

September 7, 2001

MEMORANDUM FOR: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION, 11:00
A.M., FRIDAY, SEPTEMBER 7, 2001, COMMISSIONERS'
CONFERENCE ROOM, ONE WHITE FLINT NORTH,
ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

I. SECY-01-0127 - Draft Final Rule: 10 CFR Part 63, "Disposal of High-level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain Nevada"

The Commission¹ approved a final rule which establishes licensing criteria for a proposed repository at Yucca Mountain, Nevada. These criteria have been adapted consistent with final environmental standards for Yucca Mountain as published by the U.S. Environmental Protection Agency (EPA). The staff should address the comments and incorporate the changes noted in the attachment and forward the final rule to the Office of Management and Budget (OMB). After OMB clearance is obtained, the final rule should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication in the Federal Register.

(EDO) (SECY Suspense: Submission to OMB - 9/28/01)

In applying TEDE and considering potential doses to members of the public from the repository, the staff should provide for the use of organ specific weighting factors (e.g., such as contained in Part 20 or Federal Guidance Report 12) for calculating effective dose equivalent, as opposed to using a single weighting factor of 1 with the deep-dose equivalent, when considering external exposures (as allowed under 10 CFR § 20.1003). In the consideration of actual external exposures to workers, the deep-dose equivalent should continue to be used unless DOE should seek authority to apply effective dose equivalent.

The differences in approach revealed by this issue and the recent confusion surrounding the assessment of external dose by some licensees (SECY-01-0140) demonstrate the need for staff to develop guidance that specifies when it is appropriate to use effective dose equivalent rather than deep-dose equivalent for assessing the dose from external sources of radioactivity.

(EDO) (SECY Suspense: 9/30/02)

¹ Section 201 of the Energy Reorganization Act, 42 U.S.C. Section 5841, provides that action of the Commission shall be determined by a "majority vote of the members present." Chairman Meserve and Commissioners McGaffigan and Merrifield were present in the Conference Room. Commissioner Dicus participated in the meeting via speakerphone.

In § 63.322, the staff uses the term “unlikely natural processes and events,” but provides no probability cutoffs for defining these events. Following issuance of the final Part 63, staff should initiate an expedited rulemaking to establish the annual probability of occurrence that is seen to constitute an unlikely event or process. During the separate rulemaking to define the term “unlikely”, the staff should evaluate the pros and cons of both a range of values as well as a specific value to define “unlikely”.

(EDO) (SECY Suspense: 60 days after Part 63 is submitted to OMB)

After promulgation of the Part 63 final rule, The staff should promptly publish a Federal Register notice to close out action on the petition for rulemaking originally submitted in 1985 by the States of Nevada and Minnesota and inform the affected States of this action.

(EDO) (SECY Suspense: 120 days after Part 63 is submitted to OMB)

Attachment: Comments and Changes to the Final Rule in SECY-01-0127

cc: Chairman Meserve
Commissioner Dicus
Commissioner McGaffigan
Commissioner Merrifield
EDO
OGC
CFO
OCAA
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR

Comments and Changes to the Final Rule in SECY-01-0127

General Comments

1. The final rule and Statement of Considerations (SOC) should be revised to use “total effective dose equivalent” (TEDE) instead of “annual committed effective dose equivalent” (annual CEDE) for radiological doses to individuals. The SOC should be modified to explain that TEDE is essentially equivalent to annual CEDE in its application to Yucca Mountain and the basis for the Commission’s decision to use TEDE. The term “dose limit” should be continually referenced throughout the rule language and SOC, as appropriate, in-lieu of referencing a specific dose methodology (i.e. TEDE). Although much of the original language already addresses this issue, it should be referenced consistently and continually throughout the document. The staff should revise (including removal), as needed, dosimetry terminology to be consistent with 10 CFR Part 20.
2. The EPA standard defines the Reasonably Maximally Exposed Individual (RMEI) as a rural-resident exposed through the same general pathways as a subsistence farmer. 66 Fed. Reg. 32,092 (June 13, 2001). In describing the RMEI in the SOC for Part 63, staff indicates that the RMEI is a member of a farming community (SECY-01-0127, Attachment 2, at 84). Because the terminology is different, some might perceive a conflict between the EPA standards and Part 63. The staff should ensure that the appearance of a conflict is avoided in preparing the final *Federal Register* notice.
3. The staff uses the term “soluble radionuclides” in the context of the human intrusion scenario. See § 63.322. Without further clarification, the term might invite debate as to what radionuclides should be considered as soluble. The staff should provide clarification as to the intended meaning of this term.
4. EPA’s standard has three separate components -- the individual protection standard, the ground-water standard, and the human intrusion standard. The EPA did not address or include the human intrusion standard as being a severable component in its proposed or final standards. Therefore, the Commission supports the staff’s interpretation and the draft final Part 63, which indicates that only the individual protection and ground-water protection standards are severable. See § 63.343.
5. The definition of high-level radioactive waste in § 63.202 is not appropriate for inclusion in the NRC rule because it would suggest incorrectly that the NRC intends to leave to another rulemaking the determination of whether irradiated reactor fuel should be deemed HLW.² The staff should adopt subpart (A) of the definition from the Nuclear Waste Policy Act of 1982 (42 U.S.C. § 10101(12)), as amended, as item (1) of the regulatory definition; add “irradiated reactor fuel” as item (2) of the definition; and to retain subpart (B) of the statutory definition as item (3) of the regulatory definition. The

