material for each site and vicinity properties -

Authorized limits shall be established to ensure that, as a minimum, dose limits in radiation protection requirements will not be exceeded under worst-case, plausible-use scenarios;

Authorized limits shall be set equal to generic or derived guidelines, except where site-specific data clearly show that guidelines are not appropriate (e.g., dose limits in radiation protection requirements would be exceeded).

DOE STANDARDS FOR RESIDUAL RADIOACTIVITY

(continued)

Guidelines for interim storage of residual radioactive material at FUSRAP and remote SFMP sites -

Limits on ^{222}Rn concentrations in air above background of (1) 100 pCi/L (4 Bq/L) at any point within a site, (2) 30 pCi/L (1 Bq/L) averaged over a year and over a site, and (3) 3 pCi/L (0.1 Bq/L) averaged over a year at any location outside a site;

^{222}Rn concentration of 1 pCi/L (0.04 Bq/L) corresponds to annual effective dose equivalent of 50 mrem (0.5 mSv), based on mean annual effective dose equivalent per unit concentration for outdoor residence time of 15% recommended in ICRP Publication 50.

Limit on release rate of ^{222}Rn above background of 20 pCi/m^2s (0.7 Bq/m^2s);

Limits on radionuclide concentrations in groundwater or quantities of residual radioactive material as established in Federal or State standards;

Control and stabilization features designed to ensure, to extent reasonably achievable, effective life of 50 years with minimum life of at least 25 years.

DOE STANDARDS FOR RESIDUAL RADIOACTIVITY

(continued)

Guidelines for long-term management of uranium, thorium, and their decay products -

Limits on ^{222}Rn release rate to atmosphere and concentration in air outside boundary of contaminated area as given in EPA mill tailings standards (40 CFR Part 192);

Protection of groundwater in accordance with applicable Federal and State standards;

Design lifetime for control and stabilization features as given in EPA mill tailings standards (40 CFR Part 192);

Control of access to site and prevention of misuse of onsite residual radioactive material by appropriate administrative controls and physical barriers designed to be effective, to extent reasonable, for at least 200 years.

EPA RULEMAKING 40 CFR PART 194

CLEANUP OF RESIDUAL RADIOACTIVITY

In 1986, EPA announced intent to develop standards for cleanup of land and facilities contaminated with residual radioactive material.

Standards would apply to -

- NRC licensees or Agreement States;
- sites owned or used by DOE, Department of Defense, former Atomic Energy Commission, and former Manhattan Engineering District;
- sites where naturally occurring (e.g., radium) and accelerator-produced radioactive materials have been used.

Standards presumably would not apply to cleanup of inactive radioactive waste disposal sites.

EPA has not published Proposed Rule for cleanup of residual radioactive material.

EPA GUIDANCE ON TRANSURANIUM ELEMENTS IN THE ENVIRONMENT

Proposed guidance was first published in 1977.

Draft interim recommendations on acceptable levels of transuranium elements above background (1987) -

To extent practical, annual alpha absorbed dose from transuranium elements should be limited to 1 mrad (0.01 mGy) to pulmonary lung or 3 mrad (0.03 mGy) to bone, endosteal bone surfaces, or red bone marrow - Range I;

ICRP and NCRP currently recommend quality factor of 20 for converting absorbed dose from alpha particles to dose equivalent.

Doses above Range I but less than annual effective dose equivalent of 100 mrem (1 mSv) from all sources, excluding natural background and medical practices, are acceptable provided risks to population are justified, general surveillance and routine monitoring are implemented, and doses are maintained ALARA - Range II;

Doses above Range II but less than annual effective dose equivalent of 500 mrem (5 mSv) from all sources on intermittent basis require continuing monitoring and evaluation of individuals and limitations on access or use pending remedial actions - Range III.

EPA GUIDANCE ON TRANSURANIUM ELEMENTS

(continued)

Draft interim recommendations (continued) -

Recommendations apply only to transuranium elements, and do not provide general criteria for decontamination or decommissioning of sites or facilities;

Recommendations do not apply to transient period during and immediately following accidents;

Recommendations should not be used as limits for planned releases of transuranium elements to environment;

Remedial actions should accomplish permanent reductions in risks to the public, and occupancy or land-use restrictions should not be relied on to protect future generations;

Remedial actions should assure compliance with applicable environmental standards (e.g., drinking water standards and groundwater protection requirements);

Soil contamination level of 0.2 $\mu Ci/m^2$ (7 kBq/m^2), at depth of 1 cm and for particle sizes less than 2 mm, and air concentration of 1 fCi/m^3 (0.04 mBq/m^3) for alpha-emitting transuranium elements provide screening levels for demonstrating compliance with Range I recommendations, but concentrations do not define limits for implementing Range I recommendations.

EPA STANDARDS IN 40 CFR PART 191

MANAGEMENT AND DISPOSAL OF HIGH-LEVEL WASTES (1985)

Standards apply to management (except for transportation), storage, and disposal of spent fuel, high-level waste, and transuranic waste.

Standards for management and storage (Subpart A) -

For facilities regulated by NRC or Agreement States -

Limit on annual dose equivalent, including all operations covered by 40 CFR Part 190, of 25 mrem (0.25 mSv) to whole body, 75 mrem (0.75 mSv) to thyroid, or 25 mrem (0.25 mSv) to any other organ.

For facilities operated by DOE and not regulated by NRC or Agreement States -

Limit on annual dose equivalent of 25 mrem (0.25 mSv) to whole body or 75 mrem (0.75 mSv) to any organ; or

Upon application for alternative standard, limit on annual dose equivalent from all sources, excluding natural background and medical practices, of 100 mrem (1 mSv) for continuous exposure or 500 mrem (5 mSv) for infrequent exposure.

Note difference in dose limits for civilian and defense facilities judged by EPA to be reasonably achievable.

