

STAFF POSITION  
ON HLW EPA STANDARD

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9401050053 931116  
PDR COMMS NRCC  
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6

### ACRS CONCERNS

- o LETTERS TO COMMISSION (7/17 AND 10/16) AND BRIEFINGS (10/10 AND 10/21)
- o STANDARD IS OVERLY RESTRICTIVE
  - OVERTLY SO (SOCIETAL RISK OBJECTIVES)
  - PRACTICALLY SO (10/21 COMM BRIEFING)
- o IMPLEMENTATION WILL BE A PROBLEM, BOTH LEGALLY AND TECHNICALLY
  - PROBABILISTIC NATURE OF STANDARD--"CONVINCING EVIDENCE" NEEDED THAT IS PRACTICAL TO MEET
  - "LENTENCY IN IMPLEMENTATION" OF AN "OVERLY RESTRICTIVE" STANDARD NOT APPROPRIATE
  - IF ENVIRONMENTAL MONITORING NEEDED FOR ENFORCEMENT, STANDARD IMPOSSIBLE
- o OTHER CONCERNS
  - EPA SCIENCE ADVISORY BOARD ISSUES

### STAFF REVIEW OF STANDARD

- o SUMMARY OF STAFF REVIEWS, INCLUDING CONCERNS ON PROPOSED STANDARD, PRESENTED IN SECY-85-272
- o STAFF REVIEWED STANDARD WITH RESPECT TO IMPLEMENTABILITY -- CAN COMPLIANCE WITH THE STANDARD BE DEMONSTRATED WITHOUT PROTRACTED LICENSING REVIEWS AND HEARING PROCESS?
- o STAFF DID NOT ATTEMPT TO SECOND GUESS EPA WITH RESPECT TO THE SOCIETAL RISK OBJECTIVES -- EPA RESPONSIBILITY ESTABLISHED BY LAW
- o STAFF COMMENTS (APPROVED BY COMMISSION) ON PROPOSED STANDARD EXPRESSED STRONG CONCERN ABOUT RIGID REQUIREMENTS FOR PROBABILITY ASSESSMENTS AND COMMENTED ON EPA MODEL PARAMETERS
- o COMMISSION RAISED JURISDICTIONAL ISSUES -- EPA PROPOSED ASSURANCE REQUIREMENTS
- o EPA MADE CHANGES (FINAL STANDARDS) TO RESOLVE CONCERNS

85/11/08

NRC INVOLVEMENT  
IN EPA PROCESS

- o STARTED IN 1977
- o TECHNICAL ASSISTANCE FOR REGULATORY DEVELOPMENT: REVIEW AND EVALUATION OF THE DRAFT EPA STANDARD 40CFR191 FOR DISPOSAL OF HIGH-LEVEL WASTE (NIREG/CR-3235) 4/83
- o STAFF EVALUATIONS IN DEVELOPING 10CFR60 TECHNICAL CRITERIA (1978-1982)
- o NUMEROUS MEETINGS AND LETTERS; E.G.,
  - STAFF LETTER OF 12/27/78
  - COMM LETTER OF 6/22/79
  - STAFF LETTER OF 5/10/83
  - COMM LETTER OF 5/11/83

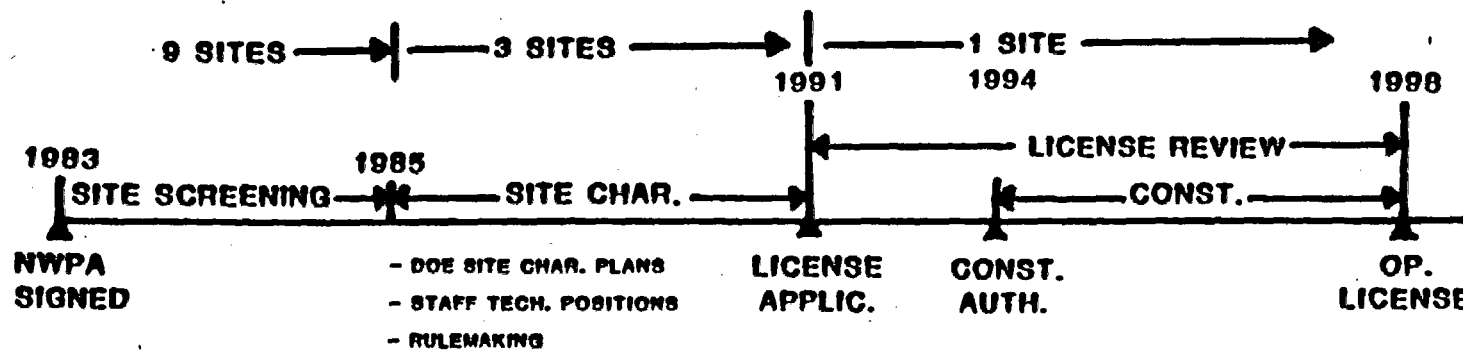
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## EPA STANDARD

