UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

December 2, 2016

MEMORANDUM TO: ACRS Members

FROM: Derek A. Widmayer, Senior Staff Scientist **/RA/**
Technical Support Branch
Advisory Committee on Reactor Safeguards

SUBJECT: CERTIFICATION OF THE MINUTES OF THE ACRS RADIATION PROTECTION AND NUCLEAR MATERIALS SUBCOMMITTEE MEETING ON OCTOBER 18, 2016, IN ROCKVILLE, MARYLAND

The minutes for the subject meeting were certified on November 22, 2016. Along with the transcripts and presentation materials, this is the official record of the proceedings of that meeting. A copy of the certified minutes is attached.

Attachments: As stated

cc with Attachments: A. Veil
M. Banks

UNITED STATES
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MEMORANDUM TO: Derek A. Widmayer, Senior Staff Scientist
Technical Support Branch
Advisory Committee on Reactor Safeguards

FROM: Margaret Chu, Chairman
Radiation Protection and Nuclear Materials Subcommittee

SUBJECT: CERTIFICATION OF THE MINUTES OF THE ACRS RADIATION PROTECTION AND NUCLEAR MATERIALS SUBCOMMITTEE MEETING ON OCTOBER 18, 2016, IN ROCKVILLE, MARYLAND

I hereby certify, to the best of my knowledge and belief, that the minutes of the subject meeting on October 18, 2016, are an accurate record of the proceedings for that meeting.

/RA/ **November 22, 2016**

Margaret Chu, Chairman
Radiation Protection and
Nuclear Materials Subcommittee

Dated

Certified on: November 22, 2016
Certified by: Margaret Chu

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
RADIATION PROTECTION AND NUCLEAR MATERIALS SUBCOMMITTEE
MEETING MINUTES
October 18, 2016
Rockville, MD

The Advisory Committee on Reactor Safeguards (ACRS) Subcommittee on Radiation Protection and Nuclear Materials met on October 18, 2016, at 11545 Rockville Pike, Rockville, MD, in Room T2-B1. The meeting was convened at 1:45 pm and adjourned at 5:59 pm.

The entire meeting was open to the public. Mr. Derek A. Widmayer was the cognizant ACRS staff scientist and the Designated Federal Official for this meeting. Requests for time to make an oral statement was requested by three attendees. Written comments were received from two of these attendees following the meeting, and they are included as Attachments 1 and 2.

ATTENDEES

ACRS

M. Chu, Chairman
J. Rempe, Member
J. Stetkar, Member
D. Skillman, Member
W. Kirchner, Member
C. Brown, Member
D. Bley, Member
J. March-Leuba, Member
A. Veil, ACRS Executive Director
D. Widmayer, ACRS Staff
Dr. James Clarke, Consultant*

NRC Staff

J. Tappert, NMSS/DUWP
D. Esh, NMSS/DUWP
G. Comfort, NMSS/MSTR
R. Chang, NMSS/DUWP
A. Ridge, NMSS/DUWP
S. Dembek, NMSS/DUWP
R. Sun, NMSS/MSTR
A. Kock, NMSS/DUWP
H. Arlt, NMSS/DUWP
B.Eid, NMSS/DUWP
P. Yadav, NMSS/DUWP
L. London, OGC
J. Moore, COMSGB

Others

S. Thomas, Savannah River Remediation
K. Rosenberger, Savannah River Remediation
J. Schlueter, Nuclear Energy Institute
D. Shrum, EnergySolutions
E. Regnier, US Dept. of Energy
D. Tonkay, US Dept. of Energy
J. Marble, US Dept. of Energy
J. Greaves, Member of the Public
R. Seitz, Savannah River National Lab

* Participated by Phone

SUMMARY

The purpose of this Subcommittee meeting was to review and discuss SECY-16-0106, the proposed final rule, 10 CFR Part 61, "*Low-Level Radioactive Waste Disposal,"* and its accompanying draft implementation guidance in NUREG-2175. Significant items discussed and action items committed in the course of the meeting are summarized in the following Tables.

SIGNIFICANT ISSUES	***Reference Transcript Pages***
Chairman Chu called the meeting to order and provided the opening remarks.	4 – 7
J. Tappert, Director of the Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Materials Safety and Safeguards (NMSS), introduced the background for the meeting, and the presenters from NMSS.	7 – 8
G. Comfort, NMSS, provided a presentation and discussion on SECY-16-0106, including the background and history of revisions to 10 CFR Part 61, the interactions of NMSS staff with the ACRS, major revisions to the rule from the last meeting staff had with the ACRS, key comments made by the ACRS and staff responses to the comments, and major comments received on the draft proposed rule by members of the public.	8 – 101 Slides 257 – 288
The following issues were discussed during this portion of the meeting:	
• Clarifying when the rule will be final, how and when the implementation guidance becomes final, and that the Subcommittee only received the guidance at the time of the meeting so could presentations include discussions about it if possible. (Rempe/Chu/Bley)	22 – 26
• Clarifying the number of ACRS Subcommittee and Full Committee meetings that have been held on Part 61. (Bley)	38 – 40
• The time periods for compliance used for radioactive waste disposal, domestically and internationally. (Skillman)	56 – 59

• Where 10,000 years came from, its origin, how the staff chose it to evaluate, and its justification. (Bley)	62 – 69
• That the compliance period evaluates the waste after the site is closed and what does that mean for legacy or old buried waste. (Skillman)	71 – 73
• Whether the staff is consistent with the knowledge management paper recently written within NRC on defense-in-depth. (Bley)	75 – 76
• How long-term stewardship works for sites which will be taken over by an Agreement State, for sites which will be taken over by DOE, and whether the rules for disposal have been harmonized between NRC and DOE. (Bley)	79 – 88
• Whether the 10,000 year analysis is quantitative or qualitative. (Chu)	95 – 97
• Whether staff consider the long-term analyses presently done by Agreement States are conservative. (Kirchner)	97 – 100
D. Esh, NMSS, provided a presentation and discussion on the technical justifications for the main technical revisions to 10 CFR Part 61 and on the guidance provided by staff to implement the revised regulation.	102 – 196 Slides 289 – 322
• The compliance evaluation for already buried waste and how the results would be handled, concerning remedial actions and possibly exhuming waste. (Brown)	117 – 124
• The sources of uncertainty for the 10,000 year analysis and how these will be considered. (Chu)	133 – 137
• How the 500 year timeline for site characterization fits with the 1000 and 10,000 year analysis timeframes. (Kirchner)	157 – 159
• The respective roles of NUREG-2175 with the existing Standard Review Plan for low-level waste disposal and how they are to be used together. (Bley)	180 – 184
• Comments received from the public on the rule and guidance. (Bley)	194 – 195

G. Comfort, NMSS, provided a discussion on the steps to take place for rule with the Commission to approve the rule and for staff to finalize the implementation guidance in NUREG-2175. No comments or issues were discussed during this portion of the meeting.	196 – 199 Slide 286
Dr. J. Clark, from the Consortium for Risk Evaluation with Stakeholder Participation (CRESP), provided a summary of CRESP comments made on previous revisions to 10 CFR Part 61, and comments on the proposed final revisions. His main comments concerned the 10,000 year period of compliance for long lived radionuclides and the uncertainty associated with such a long term calculation. No comments or issues were discussed during this portion of the meeting.	199 – 207 Slides 323 – 336
Three members of the public provided comments on the proposed final rule in SECY-16-0106. These were: Douglas Tonkay, Department of Energy; Roger Seitz, Savannah River National Lab, and; John Greaves, member of the public. Written comments submitted by Mr. Tonkay and Mr. Greaves are included as Attachments 1 and 2, respectively. H. Arlt of the NMSS staff also made a clarifying comment on the subject of uncertainty. No comments or issues were discussed during this portion of the meeting.	207 – 221
Subcommittee Members asked final questions and made closing remarks and summary statements on the matters discussed at the meeting. The following comments and issues were discussed during this portion of the meeting: • How the staff considered the Commission's direction on including the 10,000 year analysis, and whether this was consistent with what Agreement States are currently requiring. (Bley) • When the guidance document would be final, whether it can be discussed at the November Full Committee meeting, and what would need to be done to close the session in November or make sure the discussions can	221 – 252 221 – 224 229 – 235

be held in an open session. (Rempe/Bley)	
Chairman Chu adjourned the meeting.	252

ACTION ITEMS	***Reference Transcript Pages***
1) Distribute White Paper entitled, "*Technical Analysis Supporting Definition of Period of Performance for Low-Level Waste Disposal*," to Subcommittee Members. *Completed*	69
2) NMSS staff determine if NUREG-2175 can be discussed at the November Full ACRS Committee meeting. *Completed* Answer-Yes.	233

ENCLOSURE

Official Transcript of Proceedings, Radiation Protection and Nuclear Materials Subcommittee, Tuesday, October 18, 2016, Rockville, MD.

Documents Provided to the Subcommittee:

1) U.S. NRC, "*Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN 3150-AI92)*," SECY-16-0106, September 15, 2016. (ML16188A290)

2) U.S. NRC, "*Guidance for Conducting Technical Analyses for 10 CFR 61*," Draft NUREG-2175, October 2016. (ML14357A072)

Attachment 1

Dr Chu, thank you for the opportunity to make comments. I will be brief. I, [John Greeves] and Paul Lohaus provided specific comments during the public comment period 7/24/2015.

Paul L. was a principal author Part 61 in the early 80's. Both Paul and I were NRC SES managers responsible for implementing Part 61 requirements and developing the associated guidance for over two decades. After retiring a decade ago we both provided advice to a number of national and international organizations on LLW disposal activities.

The staff has done a good job of listening to and incorporating many of the recommendations provided by us and others with extensive experience with implementing LLW disposal regulations.

One recommendation by numerous stakeholders for a clean two-tiered approach has not been incorporated.

A blended two-tiered analysis has been recommend and incorporated by the staff.

A "kind of a two tier system" [as labeled by Gary Comfort earlier today] is not clean; it will be difficult to implement and will result in unnecessary litigation risk. This moving target will be a significant risk with such a subjective approach that can be argued by multiple parties either way.

A clean two-tiered (i.e.; 1,000y compliance period; a tier-2 1,000y-to-peak dose) approach would be adequate to ensure safety through a 1,000 year compliance period, and second tier analysis out to peak dose. DOE uses such an approach two-tiered approach.

This would eliminate the need for a separate new lengthy rulemaking to address waste classification for waste streams containing large quantities of long lived material.

I would add, in my opinion, requiring compliance, pointing at a "guidance document" to determine a specific compliance period (either 1,000 vs. 10,000) is not an appropriate regulatory approach, and unnecessary, if a clean 2-tier system is specified.

The Commission needs to make a clear final call, on this 1 vs. 10k y compliance period number. It is a policy call.

Thank you for the opportunity to provide these few comments.

Attachment 2

DOE Remarks Regarding NRC Staff Revisions to Draft Final 10 CFR Part 61 (October 18, 2016) -- Revised as given

Good afternoon, I am Douglas Tonkay, the Waste Disposal Office Director with the Department of Energy's Office of Environmental Management. DOE is responsible for regulating low-level waste disposal facilities at sites across the country. In doing so we have technical requirements for maintaining our performance objectives as well as setting site-specific waste acceptance criteria at our disposal sites. In addition, our directives allows utilization of commercial disposal facilities, which are directly impacted by this rule. So, we have significant interest in any changes to 10 CFR Part 61.

I would like to thank the Subcommittee for providing the opportunity to share DOE views on the NRC staff's draft final rule. Please note that, DOE was not given an advance copy, so we have not had time to review thoroughly all of the proposed amendments and their supporting rationale. We would appreciate the opportunity to provide further observations at the full Committee meeting in November.
In July 2015, DOE provided comments on the then proposed revision. We are pleased that the NRC staff considered and accepted many of our comments. I want to address three areas for which we remain concerned based on our initial review of the Federal Register notice.

First, the draft final rule, as we understand it, effectively proposes a default compliance period of 10,000 years for long-lived waste with a performance objective of 0.25 mSv annual dose limit. The Commission directed, and we agree, that a 1,000-year compliance period be used. Multiple Commissioners observed that using a 10,000-year compliance period in this context "provides false comfort . . . [based] on guesswork and subjective speculation". We also agree with the ACRS, which stated in a letter to the Commission that, "Introducing significant uncertainties to the performance analysis through speculation on human activities, waste and site performance, and earth processes for millennia is unlikely to improve either our decision making process or our understanding of the safety decisions regarding near surface [low-level waste] disposal." We note that NRC regulations for materials and sites that are comparable to near-surface disposal of low-level waste establish compliance periods of 1,000 years at most. In light of these considerations, we prefer to see a final rule with a compliance period for an annual dose limit to 1,000 years, while requiring qualitative consideration of analyses for longer time periods, up to the point of peak dose but not extending beyond the period of geologic stability. Let me clarify Dr. Esh's statement that DOE has used 10,000 years for Waste Incidental to Reprocessing analysis. This occurred because it is in NRC NUREG guidance used by NRC technical staff and we are required to complete consultation with them. It is not a DOE directive.

Our second concern is that the rule continues to include radon in the dose-based performance objectives. This inclusion of radon is inconsistent with other EPA, NRC, and DOE regulations that address

management of uranium-containing materials. Including radon in the calculation of annual dose imposes a limit for future exposures to a limited number of hypothetical receptors that is significantly lower than the levels currently accepted as guidelines for residential exposures across the country today. To establish more restrictive limitations in the context of an extended performance assessment that entails significant and irreducible uncertainties would be particularly unwarranted. Therefore, the final rule should exclude radon from dose calculations and instead include a performance objective with a flux standard for more consistency with other national requirements for disposal of wastes containing uranium.

Finally, DOE suggests that a draft of NUREG-2175 be made available for comment before the rule is finalized. The draft final rule indicates that a substantial amount of additional information has been moved to guidance, and similarly, that a large number of "clarifications" appear in the NUREG. What information is included and how the regulatory provisions are interpreted can have a dramatic effect on implementation, particularly concerning the scope and conduct of performance assessment over extremely long time periods. While the staff indicated that changes could be made in the future, it could be many years, if not decades, before a revision to the guidance is available.

Thank you again for the opportunity to present our views. DOE will continue to monitor progress of the rulemaking and would appreciate the opportunity to provide further observations at the full Committee meeting.

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on Reactor Safeguards
Radiation Protection and Nuclear Materials

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Tuesday, October 18, 2016

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

(ACRS)

+ + + + +

RADIATION PROTECTION AND NUCLEAR MATERIALS

SUBCOMMITTEE

+ + + + +

TUESDAY

OCTOBER 18, 2016

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ROCKVILLE, MARYLAND

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The Subcommittee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B1, 11545 Rockville Pike, at 12:59 p.m., Margaret Chu, Chair, presiding.

COMMITTEE MEMBERS:

MARGARET CHU, Chair

DENNIS C. BLEY, Member

CHARLES H. BROWN, JR. Member

WALTER L. KIRCHNER, Member

JOSE MARCH-LEUBA, Member

JOY REMPE, Member

GORDON R. SKILLMAN, Member

JOHN W. STETKAR, Member

ACRS CONSULTANT:

JAMES CLARKE*

DESIGNATED FEDERAL OFFICIAL:

DEREK WIDMAYER

ALSO PRESENT:

HANS ARLT, NMSS

GARY COMFORT, NMSS

DAVID ESH, NMSS

JOHN GREAVES, Public Participant*

LISA LONDON, OGC

CHRIS McKENNEY, NMSS

ROGER SEITZ, Savannah River National Lab

JOHN TAPPERT, NMSS

DOUGLAS TONKAY, DOE

ANDREA D. VEIL, Executive Director, ACRS

PRIYA YADAV, NMSS*

*Present via telephone

C O N T E N T S

P R O C E E D I N G S

12:59 p.m.