EPA STANDARDS IN 40 CFR PART 191

MANAGEMENT AND DISPOSAL OF HIGH-LEVEL WASTES

(continued)

- Standards for disposal (Subpart B) -

Containment requirements - For 10,000 years after disposal, cumulative releases of radionuclides to accessible environment shall have likelihood of (1) less than one chance in 10 of exceeding specified limits [e.g., 100 Ci (4 TBq) per metric ton of heavy metal in spent nuclear fuel for most long-lived, alpha-emitting radionuclides] and (2) less than one chance in 1,000 of exceeding ten times the specified limits.

Cumulative release limits correspond to population risk of 1,000 health effects per repository over 10,000 years, and EPA regards release limits as reasonably achievable using foreseeable technology.

Containment requirements are probabilistic; i.e., predictions of cumulative releases will be expressed as probability distributions based on uncertainties in model parameters and likelihood of release scenarios.

Performance assessments need only provide reasonable expectation that compliance with containment requirements will be achieved.

EPA STANDARDS IN 40 CFR PART 191
MANAGEMENT AND DISPOSAL OF HIGH-LEVEL WASTES
(continued)

- Standards for disposal (continued) -

Assurance requirements - Qualitative requirements to provide confidence that containment requirements will be met.

Requirements include maintaining active institutional controls, monitoring of disposal systems, use of permanent markers at disposal sites, use of engineered and natural barriers for waste isolation, avoidance of sites with valuable resources, and provision for retrieval of waste.

Individual protection and groundwater protection requirements - Dose limits for individuals from use of groundwater and requirements for protection of groundwater for 1,000 years after disposal.

In 1987, these requirements were vacated by First Circuit Court and remanded to EPA for further proceedings.

EPA has not published proposal for modifying individual protection and groundwater protection requirements consistent with Court's opinion.

NRC STANDARDS IN 10 CFR PART 60
WASTE DISPOSAL IN GEOLOGIC REPOSITORIES (1983)

Regulations contain performance, siting, and design criteria for geologic repositories intended to provide reasonable assurance that containment requirements in EPA standards for disposal of high-level wastes (40 CFR Part 191) will be met.

Regulations apply only to repositories developed under authority of Nuclear Waste Policy Act (e.g., for disposal of spent fuel and high-level waste), but not to DOE's Waste Isolation Pilot Plant facility in New Mexico for disposal of defense transuranic waste.

Post-closure repository performance criteria -

Substantially complete containment of waste within waste packages for 300-1,000 years;

Limit on release rate of any radionuclide from engineered barrier system following containment period of (1) 10^{-5} per year of inventory of that radionuclide at 1,000 years following permanent closure or (2) 10^{-5} per year of inventory of all radionuclides placed in disposal facility that remains after 1,000 years of decay;

Pre-waste-emplacement groundwater travel time along fastest path of likely radionuclide travel from edge of disturbed zone to accessible environment of at least 1,000 years.

NRC STANDARDS IN 10 CFR PART 61

NEAR-SURFACE LAND DISPOSAL OF RADIOACTIVE WASTE (1982)

Performance objectives for near-surface land disposal -

Limit on annual dose equivalent beyond facility boundary of 25 mrem (0.25 mSv) to whole body, 75 mrem (0.75 mSv) to thyroid, or 25 mrem (0.25 mSv) to any other organ;

Releases beyond facility boundary should be maintained ALARA;

Requirement for protection of inadvertent intruders into site at any time after active institutional controls are removed (assumed to be 100 years after facility closure).

Technical requirements for near-surface land disposal -

Requirements on site suitability and design, facility operation and site closure, and waste characteristics;

Limits on radionuclide concentrations that are generally acceptable for near-surface land disposal, i.e., Class-A and -C limits for longer-lived radionuclides and Class-A, -B, and -C limits for shorter-lived radionuclides.

Waste classification system provides protection of inadvertent intruders and is based on limit on annual dose equivalent of 0.5 rem (5 mSv) to whole body and bone or 1.5 rem (15 mSv) to any other organ.

DOE ORDER 5820.2A, CHAPTER III

MANAGEMENT OF LOW-LEVEL WASTE (1988)

Performance objectives and requirements for new low-level waste disposal facilities at DOE sites -

Limit on annual effective dose equivalent beyond facility boundary of 25 mrem (0.25 mSv);

Releases beyond facility boundary should be maintained ALARA;

Limit on annual effective dose equivalent for inadvertent intruders after loss of active institutional controls (at 100 years after facility closure) of 100 mrem (1 mSv) for continuous exposure or 500 mrem (5 mSv) for acute exposure;

DOE does not use waste classification system for protection of inadvertent intruders as developed by NRC in 10 CFR Part 61.

Protection of groundwater in accordance with Federal and State standards;

Demonstrations of compliance with performance objectives shall be based on site-specific performance assessments.

EPA RULEMAKING 40 CFR PART 193

MANAGEMENT AND DISPOSAL OF LOW-LEVEL WASTE

Draft proposed standards for management and storage (1989) -

Limit on annual effective dose equivalent beyond facility boundary of 25 mrem (0.25 mSv);

Limit on annual effective dose equivalent to individual members of the public of 4 mrem (0.04 mSv) defines waste that is Below Regulatory Concern (BRC).

BRC waste does not require disposal in regulated facility for low-level waste.

Draft proposed standards for disposal (1989) -

Limit on annual effective dose equivalent beyond facility boundary of 25 mrem (0.25 mSv);

Groundwater protection requirements that include (1) no increase in levels of radioactivity in groundwater that is irreplaceable source of drinking water for substantial population and/or ecologically vital and (2) limit on annual effective dose equivalent of 4 or 25 mrem (0.04 or 0.25 mSv) from use of groundwater that is potential source of drinking water or is not potable, respectively.

Standards for disposal do not address protection of inadvertent intruders.

EPA RULEMAKING 40 CFR PART 764
MANAGEMENT AND DISPOSAL OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)

- Standards are being developed under authority of Toxic Substances Control Act, because NARM is not regulated under authority of Atomic Energy Act.