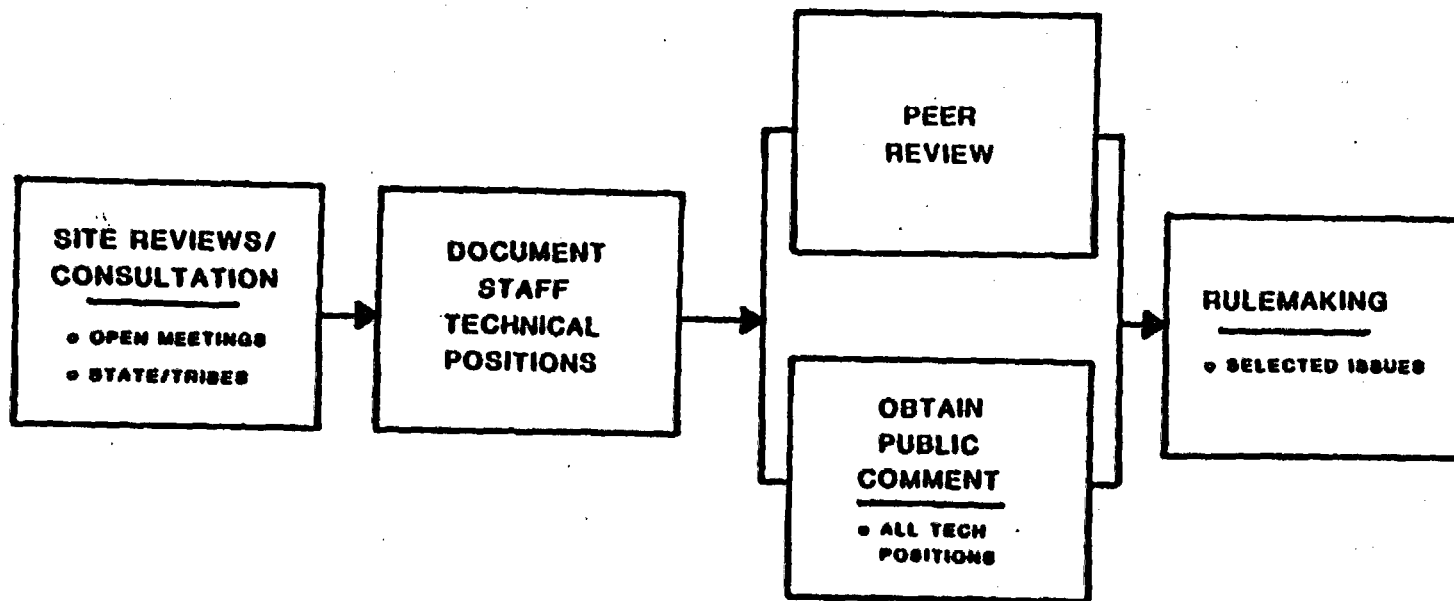
- o EMPLACEMENT OPERATIONS
- o POST EMPLACEMENT
  - LIMITS RELEASE TO "ACCESSIBLE ENVIRONMENT"
  - RELEASE - TOTAL CURIES OVER 10,000 YEARS
  - NUMERICAL PROBABILITY FEATURE
- o GROUNDWATER PROTECTION REQUIREMENTS
- o INDIVIDUAL PROTECTION REQUIREMENTS