CHAIR CHU: Good afternoon. The meeting will now come to order. This is a meeting of the Advisory Committee on Reactor Safeguards, Subcommittee on Radiation Protection and Nuclear Materials.

I'm Margaret Chu, Chairman of the Subcommittee. ACRS members in attendance are Joy Rempe, Charlie Brown, Jose March-Leuba, and John Stetkar, Dennis Bley, Dick Skillman, and Walt Kirchner.

Dr. James Clark from Vanderbilt University is participating in the meeting and joins us today by telephone. Dr. Clark will provide a summary of comments provided on previous versions of Part 61, submitted by the Consortium for Risk Evaluation with Stakeholder Participation.

We call it CRESP. Which is a research organization funded by the DOE. And then he will provide comments on the current version of the Part 61 in the role as a consultant to the ACRS.

Derek Widmayer of the ACRS staff is the designated Federal Official for this meeting. Now the purpose of today's meeting is for the NRC staff

to discuss and propose the final 10 CFR Part 61, Low Level Radioactive Disposal.

The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions as appropriate for further consideration by the full Committee.

Detailed proceedings for conduct of ACRS meetings was previously published in the Federal Register on October 1, 2014. The meeting is open to public attendance.

And we have received two requests for time to make oral statements. Time for these statements is provided on the Agenda after the presentation on this matter.

A transcript of today's meeting is being kept. Therefore, we request that meeting participants use the microphones located throughout the meeting room when addressing the Subcommittee. Participants should first identify themselves and speak with sufficient clarity and volume so they can be readily heard.

There's a telephone bridge line established for this meeting. So we request that participants on the bridge line please keep their

phone on mute to minimize interference with the audio reception on the meeting room.

At this time I ask that attendees in the room please silence all cell phones and other devices that will make noise to minimize distractions. And I remind speakers at the front table to turn on the microphone when speaking. And likewise to turn off the microphone when you're not speaking.

Before we being, I would like to take a moment to acknowledge one of our presenters today, Dr. David Esh from the office of Nuclear Material Safety and Safeguards, was the recipient of the 2016 NRC Honorary Distinguished Service Award. Namely for his work in the area of performance assessment, which we'll hear later.

The Distinguished Service Award is the highest honor granted by the NRC to an individual based on outstanding achievement. Congratulations Dr. Ech. And we look forward to hearing from you today.

We will now proceed with the meeting. I call on John Tappert, Director of the Divisions of Decommissioning Uranium Recovery and Waste Programs of the Office of NMSS to make introductory

remarks.

MR. TAPPERT: Thank you, Chairman. Again, my name is John Tappert. I'm with the Office of Nuclear Material Safety and Safeguards.

The staff appreciates the opportunity to brief the Committee today on the draft final rule for Part 61. We've been on a bit of a journey. The routes of this Rule go as far back as 2005 when the Commission directed the staff to look at the depleted uranium which was being introduced in the waste streams, and determine whether Part 61 should be modified as a result.

In the intervening years, there have been a number of SECY papers, Commission briefings, briefings with the ACRS, briefings with the Compacts and then various other stakeholders. And the culmination of that work was the draft on the Rule which we just presented to the Commission recently.

So we look forward to the opportunity to share the results of our work and responds to your questions.

Today's presentation will be given by two of our senior staff, Gary Comfort, who is a Senior Project Manager in our Rule Making Group.

And has been responsible for shepherding it through the rule making process.

And Dr. David Esh, who you just spoke of, is with our Performance Assessment Group. And he'll be relaying more of the technical elements of the Rule.

So, without further ado, I'd like to turn it over to Gary.

MR. COMFORT: Well good afternoon everybody. As John indicated, my name is Gary Comfort. I'm in NMSS, in our Division of Material, Safety, State, Tribal and Rule Making Programs.

Today Dave and I are planning on providing an overview of our draft final Rule that we recently submitted to the Commission on -- that would update the low level radioactive waste disposal regulations in 10 CFR Part 61.

We last discussed this issued before the ACRS in 2013. So it's been a number of years since we've last seen you all. Go to the next slide.

During my portion of the presentation, I'm planning to summerize the activities that have occurred since we last met with you. And provide an overview of the changes that would result from

this draft final Rule being implemented.

But first I'm going to go over what the purpose of the Rule is. Why we're doing the Rule. And what Commission direction it was based on.

Also I'll go over a quick summary for you of the part interactions that we've had with ACRS and some of the comments that we've gotten out of ACRS. After that I'll provide an overview of the draft final Rule itself. What the major, you know, summary of the changes as well as get into a little bit of the specific Rule language.

Dave will then follow up with getting into the technical basis for some of that Rule language that we -- and Rule changes that we've done.

You know, and then after that I'll provide basically a summary of where we're going to go from here. What happens to the rest of the rule making processing? Just so you're familiar with it.

We welcome your questions and comments. And you know, we're looking forward to, you know, final draft letter -- or the final letter that goes to the Commission. And they'll use that in their review of the final Rule and they're, you know,

during the decision to approve or affirm it.

On the next slide, first I'd like to get into the purpose of what the Rule is really supposed to be doing and what it's intended to solve. The current 10 CFR Part 61 regulations were mostly developed in the early 1980s.

As such they focused in dealing with wastes that were currently being disposed of at that time period. Most of the evalu -- or the evaluations were based upon inventories that were being disposed of at the time.

In the following 30 years since that time, there's been a lot of other types of wastes that weren't initially envisioned at that -- or that weren't ongoing at that time that are now potentially being disposed of.

For example, in the 1980s uranium enrichment was exclusively operated by the Department of Energy and the Government. And the wastes were therefore disposed of. And it wasn't expected that large quantities of depleted uranium could be disposed of in a commercial low-level waste site.

Since then, we've basically gone into the idea of privitiz -- we've issued licenses for

privatized uranium enrichment facilities. And so therefore, the waste from those would be expected to go to a commercial waste site.

And when we did the original 1982 revision of Part 61 as I indicated, this type of waste wasn't envisioned to the point that really it wasn't even addressed in that Rule, in the final Rule. And so therefore, it defaults into a Class A waste.

Another issue that came up since then is the idea of blending wastes. Where you basically would take higher classes of waste and combine it with larger quantities of lower class waste. And dispose of it as a low level classed waste.

So that's something else that came up upon, you know, during this rule making that we were looking at. The problem is that, you know, these blended wastes could result in quantities of waste near the top concentrations of the Class level then were originally evaluated as part of the original 10 CFR Part 61.

So, the purpose of this rule making is really to develop a strategy that would allow these different types of new waste and waste that occur

in the future that we don't know about now that would have a pathway for evaluation and potential disposal on low level waste sites. Next slide.

So, to resolve the problem -- these types of problems, the NRC staff decided to create an approach where the 10 CFR Part 61 regulations would instead focus and use a more performance and risk-based approach by requiring site specific analysis. Including for waste disposed of under the existing waste classification tables.

The site specific analysis will help to ensure that the waste streams that were not originally addressed in 1982, or that are disposed of in conditions or concentrations outside the original assumptions of the 1982 evaluations. That they're being safety disposed of.

Implementation of the new Rule is intended to reduce ambiguity and facility the disposal of these previously disposed -- previously unanalyzed wastes. In addition, some rule changes were made to better align 10 CFR Part 61 regulations with updated existing health and safety methodologies.

MEMBER SKILLMAN: Gary, before you change, and would you back up to three, please?

You mentioned in your comments that there was depleted uranium prior to this rule making activity.

It was basically DOE and it was probably defense related. Is it the vision of this rule making to reach back to those waste locations also?

MR. COMFORT: Well, I mean, if they're under the Department of Energy, they have their own regulatory scheme. So this Rule would not directly affect those, no.

MEMBER SKILLMAN: So the answer is no.

MR. COMFORT: So the answer's no. Yes sir, right.

MEMBER SKILLMAN: Okay. Thank you.

MR. COMFORT: Okay now I'm going to briefly go over, you know, some of the direction that we've gotten. Because all of this rolls into why, you know, where the Rule came out to become on it.

So, first of all, starting with the Commission direction that we've gotten over the years. Which has changed a little bit. Or, you know, become updated by the Commission as you'll see.

Subsequent -- I've got the wrong -- okay. So, basically we originally got the direction as John indicated, out of some proceedings that were ongoing with Louisiana Energy Services.

They basically took -- that took place in 2005 where the question arose as part of those proceedings about the classification of DU as a Class A low level waste. It kind of fell in default because it wasn't directly addressed in the Part 61 1982 Rule.

As a result of those proceedings, the Commission outside of the proceeding directed the staff to consider whether the potential quantities of DU, depleted uranium that were generated by commercial uranium enrichment facilities warranted amending the Waste Classification Tables.

So, based on this direction, the staff performed a technical analysis to evaluate the impacts of near surface disposal of large quantities of DU. The staff submitted the results of the analysis to the Commission as part of SECY 08-0147, which was response to Commission Order CLI-05-20, regarding depleted uranium, dated October 7, 2008.

In response to this paper, the Commission directed the staff to -- in a Staff Requirements Memorandum, or an SRM, which was identified as SRM SECY 08-147 to begin a rule making to require site specific analysis for disposal of large quantifies of DU.

With this direction the staff then began a series of public meetings where we went out and tried to get some insight of what people thought were the major issues related to this.

And basically the other thing that the Commission said, is to develop supporting guidance and technical basis for this. As well as to maintain the waste classification of DU.

Now, since that point, the Commission has told us on the waste classification to revisit that subject after we complete this Rule.

MEMBER CORRADINI: Garry, what do you mean by maintain the waste classification?

MR. COMFORT: It's right now defaulted as Class A waste. So, they said, don't go in and change the waste classification.

MEMBER CORRADINI: And maintains means?

MR. COMFORT: Keep it the same right now.

MEMBER CORRADINI: Okay. Thank you.

MR. COMFORT: Right. And that's what I was just saying. They have actually asked us after we've finished this project, to go back and re-look at the Waste Classification Tables, including DU in them.

And so we have a product due to the Commission eventually on that.

MEMBER BLEY: Could that have any substantial impact on what you've been doing for all these years to get ready for this Rule?

MR. COMFORT: Well, we had actually asked the Commission that a few years ago. I mean, you know, do we have --

MEMBER BLEY: Do we have separated for depleted uranium?

MR. COMFORT: Yes. Should we do a complete rule making, you know, now instead of this specific one. But they decided that because of the issue of DU that was going on at that time, that it was more eminent to go ahead and try to deal with that.

And we feel that actually the end result of the Rule itself creates a safety program that despite whatever the classification is, if

something is going to be disposed of in these low-level waste sites, they will be shown that it's safe to dispose of it.

So, you know, in some ways the classification system other then it's a legal, you know, coming out of statutes, it would, you know, isn't as necessary.

MEMBER BLEY: Okay.

MR. COMFORT: So, revising it may not be considered as important or absolute. But it's something that we have a project to have to do, is to look at it.

Okay. Now so we underwent -- started doing the rule making. And while we were doing that and going out and just starting the regulatory basis for the rule making, the other issue came up of blended waste.

So, basically the Commission direct -- based on a then Chairman's direction, the staff developed an analysis of issues associated with blended wastes. And submitted that evaluation to the Commission in April 2010 as part of SECY 10-0043, which is blending of low level radioactive waste.

In response to this paper, the

Commission directed the staff to incorporate the issue of blending into the ongoing DU rule making that we were doing. So, based on the updated direction, we updated the regulatory basis and continued working on the Rule.

And we went out and basically put out the regulatory basis for public comment as well as with some preliminary Rule language. While we were finishing up the proposed Rule package, the Commission instead came down with additional new direction in the form of the listed SRM up there.

That basically told the staff to allow flexibility for licensees to use recent ICRP dose methodologies in their site specific performances' assessment for the disposal of all radioactive waste. And to establish waste acceptance criteria based on a site specific technical analysis.

The Commission also directed the staff to use a two tiered approach that establishes a compliance period that covers the reasonable foreseeable future. And a longer period of performance that had no defined period or limits to evaluate the performance of a site over the longer time frames.

The period of performance was to be

developed based upon a candidate site characteristics such as waste package, waste forum disposal technology, cover technology and geo-hydrology, and the peak dose to a designated receptor.

Finally, the Commission wanted the Rule to have compatibility requirements that would ensure alignment between the States and the Federal Government. So this basically readjusted where we're going with the Rule that we put out, or for preliminary rule writing.

CHAIR CHU: Gary, I'm not familiar with the blended waste. Can you elaborate on that?

MR. COMFORT: Okay. Blended waste, you know, again, if -- you have basically a Class A, B, C wastes and greater then Class C.

Basically the idea that was being envisi -- or looked at at that time is if you have large -- if you have small quantities of let's say a Class B waste, could you combine it and basically lower the classification by combining it with large quantities of Class A waste, and dispose of it as Class A waste?

So, that's where the blending comes of the two waste categories. And that's again where

the Commission's concern was that when we had originally done the Part 61 rule making, we had looked at, well, what is the average concentration going to be disposed of?

Now we're looking at a pathway that you could be much closer to the limits of the Class A waste -- or to the waste categories.

So, we got this direction from the Commission, and we redid the Rule, you know, and basically finally we got a proposed Rule to the Commission in 2013 for review and approval. And that was identified as SECY 13-0075.

This is actually the latest ruling which that the ACRS had been reviewing. And they provided comments while that paper was up with the Commission.

In that package, the staff had proposed a new and updated technical analysis using a two-tier system, as was directed by the Commission. With a compliance period of ten thousand years, followed by a qualitative performance period.

It included a performance analysis -- or a performance assessment with a compliance period limit of 25 millirem per year. Which is basically what we were using.

But, the current regulations didn't have a time frame associated with it. And it also included a new requirement for an inadvertent intruder assessment with a limit of five hundred millirem per year.

And just as aside, when I'm mentioning the term an inadvertent intruder assessment, or when I'm talking about intruders in general, I'm not talking about somebody who's purposely going onto the site to disrupt the waste. I'm talking about somebody who after the site's been closed, really isn't aware the site is there and starts doing normal activities and the impact around that.

So, in response to the SECY that we provided the Commission, the Commission directed publication of the proposed Rule. But, they identified a significant number of changes that they had the staff do before we put it out as a proposed Rule.

I'll get over -- onto those in the next slide. But one of the other items that they did, is they encouraged the ACRS to continue involvement in the rule making. And to -- and I should have shifted the slide to start. It's just skipping -- yes.

MEMBER REMPE: Actually, before you leave that slide, did you want to finish the last bit?

MR. COMFORT: Yes. This is the one. Yes.

MEMBER REMPE: Okay.

MR. COMFORT: So, basically they directed the staff to -- or encouraged the ACRS to provide independent review and recommendations on the Rule. And which is why we're here.

MEMBER REMPE: And I looked ahead. And you're planning now to publish the Rule. But then you're going to delay and publish the guidance after the Rule is published?

MR. COMFORT: No.

MEMBER REMPE: Is that the plan? Because I thought that was in one of your slides?

MR. COMFORT: No. The Rule and the publi -- the Rule is going to be published, or the plan is to publish it at the same time as the guidance is published. Or the guidance with the Rule and stuff.

If it's incorrectly stated in one of the slides, it's a mistake.

MEMBER REMPE: Okay. I didn't

understand the words. But I just wanted to make sure. So --

MR. COMFORT: Yes. No, the intent is that both documents will be published on the same day. And be, you know, be usable on those dates.

MEMBER REMPE: Okay. So, we just got, I guess, the guidance today?

MR. COMFORT: Right.

MEMBER REMPE: Okay. I just wanted to understand that.

MR. COMFORT: And the guidance isn't publically available at this point.

CHAIR CHU: Is that the usual way? The Rule and then the Reg Guide goes together?

MR. COMFORT: Yes. The Commission now has basically for all Rules they've intended that both when we issue proposed Rules, to have proposed, you know, draft guidance for review and comment. Because it helps you, of course, you know, understand what the intent of the Rule is.