² As currently drafted, high-level radioactive waste is defined in § 63.202 to encompass highly radioactive material from reprocessing and “[o]ther highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation.”

staff should decide the appropriate place (i.e., either § 63.2 or § 63.202) for the revised definition to appear.

6. The term “ground water” is defined in one part of the regulations to include the vadose zone (§ 63.2) and in another part to exclude that zone (§ 63.302). This will create needless confusion in the implementation of the rule. The staff should develop one definition that applies in all cases, but maintains consistency with the EPA standard.
7. Section 63.16(d) as currently written can be interpreted to mean that the public will be given the opportunity to comment on NRC comments prior to sending the comments to DOE. The intent is that all comments which are sent to DOE will be placed in a public forum to allow the public to comment on them after the NRC comments are sent to DOE. The rule language should be modified to eliminate any ambiguity of when the staff intends to allow public comment.
8. The staff should consider revising, as appropriate, multiple definitions of the same term (e.g., barriers, performance assessment) into a single definition. The staff should develop single definitions that apply in all cases, but maintain consistency with the EPA standard.

Specific Changes to the Final Rule

9. On page 5, paragraph 1, line 3, delete ‘somewhat’. Revise line 5 to read ‘ ... in its final standards **for the purpose of protecting groundwater.**’
10. On page 11, revise line 1 from the top to read ‘ ... EPA standards do not **specify** specific a frequency’ Revise line 4 from the top to read ‘ ... protection. **Although** while we have provided’
11. On page 14, paragraph 1, revise line 2 to read ‘ ... enclosed in about **[The staff should insert the correct number]** 400 individual letters’
12. On page 18, paragraph 1, line 5, delete ‘time-’.
13. On page 19, last paragraph, revise lines 2 and 3 to read ‘ ... Part 63 regulations do not **in any way** lessen DOE’s responsibility ~~in any way~~ to safely site, design, and operate the proposed repository **safely.**’
14. On page 21, paragraph 1, delete the 2nd sentence (In setting these ... the region.)
15. On page 39, revise line 8 from the top to read ‘ ... has revised the rule at § 63.11**1**(b)(1) and (2)’
16. On page 47, paragraph 1, revise line 3 to read ‘ ... permanent closure. **Although** while the primary focus’
17. On page 50, last paragraph, revise line 7 to read ‘ ... confirmation activities. **Although** while the NRC recognizes’