## IMPLEMENTATION OF STANDARD

- o EPA STANDARD REVISED (SECTION 190.13(B), APPENDIX B, DEFINITIONS AND STATEMENT OF CONSIDERATIONS)
- o COMBINATION OF QUANTITATIVE PROBABILITY ESTIMATES AND QUALITATIVE JUDGMENTS ARE PERMITTED AND EXPECTED
- o REVISIONS NOT INTENDED TO AUTHORIZE "LENIENCY" IN IMPLEMENTATION
- o SPECIFIC COMPLIANCE DETERMINATION METHODOLOGIES BEING WORKED OUT PRIOR TO LICENSING ON GENERIC AND SITE SPECIFIC BASES
  - PRELICENSING CONSULTATION PROCESS OF NWPA AND NRC REGS
  - DOE SCP AND NRC STAFF POSITIONS
  - RULEMAKING ON SELECTED IMPORTANT METHODOLOGY ISSUES
- o NUREG/CR-3235 ILLUSTRATES METHODS AND IMPLEMENTABILITY
- o INDEPENDENT NRC STUDIES TO BE CONTINUED -- E.G., EXPERT PANEL ON DETERMINING PROBABILITIES OF GEOLOGIC PROCESSES AND EVENTS
- o COMPLIANCE TO BE DETERMINED ON A CALCULATIONAL BASIS AFTER DETAILED SITE CHARACTERIZATION NOT ON BASIS OF ENVIRONMENTAL MONITORING



## DOE SCHEDULE -- FIRST REPOSITORY



**REPOSITORY PRELICENSING  
ISSUE RESOLUTION PROCESS**



## EXPERTS

C. John Mann	University of Illinois	Mathematical Geology
Robert J. Budnitz	Future Resources	Regulatory Concerns
W. Jay Conover	Texas Tech University	Probability & Statistics
Herbert H. Einstein Gregory B. Baecher	MIT	Mining Engineering
John Harbaugh	Stanford University	Resource Exploration
Michael King	Lawrence Berkeley Lab/ UC Berkeley	Thermomechanical Effects
Jonathan Callender	NM Museum of Natural History	Seismicity & Tectonics
Alexander McBirney	University of Oregon	Volcanology
Thompson Webb III	Brown University	Climatology
Allan Gutjahr	NM Institute of Mining and Technology	Hydrology
C. Allin Cornell	C. Allin Cornell/ Stanford	Seismology
Heinrich D. Holland	Harvard University	Geochemistry