CHAIR CHU: Got you.

MR. COMFORT: And how we plan on, you know, implementing it.

CHAIR CHU: Okay.

MR. COMFORT: And it's the same thing

with the final Rule. Okay. So --

MEMBER BLEY: And since that subject was brought up, glancing at the slides, I think David's going to talk about the guidance. And I suspect -- well, I hope when you do that, you've got your slides laid out to make it clear to us what's changed in the guidance as you go through.

Because we will not have read it by today of course. And we will, if we have time, have read it by the time of the full Committee meeting. So, we might have a lot more questions then, then we have now.

But, if you can -- the better you can point out what's changed, the more it will help us.

DR. ESH: Sure. I can try to do that. And it is a short document. So, it shouldn't take you long at all to --

MEMBER BLEY: It is? Okay. It wasn't so short before.

DR. ESH: It's pretty long.

(Laughter)

DR. ESH: So, it will be helpful -- it wasn't the 575 pages.

MEMBER BLEY: That was the before, right? Or is that the new one? They're the same.

Okay.

DR. ESH: But, it will be helpful to point out what areas changed and where the new material is compared to the old material.

MEMBER REMPE: So, just to clarify my confusion in the second presentation, we'll hear from you, it says, the final guidance document has been developed.

And it's in concurrence. And it will be issued after the Commission approves the final Rule publication.

So, your plan is to publish both the draft guidance and the Rule. Then the Commissioners will approve the Rule. And you'll make any changes to the guidance. And then you'll finalize that.

MR. COMFORT: Right. I mean, the guidance is --

MEMBER REMPE: Because I just didn't understand that.

MR. COMFORT: Yes. The guidance is substantially completely. But the Commission can and does occasionally make changes when they affirm the final Rule that we have to incorporate.

And we'd want to make consistent

changes so we're not finalizing the guidance at this point. And I'll get into that -- you know, where do we go from here at the end of the -- you know, after Dave's presentation and stuff.

But we'll get into some of that also.

MEMBER BROWN: But before you go on, I think there's a question for Gary. We got -- one of the copies you sent us was a red lined, strike out version of the Rule.

And it had the stuff -- is that the most current? Is that the --

MR. COMFORT: Yes. That -- what you received is a red lined, strike out versus the current Rule language. It incorporates --

MEMBER BROWN: Yes.

MR. COMFORT: What we sent to the Commission. So that is the --

MEMBER BROWN: So that is -- I mean, take out all the strike outs and you end up with what you intend to publish, --

MR. COMFORT: With what the final Rule --

MEMBER BROWN: Right?

MR. COMFORT: Yes.

MEMBER BROWN: Okay. So, that had it

in red. So it was pretty easy to --

MR. COMFORT: Right. It shows you where the significant change -- or where the changes were.

MEMBER BROWN: Okay. Yes. I wasn't that. I just wanted to make sure I was looking at the right thing.

MR. COMFORT: Yes. Because I'll be going over some of the major changes. But that document shows all the editorials and small things that I'm not going to be going over.

MEMBER BROWN: Okay.

MR. COMFORT: I'm not going to go over it word by word.

MEMBER BROWN: No. I'll pass those.

MR. COMFORT: Yes. I thought that would be laborious if I tried to do that.

Okay. So, as I said, the Commission provided us a lot of changes which is not usually normal without them asking to see it back before we publish the Rule. In this case they said, you know, make these changes and go do it.

Well, for example, this basically on the right side of the -- well, left side of the chart, shows what was in the Rule that we sent to

the Commission in SECY 13-075. And this is for the proposed Rule.

And this basically is a summary of the things that were in the published Rule. And the color changes show where areas that the Commission changed.

And so you'll see they're in some substantial areas of the change -- of the Rule. For example, --

CHAIR CHU: So, the right-hand side is the --

MR. COMFORT: Is what we actually propose -- or sent out, published it.

CHAIR CHU: The proposed final --

MR. COMFORT: Yes. The published proposed Rule. Not the -- yes, it's the -- not the final Rule.

CHAIR CHU: It's not the final Rule.

MR. COMFORT: The final Rule, that's the next stage, yes. But this is what we proposed for public comment. So, this is what went out for public comment.

CHAIR CHU: Oh. For public comment.

MR. COMFORT: Right. So, this -- I want to get into this just because when we start

talking about the public comments, you need to know the time frame -- or I mean, get the frame of reference of what those comments were based on.

Because of course, we incorporated a lot of changes into the final Rule based on those comments. So, for example, on the analysis time frames, we've gone forward with a two-tier approach for time frames.

We've basically, as I had indicated before, a ten thousand year compliance period. Followed by a performance period.

The Commission instead directed us to go through and do a three-tier approach. With basically one thousand year compliance period versus a ten thousand. But they added in between this protective assurance period. Which was from one thousand to ten thousand years.

And for the performance assessments, we were to apply a five hundred millirem dose goal. It wasn't supposed to be a limit. But it's just basically do as reasonably achievable so you can get to that, you know, the minimized doses to get to that limit.

MEMBER BLEY: Did the Commission specify the thousand year?

MR. COMFORT: They specified the thousand year in their document panel. And then it was followed by the performance period. Which was again, a qualitative type rule.

For the intruder assessment it was kind of -- they basically said, leave that similar to the same. That you're going to have a five hundred millirem limit for the first thousand years.

But then you have a five hundred millirem dose goal for the second -- for the thousand to ten thousand years. And then again, a qualitative review after that in the performance period.

The other thing that they did on the intruder assessment there was for the scenarios for it, because they were concerned about uncertainties which the Committee also sent its concerns about.

They directed us to make sure that the scenarios were based on activities that were ongoing at the time of closure of the site. And so, you know, rather then looking ten thousand years out in the future and trying to guess what was going on.

So, just base the assessments on what was current -- or what was going to be happening at

the closure of the site.

They also directed us to add some discussion of defense in depth analysis as well as an explicit description of safety case. So, those were new things. I mean, again, new concepts being added into the Rule, you know, after we'd sent it to the Commission.

And then the other major thing that they did was to basically direct us to change the Compatibility Category from a C to a B for the major provisions of the Rule.

Now a Compatibility Category is when the Agreement States who are actually regulating all of current licensees, they have to adopt regulations that are compatible with our regulations. And we assign a Compatibility Category with those.

So, for example, Compatibility Category B says that you have to make the regulations effectively the same. You know, use the same language to the greatest extent in all that stuff.

Compatibility C says you have to meet the effective goal of it. But you could be more conservative.

So, for example, you know, in this kind

of case, you know, we're saying a thousand year compabil -- or a compliance period, they'd have to meet under Compatibility B, they have to have a thousand year compliance period.

Under Compatibility C, they could have a thousand years, they could have longer then that, five thousand, ten thousand, whatever period they wanted. But the Commission had directed us because they wanted the consistency in the regulations to Compatibility B.

So, -- go ahead.

MEMBER BROWN: I just want to clari -- make sure you keep talking about intruder, inadvertent intruder. And you made a comment a minute ago that an inadvertent intruder is somebody who goes there after the site is closed, inadvertently don't know what's going on.

MR. COMFORT: Right.

MEMBER BROWN: When a site is closed, does it look like just a great green soccer field? I mean, is it a green field? There's no signs, no nothing?

I mean, in a --

MR. COMFORT: I'll let Dave answer that.

DR. ESH: All right. So, when it's operating of course, there's physical barriers to somebody accessing the facility.

MEMBER BROWN: Of course.

DR. ESH: And then at the -- there's a five-year observation and maintenance period at the time of closure. That the idea is that the licensee will ensure that the changes they made to prepare the site for closure have not caused any negative affects to the potential of the -- the potential performance of the site after closure.

So then the institutional control period starts. And the institutional control period starts is still an actively maintained period where access to the site maybe prohibited by fences and signs and that sort of thing.

But the institutional control period is only allowed to be credited in the regulation of up to one hundred years after the point of closure. So, there will be some potential limitation of access to the site during the institutional control period.

But, after the institutional control period, there's no requirement to provide barriers to access of the site. So, if the engineered cover

was designed such that it looked like a green field, then yes, it would just look like a green field.

If it was like some of the engineered covers that are used for erosion protection control that have the large rick-rack designs, then it would look like a big mound of rocks essentially sitting on the surface.

So, it would depend on the design and the facility what it would look like at that point.

MEMBER BROWN: Well, if some development occurred, you could come in and there could be houses, there could be a mall, and --

DR. ESH: Right.

MEMBER BROWN: All that kind of stuff. Okay. That's -- I just wanted to understand. So, that's after the institutional period though.

DR. ESH: Right. Correct.

MEMBER BROWN: Okay. Thank you.

MR. COMFORT: And that's why again, they were saying, you know, look at what's going on at that time period, you know, when closure occurs as to what the ongoing activity is. So, if you've got housing near there, you know, assume it -- if there isn't, if it's a big, you know, desert kind

of thing, we're not going to make you assume that somewhere a thousand years from now that population will move in there at all.

You may consider some sorts of intrusions, but, you know, they said use realistic scenarios. Or that's what the regulations are requiring.

MEMBER SKILLMAN: Gary, let me ask this. As I looked at the Compatibility Categories, this is from the handbook, 5.9 part two.

MR. COMFORT: Right.

MEMBER SKILLMAN: It's certainly confusing to me how you can -- not you -- how this discussion can say, now it's a B and not a C when it almost appears Category A is the most applicable.

MR. COMFORT: Because of the health and safety --

MEMBER SKILLMAN: Yes.

MR. COMFORT: Right.

MEMBER SKILLMAN: So, what is the discussion that certifies?

MR. COMFORT: Yes. Because Category B is trans-boundary issues and stuff, and how you say these are trans-boundary issues. This is one of

those why, you know, I mean, partly why we looked at these. And This is an area where we got a lot of comments on and stuff.

And so I'll get into that. But we -- you know, most people agreed with you, how would -- does that occur? Why wouldn't it be A? Or why isn't C appropriate?

You know, for example on the compliance period evaluations, a lot of stakeholders were like well, my current State, you know, requires ten thousand years for the evaluation. You're basically saying limit that.

You know, it's going to make an unsafe -- a less safe review and all.

MEMBER SKILLMAN: Right.

MR. COMFORT: So, that's one of the things we considered when we did the final Rule. And we basically did go back and revert some of these major things from B. Or we recommending to the Commission that they be revered from what was designated as C -- or B, back to the C category.

So, the Agreement States can have their flexibility and, you know, maintain safety appropriately and all.

DR. ESH: And one thing I would add to

that as -- the Commission did give direction for compatibility B. But that's an area they specifically said to seek comment on.

Because I think they said we're going to make it B. But, let's see what our stakeholders think about it, was my interpretation of their direction.

MEMBER SKILLMAN: So, the conclusion is, it will be B. And while it's not universal consensus, there is acceptance of that category?

MR. COMFORT: Well, for publication of the proposed Rule it would be. In the final Rule we did change some of the major provisions back to C so that they have more flexibility as to, you know, they didn't have to meet it exactly. They could use longer time periods. Or use some alternatives.

MEMBER SKILLMAN: And you're going to discuss this a little more?

MR. COMFORT: Yes. I'll be getting into that. Just what about their comments --

MEMBER SKILLMAN: A little later. Thank you.

MR. COMFORT: Into the final Rule that we've done.

MEMBER SKILLMAN: Thank you.

MR. COMFORT: Okay. So, that really brings us up to the publication of the proposed Rule. I'm going too just quickly step back to discuss the past ACRS interactions that we've had with you.

Just to remind you, the Committee and the new members, of what types of comments that we've gotten in the past on it. I'm not going to try to go over our feelings on some of them and all.

But, as you can see by the slide, we have had a number of interactions with you on Part 61 in the past. They started in 2009. The last one as I said, was in 2013.

After most of them, I mean, we had two in 2011. One was on the Rule. One was on the guidance. We got a single letter.

But, after each of those we did get a letter from -- or the Commission got a letter from the ACRS. And we, you know, the staff responded to those letters.

On the next slide I go over some of the key issues so that you --

MEMBER BLEY: Not to bicker, but I'm

looking at what I have is our last letter was issued in February 2014. And we'd had a meeting in February, a full Committee meeting with you in February 2014.

MR. WIDMAYER: I can clarify that. They're identifying Subcommittee meetings that they were presenters at.

MEMBER BLEY: Oh.

MR. WIDMAYER: We've had meetings where they were not presenters.

MEMBER BLEY: Okay. But this was a full Committee meeting.

MR. WIDMAYER: Yes. Our meeting was a full Committee meeting.

MEMBER BLEY: We wrote a letter in 2013.

MR. WIDMAYER: Right.

MEMBER BLEY: We wrote another one in 2014.

MR. WIDMAYER: They were three meetings that were just stakeholder involvement.

MEMBER BLEY: Okay. So that 2014 was just stakeholders?

MR. WIDMAYER: Yes.

MEMBER BLEY: That's the ones we've

had. Okay. I remember. Sam asked for those.

MR. WIDMAYER: Right.

MEMBER BLEY: Yes. Okay. Thank you.

MR. COMFORT: Thank you for bringing that up. So, going through the letters, I mean basically a lot of them had consistent issues from, you know, each letter.

I'm going to go over some of the general issues that I identified that you listed. First of all it said that you -- that the Committee had identified the Rule should be risk informed, based on site specific, realistic performance assessments with considerations for uncertainties.

The realistic assumptions for release in fate transport of view, using a realistic likelihood of intrusion, and a range of site specific conditions. I think actually, you know, when we got that the Commission did, as you saw in one of the slides, at their direction, they were telling us, you know, use realistic scenarios.

They did tell us to address uncertainties and things. So, they clearly adopted a lot of those recommendations.

Your Committee also suggested we use time frames determined on a case by case site

specific basis rather then defining specific fixed period performance and all. That's not something that the Commission went forth with.

They did define the periods of performance, you know, in the forms of the compliance period as well as the performance period with specified time frames and all. Next slide.

The ACRS recommended compliance with the performance objectives after institutional periods should be evaluated considering features, events, and processes, otherwise known as FEPs. Commensurate with the site specific risk.

The ACRS indicated their concerns with the value of requiring inadvertent intruder analysis because of the large uncertainties associated with human intrusion scenarios. And instead indicated that reliance on the durability and stability of the site was sufficient.

And finally, the letters stated that previously disposed waste should not be subject to the new requirements. You know, we've adopted some of these in some form, the Commission has. And others they went forth with, you know, with other approaches, you know, based on what the Commission had published in the proposed Rule.

And although we appreciate all the recommendations put by the, you know, the ACRS as I said, you know, not all of the recommendations have been adopted. And we look forward to see what, you know, comments you do come out for the final Rule.

I think that will be important for the Commission to consider in making their determinations.

MEMBER BROWN: Can I ask to go backwards?

MR. COMFORT: Sure.

MEMBER BROWN: I guess one of my -- I was trying to -- I'm not sure I under -- no. Ahead again.

MR. COMFORT: Okay.

MEMBER BROWN: It's the bottom one. Did you -- let me read that. Should not be subject --

MR. COMFORT: Yes. Based --

MEMBER BROWN: You all did not -- you actually did require the sites to be -- the past, previously posted, to do additional compliance. Is that correct?

MR. COMFORT: Correct. To the extent that they're -- if they're currently operating and

not completely terminated. So I mean, if it's a site that's completely terminated and closed down, we're not requiring.

But, if they're continuing to dispose of waste, then they would have to meet the new regulations and all.

MEMBER BROWN: For the new waste or the old waste?

MR. COMFORT: They'd have to do the performance assessment, which would have to include or address the old waste. But, there would not be an expected impact on it.

MEMBER BROWN: Okay. So, it's new requirements in fact.

MR. COMFORT: But there are -- yes.

MEMBER BROWN: Basically. Okay.