18. On page 52, paragraph 1, revise line 3 to read ‘ ... the rule ~~on~~ in this ~~issue~~ matter.’
19. On page 54, paragraph 2, revise the last line to read ‘ ... are appropriate and ~~has~~ ~~will~~ retained ~~ed~~ them in the’
20. On page 56, last paragraph, revise line 2 to read ‘ ... single performance measure ~~for~~ ~~individual protection~~, the NRC’ Revise the last line to read ‘ ... is appropriate and ~~it~~ is retained in the’
21. On page 57, 1st full paragraph, revise line 8 to read ‘ ... contained requirements to ensure ~~that~~: (1) uncertainties’
22. On page 60, last paragraph, revise the next to last line to read ‘ ... complicate the specification. ~~The approach defined in~~ Part 63, which’
23. On page 61, revise line 1 from the top to read ‘ ... uncertainty, is ~~considered an~~ appropriate ~~approach~~.’
24. On page 63, 1st full paragraph, revise line 8 to read ‘ ... flexibility in deciding ~~on~~ how best to’
25. On page 64, paragraph 2, revise lines 4 and 5 to read ‘ ... the Statements of Considerations ~~s~~ for Part 60’
26. On page 66, 1st full paragraph, revise line 3 to read ‘ ... Commission ~~has~~ ~~will~~ incorporated ~~d~~, an ~~individual~~ dose limit’ Revise lines 5 and 6 to read ‘ ... long held that an ~~individual~~ dose limit of 0.25 mSv/year (25mrem/year) ~~TEDE~~ is (1) a’
27. On page 67, last paragraph, after the period in line 8, insert the following footnote:
“Although an individual might be exposed to more than one source of radiation, it would be a very rare circumstance for that individual to retain the lifestyle and other characteristics of the RMEI for more than one source.” Revise the last line to read ‘ ... result in exposures above the ~~100 mrem/year~~ public dose’
28. On page 69, 1st full paragraph, revise the next to last line to read ‘ ... the total release limit ~~yields less information~~ ~~is less insightful~~ in its application’
29. On page 70, paragraph 2, revise line 1 to read ‘~~Although~~ ~~while~~ a distribution of’
30. On page 71, paragraph 1, revise line 1 to read ‘~~Although~~ ~~while~~ the Commission’
31. On page 71, last paragraph, revise line 11 to read ‘ ... the RMEI assures that ~~the vast majority~~ ~~all other members~~ of the population’
32. On page 72, paragraph 3, revise line 1 to read ‘ ... believes that, ~~although~~ ~~while~~ it is appropriate’ Revise line 3 to read ‘ ... to achievement of ~~the~~ long-term performance objective is not ~~appropriate~~.’
33. On page 72, paragraph 4, revise line 4 to read ‘ ... individual will receive ~~a dose in excess of the~~ ~~greater than his or her respective~~ annual dose’

34. On page 73, 1st full paragraph, revise line 6 to read 'Therefore, ~~although while~~ the Commission'
35. On page 73, last paragraph, revise the last line to read '... Commission ~~has~~ will incorporated~~d~~, a dose limit'
36. On page 74, revise line 1 from the top to read '... ~~believes that this limit is fully protective, and has, in fact, long held that~~ ~~its proposed~~ the slightly higher dose' Revise lines 6 through 9 from the top to read '... in the final rule ~~because it is required in order to be consistent with EPA's final standards,~~ ~~and but~~ not because the Commission is persuaded that its earlier proposal is unsafe, ~~inadequate, or not appropriate~~ in any way. The Commission is confident that the ~~even greater margin of safety afforded by the 0.15 mSv/yr (15 mrem/yr) limit is~~ ~~also~~ amply'
37. On page 74, delete the 1st full paragraph (The Commission believes that ... fully protected.)
38. On page 75, 1st full paragraph, revise line 6 to read '... TEDE ~~to be~~ as the appropriate dose'
39. On page 75, 2nd full paragraph, revise line 4 to read '... 10 CFR 72.104, ~~10 CFR 61.41~~ ~~10 CFR 61.40~~, and'
40. On page 77, revise line 1 from the top to read 'However, ~~to conform to~~ consistent with the EPA standards, the Commission'
41. On page 77, 1st full paragraph, revise the last 3 lines to read '... part of the background radiation ~~and notes that EPA specifically accounted for these sources potentially exposing the RMEI in selecting the relevant dose limits for inclusion in its standards for Yucca Mountain.~~
42. On page 79, last paragraph, revise lines 1 through 3 to read '... agencies (including EPA) ~~follow ICRP's current guidelines that the overall annual dose to members of the public agree that the overall annual public dose limit from all sources should~~ ~~not exceed~~ 1 mSv (100 mrem), ~~in order to be which is~~ protective of all individuals and the environment. ~~These guidelines also hold that exposures from a single practice should be limited to a fraction of this overall dose.~~ The purpose of the'
43. On page 80, delete the sentence in lines 3 through 6 from the top (Consequently, the limit of ... was derived.)
44. On page 80, paragraph 1, a reference should be provided for the statement in the 1st sentence. Revise line 6 to read '... the ground water. ~~Although while~~ the contaminated ground' Revise line 8 to read '... contaminants will ~~be have been~~ diluted to much'
45. On page 80, delete the last paragraph (The International Community ... are necessary.)
46. On page 82, paragraph 1, revise line 10 to read '... There ~~also~~ are ~~also~~ a number of'