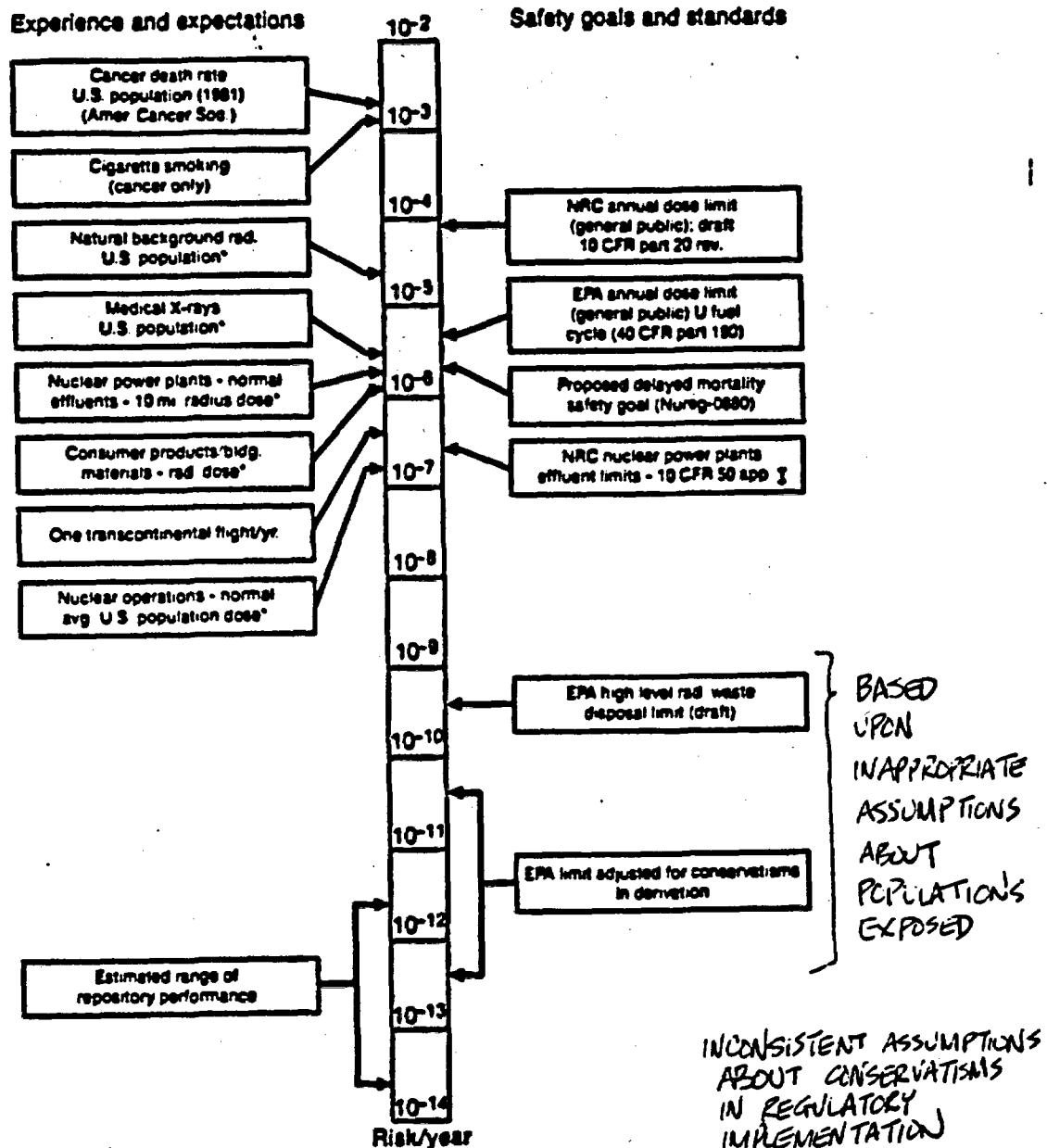
## SUMMARY

- A Group of Experts, Under the Direction of Sandia National Laboratories, is Reviewing the State of the Art for Probabilistic Prediction of Geologic Processes and Events
- NRC Will Use This Work During Its Evaluation of DOE's License Applications

STRINGENCY OF STANDARD.

- o NOT NRC'S JOB TO SET RISK LEVELS BUT STAFF DID NOT FIND STANDARDS WERE UNREASONABLE—RISKS COMPARABLE TO OTHER STANDARDS
- o COMPARISONS WITH OTHER REGULATED RISKS
  - POPULATION RISK
  - INDIVIDUAL RISK
  - COMPARISONS MUST BE SENSITIVE TO NUMEROUS ASSUMPTIONS (E.G., POPULATION SIZE, DISTRIBUTION, MODELS, PERIOD OF INTEGRATION, ETC.)
  - "EPRI DIAGRAM" MISLEADING
- o INDIVIDUAL RISK CRITERIA ADDED BY EPA IN RESPONSE TO NATIONAL ACADEMY OF SCIENCES AND SAB COMMENTS

From: Culler, F. E., Catlin, R. J., and Williams, R. F.,  
 "Objectives in High-Level Wastes/Spent Fuel Disposal,"  
 Paper Presented at the Twenty-First Annual Meeting of  
 the National Council on Radiation Protection and Measure-  
 ments, Washington, DC (April 3-4, 1985).



Sources: (1) EPA presentation EPA-SAB San Francisco March 24, 1983  
 (2) Wilson, Richard. Testimony for OSHA hearings on toxic substances, February, 1978.  
 \* BEIR III

Figure 2. Individual annual risk of cancer.

OTHER CONCERNS

- o SAB COMMENT RESPONSES -- EPA 520/1-85-024-1 AUGUST 1985
- o SUMMARY CHART ON MAJOR SAB COMMENTS

# FROM SAB REPORT

TABLE A

NUMBER OF POSSIBLE CANCER CASES DUE TO IONIZING RADIATION<sup>1</sup>

<u>ORIGIN</u>	<u>NO. OF CASES PER YR.<sup>2</sup></u>	<u>NO. OF CASES PER 10,000 YR.<sup>2</sup></u>
High-level Rad. Waste Disposal <sup>3</sup>	up to 0.1	up to 1,000
Uranium Mill Tailings <sup>4</sup>		
- Unprotected†	3	30,000*
- Protected (covered, etc.)	0.03	300*
Indoor Air Pollution		
- Residential Exposure <sup>5</sup>	1,000 to 20,000	10,000,000 to 200,000,000*
- Residential Weather- ization (added cases) <sup>5</sup> (Nero Estimate)	250 to 5,000	2,500,000 to 50,000,000*
- Residential Weather- ization (added cases) <sup>6</sup>	10,000 to 20,000	100,000,000 to 200,000,000*
Background Radiation <sup>7</sup>	3,000 to 4,000	30,000,000 to 40,000,000

[Cancer Deaths (U.S.)<sup>8</sup> (all causes) 430,000]

Notes: <sup>1</sup> These numbers are all calculated on the same basis using a linear non-threshold dose response model, as noted on pp. A-7-3 and A-7-4 of this report. The linear non-threshold model involves a high degree of speculation, and the resulting values have little merit as absolute indicators of the numbers of biological effects that may occur. It has been used here to provide a framework within which relative risks from various radiation exposure situations can be compared.