Draft proposed standards for management and disposal (1989) -

NARM includes any radioactive material except source, byproduct, or special nuclear material as defined in Atomic Energy Act;

Regulated NARM waste has specific activity greater than 2 nCi/g (0.07 kBq/g) but does not include smoke detectors and timepieces using radioluminescent paint;

NARM waste must be classified as Class-A, -B, or -C waste based on waste classification system in NRC's 10 CFR Part 61 modified to include long-lived isotopes of radium, thorium, and uranium;

Classification of NARM waste provides protection of inadvertent intruders.

Regulated NARM waste would be subject to disposal requirements for low-level waste in 40 CFR Part 193, and NARM waste may be classified as BRC according to 4-mrem (0.04-mSv) criterion for low-level waste.

DRAFT DOE ORDER 5480.14

CERCLA PROGRAM (1988)

Requirements of CERCLA will be applied to cleanup and closure of DOE sites contaminated with radioactive materials.

CERCLA requirements would apply to sites for disposal of radioactive wastes closed prior to issuance of DOE Order 5820.2A in 1988.

Under CERCLA, dose limits for individuals beyond site boundary or inadvertent intruders that will be applied to new radioactive waste disposal facilities are not used to define need for or acceptability of remedial actions at inactive disposal sites.

EPA STANDARDS IN 40 CFR PART 61
AIRBORNE EMISSIONS OF RADIONUCLIDES (1989)

Standards for airborne releases of radionuclides developed under authority of Clean Air Act -

Limit on annual effective dose equivalent of 10 mrem (0.1 mSv) for -

- DOE facilities emitting any radionuclide other than radon except for disposal facilities subject to EPA's 40 CFR Part 191, Subpart B, or 40 CFR Part 192 and excluding dose from ^{222}Rn and its decay products;

- NRC-licensed and non-DOE Federal facilities except for disposal facilities subject to EPA's 40 CFR Part 191, Subpart B, disposal of uranium mill tailings subject to EPA's 40 CFR Part 192, or NRC licensees that use only sealed sources, but limit is 3 mrem (0.03 mSv) from any isotope of iodine and dose from ^{222}Rn is excluded;

- emissions of ^{222}Rn from underground uranium mines.

Dose limits for NRC licensees are in abeyance pending outcome of negotiations between EPA and NRC.

EPA STANDARDS IN 40 CFR PART 61
AIRBORNE EMISSIONS OF RADIONUCLIDES
(continued)

- Standards for airborne emissions (continued) -

Limit on emission rate of ^{222}Rn of 20 pCi/m^2s (0.7 Bq/m^2s) from -

- DOE facilities for storage and disposal of material containing radium (i.e., uranium mill tailings);
- phosphogypsum stacks;
- operating and inactive uranium mill tailings piles.

Limit on annual emissions of ^{210}Po from elemental phosphorus plants of 2 Ci (0.07 TBq).

EPA did not issue standards for "insignificant sources of radionuclide emissions to air" -

- high-level nuclear waste facilities (none operating at present time);
- surface uranium mines (two operating facilities);
- coal-fired boilers.

Radiation dose from coal-fired boilers generally is greater than dose from nuclear power plants.

EPA STANDARDS IN 40 CFR PART 61
AIRBORNE EMISSIONS OF RADIONUCLIDES
(continued)

- In setting standards for radionuclides, EPA followed previous order by Court of Appeals to use two-step decision process -

  (1) determine safe or acceptable risk to individuals or populations;

  (2) determine ample margin of safety below safe or acceptable risk for protection of public health.

  Technical feasibility and cost could not be primary basis for standards, as is the case for EPA standards developed under authority of Atomic Energy Act.

On basis of risk considerations, EPA set standards such that -

- lifetime risk to maximally exposed individuals would not exceed about 10^{-4};

- lifetime risk to greatest number of individuals in exposed populations would not exceed about 10^{-6}.

EPA STANDARDS IN 40 CFR PART 61
AIRBORNE EMISSIONS OF RADIONUCLIDES
(continued)

- Comments on decision process for setting standards -

EPA envisions that two-step decision process based on considerations of risk will be applied only to setting National Emission Standards for Hazardous Air Pollutants (NESHAPs) under authority of Clean Air Act but not to -

- other regulations developed under authority of Clean Air Act;
- regulations developed by EPA under any other laws (e.g., Atomic Energy Act, Safe Drinking Water Act).

EPA decision process ignored established precedents in radiation protection of the public that -

- limit on annual dose equivalent of 100 mrem (1 mSv) from all sources provides acceptable risk to individuals; and
- limit on annual dose equivalent of 25 mrem (0.25 mSv) for specific practices or sources provides adequate margin of safety for individuals and populations.

EPA STANDARDS IN 40 CFR PART 302

REPORTABLE QUANTITIES OF RADIONUCLIDES (1989)

CERCLA requires that if any hazardous material is released to environment in amounts equal to or greater than its reportable quantity (RQ), then National Response Center must immediately be notified.

Radionuclide-specific RQs in Ci (Bq) are based on -

- limit on effective dose equivalent of 500 mrem (5 mSv);
- very conservative analyses of dose from external exposure, inhalation, and ingestion of contaminated vegetables, groundwater, or surface waters.

RQ for each radionuclide is based on most restrictive exposure pathway.

National Response Center must be notified if non-Federally permitted releases exceeding RQs occur within 24-hour period.

RQs are not directly related to doses that might be received by members of the public, particularly for past releases.

RQs do not define (1) acceptable releases, (2) releases requiring remediation, or (3) acceptable levels of contamination following remediation.

FEDERAL GUIDANCE ON RADON IN HOMES (1986)

EPA and Department of Health and Human Services recommended maximum indoor radon concentration in homes of 4 pCi/L (0.15 Bq/L) [about 0.02 WL (4×10^{-7} J/m^3)] as guidance on need for mitigation of exposures.

Guidance is <u>not</u> a standard for limiting public exposures to indoor radon.