MR. COMFORT: And do you have anything to add, Dave, on that?

DR. ESH: And this was an area that we received a fair number of comments on. And the way I like to think about it is, you know, if you have a disposal facility that has some waste in it today, and then you have some unused capacity that you're going to put some more waste in in the future, the technical analysis that you do is going

to look at the impacts from all the wastes in terms of whether you're meeting the performance objective or not.

There's no -- all of it will contribute say to a ground water plume. And there's no way to separate the contribution, or should you separate the contribution from the waste that was put in previously to the new waste.

All of it contributes to a human health impact. So, if you want to continue to operate, you should include all the waste in your inventory in your assessment. In simple terms that's the description for this question.

CHAIR CHU: Even the old waste and the new waste are the same? You still --

DR. ESH: The old waste and the new waste maybe the same. It maybe different. It maybe similar isotopes. It maybe different isotopes.

If it was different isotopes, then it would be easier to separate it. But that's generally not the case is, you know, the waste that's in the older -- or the isotopes that are in the older waste are going to be similar to the isotopes that are in the new waste.

So, from a health and safety standpoint, if you want to continue to operate, you should be meeting the performance objectives for all the waste that you have accumulated to date and that's the same idea that would apply even if you didn't change the regulations.

Whenever you get the closure, you want to be able to demonstrate that you're meeting the performance objectives for all the waste that you've taken to date. Not just oh, I'm going to separate out some section of the waste that because it was done under earlier requirements and then the new section of waste that I'm going to treat differently.

We didn't think that was a practical or a smart policy approach to deal with operation of these facilities. Now, a facility that's closed, these requirements are not applying to.

So, West Valley or Sheffield or some of the older legacy sites, these are not retroactively being applied to those older sites, these requirements.

MR. COMFORT: Okay. So, moving onto the next slide. I'm going to quickly go over.

We stopped, you know, originally on our

time line at submitting the proposed Rule and it being published. Now I'm going too just briefly update you from that point to the current date.

The proposed Rule was actually published in February 12, 2014. It was published for a 120-day comment period. On March 20 -- or actually, the SRM was provided on February 12, 2014. And the proposed Rule was actually published on March 26, 2015 for 120 comment period.

Because of a number of stakeholder requests, we reopened the comment period from August 27 to September 21. And we received, you know, another few dozen comments on it.

We looked at those comments and we processed them as I'll discuss in a minute. And we finally, you know, developed a final Rule package that we submitted to the Commission on September 15, 2016, SECY 16-0106.

So now I'm going to go over basically the comments that we received during the proposed Rule. Some of the major areas that we received comments on. So, next slide.

We did receive 24 hundred and one comment letters. Of which about 23 hundred were form letters. So, about one hundred discrete, you

know, comment letters.

We did extensive public outreach while the Rule was out there. We held six workshops and a webinar. And we did those workshops at, you know, we recorded them and basically analyzed the information coming out of them to develop any additional comments that weren't in part of the letters. And added them to our comment list.

As indicated, I have a number of the groups that we did get comments from and all. Overall we identified over eight hundred comments.

Which we then bend into groups together. And then responded to as part of the Statements of Consideration that's in the draft Rule package.

Next one. Some of the example -- next slide. Some of the examples of the public comments, one of the big areas was this whole idea of the time frames and how they're doing it.

The Commission as I said, had directed us to put in the proposed Rule the three tiered system. A lot of the comments were that it's much more complicated then necessary.

The comments, you know, felt that it was difficult to understand how to implement in

some ways and what we were wanting out of it.

Some of the stakeholders were concerned about this idea of the five hundred millirem dose goal. I mean, the current requirement in Part 61 is a 25 millirem limit, annual limit for the performance assessment health for -- or for the public dose exposures.

But, you know, that -- there's no time frame associated with it. So, by putting clear time frames, you know, you may not have been going out that far anyway.

So, were we really reducing health and safety? Not really. But to the perception of the public, that five hundred millirem limit was something that, you know, much higher then they expected and all.

So, the response to a lot of these comments, you know, the staff went back and revisited it. And we came up with a new system that we felt was simpler and based upon the public comments overall.

And, you know, we'll get into it in more detail. But, effectively it created back to a kind of a two-tier system. But, the first tier was more site specific based upon what types of waste

that you were going to dispose of.

So, effectively the compliance period would be a thousand years. Or if you're disposing of significant quantities of long-lived waste, then it would be ten thousand years.

And if you didn't have ten thousand year compliance period, you wouldn't even have to worry about the performance period at all. So, if you were just doing, you know, normal low-level waste that's short lived without the significant, you don't have to be -- you'll only be responsible for doing these performance assessments after a thousand years.

MEMBER BROWN: And this change is both in the rule and in the guidance?

MR. COMFORT: This -- yes. Everything that we've made in the rule will be reflected in the guidance that you have, in the draft guidance that we've developed.

And things such as, like I use the word significant quantities of long-lived waste, that's discussed in the guidance. And Dave will get into that a little bit more.

Any other questions? Another area as we discussed earlier was the Compatibility

Categories. You know, a lot of the stakeholders felt that it reduced current health and safety because some of the States had longer compliance periods where they had the limits of 25 millirem after, you know, after ten thousand years.

Or some States even went further to 50 thousand. Or peaked theirs that they evaluated or required the evaluations.

Most of the commentors recommended C. A few liked the idea of having, you know, a comment basis across all the waste sites. But again, you know, there are -- in different areas and how, you know, in each State should be, you know we felt should be allowed if they want to put a little bit more restrictive or do it.

And also, we didn't want to disrupt the current programs significantly of what they were going. So in that case we, you know, in order to help adapt that, we changed in the final Rule the compliance period definition to a Compatibility C.

That's where the time frames are, are the thousand year time frame, or ten thousand year time frame was. So they can use longer.

Some of the areas remained C, such as the performance period review. We had a, you know,

had in the proposed Rule and stays as C.

The other big area though that we changed from B to C was in 61.58, which is the waste acceptance criteria. So, we were allowing more flexibility on the States of what they required for that.

I'll go up, continue on with some of the comments. Again, we were talking about a few minutes ago about the grand fathering and all. We got a lot of comments on that.

A certain number of the comments were hey, 61, you know, 10 CFR 61.1.a kind of seems to have a grandfather clause in there. That it says effectively that, you know, States can adopt these on a site by -- or a case by case basis. You know, the regulations on a case by case basis.

Well, the intent of that was when we published the original Part 61, that there wasn't a frame work at that time other then Part 20 for doing these rules. So, we were creating a whole new frame work.

And so the idea was, it may be harder for some of these States to adopt these requirements immediately. And so we put that language in there.

So, it's kind of an artifact. But they were saying hey, it's still in there. Well, clearly it wasn't intended to apply to this type.

So, we basically have gone through and addressed the comments on grand fathering that we do, as Dave said, think that it's important to include sites that are currently operating under this new requirement.

And as well to make sure there's no future concern, we have removed that clause from 61.1.a so that, you know, people won't go back and say hey, you know, the States don't have to adopt that because of that language.

That was really as I said, an artifact from the original Rule. And should have had a time frame that it was based on and removed previous to this.

Another interesting --

CHAIR CHU: Gary, can I ask a quick question?

MR. COMFORT: Yes.

CHAIR CHU: How often do licensee, operating licensees have to renew their license? Every how many years? Or do they differ from State to State? Or what?

MR. COMFORT: It's dif -- my understanding is it's different from State to State. But they may have more information on that. Okay.

CHAIR CHU: Okay.

MR. COMFORT: Yes Because as part of the regulatory analysis, I'm pretty sure that I saw some States that were evaluating. Because we tried to do it based upon what their actual renewal cycles would be.

And I think it varied, you know, some maybe like ten years. Some maybe 20 years on what it is. But, it depends upon the State and what they've required.

Another bit area that we had that was interesting was backfit. A lot of NRC's requirement, or regulations basically require us to do a backfit evaluation when we're changing the regulations.

Part 61 does not have that kind of a requirement in it. I mean, we do look at, you know, that we do through the regulatory analysis that I just mentioned, some cost benefit analysis on it. But we don't do a formal backfit.

The comments that we received were

well, basically this is going to impact, you know, a Part 70 licensee doing uranium enrichment. They do have a backfit provision. So why doesn't backfit apply because of that?

And basically we went through our review and determined that, you know, and normally unless the Commission directs otherwise, we don't do backfit for areas where, you know, there's kind of the subsequential impact to somebody. So, you know, this impact is directly to the regulations for low-level waste disposal.

And it just happens that somebody disposing of their maybe impacted, but we don't look at that as part of, you know, being under the backfit of the Part 70 provision, or having to be reviewed under that. Because we're not changing Part 70 on it.

So, as a result, we have not included backfit. We feel satisfied the regulatory analysis, which we did do a lot of update to trying to -- we've talked to a lot of the licensees in States to get better estimates of the costs.

And the costs have showed to be a, you know, potentially a lot higher then what was in the proposed Rule in the final regulatory analysis.

Which is publically available as part of the package.

So those are some of the major areas of where we had, you know, comments in. I mean, we've got a lot of other comments that some were great editorials where, you know, use consistent rule language.

There were other comments, you know, that were identifying, you know, problems that we had that we clarified. You know, such as you referenced one part you've changed. But you didn't fix it in the other part in Part 61.

So, we really appreciated all the comments. And as I said, we have an extensive write up as a response to all the comments that we did identify.

So now I'm going to go over to what the meat of what we're really here for, is to look at the draft final Rule changes that we've done. Basically this chart, or table, indicates the changes from the current Part 61.

We're going to forget about the proposed rule and previous iterations that we had. I'm going to go now just talk about changes that are from the existing Part 61. That's what I

provided you, you know, the Committee with the red lined, strike out version of.

So, first thing is that was that we're requiring a site specific analysis. That's not in the current Rule.

And then we're going into these -- we're specifying time frames for the technical analysis. And I'll go into a little bit more detail in a couple of minutes of where these changes are in the Rule, and detail what they are.

But, for this one we're basically putting the time frames as I said, for a compliance period of a thousand year or ten thousand year, depending upon how much long-live radionuclides are being disposed of at the site.

MEMBER SKILLMAN: Gary, let me ask this please. Is there any other points in government where a one thousand year or ten thousand year analysis horizon is utilized? Is there any other place?

MR. COMFORT: You mean the combination of one or the other?

MEMBER SKILLMAN: Of either?

MR. COMFORT: Oh, yes. Dave can go over that.

MEMBER SKILLMAN: I mean we're in 2016. 3016 sounds like a long way away.

DR. ESH: Right. So, the thousand years is used in NRC's decommissioning under 10 CFR Part 20. We have a thousand year period to do an assessment for unrestricted or restricted release in decommissioning.

For the disposal of high level waste, the analysis time frame goes out to a million years. Broken into two phases up to ten thousand years. And then from ten thousand years to a million years.

So, that requires a million year analysis. For the waste isolation pilot plant, I believe they do ten thousand year analysis there for analysis of the disposal of transuranic waste at WIPP.

Internationally, there's a whole variety of time frames that are considered. And generally when you speak to the international people, they're somewhat taken aback by the U.S.'s position that we would look at significant quantities of long-lived waste for a thousand years, if that's what we were proposing.

They generally are much more

comfortable looking at longer time frames. So, they either look at longer time frames, or they first put a limit on the amount of long-lived wasted that's suitable for near surface disposal.

And the IAEA pretty much does this too. Although the IAEA generally gives higher level guidance to how to solve a problem. They don't say, you know, use this number and that number for the time frame and the concentration.

But, their framework is pretty good. So they have, I would say, a better framework in terms of waste classification then we do. And so do some of the other countries like France for instance.

So, in the U.S. we mix long and short-lived waste together in our waste classification system. And some other programs they distinguish the type of waste not just based on the concentrations of the current day, you know, radiation hazard from handling the material.

But also in terms of the longevity of the waste they make distinctions. And so, for instance in France, their long-lived waste once you get to a certain threshold, is all destined for a geologic or a deep disposal system. They don't put

any of that in the near surface.

Whereas, in the U.S., what we're taking about here, partly because of our classification system is, in some circumstances like with the large quantities of depleted uranium, you're putting significant quantities of long-lived waste in the near surface.

So, that distinction needs to be made. I went kind of off on a tangent in the international space and answered your question.

MEMBER SKILLMAN: That was very helpful. And I appreciate that.

DR. ESH: Right. So, but in the domestic side, there are instances where the time frames are developed. And I'm going to talk about that in more detail whenever we get there.

MEMBER SKILLMAN: Thank you. That was very helpful. Thank you.

MR. COMFORT: And so the key point about the thousand or ten thousand years, currently in our current regulations there aren't any time frames at all. So, it does lead to some ambiguity as to how long do you need to analyze that for.

It says you've got to protect the members of the public, you know, and maintain a

dose of 25 millirem. Some people could say, you know, hey that's out for whatever the peak dose or long time. Others are, you know, hey, we're really in general talking about short-lived waste. So we're only going to analyze that to five hundred years.

But, that's what we're trying to do, is create a system that reduces that ambiguity by providing time frames for these analysis.

The other thing this has that we do, is we're adding a new requirement for technical analysis for protection of the inadvertent intruder. That's, you know, not -- there are -- there is a requirement to protect them.

But it doesn't have a dose limit associated with it. As part of this new requirement, you'll have a five hundred millirem annual dose limit that you have associated with.

Now one of the changes that we've done from what the Commission directed based on public comment is the same ideas. Doing scenarios out into the future and guessing what's going to happen at the site is difficult.

So, even closure, if you've got a new site, that could be 50, a hundred years away from

now. Trying to guess what's going to happen in a hundred years could be significant.

Instead what we've change, or what we're recommending in the Rule language to change to is to basically say, do the analysis of what's going on at the site at the time the analysis is done. You know what that is. There's not a lot of question about what's going on. So, it's easier to analyze.

But, you'll have to update those analyses during renewal. And then we'll have a final requirement to update them at closure. So again, you're getting an effective goal of the analysis will be based on closure when the site closes.

MEMBER BLEY: When does renewal come up?

MR. COMFORT: Renewal is based upon whenever, you know, whenever the requirement for the Agreement State is. I mean, what period they've selected at what point.

MEMBER BLEY: And that's different for every?

MR. COMFORT: It's my understanding it's different for each site. Or each State I

should say.

MEMBER BLEY: Well, okay.

MR. COMFORT: We've also added this new ten thousand year performance period analyses. Now, it's intended to be more of a qualitative analysis. It can be based on technical analysis itself.

But we're not putting any type of specific limit, you know, that you have to meet during that post time frame. It's more for the regulator to be able to make a decision particularly for these long-lived radionuclides.

You know, that there will be some form of public health and safety going on in that future. But it's difficult to tell what's going to happen, you know, a thousand years, let alone ten thousand or 50 thousand years out there.

MEMBER BLEY: Question. You're using a thousand and ten thousand because that's what the SRM said. Is that right?

MR. COMFORT: Well yes. The original proposed Rule for the SRM. But also, I mean, it's members of the staff had provided in the original proposed Rule, we used ten thousand years.

But the Commission's divided it into

the one thousand and ten thousand years.

MEMBER BLEY: Okay.

MR. COMFORT: So, we're trying to be more site specific by allowing, you know, instead of just one flat for all waste that there are differences in what types of wastes some sites may want to accept.

MEMBER BLEY: Take me back. Because I don't remember. Is there -- is anywhere the rationale laid out in the Rule and the SRM or somewhere else about where ten thousand years comes from?

Why is it ten thousand years? This is bothering me. I don't understand that at all.

DR. ESH: As opposed to seven thousand or --

MEMBER BLEY: Anything else.

DR. ESH: Twenty-three thousand, or something else right?

MEMBER BLEY: Or just a thousand. I mean, here's what I remember.

DR. ESH: Okay.