<sup>2</sup> Assuming constant U.S. population and culture - numbers with (\*) are extrapolated from annual values.

<sup>3</sup> EPA proposed rule 40 CFR Part 191 (December 1982) number per 100,000 MTHM high-level radioactive waste repository.

<sup>4</sup> NRC (October 1980). "Uranium Mill Licensing Requirements: Final Rules," Federal Register, 45, No. 194, 65521-65538. Radon inhalation exposures.

# EPA ACTION ON SELECTED SAB RECOMMENDATIONS

ITEM	PROPOSED STANDARDS 12/29/82	SAB RECOMMENDATION	FINAL STANDARDS 9/17/85
RISK TO PUBLIC	CORRESPONDS TO 1,000 PREMATURE CANCER DEATHS OVER 10,000 YEARS	RELAX STANDARD (INCREASE RISK) BY A FACTOR OF TEN AND REDUCE CONSERVATISM IN PREDICTIVE MODELS	RETAINED SOCIETAL RISK. REDUCED CONSERVATISM IN ANALYSIS, THEREBY INCREASING RELEASE LIMITS
PROBABILISTIC CRITERIA	MEET BY QUANTITATIVE ASSESSMENTS	DEMONSTRATE CONDITION IS PRACTICAL TO MEET OR ADOPT NRC QUALITATIVE LANGUAGE	ALTERNATE QUALITATIVE LANGUAGE PROPOSED BY NRC & ADOPTED BY EPA (AMPLIFIED IN EPA STATEMENT OF CONSIDERATIONS)
RELEASE LIMITS			
TABLE 2* RELEASES	1/100 CHANCE OF EXCEEDING IN	1/2 CHANCE OF EXCEEDING	1/10 CHANCE OF EXCEEDING
10 TIMES TABLE 2* RELEASE	1/10,000 CHANCE OF EXCEEDING IN 10,000 YEARS	DROP	1/1,000 CHANCE OF EXCEEDING

\* TABLE 2 IN PROPOSED STANDARDS, WHICH IS TABLE 1 IN FINAL STANDARDS.