Estimates of 70-year lifetime risk corresponding to Federal guidance -

$1\text{-}5 \times 10^{-2}$ - EPA's estimate of mean risk of fatal lung cancer, assuming indoor residence time of 75%;

8×10^{-3} - Based on mean annual effective dose equivalent per unit exposure for indoor residence time of 85% recommended in ICRP Publication 50 and risk factor for uniform whole-body irradiation from ICRP Publication 26;

2×10^{-2} - Based on risk factor for fatal lung cancer recommended by Committee on the Biological Effects of Ionizing Radiation in BEIR IV report and indoor residence time of 85%;

1×10^{-2} - Based on annual risk of fatal lung cancer after age 40 recommended in NCRP Report No. 77 extrapolated over a lifetime and indoor residence time of 85%.

FEDERAL GUIDANCE ON RADON IN HOMES

(continued)

- In response to Indoor Radon Abatement Act of 1988, EPA is developing revised Federal guidance on indoor radon.

  - Act sets goal of reducing indoor radon concentrations to background (outdoor) levels.

    - Outdoor radon concentrations in U.S. are 0.2-0.8 pCi/L (0.007-0.03 Bq/L).

  - EPA probably will recommend reduction in present guidance on need for mitigation of exposures based on cost-benefit analysis, and levels as low as 0.5 pCi/L (0.02 Bq/L) are being considered.

SUMMARY OF ENVIRONMENTAL RADIATION STANDARDS

Standards based primarily on considerations of dose limits that are reasonably achievable using best-available effluent control technologies -

Design objectives for civilian nuclear power reactors (10 CFR Part 50, Appendix I);

Uranium fuel-cycle operations (40 CFR Part 190);

Mining effluent limits for radium and uranium (40 CFR Part 440);

Thorium processing operations (40 CFR Part 192);

Management and disposal of high-level wastes (40 CFR Part 191; 10 CFR Part 60);

Near-surface land disposal of radioactive waste (10 CFR Part 61; DOE Order 5820.2A, Chapter III; draft proposed 40 CFR Parts 193 and 764).

Limit on annual effective dose equivalent of 25 mrem (0.25 mSv) is de facto environmental radiation standard for many of these practices or sources.

Standards for airborne emissions of radionuclides (40 CFR Part 61) are based primarily on considerations of acceptable risk to individuals and populations; annual dose limit is 10 mrem (0.1 mSv) for most releases.

SUMMARY OF ENVIRONMENTAL RADIATION STANDARDS

(continued)

Standards or guidances based primarily on considerations of ambient background levels of radioactivity and application of ALARA principle to reductions in environmental levels -

Radioactivity in drinking water (40 CFR Part 141; DOE Order 5400.5);

Uranium and thorium mill tailings (40 CFR Part 192; 10 CFR Part 40, Appendix A);

Residual radioactivity in the environment (DOE Order 5400.5), except dose limits in radiation protection requirements must be met;

Transuranium elements in the environment (draft EPA interim guidance);

Federal guidance on radon in homes.

Standards or guidances for radioactivity in drinking water, containment requirements for disposal of high-level wastes, and indoor radon serve primarily to limit population risks; other standards and guidances serve primarily to limit risks to maximally exposed individuals.

SUMMARY OF RADIATION STANDARDS FOR THE

PUBLIC - PERSPECTIVE ON RISK

FRAMEWORK FOR RADIATION PROTECTION OF THE PUBLIC

Current framework for regulating radiation exposures of the public to man-made radionuclides under authority of Atomic Energy Act may be referred to as "top-down" approach.

- Dose limit for individuals corresponding to upper limit on acceptable risk from radiation exposure is established in radiation protection standards [e.g., limit on annual effective dose equivalent of 100 mrem (1 mSv)].

- Doses are reduced below the limit based on application of ALARA principle, usually by means of environmental radiation standards for specific practices or sources.

Framework is in accordance with radiation protection principles recommended by ICRP and NCRP.

For exposure to naturally occurring radionuclides, goal is reduction of environmental radioactivity ALARA, taking into account ambient background levels, but no upper limit on acceptable risk has been established.

- Dose from naturally occurring radionuclides often exceeds dose limit from man-made radionuclides in radiation protection standards.

RISKS ASSOCIATED WITH RADIATION STANDARDS FOR THE PUBLIC

Following table gives estimates of lifetime risk associated with (1) selected radiation protection standards and environmental radiation standards and guidances and (2) exposures to natural background radiation.

Risk estimates are based on assumption of continuous exposure of adults over 70 years.

Estimates assume risk per unit dose equivalent to whole body, i.e., risk per unit effective dose equivalent, of 2×10^{-4} rem^{-1} (2×10^{-2} Sv^{-1}) and risk factors for specific organs and tissues from ICRP Publication 26 (1977).

New risk factors to be recommended by ICRP would result in increases in most risks, e.g., by factor of about four for risk per unit effective dose equivalent, but risks for guidance on radon in homes, uranium mill tailings standards, and high-level waste disposal would not be affected.

RISK ESTIMATES

3×10^{-2} - Guidance on radon in homes

1×10^{-2} - Uranium mill tailings standards

7×10^{-3} - Annual dose equivalent to whole body of 500 mrem

4×10^{-3} - Annual effective dose equivalent of 300 mrem (average exposure to natural background)

3×10^{-3} - Annual effective dose equivalent of 200 mrem (average exposure to indoor radon)

1×10^{-3} - Annual effective dose equivalent of 100 mrem

4×10^{-4} - Annual dose equivalent to whole body or effective dose equivalent of 25 mrem

1×10^{-4} - Annual effective dose equivalent of 10 mrem

6×10^{-5} - Radium concentration in drinking water of 5 pCi/L

6×10^{-5} - Annual dose equivalent to whole body or effective dose equivalent from drinking water of 4 mrem

4×10^{-5} - Annual dose equivalent to bone from inhalation of insoluble Pu-239 of 25 mrem

3×10^{-5} - Annual dose equivalent to thyroid from ingestion of I-131 of 75 mrem

5×10^{-6} - Annual dose equivalent to bone from Sr-90 in drinking water of 4 mrem

2×10^{-6} - Annual dose equivalent to thyroid from I-129 in drinking water of 4 mrem

5×10^{-8} - Containment requirements for high-level waste disposal (average risk in U.S. population)

RISK ESTIMATES

(continued)

Observations on risk estimates -

Excluding containment requirements for high-level waste disposal, lifetime risks associated with different environmental radiation standards for specific practices or sources vary by four orders of magnitude.