MEMBER BLEY: What I remember is what the Rule says is if the peak comes after a thousand years, then you use a ten thousand year. And

there's one other case where, and I forget what that is -- oh, if the daughters continued to grow after a thousand years, you use ten thousand.

The one I know we're concerned about is depleted uranium. It doesn't peak at ten thousand years. It peaks way out by forever. So, ten thousand years isn't much different from a thousand years.

I don't have a clue why we come up with this second number. And why it's what it is. And I don't remember reading a justification that convinced me in any way.

DR. ESH: Well, we did a white paper on considerations for selecting the analysis time frame. And if you don't have that, we should get you that. And I'll put an action item for that.

MEMBER BLEY: This was back in '13 or something.

DR. ESH: I believe it may have been generated in about 2011 or so.

MEMBER BLEY: Okay.

DR. ESH: Somewhere in that time frame.

MEMBER BLEY: But my memory of it was, it just said because DU keeps growing, we're going to use a later time period. But ten thousand

doesn't get you anywhere near where the peak occurs.

DR. ESH: Right. Well, the situation with depleted uranium is a little unique in that depleted uranium is essentially free of its daughter products whenever it's generated. So, it's a very pure material.

And then those daughter products build in over time. And -- but the uranium can cause health impacts and it's pretty significant because it's such a large amount of material and it's very concentrated in uranium.

The daughter products are the ones that really can drive things. Especially say the radon. So, at a thousand years, the build up of the daughter products, you're only at about one one-thousandth of the peak dose from the material.

MEMBER BLEY: Right.

DR. ESH: By ten thousand years you're within one tenth of the peak dose of the material.

MEMBER BLEY: Well, more -- I don't --

DR. ESH: It's -- no, it's very nonlinear, right. It gets good -- it depends on the ratio of the isotope of U-238 and U-234. The ratios -- the isotopic fractions of the various

uranium isotopes.

MEMBER BLEY: Right.

DR. ESH: But no, you're at about one tenth of the peak, the other direction. Right. Yes. So, you're not at 90 percent. You're at one-tenth.

But the view was that if we have to do something with deleted uranium, if you're only at one one-thousandth of what you might estimate the impact to be, you're really missing the target there.

I mean, if you're within one-tenth given what goes on in performance assessments and the uncertainties and all the various calculations and those sorts of things, that's fairly reasonable when you combine it with the performance period after that.

So, the performance period is still likely to involve quantitative calculations, but a qualitative interpretation of those calculations. So, you don't have a firm dose standard for those very long times. Very long being after ten thousand years.

But you still have somebody doing the calculation to see what they think is going to

happen. So, that we felt was an appropriate way to address depleted uranium or other waste that might have similar characteristics to depleted uranium.

So, greater then Class C waste, CTCC has the potential to have a very large amount of long-lived, alpha emitting radionuclides. They have the same sort of performance issues associated with them that the depleted uranium will have.

So, if you say well, I want to dispose of GTC -- too many C's. There's two Cs on there. In a low level waste disposal facility, that would be a consideration for that waste too.

So, the way we structured it with this kind of tiered approach is we had a lot of comments that said okay, but should you really be doing ten thousand years for short-lived waste, traditional waste that has very low amounts of long-lived radioactivity.

MEMBER BLEY: Right.

DR. ESH: And we generally would say no. You know, you can analyze that for a shorter period of time. If everything's decaying out of your system, fine. You know, don't muck up your calculations with the --

MEMBER BLEY: Is the guidance clear on

that?

DR. ESH: The guidance, I hope, is very clear on that.

MEMBER BLEY: Okay. Because I haven't seen that yet.

DR. ESH: Right. Right. So, you have it on your CD. And I'll point you to where that discussion is.

MEMBER BLEY: Okay.

DR. ESH: So but the idea was that in this -- what we've generated here that has elements that I think various stakeholders were looking for. But still has enough technical credibility for that challenging problem, which was the direction why we did all this to begin with.

So, if we were given that direction to deal with this difficult waste stream in our low-level waste regulations, and then we didn't come up with requirements that we think are appropriate for that sort of material, then what exactly did we do?

So that's, you know, in plain terms that's what we were attempting to achieve here.

MEMBER BLEY: That helps a lot. And I did not remember that you built up to a substantial fraction of the daughter.

I've probably got the white paper.

DR. ESH: Yes, I was just going to say that --

MEMBER BLEY: But it would be good to circulate that to everybody.

MR. WIDMAYER: Yes, I'll put it back out. At probably two previous meetings, David's provided a chart --

(Simultaneous speaking).

MEMBER BLEY: I remember that, but I don't remember all the details.

MR. WIDMAYER: -- probably gave a nickname to it, like Esh's Bullseye or something.

MEMBER BLEY: This was a good discussion. Thank you, David.

MEMBER REMPE: We forget things. Could you talk a little bit about uncertainty and how you are -- that was one of the stakeholder comments, and the commissioners have said do something about it -- and how you are dealing with it in the guidance document, and also a little bit about how does that compare with the international community's approach?

MR. ESH: Do you want to talk about that now, or do you want to wait until I get in

tonight?

MEMBER REMPE: If it's in your presentation -- it wasn't obvious from looking at the slides, but if it fits better, that's fine, but I'd like to see it discussed.

MR. ESH: Let me try to address it there, and if I don't, remind me again, and we'll pick it up there.

MEMBER REMPE: All right, thanks.

MR. COMFORT: Any other questions? The other things that we did were basically add a new requirement to update the technical analyses at site closure, add a new requirement to identify defense-in-depth protections and to have -- the rule will also facilitate implementation and better align the requirements with the current safety standards by changing the performance objectives.

I'm going to go over, now, the significant changes to the rule language, going through the entire rule real quickly. Where we did a lot of changes were in definitions. We've added definitions for compliance period. This is where we set up the 1,000 year and the 10,000 year. As I indicated, this is Compatibility Category C, so an agreement state could change this, be more

conservative on how long they want the compliance period to be.

It would have to be no shorter than these, but it could be longer. We also added a definition of defense-in-depth. We believe that defense-in-depth is already implicit in the current Part 61, but the commission wanted us to spell it out and to have licensees identify their defense-in-depth protections, so we've put in a new requirement, as you'll in 61.12, I'll get into in a couple of minutes. Moving on --

MEMBER SKILLMAN: Gary, let me ask this. Compliance period -- why doesn't the compliance period begin on the day of the rule for an active site? The way this definition is written, it means the time from --

MR. COMFORT: Site closure.

MEMBER SKILLMAN: -- closure. Say one of these sites is out there for the next 60 years. It has the legacy inventory been underground for maybe 30 years. It's receiving inventory for the next three or four decades. Why doesn't the -- what governs from today to the day the site is closed?

MR. COMFORT: They have an active

license, so the protections from that is where you'd be getting the health and safety protections. The idea of the compliance period is after there's nobody at the site anymore, that you're trying to evaluate. You have somebody actively at the site, so if you see issues coming up, you know, they're going to be doing monitoring and stuff like that actively at the site --

(Simultaneous speaking).

MEMBER SKILLMAN: The final rule is really for low-level radioactive waste disposal after the site is closed?

MR. COMFORT: These new requirements are for it. There are other requirements on what they have to do while the site is operating.

MEMBER SKILLMAN: I certainly understand that.

MR. ESH: 61.43, the performance objective, provides for protection of the people operating the facility and members of the public during operations. That's where the issue you just raised would come into play, and all the associated requirements (Simultaneous speaking).

MEMBER SKILLMAN: Let me ask one more, and this is really an off-the-wall question, but

I'd like to get it out of my system because I lived the life, and so did my colleague here. What about stuff that got dumped at sea? There was a lot of stuff that went overboard, and it's wherever it is. How do you think about that in the context of this rule?

MR. ESH: The sea disposal of material happened in both oceans, of course, the Atlantic and Pacific. Other countries pursued that, too. But then I believe it was maybe in the early '70s that basically, that practice was ended. There was a moratorium placed on that practice because it was not viewed as being environmentally responsible, I guess, or ethical, whatever word you want to (Simultaneous speaking).

MEMBER SKILLMAN: That's all, thank you.

MR. ESH: That was pre-Part 61. The same sort of logic that applies to the older sites were closed prior to Part 61 would apply to the sea disposal -- the material that was disposed at sea.

MEMBER SKILLMAN: Thank you.

MR. TAPPERT: Just to clarify, on the performance assessment, you're doing that during the operation of the facility? You're not

operating it for 60 years and then applying the compliance period, right? The compliance period begins after the site closure, but you're doing that analysis to inform what's being accepted into the facility, right?

MEMBER SKILLMAN: I appreciate your comment because that's why I was picking away at what is compliance period. I'm not suggesting that something is in error. I was going for clarity. What I heard the gentleman say is, "While you've got your license, you're in a different set of protections. Compliance period really begins when you close the site and you go to your first 1,000 years. I believe that's what you're trying to communicate.

MR. TAPPERT: Yes, so that's the compliance period for the analysis period. My understanding is that you're doing that during the operation of the facility, and you're updating it periodically. You don't continue to operate the facility and then do the analysis at the very end. Even though that's the compliance period, it informs the operation of the facility.

MR. COMFORT: They have to provide the performance assessment as part of the initial and

updated applications that they do. They'll do the evaluation, so it's not that they're going to all of a sudden dispose of a bunch of stuff, and then say, "We're not going to meet these requirements, and we now have to do something with it. Whether they should have before -- that they're permitted to dispose of material that some of these analyses --

MEMBER BLEY: This might not be a fair question, but since we're writing defense-in-depth into the rule, were you guys tracking or involved in, or at least knowledgeable of the fairly recent NUREG KM, knowledge management on defense-in-depth?

MR. COMFORT: We were aware of it, yes.

MEMBER BLEY: Are you consistent with it in any way?

MR. ESH: I guess you should tell us whether we're consistent with it. We looked at that document when the regulation was developed and these requirements were developed. I believe we're consistent with it.

MEMBER BLEY: Okay, you're aware of it and you followed it. Thank you. That's what I wanted (Simultaneous speaking).

MR. ESH: I'm going to talk about

defense-in-depth and --

MEMBER BLEY: I haven't looked carefully, so maybe we'll let you know if we don't agree.

MR. ESH: I'm going to talk about defense-in-depth when we get to my part. There were some challenges with implementing it for a waste disposal problem compared to, say, other problems, and I was planning to talk about that.

MEMBER BLEY: Thanks, David.

MR. COMFORT: We've added a definition for an inadvertent intruder assessment, as indicated on it. As I indicated before, one of the things that it is important to note is that we changed the scenario, that basically, somebody that engages in normal activities and other reasonably foreseeable pursuits that are realistic and consistent with expected activities in and around the disposal site at the time of the assessment. That was, again, a change both from writing this definition, but it's also from what was in the proposed rule. It examines the capabilities of the intruder barriers to inhibit contact with the waste, and it estimates the inadvertent intruder's potential annual dose considering uncertainty.

We added a definition for long-lived radionuclide because that becomes an important role as to particularly setting the compliance period as indicated. I won't go over the different ideas. We added definitions for performance assessment and performance period, again just to fulfill the requirement -- to add more definition into what the rule is and when we use those terms.

For example, in the current 61.13, we talk about technical analyses and technical analysis. That technical analysis is really what became the performance assessment. It's one of the technical analyses that's now required in the new rule, including the inadvertent intruder assessment and all. Performance period, as I said, is a time frame established to provide disposal after the compliance period, but is not going to be -- it doesn't have any technical quantitative requirements or dose limits that you have to meet on it in our role. Again in compatibility C, so an agreement state could determine to do something otherwise. We also added, again, per commission direction, a safety case. Again, we think the regulations already have safety case implicitly involved, but the commission wanted us to more

explicitly state what a safety case and what makes it up and have the licensee show that the site that they're operating on a holistic level is safe.

Going to some of the new requirements, one of the ones I'm pointing out, the 61.12, because we got a lot of comments on it regarding defense-in-depth. Originally, this was in the proposed rule, in 61.13, which is a category of technical analyses. The way it was written, a lot of people looked at this was going to be a big new elaborate analysis that licensees were going to have to undertake.

That wasn't our intent, nor the commission's intent. To make sure that's not the case, we moved it to 61.12, which is technical information. Now we're just basically saying they have to identify defense-in-depth protections. As Dave indicated, he'll get into that some more. The key thing we're trying to say, it's not supposed to be a brand-new big analysis. 61.13 is where probably the meat of the rule really is, in the technical analyses. We've broken this into a number of analyses that make up all the technical analyses, or a number of assessments that make it up. The first one is the performance assessment,

which is really showing the protection of public health and safety.

It basically relates to the performance objective in 61.41 for the compliance period, now that we've defined as -- I have 25 millirem on an annual basis, but you have to consider the future events and processes that represent the phenomena. You consider the likelihood of disruptive -- what I have listed here is basically a write-down of the requirements of what you have to do as part of that performance assessment. Continuing on the technical --

MEMBER BLEY: Can I --

MR. COMFORT: Sure.

MEMBER BLEY: -- interrupt you for something? Earlier, it'd be 61.7, you mentioned this. In 61.7, it talks about if after closure, the license will transfer to the state or federal government, if it's US it's DOE, and you don't regulate that anymore. If it's a state, our regulations do continue to apply. Two questions related to this. Are all of the existing facilities either going to be DOE or are in states that are agreement states?

MR. COMFORT: All of the existing sites

are in agreement states.

MEMBER BLEY: So there's no (Simultaneous speaking) not in an agreement state, then what would happen? It's not now, but if one shows up in a state that's not an agreement state in the future, the license won't transfer to the state then?

MR. COMFORT: I'll have to turn to Chris McKenney. I think he's getting up to --

MEMBER BLEY: Or is this a hole that you don't think will ever occur?

MR. COMFORT: I'll ask --

MR. MCKENNEY: Chris McKenney, NRC. That is one of the factors of defense-in-depth for institutional control that's built into the rule. That's one of those inclusive events of defense-in-depth that's already built in, that by requiring either state or federal ownership of the land for long term, that reduces the probability. Almost all of them are on state-owned land. One is an interesting situation is state-leased land. It will then revert to federal ownership later, which is U.S. Ecology on the Hanford facility. At that point, it will revert to the Hanford Nuclear Reservation in 2063.

But the Barnwell facility's already owned by the State of South Carolina, and the Texas facility has, if I remember correctly, joint -- one cell federal ownership, and one cell's state ownership, but there's a combined issue there for some stuff. Those are there for, again, for defense-in-depth for the institution control is long term.

MEMBER BLEY: I guess what I didn't understand is should there be a future site that's in a state that's not an agreement state, then the way the rule's written, it still reverts to the state, I guess.

MR. MCKENNEY: The state is an option to have that there be, again, as a long-term steward, to make sure that there's less possibility that you don't have to worry about a commercial entity owning the property and maintaining it from sale to another party and having an intruder move on to the site. If it's owned by the state or federal ownership, it has a higher probability of not being used for future development of something other than (Simultaneous speaking).

MEMBER BLEY: That kind of makes sense to me, but it doesn't quite tell me we can't -- I

don't think NRC can order the states to (Simultaneous speaking).

MR. MCKENNEY: Which is why we don't rely on them for more than 100 years. That was the intent of why that was placed in the rule was because by putting it under state or federal ownership, it was likely that you could maintain it as not being used for other purposes, but as just an unused property, basically, for very long periods of time. But if it was owned by a company, then you'd have to rely on deed restrictions and other things like that, as it was passed from company to company, or as those corporations evolved in time. So that's why that situation occurs.

MEMBER BLEY: Okay, thanks. The second question I had on that one was for the sites that revert to the DOE after closure, and DOE regulations apply, do we have harmonization between this new rule and what DOE is doing, or are we just doing our own?

MR. ESH: Whether the state or the federal government owns the lands, our regulations will apply until the license is terminated, I believe. I don't know. I looked (Simultaneous

speaking). Even if DOE assumes ownership of the land, they would be responsible for carrying out the institutional control activities until the end of the institutional control period.