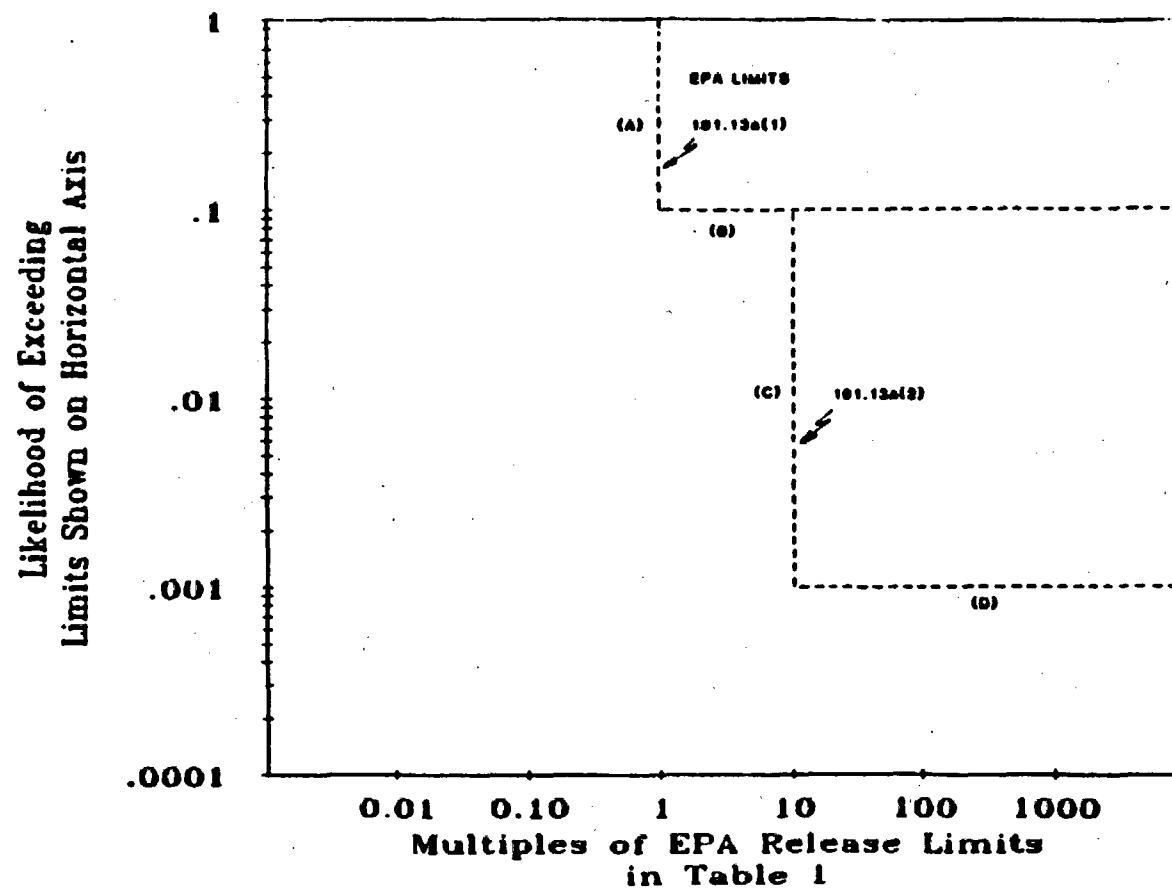
### SUMMARY

- o REGARDLESS OF FORM AND NATURE OF STANDARD, DETAILED ASSESSMENTS OF POTENTIAL FUTURE RELEASES FROM REPOSITORY WILL BE REQUIRED. RELATIVELY LARGE UNCERTAINTIES INEVITABLE
- o BROAD METHODOLOGIES ESTABLISHED; NHPA/10CFR60 PROCESS FOR SETTLING SPECIFIC METHODOLOGY AND DATA NEEDS QUESTIONS ON A TIMELY SCHEDULE BEFORE LICENSING IS UNDERWAY
- o STANDARD CAN BE IMPLEMENTED WITHOUT PROTRACTED LICENSING REVIEWS AND HEARING PROCESS