Risks associated with guidance on radon in homes and uranium mill tailings standards, which are concerned with exposure to naturally occurring radionuclides, exceed risks associated with all radiation protection standards, which do not apply to exposure to natural background.

Average risks in U.S. population from all natural sources and from indoor radon only (1) are greater than risks associated with current radiation protection standards and (2) are at least an order of magnitude greater than risks associated with all environmental radiation standards except for mill tailings and residual radioactivity.

Risks associated with some environmental radiation standards, particularly drinking water standards for some radionuclides, are less than negligible individual risk level of 10^{-5} recommended in NCRP Report No. 91 (1987).

DE MINIMIS DOSE, EXEMPT LEVELS OF RADIOACTIVITY, AND BELOW REGULATORY CONCERN

DEFINITIONS

De minimis dose -

Dose applicable to all sources below which control of exposures by regulatory authorities would be deliberately and specifically curtailed; i.e., if all individual doses were below de minimis level, no further reductions in dose using ALARA principle would be attempted.

De minimis dose is based only on consideration of negligible or trivial risks to individuals.

De minimis dose for maximally exposed individuals is not the goal of ALARA.

Exempt or Below Regulatory Concern (BRC) -

Level of radioactivity or dose judged by regulatory authorities to be ALARA for specific practice at any site.

Exempt or BRC levels may vary among different practices and may be higher than levels corresponding to de minimis dose.

CURRENT RECOMMENDATIONS OF NCRP

De minimis dose recommended in NCRP Report No. 91 (1987) -

Annual effective dose equivalent of 0.01 mSv (1 mrem);

Collective dose assessments for particular practices or sources should exclude annual effective dose equivalents for individuals of 0.01 mSv (1 mrem) or less.

Recommendations are based on assumed negligible individual risk level from radiation exposure of 10^{-7} per year, i.e., lifetime risk from continuous exposure of 10^{-5}.

De minimis dose of 0.01 mSv (1 mrem) applies only to man-made radionuclides, because naturally occurring radionuclides in their undisturbed state result in higher doses.

INTERNATIONAL RECOMMENDATIONS ON EXEMPTION PRINCIPLES

Principles for exemption from regulatory control of radiation sources and practices have been recommended by International Atomic Energy Agency in Safety Series No. 89 (1988).

Single practices could be exempt from regulatory control if -

- annual effective dose equivalent to maximally exposed individuals would be less than 0.01 mSv (1 mrem); and
- collective effective dose equivalent from one year of unregulated practice would be less than 1 person-Sv (100 person-rem).

CURRENT NRC RADIATION PROTECTION STANDARDS IN 10 CFR PART 20

Current NRC radiation protection standards for the public specify quantities of waste materials that are exempt from further regulatory control as radioactive material -

Concentrations or annual releases of radionuclides for discharge into sanitary sewer systems less than specified limits;

Any excreta from individuals undergoing medical treatment with radioactive material are exempt from limits for discharges into sanitary sewer systems.

Land disposal of scintillation materials and animal carcasses containing 0.05 μCi/g (2 kBq/g) or less of ^{3}H or ^{14}C.

PROPOSED REVISIONS OF NRC RADIATION PROTECTION STANDARDS

Impending revisions of NRC's 10 CFR Part 20 contain exemption provisions similar to current standards for (1) discharge of radionuclides and excreta from medical patients into sanitary sewer systems and (2) land disposal of scintillation materials and animal carcasses containing ^{3}H and ^{14}C.

Revised concentration limits of radionuclides for discharge into sanitary sewage are based on internal dosimetry models in ICRP Publications 30 and 48, but limits on annual discharges are unchanged.

EXEMPT QUANTITIES OF RADIOACTIVE MATERIALS IN OTHER NRC STANDARDS

10 CFR Part 30, Domestic Licensing of Byproduct Material -

Exempt concentrations of byproduct material in gaseous or liquid and solid form;

Conditions for exemption of specified items containing byproduct material (e.g., timepieces, self-luminous products, gas and aerosol detectors).

10 CFR Part 40, Domestic Licensing of Source Material -

Conditions for exemption of specified items containing source material (e.g., thorium gas mantles, tableware and glassware containing uranium).

10 CFR Part 71, Packaging and Transportation of Radioactive Material -

Exemption from all requirements for any radioactive materials containing less than 2 nCi/g (0.07 kBq/g);

Exemption from certain requirements for packages containing fissile material or americium and plutonium only.

All exemption levels in NRC standards, including those in 10 CFR Part 20, are not easily related to dose to the public, and doses may be well above de minimis level recommended by NCRP.

NRC GUIDANCE ON DISPOSAL OF RESIDUAL THORIUM OR URANIUM (1981)

NRC Branch Technical Position on concentration limits for disposal with no restrictions on burial method -

- 10 pCi/g (0.4 Bq/g) for natural thorium or uranium with daughters present and in equilibrium;
- 35 pCi/g (1.3 Bq/g) for depleted uranium;
- 30 pCi/g (1 Bq/g) for enriched uranium.

Limits are intended to provide risk to the public equivalent to cleanup standard for ^{226}Ra in surface soil of 5 pCi/g (0.2 Bq/g) in EPA mill tailings standards (40 CFR Part 192).

Resulting dose would be well above de minimis level recommended by NCRP.

Regulations based on Branch Technical Position have not been proposed.