MEMBER BLEY: Can I read you a sentence from --

MR. ESH: Let's hear from Lisa (Simultaneous speaking).

MEMBER BLEY: Let me read the sentence, and then go ahead. The sentence I'm looking at is Item 4. I can't track all of the things, but it's under 61.7. "After finding of satisfactory disposal site closure, the commission will transfer the license to state or federal government that owns the disposal site." Two sentences. "If the U.S. Department of Energy is the federal agency administering the land on the federal government, the license will be terminated because the commission lacks regulatory authority over the Department for this activity."

MS. LONDON: Yes, that's what I was going to say. Once the license is terminated and DOE is taking ownership, their regulations will apply.

MEMBER BLEY: My question was how does

this new rule harmonize or not harmonize with DOE regulations?

MR. ESH: If this rule was finalized the way it is, DOE's regulations would be less restrictive, so there should be no issue with it being taken over under DOE's regulations.

MEMBER BLEY: Kind of the point I'm getting at it is --

MR. ESH: But the one area where I would say that's not the case is DOE applies 100 millirem dose limit for a chronic intruder. Whereas, under these regulations, we have a 500 millirem dose limit for -- whether it's acute or a chronic intruder. They make a distinction between an acute and chronic intruder.

MEMBER BLEY: Kind of the point I was getting at is I know there are international efforts to harmonize regulations. In the nuclear area, there are similar things within the states. We're coming up with a new rule that will apply to some, but not all of these facilities. I don't even know what fraction would go to DOE and what fraction would go to the states. Have we tried to match, so that both the DOE and NRC will be given the same rules, or is it just you flip a coin which

site it is, and you get different rules?

MR. ESH: No. I wouldn't say -- of course, the perception could be that, but the -- in the last letter that we received from the ACRS, it said don't define, say, the analysis time frames and do it completely site specific. If that's the case, then you are going to be using different values for all different sites.

This idea that the NRC and DOE and EPA and whomever all need to do the same thing, I don't think that's the case. I think you can have different regulatory requirements and make everything work. Whenever I go through the technical elements of the regulation, I'll talk about examples where this draft final proposed approach is already being made to work in the U.S. for both NRC and DOE.

Yes, you could do some harmonization, but would you then try to harmonize EPA's approach to management of hazardous waste with the DOE and the NRC approach to management of radioactive waste? Those are diametrically opposed, compared to just arguing over what the proper compliance period should be. They do a 30-year evaluation period using a standardized design, and then at the

end of 30 years, they'll re-assess and decide whether they still need to maintain the proper controls and restrictions in place. That's a lot different approach then what's being done waste disposal in the NRC commercial side and the Department of Energy.

MEMBER BLEY: As you go through your presentation, if you'd point out the places where things are different between this proposed rule and the DOE regulations, I'd appreciate it.

MR. ESH: I would argue that there is a difference right there, of course, but there are a lot of things that are very similar. Do they need to be identical? I don't think they need to be, partly because in the commercial side, the NRC's philosophy is that you're going to release these sites at some time in the future, and that the present generation has made proper and good decisions as to how to manage that material.

It's not going to create an impact to somebody in the future, whether that is a health and safety impact, or whether that's a financial impact. If you want to say I'm going to provide a much longer period of, say, institutional control to manage the waste, then that comes with financial

implications. On the public side, or on the commercial side, we have financial assurance requirements associated with how much money you need to put aside to meet your obligations. Those can be significant in some cases. If you extend the time that you're going to control it, you're going to greatly increase the size of those obligations that you may need to put aside to do all the activities that you may need to do.

On the Department of Energy side, I don't believe they, when they're self-regulating, that they have those same sorts of financial assurance requirements because they receive funding from Congress to do all their activities and Congress, year after year, maintains their funding to make sure they can meet their obligations. There's some differences like that that you have to keep in mind whenever you're talking about -- yes, at the highest level, I agree with you completely.

We should all be able to come to the same point. But when you start getting down to the implementation stage and look at some of the differences, it makes sense why there could be some differences between the requirements. They may be presented as being difficult and extreme, but from

a practitioner, and the other practitioners I talk to, they don't view them the same way. What you may receive from some stakeholders as to how significant of an issue this is, you'll receive a lot different message from other stakeholders. The practitioners don't view this as, generally, it's as big of an issue as maybe some of the policymaker-type stakeholders.

MEMBER BLEY: I'm going to chase this just a little further. Thanks for that explanation. I like that. Are those kind of arguments laid out in the statements of consideration or somewhere else? We don't have the statements of consideration.

MR. WIDMAYER: Yes, it's part of the red package I gave you.

MEMBER BLEY: It's in this package? It's not called statements of consideration in that package.

MS. LONDON: It's in the Federal Register notice.

MR. COMFORT: The draft Federal Register notice includes the statements of consideration. No, it won't get into that -- it won't get into this harmonization issue in there at

all and stuff on it. Part of it --

(Simultaneous speaking).

MEMBER BLEY: The arguments were pretty interesting about commercial versus a tax-supported operation, but that's not anywhere in there?

MR. COMFORT: Yes, we didn't get a question specific to that that would have been answered that way. The actual rule language that you're addressing in 61.7 regarding the states and all has not changed. That's in the existing regulations anyways and stuff. The part that we may want to look at is the statements of consideration for that rule, which I guess they really didn't have one. They had the environmental impact statement to see if they were -- what they were envisioning in the way of the turnover to a state or Department of Energy and stuff on it --

MR. WIDMAYER: Hey, Dennis.

MR. COMFORT: -- but it does not discuss this at all.

MEMBER BLEY: Thanks, Gary.

MR. WIDMAYER: One of the parties that wants to make comments this afternoon is the Department of Energy, so you'll hear from them later on in the day.

MEMBER BLEY: I was figuring that would happen.

MR. COMFORT: Okay, continuing on, another part of the technical analysis, and a big one, is the new inadvertent intruder assessment for the compliance period. It requires that -- it assumes the inadvertent intruder occupies a disposal site and engages in normal activities and other reasonable foreseeable pursuits that are consistent with the activities and pursuits occurring in and around at the time of the development of this intruder assessment, as I indicated in the definition.

It's updated prior to closure, and it identifies barriers to inadvertent intrusion that inhibit contact with the waste or limit exposure, and it provides the basis for the time period over which the barriers are effective. Finally, it accounts for the uncertainties in variability in the projected behavior of the disposal site and general environment. This relates to the performance assessment in 61.42, which, for the compliance period, has an annual dose limit of 500 millirem, which is new, which is not in the current rule now.

CHAIR CHU: Can I ask a quick question?

MR. COMFORT: Sure.

CHAIR CHU: The intrusion scenario, within the compliance period, do you do one-time assessment, or several, or what? It's not clear to me.

MR. ESH: The intruder assessment covers the whole compliance period. If you had significant quantities of long-lived waste, then the performance period, also. The evaluation would look at intruder impacts --

CHAIR CHU: (Simultaneous speaking.)

MR. ESH: Yes, it'd calculate the intruder impacts over the whole time period, and then generally pick the peak value within the time period.

MR. COMFORT: Dave, I think, will get into more on that. The types of scenarios I think that we have them look at are relatively defined on it. In addition, in 61.13, Item C, D, and E, are that you do it announced as a protection of individuals during operations. That hasn't changed from what's currently in the regulation. We have a long-term stability analysis.

Again, that's required in the current

regulation. The big change is that it now has a time period that you have to associate that stability analysis with. Then we've added this new performance period analysis, which is only required if you have to do a 10,000-year compliance period for the performance assessment or for the inadvertent intruder assessment. It basically looks at how the site would limit the potential long-term radiological impacts, consistent with the available data and current scientific understanding. There's no dose limit associated with that. It's just basically try to minimize doses that you can find or seem to be a reasonably achievable level in the far future. But again, with all the uncertainties, that's why we decided not to put a limit on that.

We had some other changes throughout, again, editorial, but the next area where there's a significant change in the performance objectives is 61.41. Again, this is basically added a 25 millirem dose limit for the protection of the public. We've defined a compliance period, rather than just for the assessment, in general. It basically stays the 25 millirem limit. However, the previous was based on methodology, older ICRP

methodologies.

We've updated the language in there so that the more modern methodologies or more recent methodologies can be used. It's, as I said, demonstrated through the analyses for the performance assessment that are specified in 61.13(a). For the performance period, as I said, it must minimize the releases to radioactivity to the general public, to the extent reasonably achievable. That's basically the qualifier on it, and it's demonstrated through 61.13(e), which I had just shown you. 61.42 is basically the performance objective for the inadvertent intrusion. This is where there was no limit before. It was basically evaluate it and keep it reasonable. Now we've put a limit of 500 millirem to the inadvertent intruder, which is demonstrated through the analysis that we discussed for 61.13(b).

Similar to the 61.41 requirement, the performance period, you have to minimize exposures to inadvertent intruders to the extent reasonably achievable. The final area that I'm going to go over is really the draft final -- is 61.58, which is the alternative requirements for waste classification. In the current rule -- well, this

section was really replaced in its entirety.

The original 61.58 allowed the commission to authorize provisions for the classification and characteristics on a specific basis if there were reasonable assurance that the performance objectives of Subpart C in 10 C.F.R. Part 61 could be met, so basically the 61.41, 61.42. In this draft final rule, we've replaced requirements to better specify a process for requesting and approving alternative requirements for waste classification by specifying the waste acceptance criteria must be provided and specify, at a minimum, the allowable activities and concentrations, the acceptable waste form characteristics, and identifying restrictions or prohibitions on the waste materials or containers that might affect the facility's ability to meet the performance of objectives.

The final rule also requires that the applicant provide acceptable methods for characterizing waste for the acceptance and program to certify the waste. These programs are required to be reviewed annually by the licensee. Really, a overview of the big ideas of the changes. Dave, in his presentation, will be getting into more of the

technical basis for it and how the changes will work through guidance and all of this stuff. Are there any questions I have before we potentially take a break or move over to Dave?

CHAIR CHU: I have a question on the performance period analysis. Are these quantitative or qualitative?

MR. COMFORT: The results are evaluated qualitatively. You can develop a quantitative evaluation. A lot of times, it may just be running out your model that you've already developed and keeping things consistent.

(Off mic comment)

MR. COMFORT: Right, but we're not requiring you to meet a certain limit or anything. It's more to give an idea of what's the potential.

CHAIR CHU: Even if it peaks a lot?

MR. COMFORT: That's what you're trying to evaluate. If you see a huge peak somewhere in the future, when you run it out past -- in this performance period, the regulator may say, "If there's something that can be done about it, we may want to do something about it."

CHAIR CHU: Because I was thinking of what, Dave, you said earlier about depleted

uranium. In 10,000 years, only 10 percent decayed.

MR. ESH: At 10,000 years, you're only at about one tenth of the peak risk is what it is generally. Of course, that would depend -- that's just from a radiological decay and in growth perspective. When you move to a real system and, say, you put that waste in a disposal facility and you analyze what the impacts to the drinking water are, or an inadvertent intruder, the peak may occur a lot earlier than the peak radiological time. The peak radiological time is something like 2.1 million years, but in the dose assessment, the peaks may occur earlier. It would depend on your specific site physics and chemistry, that sort of thing.

CHAIR CHU: I was just wondering have you done any reference case calculation way beyond 10,000 years to test that performance period, see what happens?

MR. ESH: Not specifically in, say, this iteration of the rulemaking, but back in 2008 time frame, whenever we looked at can you even put depleted uranium in a near-service disposal facility, we ran calculations out to much longer time then. The general messages from that were

that you're going to be very challenged to put that material in a human site, and you're going to be very challenged to put that material in a shallow, arid site. You need to start getting the material fairly deep, in order to knock the radon impacts down.

MR. COMFORT: Any other questions?

MEMBER KIRCHNER: Yes, I have a question. You mentioned earlier that several of the agreement states would take a longer time of compliance. When they do that, is the justification for that just to be conservative, or does it fit in with your long-lived radionuclides definition?

MR. ESH: I can't answer, necessarily, why the agreement states may have used different values. Originally, prior to starting this rulemaking activity, all the existing facilities were located in four agreement states. The analysis time frames that they used ranged from 500 years to 1,000 years or peak dose, whichever is longer. For that particular case, their peak was at approximately 50,000 years.

Their compliance periods that the four sites used ranged from 500 to 50,000. As we went

through this rulemaking process, the one agreement state that had used 500, they had a proposal from their licensee to dispose of larger quantities of depleted uranium, so they did a revision to their rulemaking to specify requirements for large quantities of depleted uranium.

For that, then, they look at 10,000 years, and they do a longer term analyses. Their new requirement mimics what's in our draft final rule pretty well. As to why they picked those different values, I think it's part of what you may have heard if you were part of the subcommittee or full committee at previous meetings in all this last eight, nine, or ten years that we've been discussing it. There's a big diversity of opinion on the topic. It can be quite subjective. Everybody has an opinion, and they tend to all be different. The thing that I have looked at in both the response to comments and in the draft final approach is right now, all of these facilities are in agreement states. The agreement states do the regulation, and in most cases, the states have to receive the facility after closure from the licensees.

They have standards on the book that

they've used to license their existing facilities. Who am I, sitting here in Washington, to come and say, "No, you've got it all wrong. You need to do it this way." They have to make the decisions based on their processes and rulemaking and interaction with their state stakeholders what they think is appropriate to do for that facility in their state.

Because it's not something that I think you can pull a number and say absolutely, this is the perfect number for it, then we should afford flexibility to them to look at the problem in a manner that they think is suitable for their agreement states and to managing -- go ahead.

MEMBER KIRCHNER: I might invert my question, then. Once you promulgate this final rule, would any of the agreement states be less conservative, not bounded by the rule?

MR. ESH: No, all of the agreement states -- South Carolina has -- they've used an analysis of up to 2,000 years in their technical evaluation. They don't have a requirement -- or they haven't done an intruder assessment. In the existing rules going forward, if they determine that they do not have significant quantities of

long-lived radionuclides, then they would be fine because they could use 1,000, or they could keep their 2,000 if they want, whatever they choose.

If they found that they did have significant quantities of long-lived radionuclides, then they would get pushed up to the 10,000. Otherwise, the other three existing agreement states are all at or greater than the requirements that we've proposed.

MEMBER REMPE: You don't know whether they have long-lived radionuclides? Surely, they know (Simultaneous speaking).

MR. ESH: No, they have long-lived radionuclides in their facility. As I'll outline when I talk about it, half of that decision -- or the part of the decision associated with the inadvertent intruder, where it's much more straightforward to determine what is significant. For 61.41, the protection of the public through releases of the facility that might occur, say, into an aquifer or if you had erosion at the facility or those sorts of things, release to surface water, those are much more site-specific calculations. What's significant for one site can be a lot different than what's significant for

another. Without having the details of their hydrogeology and all the things that might go into that, it's hard for me to say, clearly, whether they are in the camp of having significant or not.

They have some long-lived radioactivity, and based on the fact that their waste was pretty similar to what's generated commercially, without any special waste streams, my educated guess would be that they don't have significant quantities of long-lived isotopes, but it would depend on some of the details of the problem. Based on inventory, alone, and the fact that they're a humid site, it makes it much more challenging for them to make that argument than it does, say, for a site in Utah or a site in West Texas.

MEMBER REMPE: Thank you.

CHAIR CHU: Any other questions? If not, I suggest we take a break. We'll come back at five until 3:00. Thank you.

(Whereupon, the above-entitled meeting went off the record at 2:40 p.m. and went back on the record at 2:56 p.m.)

CHAIR CHU: Let's resume the meeting and have Dr. Esh give his presentation.

MR. ESH: Thank you, Dr. Chu. Thank you for your kind introduction earlier. To me, that's really a reflection of who I work with, rather than my own abilities. I'm going to give you an overview of the major technical elements of 10 C.F.R. Part 61. Before I do that, I'd like to recognize some of the people that aren't here that have contributed to that.