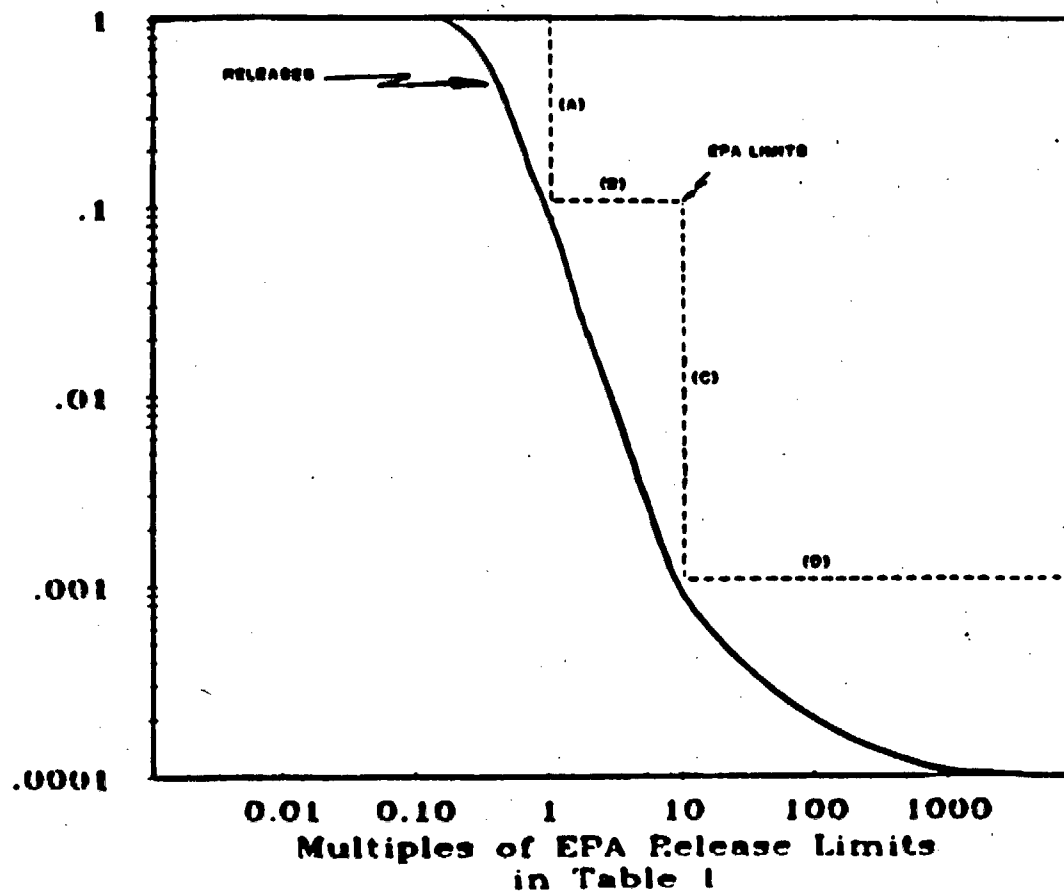
BACKUP CHARTS

STAFF POSITION  
ON HLW EPA STANDARD





LIKELIHOOD OF EXCEEDING  
LIMITS SHOWN ON HORIZONTAL AXIS



BACKUP CHARTS

EXCERPTS FROM EPA RULE

Thursday  
September 19, 1985

# Federal Register

## Part II

## Environmental Protection Agency

### 40 CFR Part 191

Environmental Standards for the  
Management and Disposal of Spent  
Nuclear Fuel, High-Level and Transuranic  
Radioactive Wastes; Final Rule

## / Rules and Regulations

formulated in terms of releases that might be caused by geologic processes and events.

In the second round of comment, the Agency sought information on whether to adopt the NRC's recommended wording or to retain definitions based on quantitative probabilities. Although a number of commenters agreed with the NRC position, the preponderance of comments supported retention of the quantitative probabilities. The SAB Subcommittee strongly supported retention of the probabilistic structure, but with substantially less restrictive probabilities and with the proviso that the Agency be sure that such conditions would be "... practical to meet and [would] not lead to serious impediments, legal or otherwise, to the licensing of high-level waste repositories." After considering all of this information, the Agency has revised the structure of the containment requirements in several ways that will retain quantitative objectives for long-term containment while allowing the implementing agencies enough flexibility to make qualitative judgments when necessary.

First, the final rule does not use the terms "reasonably foreseeable" and "very unlikely" releases. Instead, the permissible probabilities for two different levels of cumulative releases (over 10,000 years after disposal) are now incorporated directly into the containment requirements.

Second, the numerical probabilities associated with the two release categories have been increased by an order of magnitude to reflect further assessments of the uncertainties associated with protecting the probabilities of geologic events such as fault movement.

Third, the final rule clearly indicates that comprehensive performance assessments, including estimates of the probabilities of various potential releases whenever meaningful estimates are practicable, are needed to determine compliance with the containment requirements.

Fourth, a paragraph has been added to the final containment requirements (Section 191.13) to emphasize that unequivocal proof of compliance is neither expected nor required because of the substantial uncertainties inherent in such long-term projections. Instead, the appropriate test is a reasonable expectation of compliance based upon practically obtainable information and analysis. This paragraph was patterned after a paragraph that considered similar issues in NRC's 10 CFR Part 80.

Finally, the "Guidance for Implementation" section has been

### *Use of Quantitative Probabilities in the Containment Requirements*

The containment requirements in the proposed rule applied to two categories of potential releases ("reasonably foreseeable" and "very unlikely") based upon their projected probabilities of occurrence over the first 10,000 years after disposal. In its comments on the proposed rule, the NRC objected to the proposed quantitative definitions of these probabilities on the basis that calculation of such probabilities could be so uncertain that it would be impractical to determine whether the standards had been complied with. Instead, the NRC suggested substitution of qualitative terms to identify the two categories of potential releases. The wording proposed by the NRC was

added (Appendix B). This part of the rule describes the Agency's assumptions regarding performance assessments and uncertainties and should discourage overly restrictive or inappropriate implementation of the containment requirements.

The Agency believes that these revisions to the proposed rule preserve an objective framework for application of the containment requirements that requires very stringent isolation while allowing the implementing agencies adequate flexibility to handle specific uncertainties that may be encountered.