NRC POLICY STATEMENT ON
BELOW REGULATORY CONCERN (1990)

NRC has proposed dose limits for practices by its licensees that would be BRC -

- annual effective dose equivalent to individuals of 10 mrem (0.1 mSv) for practices affecting limited number of people;
- annual effective dose equivalent to individuals of 1 mrem (0.01 mSv) for practices affecting large number of people;
- annual collective effective dose equivalent of 1,000 person-rem (10 person-Sv), with annual effective dose equivalents to individuals less than 0.1 mrem (1 μSv) not needing consideration in estimating collective dose.

Purpose of proposal is to provide common basis for exempting specific practices, as opposed to present system of exemptions in NRC regulations that are not clearly related to dose.

Policy statement would be implemented for specific practices by rulemaking.

NRC is evaluating existing exemptions for compliance with proposed policy statement.

EPA PROPOSAL FOR EXEMPTION LEVELS FOR RADIOACTIVE WASTE DISPOSAL

Draft proposed rule 40 CFR Part 193 on management and land disposal of low-level radioactive wastes (1989) -

Low-level waste and waste containing naturally occurring and accelerator-produced radioactive materials (NARM) may be classified as BRC if annual effective dose equivalent to maximally exposed individual from unregulated release would not exceed 4 mrem (0.04 mSv).

BRC wastes would be determined from analyses of exposure scenarios for unregulated waste (e.g., exposure of worker at sanitary landfill).

PROTECTIVE ACTION GUIDES FOR ACCIDENTS

PURPOSE AND SCOPE OF PROTECTIVE ACTION GUIDES

Protective Action Guides (PAGs) define projected doses or measured levels of radioactivity following accidents (e.g., at nuclear power plants) at which countermeasures to avoid exposures of the public are warranted.

Available countermeasures include sheltering, evacuation, stable iodine administration, control of foodstuffs and water, control of access, decontamination of persons and areas, and relocation.

PAGs are needed because dose limits in radiation protection standards for the public do not apply to accidental releases.

PAGs do not define limits for deliberate releases.

TIME PHASES FOR DEFINING PROTECTIVE ACTIONS

PAGs may be defined for three phases of an accident -

- early phase lasting from hours to days, when immediate decisions based on predictions of radiological conditions are required;
- intermediate phase lasting from weeks to months after accident has been brought under control, when environmental measurements can be used to assess need for additional protective actions;
- recovery phase lasting from months to years, when actions to reduce radioactivity to acceptable levels for permanent residence under normal conditions may be undertaken.

PROTECTIVE ACTION GUIDES OF FEDERAL RADIATION COUNCIL

In 1964 and 1965, FRC developed recommendations on PAGs for ^{131}I, ^{89}Sr, ^{90}Sr, and ^{137}Cs.

PAGs were developed in response to fallout from atmospheric testing of nuclear weapons and were intended for application to long-term intakes of radioactivity in food.

PAGs have largely been superseded by later guidances developed by Food and Drug Administration (FDA) and EPA.

PROTECTIVE ACTION GUIDES OF FOOD AND DRUG ADMINISTRATION FOR RADIOACTIVITY IN FOOD (1982)

FDA developed recommendations on PAGs for radioactive contamination in food.

Preventive PAG is dose commitment at which protective actions having minimal impact should be taken -

- 1.5 rem (15 mSv) to thyroid;
- 0.5 rem (5 mSv) to whole body, bone marrow, or any other organ.

Emergency PAG is dose commitment at which food containing radioactivity should be isolated -

- 15 rem (150 mSv) to thyroid;
- 5 rem (50 mSv) to whole body, bone marrow, or any other organ.

FDA PROTECTIVE ACTION GUIDES FOR RADIOACTIVITY IN FOOD (continued)

Response Levels for Preventive and Emergency PAGs give levels of radioactivity at which recommended protective actions should be undertaken -

- initial activity per unit area deposited on the ground;
- activity per unit mass in forage (fresh weight);
- peak activity concentration in milk;
- total activity intake in foodstuffs.

Response Levels are given for ^{131}I, ^{134}Cs, ^{137}Cs, ^{89}Sr, and ^{90}Sr.

Response Levels for Preventive PAGs are given for newborn infants as critical population group, except fetus is critical group for ^{131}I.

Response Levels for Emergency PAGs are given for (1) fetus as critical group for ^{131}I, (2) child less than one year of age as critical group for other radionuclides, and (3) adult for all radionuclides.

EPA PROTECTIVE ACTION GUIDES (1990)

EPA has developed new PAGs for nuclear incidents (except nuclear war) to supersede 1980 EPA recommendations and previous recommendations of FRC.

For early phase -

- Dose equivalent to whole body from external exposure of 1 rem (10 mSv) and dose equivalent to thyroid from inhalation of 5 rem (50 mSv) are suggested levels for undertaking countermeasures (e.g., evacuation);

- Dose equivalents to whole body and thyroid five times higher than suggested levels are mandatory levels for undertaking countermeasures.

For intermediate phase -

- Relocation of general population for effective dose equivalent in first year above 2 rem (20 mSv) or beta dose to skin above 100 rem (1 Sv);

- Simple dose reduction techniques should be applied for effective dose equivalent in first year below 2 rem (20 mSv);

- PAGs for radioactivity in food as given in 1982 FDA recommendations.

EPA PROTECTIVE ACTION GUIDES

(continued)

Longer-term objectives for recovery phase -

- Dose equivalent in any year after first should not exceed 0.5 rem (5 mSv);
- Dose equivalent over 50 years, including first and second years, should not exceed 5 rem (50 mSv).

PAGs developed by EPA are being revised.

For early phase, PAGs probably will emphasize 1 rem (10 mSv) from external exposure and 5 rem (50 mSv) to thyroid from inhalation as doses above which evacuation normally should be initiated.

For intermediate phase, new guidance on radioactivity in food and water to replace 1982 FDA recommendations may be developed.