Of course, you've heard from Gary Comfort, but also, we had Andrew Carrera in rulemaking that did a significant amount of work on this project, Chris Grossman, who's on the telephone, and Hans Arlt, from my group in performance assessment, Lisa London, who you heard from earlier, from our office of general counsel, Tim McCartin, senior level advisor in all things waste, I would say.

I don't know what his particular title is. We had members from agreement states on our working group that provided valuable input to this process. Then in the low-level waste branch, our current project manager, Steve Dembek and Priya Yadav, who's our excellent project manager on the guidance document. All of those people had significant contributions to this project. We also

would like to indicate that we appreciate the time and effort of all the commenters and stakeholders in this process. I'm particularly impressed by members of the public when they give their time for something like this. Everybody's time is valuable.

They come in the evening and listen to the meetings for three hours and read some pretty substantial documents. That's impressive to me when we get that sort of input from members of the public. We did our best to respond to all the comments, which was part of the package.

The draft final rulemaking package has been through review at, basically, all levels of the NRC, except the commission, and except your committee, possibly, but it went through the full concurrence process on its way up there. Of course, not everybody is going to be happy with the final outcome, but that's generally impossible to do when you have some pretty diverse and strong opinions on some of the topics.

MEMBER BLEY: Sorry to interrupt. That statement that everything's been reviewed all the way up, does that include the NUREG?

MR. ESH: Sorry, no. The NUREG is at a little bit slower pace than the rest of the

package. I've kind of learned, through my experience, that maybe a good rule of thumb for a regulator is if everybody's kind of unhappy with you, then you've done a good job, so we'll see. Next slide, please, Gary.

The outline I'm going to follow is a little bit different than if you just picked up the regulation and started reading through it because some of these pieces kind of fit into others. This is more of a top-down view of the technical elements of the regulation. I'll start off with the safety case, which is kind of the overarching summary of the arguments for why you believe the facility is safe.

A lot of information flows into the safety case, but the two primary ones are the identification of the defense-in-depth protections, and then the technical analyses. They provide much of the basis for the safety case. But that isn't to diminish many of the other components of the regulation that might, in some respects, play an equally important role in the overall safety case. The analysis time frames I'll discuss because it is an area of interest to a lot of stakeholders. The way I would describe it is it kind of provides a

boundary condition for the technical analyses. What you decide with analysis time frames can then condition or dictate what you need to consider in your technical analyses. As you heard earlier, part of the approach in the final rule is to try to make a distinction between "normal waste" and waste that may contain significant quantities or higher amounts of long-lived radionuclides.

The technical analyses that I'll discuss, I'm going to describe the performance assessment, intruder assessment, and site stability analyses. Then all of that information can flow into the waste acceptance requirements. As Gary discussed, the waste acceptance requirements or the waste acceptance criteria can be based on the waste classification tables in Part 61, Table 1 and Table 2, or they can be based on the results of the technical analyses, or they can be a combination of both.

I'll go through that approach in the waste acceptance requirements because the waste acceptance requirements are really how you put something in place that ensures that all the analysis and evaluation you did in developing the licensing of the facility is going to be achieved

in the actual facility. We'll talk about the guidance document in a kind of high-level form, but any of these things I talk about or areas I don't talk about, if you have questions when I'm done, hopefully we have enough time. Feel free to talk about any things, whether I talked about them in the slides or not.

MS. YADAV: Dave, can I add one comment?

MR. ESH: Yes, go ahead.

MS. YADAV: Hi, this is Priya Yadav. I'm glad you guys can hear me and Chris Grossman. We were trying to say a couple things a little earlier, but we were on mute. I just wanted to add, on the guidance -- because I know that it is a long document -- on the CDs that you have, I also added a file that's called, "Please Read Me First." I thought hopefully, you might glance at it and read it. Dave and I and Chris just tried to kind of pick the most important areas for you to look at first, since it is so voluminous.

We identified, "Look in this section for a discussion of significant quantities. Read this section carefully." It's just a quick one pager, saying, "Here are the most important

sections that you might want to start with." Of course, all 500 pages are available to you, as an official use only copy. Right now, it's not publicly available, just because we don't want to have multiple versions of a NUREG out before the rule is not changed anymore. After we get definition on the rule, that it's final, then we'll issue the publicly available version of the NUREG. So the OUO copy you have on CD is for your use, but I hope that the Please Read Me file helps you in what areas to start with.

MR. ESH: Thank you, Priya. On Slide 3, the first item I'll talk about is the safety case. The safety case is a collection of arguments and evidence to demonstrate the safety of the land disposal facility, e.g. the defense-in-depth protections and the technical analyses. Our representation of safety case is quite similar to the international atomic energy agencies, but not identical.

There are some differences between what we're considering a safety case and how they would describe a safety case. Those differences primarily arise from the role of stakeholders in their processes, and also the fact that in the

IAEA's vision, for many of their member states, they will do multiple safety cases. They'll do a safety case for site selection. Then they'll do a safety case to determine whether they can construct the facility. Then they'll do a safety case for operations, a safety case for post-closure, and so on and so forth. Whereas, in the NRC licensing process for low-level waste, we basically do one safety case for the whole thing. You could maybe make an argument that we're kind of doing two because once you get to the closure point, which may be a considerable distance in the future, you might be doing, essentially, another safety case then, if your information has changed significantly.

If your information has not changed significantly, then I would make the argument you've only done one safety case. It's the 10 C.F.R. Part 61 licensing process. But the safety case is to describe all relevant safety aspects of the disposal site and things like the design, the managerial controls, the regulatory controls, all of that feeds together to make the safety case.

Much of the information for the safety case is already in the existing 10 C.F.R. Part 61

requirements, under 10 C.F.R. 61.10 through 10 C.F.R. 61.16. The idea is that the safety case will be updated over time, as new information is gained during the various phases of the facility, but depending whether that update is simple or significant depends on, No. 1, how much your information has changed and, No. 2, how much margin you may have built into your facility to begin with. If you are smart about your design and maybe do a good job at anticipating changes that may occur over time or things that might stretch your system, then your safety case is going to be a pretty robust argument through time, no matter what phase of the facility operation or closure, that sort of thing, you may be in.

Next slide, please. The main point, and the main view of the safety case from us, is that it should be a plain language description. You're kind of looking at an executive summary of your licensing basis for the safety of the facility. You'll describe the strategy for achieving the safe disposal, the safety arguments that go into that, describe your site and facility, provide information about the characteristics of the waste and the design and the proposed operation

of the facility, and then also summarize the technical analyses, the strategy for institutional control, and the licensee's financial qualifications.

This description should be something that is understandable by many. It may be technical, but it doesn't have to be. But it should, in a concise form, summarize all the key features that go into making the safety argument. The safety case was added, as Gary had indicated, based on direction from the commission that we received on the prior rule, as published. Go ahead, Gary. On Slide 5 here, now we'll move into defense-in-depth, which is one of the components that feeds into the safety case. The definition is up here at the top. I'm going to read it.

"The use of multiple independent and, where possible, redundant layers of defense, so that no single layer, no matter how robust, is exclusively relied upon." One thing that we wanted to do here, NRC has existing definitions of defense-in-depth. We did want to deviate and come up with multiple definitions of defense-in-depth. We thought that's going to be confusing to people, and people may say, "Why do you have a different

definition? Which definition should I use?"

We felt that it was much better to have, as much as we could, a single definition because defense-in-depth is really a principle, and it shouldn't change depending on the application. But in the case of a waste disposal facility, there are some pretty substantial differences than many other nuclear facilities because the waste disposal facility, at least as you progress out in time, their reliance on active safety systems and controls diminishes, and it becomes almost totally reliant on passive safety systems and controls. At the bottom of this diagram, you see the various arrows here. That's just increasing time from left to right, but it's basically indicating the various things that may come into play to make a defense-in-depth argument.

Those include personnel controls, active barriers, passive barriers. But the bottom big arrow is different phases or different life cycle time frames of the facility. You see that the items above it, the various types of defense-in-depth protections, may diminish as you go out in time, especially the impact of personnel.

Because after the institutional control

period, generally, you're not going to have any personnel there, and the same thing with controls and active barriers because there'll be nobody there to maintain an active barrier. Examples of defense-in-depth protections can include things like the site characteristics and the waste characteristics. This feature was also added in response to commission direction. As I indicated, a challenge with the waste disposal is that it is different from active and other nuclear facilities, in that you are relying more heavily on passive components and less heavily on active components. So the problem came into play, especially with the word redundant in the layers of defense. We had this question -- this was an area of question from a variety of stakeholders. They said, "What does that mean for a waste disposal system, then?"

Say in a reactor, you have a pump and a backup pump. In a waste disposal system, you have a drainage layer and an engineering cap. Does that mean you have a backup drainage layer and the engineering cap? What we basically explained, and especially in the guidance, is that we're looking for redundancy at the functionality of what you're trying to achieve, but not necessarily redundancy

of the layer or barrier itself.

If minimizing water flow to the waste is very important to you, then you should have some redundancy of trying to prevent the water flow to the waste, not that you have to have redundant barriers to achieve that function. You can, if that's the way you choose to go about it. But the other important point, then -- sorry, next slide, Gary. The other important point, though, is that as we discussed earlier, we aren't asking for defense-in-depth analyses. We're asking for identification for the defense-in-depth protections commensurate with the risks. We want the licensees to describe the capabilities of their defense-in-depth protections and provide a technical basis for those capabilities.

The requirement, as formulated now, provides considerable flexibility for how somebody demonstrates that they meet these requirements associated with defense-in-depth protections. They are not prohibited from doing what I would call defense-in-depth analyses. If I was faced with the problem, that's what I would do.

I would be most straightforward and more quantitative and less subjective, but they

aren't necessarily required -- they aren't required to do that. They're only required to identify the protections, so it may take a more qualitative form, the description of how they've achieved the defense-in-depth requirements. Next slide, Gary.

As I indicated, operations and post-closure may have some differences based on the phase of the facility you're in. During operations, you can have both active and passive safety systems commensurate with the hazard and complexity of activities. Whereas, when you move to the post-closure phase, you're really looking at essentially just the passive features of the system. Post-closure is, of course, after the closure and, really, after the institutional control period. After closure of the facility, only if problems were identified would you imagine that there's going to be changes to the design or other sorts of activity at the facility.

Otherwise, the institutional control period is mainly a passive monitoring of the facility performance and active monitoring of -- or preventing access to the site. There are some benefits associated with defense-in-depth that are identified here. Under the post-closure one, I'd

say it's the second and fourth items.

Defense-in-depth, we believe, provides the diversity of the capabilities associated with defense-in-depth of the components and the attributes, provides you more resilience to unexpected failures or external challenges. Then in addition, the use of defense-in-depth should help mitigate some uncertainties or lessen the impact of uncertainties. It's not going to mitigate all uncertainties, but it can help you mitigate some of the uncertainties. The defense-in-depth is made to work with and not inhibit, in any way, the demonstration of compliance with the performance objectives. Those two things work together to provide information that supports the overall safety case. Next slide.

CHAIR CHU: Dave?

MEMBER BROWN: Go ahead, Margaret.

CHAIR CHU: Can I ask you to give some specific examples of post-closure defense-in-depth specifically (Simultaneous speaking)?

MR. ESH: The defense-in-depth for post-closure, you're really looking at the passive performance of the system. That's going to be things like your engineered cover. Even though

it's an engineered cover, and some engineered covers, based on their design, might require more active efforts to maintain them, many of them can have some passive performance credit to them.

Department of Energy, at the Hanford Site, has the Hanford barrier that they've done a lot of work on and tried to evaluate how much passive performance you might expect from that sort of engineered cover. They've even looked at things like fires, kind of unlikely events that you might expect and how they might stress the system. Then as you move into the system, of course, if you have waste forms for some types of waste, the waste form is going to have passive performance in the system. You might have an engineered cover that helps limit infiltration or release of the waste, and the waste form, itself, might help limit infiltration contacting the radioactivity that's embedded in it or encapsulated, depending on the design, and then the release from it.

You could also, in some cases, have waste containers that might have some performance credit. That's generally more rare in the commercial side of low-level waste disposal, but certainly, people aren't prohibited from using an

engineered container and taking credit for it as a barrier. That's an example with respect to infiltration.

I would look at the arguments -- also, say if I was a location that was a very arid site, that arid site is a barrier to release or a component to the argument to release because you've selected a location where the precipitation is very low, and the infiltration rate is low. That's one of your active parts of selecting the facility to make your safety argument that provides you some confidence that you're going to be meeting the criteria. That sort of thought, that's just an infiltration example, but we could go through other ones, transport and things like that.

MEMBER BROWN: Could I ask a question here, also?

MR. ESH: Yes.

MEMBER BROWN: Back when you answered my question relative to active site, old stuff, when it has to be evaluated for compliance, in accordance with the new rules, which, I guess, includes defense-in-depth compliance evaluations, does that mean they have to dig it back up if you find you don't comply?

MR. ESH: Right. This is a question that came up in the public comment process and has come up multiple times in our eight or nine years that we've been discussing it. This idea that if you're not in compliance, you need to take some action is always in place. NRC, we regulate a facility.

We have requirements you're attempting to meet. We then inspect and verify and monitor that you are meeting the requirements. If you're not meeting the requirements, then some action is taken to get you into compliance and meet the requirements. You could, hypothetically, identify a situation where a facility has a challenge meeting the compliance criteria in the future. They would have to come forward and say what actions they're going to take to try to mitigate the impacts of that.

MEMBER BROWN: But you changed the rules. You've changed the rules on them after -- the stuff could have been there for 10 or 15 years, and now you've changed the rules. Now you're going to say, "We've got new rules." It seems like their only recourse to make compliance would be to come back and dig it up, put more barriers around it,

etc. Is that --

MR. ESH: Digging it up would be the last action you would take, I would believe. I think at first, you would see if there were barriers you could put in place to mitigate the impacts. Secondly, you might even do a risk analysis to look at the socioeconomic considerations -- the technical plus socioeconomic considerations to see whether it's justified to take that action.

Because you have a hypothetical dose impact sometime in the future. You have a real impact from doing remediation or digging up radioactivity. We deal with this all the time in decommissioning, where there's actual material in the environment that somebody has to decide whether to take action for and what action to take. That's not unique to this problem. The existing requirements in Part 61 are silent on -- say if you're coming at this from an analysis time frame standpoint, they're silent on what the compliance period is. The intruder protection performance objective says the intruder must be protected at any time in the future. Is that changing the requirements on them if now, we specify a time, if

you go from any time to specifying a time? I would say any time encompasses any time.

MEMBER BROWN: It sounds like mouse milking to me. You answered my question. I understand your point. I just wanted to make sure I understood the thought process. You're kind of bouncing around a little bit. There's a lot of things to think about, which take time to assess and all types of other things.

MR. ESH: I don't think that the -- we don't have Charlie Brown and Lucy going on here.

MEMBER BROWN: That's me.

MR. ESH: I know you're Charlie Brown.

(Simultaneous speaking.)

MEMBER BROWN: Should I take that with a grain of salt, or should I be angry?

MR. ESH: That's purely by accident. We aren't intending to change the target on somebody. There are some considerations that -- yes, there are new requirements put in place, but the fundamental backbone to what's trying to be achieved in low-level waste disposal is still there in the existing Part 61, and in the proposed one. The one area where it's different, and I would say is the most significant area, is in the area of

requiring the intruder assessment.

When the existing Part 61 was developed, the intruder was protected by the regulator doing an analysis of what waste they thought would go in the facilities in the future, and then doing -- basically we call it a back calculation to determine what concentrations would result in the impact they were trying to protect people to.