47. On page 83, paragraph 2, revise line 4 to read '... Commission ~~also~~ is ~~also~~ aware'
48. On page 86, revise line 8 from the top to read '... physical ones, ~~also~~ have ~~also~~ contributed'
49. On page 88, last paragraph, revise line 1 to read '~~Although~~ ~~While~~ the Commission'
50. On page 89, revise line 6 from the top to read '... ~~Although~~ ~~While~~ there are slight'
51. On page 91, paragraph 2, revise line 1 to read '~~Although~~ ~~While~~ the Commission'
Revise line 4 to read '~~Although~~ ~~While~~ there are'
52. On page 92, revise line 2 from the top to read '... of the RMEI ~~to be~~ is protective of'
53. On page 92, 1st full paragraph, revise line 7 to read '... present day conditions ~~to be~~ as the most'
54. On page 95, paragraph 1, revise line 1 to read '~~Although~~ ~~While~~ it is beyond' Delete the sentence in lines 9 through 12 (The Commission encourages ... (www.nrc.gov/NMSS/DWM/usfic.html)).) Revise line 14 to read '... NAS committee ~~also~~ was ~~also~~'
55. On page 96, revise line 2 from the top to read '... ~~Although~~ ~~While~~ NRC analyses'
Revise line 8 from the top to read '... these processes in ~~its~~ ~~their~~ performance'
56. On page 98, revise line 7 from the top to read '... requirements ~~for the purpose of protecting groundwater.~~'
57. On page 99, item number 2, revise lines 3 and 4 to read '... Part 60, or any others ~~criteria, could~~ ~~can~~ provide truly'
58. On page 100, paragraph 1, revise line 1 to read '... safety and to ~~ensure~~ ~~assure~~ compliance'
59. On page 101, 1st full paragraph, revise the next to last line to read '... and provides the ~~associated technical~~'
60. On page 101, 2nd full paragraph, revise line 1 to read '... would have required ~~and the final rule requires~~ DOE'
61. On page 102, revise line 9 from the top to read '... assessment should ~~ensure~~ ~~assure~~ an evaluation'
62. On page 102, revise line 3 from the bottom to read '... the barriers should be a presented'
63. On page 104, 1st full paragraph, revise lines 7 and 8 to read '... contaminants ~~exists whether or not the waste package is breached. Thus a geologic barrier can provide is present, and provides~~ defense in depth ~~irrespective of releases, even when releases~~

- from the waste package ~~are not occurring.~~’ Revise line 14 to read ‘ ... repository system that can increase confidence’
64. On page 123, 1st full paragraph, revise line 4 to read ‘ ... from Appendix B ~~have been~~ will be incorporated’
65. On page 125, paragraph 1, next to the last line, delete the comma after ‘2001’.
66. On page 134, last paragraph, revise line 3 to read ‘ ... requirements ~~have been~~ will be clarified to’
67. On page 136, revise to next to last line to read ‘ ... abreast of DOE activities ~~and interacting with other stakeholders at the Yucca Mountain site.~~’
68. On page 137, revise line 1 from the top to read ‘ ... interact ~~on various~~ with the principal DOE staff engaged in site characterization’
69. On page 137, last paragraph, revise line 3 to read ‘ ... ~~Although~~ While these activities primarily’
70. On page 138, revise line 1 from the top to read ‘ ... because this provision ~~is consistent with~~ mimics section’
71. On page 139, last paragraph, revise line 1 to read ‘ ... All of the above is in’
72. On page 141, paragraph 1, revise line 9 to read ‘ ... these levels represents, comparisons’
73. On page 142, revise lines 2 and 3 from the top to read ‘ ... ~~the from~~ characteristics of ... group or RMEI. ~~The Commission is quite certain that~~ The NAS did not’ Revise line 5 from the top to read ‘ ... explain more clearly ~~the risks associated with the potential repository at Yucca Mountain~~ complex technical and regulatory issues.’
74. On page 142, last paragraph, revise line 5 to read ‘ ... ~~it we~~ can ~~improve its~~ and need to ~~do better in our~~ public outreach’
75. On page 143, 1st full paragraph, revise line 3 to read ‘ ... Yucca Mountain site. ~~itself.~~ Lastly, DOE maintains an’ Revise line 9 to read ‘ ... program. ~~For those that are interested,~~ The State of’
76. On page 143, last paragraph, revise line 3 to read ‘ ... related to the HLW program ~~also~~ are also distributed to DOE, ~~the State, Affected Units of Local Government, and other stakeholders.~~’ Revise lines 3-5 to read ‘~~Since~~ Effective November 1, 1999, NRC ~~has made~~ is making HLW program documents generated and received available on its Electronic Public Reading Room located at <http://www.gov/NRC/ADAMS> ~~nrc/adams/index.html~~. Revise line 6 to read ‘ ... currently be found at the ~~two~~ designated’ Revise line 7 to read ‘ ... reading rooms (in Nevada):’