ICRP RECOMMENDATIONS FOR ACCIDENTS

Recommendations for early and intermediate phase countermeasures in ICRP Publication 40 (1984) include -

- lower dose levels below which introduction of countermeasures is not warranted;

- upper dose levels above which introduction of countermeasures should almost certainly be attempted.

Recommendations for early phase countermeasures -

- For sheltering and stable iodine administration, (1) lower dose levels of 5 mSv (0.5 rem) effective dose equivalent and 50 mSv (5 rem) dose equivalent to lung, thyroid, or any other organ and (2) upper dose levels a factor of ten higher than lower dose levels;

- For evacuation, (1) lower dose levels of 50 mSv (5 rem) effective dose equivalent and 500 mSv (50 rem) dose equivalent to lung, thyroid, or any other organ and (2) upper dose levels a factor of ten higher than lower dose levels.

ICRP RECOMMENDATIONS FOR ACCIDENTS

(continued)

Recommendations for intermediate phase countermeasures -

- For control of foodstuffs, (1) lower dose levels in first year of 5 mSv (0.5 rem) effective dose equivalent and 50 mSv (5 rem) dose equivalent to any organ and (2) upper dose levels a factor of ten higher than lower dose levels;

- For relocation, (1) lower dose levels in first year of 50 mSv (5 rem) effective dose equivalent and 500 mSv (50 rem) dose equivalent to any organ and (2) upper dose levels not anticipated to be relevant.

ICRP also discusses available countermeasures for long-term recovery phase and optimization of dose level for withdrawal of countermeasures based on cost-benefit analysis.

INTERVENTION LEVEL FOR RECOVERY PHASE FOLLOWING CHERNOBYL ACCIDENT

For recovery phase after Chernobyl accident, radiation protection authorities in USSR have recommended lifetime dose equivalent of 350 mSv (35 rem) as intervention level for relocation of population.

Intervention level corresponds to average annual dose equivalent over 70-year lifetime of 5 mSv (0.5 rem) and was based on limit on annual dose equivalent from occasional routine exposure recommended by ICRP.

Lifetime risk at intervention level would be about 10^{-2}.

Recommended intervention level is controversial within USSR because -

- level is regarded by some as far too high;
- level is regarded by others as too low considering risks from hazardous chemicals in the environment which are experienced by large populations in USSR.

II. THE REGULATIONS FOR HAZARDOUS CHEMICALS

SAFE DRINKING WATER ACT

EPA sets standards for hazardous chemicals in drinking water (40 CFR Part 141) under authority of Safe Drinking Water Act.

Act requires that EPA establish Maximum Contaminant Limit Goals (MCLGs) and Maximum Contaminant Limits (MCLs) for drinking water.

MCLGs are non-enforceable health goals set at level where no known or anticipated adverse effects on human health occur and adequate margin of safety is provided.

For known carcinogens, MCLGs must be set to zero.

MCLs are legally enforceable standards which must be set as close to MCLGs as possible, taking into account technical feasibility and cost.

MCLs for different carcinogens may correspond to different levels of risk.

SAFE DRINKING WATER ACT

(continued)

In setting standards for hazardous materials in drinking water, EPA generally -

- regulates each contaminant (either carcinogens or noncarcinogens) on case-by-case basis;
- sets MCLs for known carcinogens corresponding to limit on lifetime risk of 10^{-4}-10^{-6}.

There is no standard in law or regulations for acceptable risk from exposure to all contaminants in drinking water.

CLEAN AIR ACT

Clean Air Act requires EPA to establish National Emissions Standards for Hazardous Air Pollutants (NESHAPs) for any substance declared to be hazardous material.

NESHAPs must provide ample margin of safety to protect public safety.

Substances declared to be hazardous materials include Be, Hg, As, vinyl chloride, benzene, asbestos, and radionuclides.

EPA has identified about 25 other substances considered as carcinogenic from air emissions.

In response to lawsuit over standard for vinyl chloride emissions, Court of Appeals in 1987 set out two-step decision process for EPA to follow in setting NESHAPs -

(1) determine safe or acceptable level of health risk;

(2) set standard at level, which may be lower but not higher than safe or acceptable level, that protects public health with ample margin of safety.

Thus, standards must be based primarily on considerations of health risk, rather than technical feasibility and cost.

CLEAN AIR ACT

(continued)

In setting NESHAPs in 40 CFR Part 61 in response to Court order in vinyl chloride case, EPA generally -

- regulates each hazardous air pollutant on case-by-case basis;

- sets standards such that lifetime risk would not exceed about (1) 10^{-4} for maximally exposed individuals and (2) 10^{-6} for greatest number of individuals in exposed population.

There is no standard in law or regulations for acceptable risk from exposure to all hazardous air pollutants.

RESOURCE CONSERVATION AND RECOVERY ACT

RCRA imposes "cradle-to-grave" management system for generation, transport, treatment, storage, and disposal of solid hazardous waste with objective of protecting human health and the environment.

EPA's regulations implementing RCRA in 40 CFR Parts 260-268, 270-272, 280, and 281 establish -

- detailed reporting requirements to provide continuous accountability in handling hazardous waste;
- detailed and prescriptive technical standards for treatment, storage, and disposal;
- permitting system for treatment, storage, and disposal facilities to ensure adherence to technical standards.

RCRA and EPA regulations do not include risk limits or other quantitative standards to define "protection of human health and the environment."

Objective is assumed to be met by complying with technical standards for obtaining operating permits for waste treatment, storage, and disposal facilities.

RESOURCE CONSERVATION AND RECOVERY ACT

(continued)

Future regulations developed under RCRA may -

- establish de minimis levels of hazardous materials in solid waste;

- incorporate risk assessment into permitting system.

APPLICABILITY OF RCRA TO RADIOACTIVE WASTE DISPOSAL

(1) Definition of hazardous waste in RCRA excludes source, special nuclear, and byproduct materials as defined in Atomic Energy Act.

Result was uncertainty regarding applicability of RCRA to hazardous waste containing radioactive materials.