Within this framework, the possibility of inadvertent human intrusion into or nearby a repository requires special attention. Such intrusion can significantly disrupt the containment afforded by a geologic repository (as well as being dangerous for the intruders), and repositories should be selected and designed to reduce the risks from such potential disruptions. However, assessing the ways and the reasons that people might explore underground in the future—and evaluating the effectiveness of passive controls to deter such exploration near a repository—will entail informed judgment and speculation. It will not be possible to develop a "correct" estimate of the probability of such intrusion. The Agency believes that performance assessments should consider the possibilities of such intrusion, but that limits should be placed on the severity of the assumptions used to make the assessments. Appendix B to the final rule describes a set of parameters about the likelihood and consequences of inadvertent intrusion that the Agency assumed were the most pessimistic that would be reasonable in making performance assessments. The implementing agencies may adopt these assumptions or develop similar ones of their own. However, as indicated under the discussion of institutional controls, the Agency does not believe that institutional controls can be relied upon to completely eliminate the possibility of inadvertent intrusion.

**§ 191.13 Containment requirements.**

(a) Disposal systems for spent nuclear fuel or high-level or transuranic radioactive wastes shall be designed to provide a reasonable expectation, based upon performance assessments, that the cumulative releases of radionuclides to the accessible environment for 10,000 years after disposal from all significant processes and events that may affect the disposal system shall:

(1) Have a likelihood of less than one chance in 10 of exceeding the quantities calculated according to Table 1 (Appendix A); and

(2) Have a likelihood of less than one chance in 1,000 of exceeding ten times the quantities calculated according to Table 1 (Appendix A).

(b) Performance assessments need not provide complete assurance that the requirements of 191.13(a) will be met. Because of the long time period involved and the nature of the events and processes of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with 191.13 (a) will be achieved.

(q) "Performance assessment" means an analysis that: (1) identifies the processes and events that might affect the disposal system; (2) examines the effects of these processes and events on the performance of the disposal system; and (3) estimates the cumulative releases of radionuclides, considering the associated uncertainties, caused by all significant processes and events. These estimates shall be incorporated into an overall probability distribution of cumulative release to the extent practicable.

### Appendix B—Guidance for Implementation of Subpart B

[Note: The supplemental information in this appendix is not an integral part of 40 CFR Part 191. Therefore, the implementing agencies are not bound to follow this guidance. However, it is included because it describes the Agency's assumptions regarding the implementation of Subpart B. This appendix will appear in the Code of Federal Regulations.]

The Agency believes that the implementing agencies must determine compliance with §§ 191.13, 191.15, and 191.16 of Subpart B by evaluating long-term predictions of disposal system performance. Determining compliance with § 191.13 will also involve predicting the likelihood of events and processes that may disturb the disposal system. In making these various predictions, it will be appropriate for the implementing agencies to make use of rather complex computational models, analytical theories, and prevalent expert judgment relevant to the numerical predictions. Substantial uncertainties are likely to be encountered in making these predictions. In fact, sole reliance on these numerical predictions to determine compliance may not be appropriate; the implementing agencies may choose to supplement such predictions with qualitative judgments as well. Because the procedures for determining compliance with Subpart B have not been formulated and tested yet, this appendix to the rule indicates the Agency's assumptions regarding certain issues that may arise when implementing §§ 191.13, 191.15, and 191.16. Most of this guidance applies to any type of disposal system for the wastes covered by this rule. However, several sections apply only to disposal in mined geologic repositories and would be inappropriate for other types of disposal systems.

**Consideration of Total Disposal System.** When predicting disposal system performance, the Agency assumes that reasonable projections of the protection expected from all of the engineered and natural barriers of a disposal system will be considered. Portions of the disposal system should not be disregarded, even if projected performance is uncertain, except for portions of the system that make negligible contributions to the overall isolation provided by the disposal system.

**Scope of Performance Assessments.** Section 191.13 requires the implementing agencies to evaluate compliance through performance assessments as defined in § 191.12(e). The Agency assumes that such performance assessments need not consider

categories of events or processes that are estimated to have less than one chance in 10,000 of occurring over 10,000 years. Furthermore, the performance assessments need not evaluate in detail the releases from all events and processes estimated to have a greater likelihood of occurrence. Some of these events and processes may be omitted from the performance assessments if there is a reasonable expectation that the remaining probability distribution of cumulative releases would not be significantly changed by such omissions.

**Compliance with Section 191.13.** The Agency assumes that, whenever practicable, the implementing agency will assemble all of the results of the performance assessments to determine compliance with § 191.13 into a "complementary cumulative distribution function" that indicates the probability of exceeding various levels of cumulative release. When the uncertainties in parameters are considered in a performance assessment, the effects of the uncertainties considered can be incorporated into a single such distribution function for each disposal system considered. The Agency assumes that a disposal system can be considered to be in compliance with § 191.13 if this single distribution function meets the requirements of § 191.13(a).