James R. Dickinson Library
Government Publications Department

University of Nevada at Las Vegas
4505 Maryland Parkway
Las Vegas, NV 89154 (702) 895-1572 and

Business and Government Information Center
University of Nevada Library
University of Nevada, Reno
Reno, NV 89557-0044 (702) 784-6500 ext. 257

77. On page 144, delete the Response to Issue 8 (The NRC is developing a regulatory ... its inspection, licensing,)
78. On page 145, delete everything from the top of the page through the 1st paragraph (... and other activities on those areas ... totally different proposal.)
79. On page 145, paragraph 2, revise line 8 to read ' ... are in place to **ensure** ~~assure~~ an appropriate'
80. On page 150, last full paragraph, revise line 1 to read ' ... potential risk of **radiological sabotage** to the repository ~~to radiological sabotage~~ during the'
81. On page 153, paragraph 1, revise lines 2 and 3 to read ' ... consultants have been engaged **over the years** in scientific investigations and research ~~over the years~~ necessary to'
82. On page 153, add the following to the last line: 'In addition, this final rule amends 10 CFR 60.1 to clearly state that Part 63, not Part 60, applies to licensing a disposal facility at Yucca Mountain, Nevada.'
83. On page 155, last paragraph, revise lines 8 through 10 to read ' ... with the rule. **At the appropriate time**, ~~t~~~~The YMRP is currently under development by the staff and will be shared with interested stakeholders , as it is developed, and will be published for public comment. After the public comment period, the Commission~~ **Based on the public comments received, the staff** will determine if additional revisions to the **YMRP or** regulations'
84. On page 158, paragraph 1, revise line 5 to read ' ... they **already** have ~~already~~ been determined'
85. On page 159, 1st full paragraph, revise line 9 to read ' ... rule to provide changes **to** ~~of~~ that' Revise line 11 to read ' ... September 14, 2001 (**extension of comment period, 66 FR 27045; May 16, 2001**).'
86. On page 161, revise line 6 for the top to read ' ... 49 CFR **§§** 397.101, 397.103, and'
87. On page 168, paragraph 1, delete the 1st sentence (The NRC is not required ... comment period.)
88. On page 176, in Section 63.111, the staff should describe the revisions to §§63.111(b)1 and 2 -- see the response to issue 3 on page 37.

89. On page 179, revise line 3 from the top to read ‘ ... assurance requirements and ~~more~~ clearly’
90. On page 204, revise line 2 from the bottom to read ‘ ... ~~its~~ their performance assessment used to’
91. On page 206, revise line 2 from the bottom to read ‘ ... specifies how DOE will ~~determine~~ identify which features,’
92. On page 251, revise line 4 from the bottom to read ‘ ... function is to provide a reasonable’
93. On page 253, revise line 7 from the bottom to read ‘ ... which statistically all voids, large and small, are ~~ideally~~ filled with water’
94. On page 270, revise item (a) to read ‘ ... complete as possible in the light of the information that’
95. On page 277, revise item (4)(i) to read ‘ ... important to safety or barriers important to waste’
96. On page 281, item (1), revise line 3 to read ‘ ... under the program required by ~~under~~ Subpart’
97. On page 286, item (e), revise line 2 to read ‘ ... or any part of a proposal is’
98. On page 291, last paragraph, revise line 6 to read ‘ ... performance ~~is~~ are not to be’
99. On page 299, 1st full paragraph, revise lines 5 and 6 to read ‘ ... annual, drinking water ; dose to the whole body or any organ ~~of no greater~~ less than 0.04’
100. On page 305, item (f), next to last line, correct the spelling of ‘environment’.
101. On page 305, revise the last line to read ‘ ... characterizing and modeling the behavior of the barriers.’
102. On page 311, revise line 7 from the top to read ‘ ... to ~~ensure~~ assure safe operation in its safety’
103. On page 317, in the paragraph on “*Test control*”, revise line 2 to read ‘ ... systems, and components ~~important to safety~~ will perform’
104. On page 327, item (a), insert a colon at the end of the line.
105. On page 332, paragraph (d), revise line 1 to read ‘ ... assessments and analyses upon the full range’
106. On page 332, paragraph (c) under Section 63.305, revise line 2 to read ‘ ... reasonable assumptions ~~consistent with present knowledge~~ of the changes in these factors that’