(2) Federal agencies have agreed that source, special nuclear, and byproduct materials refer only to radionuclides.

"Mixed" waste thus contains radionuclides regulated under authority of Atomic Energy Act and other hazardous materials regulated under authority of RCRA.

(3) Mixed waste is subject to dual regulation, i.e., by EPA and NRC for civilian waste or by EPA and DOE for defense waste.

RCRA precludes any hazardous waste regulation for mixed waste that is "inconsistent" with Atomic Energy Act.

In event of inconsistencies, Atomic Energy Act would take precedence and RCRA would not apply.

COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT (SUPERFUND)

EPA's 40 CFR Part 300, the National Contingency Plan (NCP), contains standards for cleanup of unpermitted releases of hazardous materials to the environment including old, abandoned waste disposal sites.

CERCLA and NCP specify that remediation goals shall be protective of human health and the environment and shall be developed taking into account -

- Applicable or Relevant and Appropriate Requirements (ARARs) under Federal or State environmental laws;

  ARARs for cleanup of groundwater and surface water specifically include drinking water standards established under authority of Safe Drinking Water Act.

- other information to be considered (TBCs) which are not ARARs (e.g., EPA's groundwater protection strategy, DOE orders);

- for known or suspected carcinogens, upper bound on lifetime cancer risk of 10^{-4}-10^{-6} from all substances and all exposure pathways at specific sites.

COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT (SUPERFUND)
(continued)

CERCLA provides several conditions under which requirement that remedial actions comply with ARARs can be waived -

- Remedial action is interim measure;
- Compliance with ARARs results in greater risk than noncompliance;
- Compliance with ARARs is technically infeasible or impractical;
- Another response will achieve equivalent level of protection;
- Compliance with ARARs does not balance cost of response against benefit in protecting health and environment.

Result has been that negotiated cleanup levels vary greatly from one Superfund site to another.

FRAMEWORK FOR PROTECTION OF THE PUBLIC FROM HAZARDOUS CHEMICALS

Current framework for regulating exposures of the public to hazardous chemicals, as exemplified by drinking water standards, may be referred to as "bottom-up" approach.

There is no generally applicable standard, analogous to radiation protection standard for the public, defining upper limit on acceptable risk from exposure to all hazardous chemicals and for all sources or practices.

Goal for lower limit on acceptable risk is established for particular exposure situations, e.g., lifetime risk of zero for contaminants in drinking water or 10^{-6} for cleanup of Superfund sites.

Goal is increased above lower limit in specific cases to reflect risk levels judged to be reasonably achievable, taking into account technical feasibility and cost.

The "bottom-up" approach used in regulating exposures to hazardous chemicals is opposite of "top-down" approach used in regulating exposures to radionuclides under authority of Atomic Energy Act.

CONSISTENT BASIS FOR REGULATION OF RADIONUCLIDES AND HAZARDOUS CHEMICALS

Use of "top-down" and "bottom-up" approaches in regulating public exposures to radionuclides and hazardous chemicals, respectively, leads to apparent inconsistencies in levels of acceptable lifetime risk in the two cases.

Public exposures to radionuclides and hazardous chemicals can be regulated on consistent basis if -

- lifetime risk of 10^{-1}-10^{-3} is established as generally applicable *de manifestis* level (i.e., level requiring action to reduce risk regardless of cost);
- lifetime risk of 10^{-4}-10^{-6} is established as generally applicable *de minimis* level;
- control of all exposures between *de manifestis* and *de minimis* levels is based on application of ALARA principle.

Consistent regulation requires recognition that lifetime risks often used in limiting public exposures to hazardous chemicals (e.g., 10^{-4}-10^{-6}) constitute *de minimis* values.

Interpretation of these risk levels as *de minimis* is consistent with past decisions not to take regulatory action to reduce risks for some hazardous chemicals.

CONSISTENT BASIS FOR REGULATION OF RADIONUCLIDES AND HAZARDOUS CHEMICALS (continued)

- Use of ranges for de manifestis and de minimis risk levels would permit accounting for size of exposed population.

  Higher risk levels (e.g., 10^{-1} and 10^{-4}) could be used when few individuals are at risk.

  Lower risk levels (e.g., 10^{-3} and 10^{-6}) could be used when large populations are at risk.

For most situations, de manifestis and de minimis risks could be about 10^{-2} and 10^{-5}, respectively.

Substantial difference between de manifestis and de minimis risk levels would provide wide range for application of ALARA principle.

CONSISTENT BASIS FOR REGULATION OF RADIONUCLIDES AND HAZARDOUS CHEMICALS (continued)

Consistent framework for regulating public exposures to radionuclides and hazardous chemicals also would require resolution of other inconsistencies.

(1) Risk per unit exposure

Risk factors for radiation exposure generally are "best estimates" (i.e., mean values).

Risk (slope) factors for hazardous chemicals generally are "upper bound estimates" (i.e., 95% confidence limits).

(2) Measure of risk

For radiation exposure, measure of risk usually is fatal cancers or genetic effects.

For hazardous chemicals, measure of risk often is cancer incidence.

ICRP will introduce risk factors for radiation exposure that account for cancer incidence as well as fatalities.

CONSISTENT BASIS FOR REGULATION OF RADIONUCLIDES AND HAZARDOUS CHEMICALS

(continued)

- Other inconsistencies between regulatory framework for radionuclides and hazardous chemicals (continued) -

(3) Risk assessment

Risk assessments for radionuclides usually emphasize <u>average</u> risks to members of critical population groups, assuming reasonably likely exposure scenarios.

Risk assessments for hazardous chemicals often emphasize worst-case scenarios and assumptions for exposure.

(4) Accounting of background risk

Standards for man-made radionuclides generally apply to exposures in excess of natural background.

Standards for hazardous chemicals usually do not exclude exposures to natural background.

Risk from natural background radiation probably is better understood than risk from naturally occurring hazardous chemicals.

Background lifetime risks from radionuclides and hazardous chemicals each may be greater than 10^{-3}.