Those concentrations are what are shown in Table 1 and Table 2 of the regulation. The existing regulation says protect the intruder at all times in the future, but the way that you do that is by showing that the waste meets Table 1 and Table 2. It also has other requirements associated to intruder barriers and depth of the waste that you must meet. That's the area where I would more agree with you that you could say that the target was shifted because you're now requiring an analyses, but in our -- in practical application of that, three of the four existing sites have already done an intruder analysis. It's only one out of the four that didn't do the intruder analysis. The majority of them have.

MEMBER BROWN: Thank you.

MS. LONDON: This is Lisa London from OGC. I just wanted to highlight a couple of points that Dave made that I think it's really important -- key take-away points. That is that the performance objectives in Part 61 always have to be complied with. That was always the case. If a site had reached its closure point ten years ago, it would be incumbent upon them to be able to demonstrate compliance with the performance objectives.

These rule revisions are not imposing anything that says -- we're simply not requiring anything to be dug up. You're not going to find anything in the rule that requires that. It's incumbent upon the licensee to propose how they would want to approach dealing with a situation if they were to determine they would not be able to meet the performance objective. We're not requiring anything to be dug up. Just wanted to make sure -- because as Dave noted, this has come up numerous times. I think it's really important that we stress that we are not requiring anything to be dug up. It will be incumbent upon the licensee to propose how they solve a problem.

MEMBER BROWN: Yes, but that's kind of

-- you're not requiring it, but in order to be -- they're going to evaluate, and in order to comply, they might have to dig it up. (Simultaneous speaking) you're not requiring it, but it's a backdoor way of they're required to be doing something.

I'm not saying it's not right or wrong. I just wanted to make sure I understood what you're doing in here. I'm talking about while you're active right now. He already went over the post-closure part, that there's an institutional period. I'm not quite sure what happens there, but then the post-institutional period is another set of things you deal with.

It was while you're still -- you've got stuff you put in, site's active, now you put more stuff in, has to meet the new. Now how do they have to evaluate that for compliance and go back? You say you're not requiring digging up, but, in fact, the only way to comply may be to dig it up, in which case, then you go through the rest of the risk assessments, the dose assessments, etc. Where's the rational person that sits down -- I could use where's the adult in the room that says, "No, we're stopping right here because it's just

not clear that the balance is not met"? It's just hard. Maybe the state -- should the state be in charge of that, as opposed to the NRC regulations, or what? It just seems to be a little bit open.

MS. LONDON: I wanted to make sure everyone understood that the requirement to comply with the performance objectives, those were always there. At closure, that's something -- the site would have always had to demonstrate. If we had never done these rule requirements, they may have still gotten to that point where at closure, they couldn't demonstrate compliance with the performance objectives. Then they would have had a problem.

MEMBER BROWN: Based on some of the stuff they have to look at now, that's not overwhelmingly obvious to me, but I understand your point, or what you said, thank you.

MR. ESH: Next slide, Gary. Probably one of the most challenging issues in this process was the issue of the analysis time frames. This figure is designed to give you an overview of the variety of time frames that are in the regulation. The second and third line down are really the only new parts in the regulation. The top line and the

three below that are all existing in the regulation. Each of these time frames has a basis for how they've been placed in the regulation and the purpose of them.

For instance, in the area of site characteristics, this is our representation for the guidance document on how to look at the site characteristics because the regulation in 61.7 says that you should consider site characteristics for 500 years or the indefinite future, I think, is the language that's in the existing regulation.

How long is the indefinite future? What we said in our guidance document is that you should generally be looking at the site characteristics commensurate with the type of waste that you're trying to dispose. If you have -- if you're in the situation that you have -- you don't have significant quantities of long-lived waste, then a 500-year to 1,000-year type of time frame is appropriate.

If you're in the situation where you do have significant quantities of long-lived radioactivity, then you should look at your site characteristics commensurate with how long you're trying to evaluate the problem for. The ones that

I'll focus on, though, are the ones that are different here. We can talk about the other ones if you have questions, but the compliance period and the performance period. We understand -- and we looked at them carefully -- the ACRS's positions on this topic, both the recent ones and the ones in the very distant past.

This issue has been discussed even back in the 1990s because the NRC was developing a guidance document for 10 C.F.R. Part 61, how to do the performance assessment analyses. One of the issues that they tackled was the compliance period. They had interactions with the ACRS, the staff, at that time, in the 1990s, and the ACRS wrote various letters on that topic then. We considered those, too, when we developed our approach. There's a lot of confusion on time frames.

One other thing we saw in the comments from various stakeholders is that the compliance period in Part 61 is 500 years. That is not correct. Part 61 is silent on what the compliance period is. For 61.42, it says, "Intruder must be protected for any time in the future." That's the existing regulation; that's what it says with respect to compliance period and time frames. We

only added or altered, really, the compliance period and the performance period. Next slide, please. As we talked about earlier, all of our existing facilities are in agreement states. We took that into consideration as we developed the approach for time frames and how we tried to solve this problem. Throughout the process, we've had significant interest in the topic.

We received significant comments, and we devoted significant effort to formulation of the final position. As Gary described earlier, the key features of the final position is a compliance period of 1,000 years or 10,000 years, depending on if the site will contain significant quantities of long-lived radionuclides. Then the performance period only applies if you're using the compliance period of 10,000 years.

So long-lived waste, you're looking at 10,000 years, plus the performance period. Insignificant quantities of long-lived waste, you're going to be using 1,000-year compliance period. For a low-risk problem, we would be in alignment with what we do in 10 C.F.R. Part 20 for decommissioning, or what the Department of Energy does in their analyses. The other important factor

here is that, as Gary discussed, the Compatibility Criteria C. Agreement states can be more restrictive if they choose to. That's one of the consistent comments that we received in this process from the agreement states. All four of the existing agreement states currently use a compliance period longer than 1,000 years.

The only unique case is for Utah, that has this distinction between large quantities of uranium and traditional waste, where they say use 10,000 years, plus look longer for the large quantities of uranium because they were trying to come up with criteria that they thought were appropriate for depleted uranium.

Our rulemaking, though, was a little more broad than just depleted uranium. We were also tasked with looking at blended waste, and we had to consider the potential for new waste streams to come into play in the future. Because the existing regulation, especially with the 61.42 requirements, are based on assumed quantities and concentrations of waste.

If you've done an inverse calculation to develop what the concentrations are that you need to use to demonstrate compliance with 61.42,

if you change your waste, then what does that mean for those concentrations that you calculated? The concentrations that you may need as limits can be quite a bit different if you change your waste. We did not want to be in the situation, after eight or nine years, of somebody coming in with a new waste stream, and we would need to turn around and say, "Now we need to go through this process again to look at the new waste stream that may have developed, that we need new criteria for. We wanted something that would work, no matter what the waste streams are, that somebody could do the analyses and demonstrate compliance with it.

MEMBER REMPE: David, I'm a bit slow. Tell me again what Utah does, and they did it because of -- expound a bit about their reasoning for doing something different there.

MR. ESH: They make a distinction -- they originally had analyzed 500 years. They used 500 years as a compliance period for evaluation of their low-level waste facility. There's members in the audience here that can correct me if I get anything wrong on this.

Part of the reason for that was their site, they believe, has ground water that's not

potable. It eliminates a large part of the analyses that you commonly look at in a low-level waste facility. I would say if you're trying to site a facility, that's a great idea. If you put it someplace where somebody's not likely to use the water, you would want to take advantage of that. But then the licensee proposed one of the entities to take some of the large, significant quantities of depleted uranium. They said, "Okay, that raises some unique issues for us.

What may we need to do differently to regulate that material, as opposed to this traditional material that doesn't behave like that?" They went through a rulemaking process and developed criteria for -- I don't know the specific language they used, but basically, large quantities of uranium, they use a different compliance period for that compared to other waste.

MEMBER REMPE: That period is?

MR. ESH: They use 10,000 years for that, and then they look longer. They have something similar to what we're calling our performance period here. They have that in their regulations.

MEMBER REMPE: Thank you.

MR. ESH: Let's see if I had anything else I wanted to say on here. All our agreement states have been licensed and are operating. All of them have used a compliance period longer than 1,000 years. One of the arguments we heard from some of the stakeholders is using a 10,000-year compliance period is going to make these facilities unlicenseable, and it's going to create a huge burden for them to be licensed. All our facilities already use values longer than 1,000, and they are licensed and operating.

To me, that's factual information that demonstrates that position was not entirely correct. We also discussed with a variety of the contractors that developed the performance assessments -- because I had an opinion that if you have a site that might be stressed by some unique processes or events in the future that occur, say, with a frequency that they're likely to occur after 1,000 years, but not really likely to occur within 1,000 years, then that would be a situation where maybe you can have some additional burden in your licensing.

Because maybe you're worried about a seismic event, for instance. That's not a good one

for waste disposal, but it's just the one I'll use for an example. Maybe you're worried about a seismic event that could damage or stress your facility. That could introduce burden if you're doing a 10,000-year analysis, compared to 1,000, because maybe it's at low enough frequency you don't expect it to occur with a frequency to affect your 1,000-year analysis. But in the vast propensity of cases, what you have to do to develop a 1,000-year analysis, a performance assessment, intruder assessment, etc., a huge part of that effort is the same for the 10,000-year analysis. It's not a significant increase in effort to go from the 1,000 year to the 10,000 year.

You have to develop the models. You have to develop all the data for it. You have to write all the reports, all that sort of stuff you have to do for the 1,000-year analysis. This idea that the 10,000-year analysis is significantly more burdensome I don't believe is true. It wasn't true from our experience, and then it also wasn't true when we talked to the various contractors on the private side that developed the models. They said no, the additional burden for the 10,000-year analysis, compared to the 1,000, is not significant

to them.

CHAIR CHU: David, I do want you to comment on something. I agree with you on the extra burden between 1,000 to 10,000 is not that much more, but a lot of people comment on the fact that because the uncertainty increases as time goes on, your answer is not credible.

MR. ESH: Right.

CHAIR CHU: So would you --

MR. ESH: Right --

CHAIR CHU: -- here --

MR. ESH: Yes, that's -- that's another argument that we heard, and -- and I think that creates a -- in my opinion, a policy challenge associated with the uncertainty, and where I would go with that is so the argument that was put forth is the uncertainty is increasing, okay, in some cases it is, and in some cases it is not.

You know, we looked at the uncertainty and different sources of uncertainty when we did our white paper, and our opinion was basically that the socioeconomic source of uncertainty is much much larger than many of the other sources of uncertainty associated with like flow and transport and, you know, all the -- all the gs that go into a

performance assessment because, if you think about how the world has changed in the last even 100 years, you know, and I like to use -- I like to use the Las Vegas argument.

So the argument I would make is if you could go back in time say 300 years and talk to somebody living in the environs of where Las Vegas is today and ask them what Las Vegas was going to look like 300 years from then, they would not have predicted what they got. They would have been probably way off on that estimate, and that is the type of uncertainty you're dealing with on the -- on the -- the human side of it.

And one way we try to manage that in the regulatory process is we say, use some fairly conservative receptors that are representative of what people might try to do today and just eliminate that source of uncertainty that does not do you any good to speculate about exactly what somebody is doing, but if you want to refine your receptor scenario and say, well, today, we have nobody living there, and we have hunters that spend five hours a day there, well then in the future, if, you know, they hit a gold rush of the next natural resource in that environs and they -- say,

for instance, fracking.

I think fracking is a great example, too, you know. 50 years ago, fracking wasn't so widely done, if at all, but now, fracking is pretty prevalent. So if you did an assessment 50 years ago and said, you know, what's the likelihood of somebody drilling in my facility, well, fracking wouldn't have been part of the consideration, but today, if you're in West Texas or at WIPP, or, you know, some other -- even Western New York, it's a consideration for all of those places.

So anyway, I am sorry I am rambling a bit, but the uncertainty piece is an important consideration, but I think the policy challenge is I don't -- I am not aware of other areas in the NRC, or even in risk management in general, that use the argument of the uncertainty is so large, therefore I should reduce my requirements, which is basically the argument that is put forth, okay? So if you're saying, well, the uncertainty is so large with 10,000 years, therefore I should make it 1,000, I don't know. I think from a policy standpoint, that is difficult.

You know, think about in everyday experience what you would do. If I was going out

and trying to cross Rockville Pike and there was a big truck parked there, I would not just start walking, you know? I would try to do something to mitigate my risk or mitigate my uncertainty associated with the decision I was trying to make. I think the same thing should apply here in the waste disposal areas, that you should be doing things -- if you truly think the uncertainty is prohibitive, then you should not be taking that action, you should be taking some other action where you can understand the uncertainty and you can uncertainty the risks associated with it.

I personally do not believe that those uncertainties are prohibitive in these calculations. I think they serve a very good purpose. They communicate to the best of our ability how we expect things to behave in the future, and they are useful for making regulatory decisions, which is what you are trying to do.

Part of the problem in waste disposal is that the risk gets liberally applied throughout the vernacular, but in many cases, we aren't necessarily talking truly about risk. We are talking about radiological dose, which might be different, especially considering what you're doing

to get from Point A to Point B in that calculation, so it's kind of a long answer to your question about uncertainty, but I think fundamentally, I don't agree with the idea that if the uncertainties are prohibitive, you should reduce your requirements. I think it means you should solve the problem a different way, or you need some different requirements --

CHAIR CHU: Thank you.

MR. ESH: -- not -- not that you should -- not that you should lessen them.

MEMBER REMPE: To belabor it, I think this is a good time to re-ask my question about the international community because I think the same situation occurs, even if they go to 50,000, they've got to deal with uncertainties for that period, and do they treat it the same way? They basically --

MR. ESH: Right.

MEMBER REMPE: -- don't try and -- they use the conditions the way it is today, and they run their calculation out for 50,000 years instead of 1,000, or something like that.

MR. ESH: Right. Internationally, they will take a variety of approaches. Some of them

say for like -- I know some countries even for like chemical waste disposal, their requirements is they analyze to peak, whenever that might be. It might be five million years that they analyze for, and so they are talking about uncertainties that are quite significant compared to what we're talking about.

But they -- especially in Europe, I would say, the people are much more comfortable with this idea of longer time frames, and partly because they've been around -- they have been there longer, and you'll talk to people who their family may have lived in the same town for like 700 years, and for us, we're kind of an infant compared to that in terms of a country and our development and everything, so part of that cultural idea reflects -- or comes into play.

But then in many cases in the international space, they will set a limit for what they think is appropriate for near-surface disposal, and it might be a -- a general limit of, you know, x becquerels per kilogram of long-lived alpha. Once you have set that limit, that is their way of mitigating the uncertainty associated with the longer time frames.

If you have limited how much of the

long-lived material can go in the near-surface, then you can use a much shorter compliance period because you have restricted what the risk may be at a longer time by prohibiting that material from going there. So that is -- you see that quite commonly in a lot of the other programs, is they will set some sort of waste limit that is separate from the technical analyses.

And here, in the U.S. and in this rulemaking, we're trying to strive for a much more site-specific analysis-based approach, and so you could set some sort of similar concentration limit, say, for uranium. In fact, limits for uranium were calculated in the original regulation, in the draft regulation for 10 CFR Part 61. But between the draft and the final, they decided that there wasn't going to be much uranium that was going to be disposed in a commercial low-level waste disposal facility.

Well, that looks like that was a bad assumption today, but the limits that they calculated were a very small fraction of the concentrations of the depleted uranium that you're -- that you're dealing with, so they did generate some -- they -- we, being the NRC, we generated

values for say concentration limits for uranium. That option was proposed to the Commission during the early stages of this process, and they didn't adopt that approach. They decided, no, the site-specific analysis approach was the better way to go because you can do it in a more risk-informed manner. You can reflect the actual say radiological dose impacts at the site rather than some hypothetical calculation that the regulator would do.

So that -- that option was provided to the regulator of how to -- how to -- it was provided to the Commission of how to manage uncertainties, and they adopted the approach we're talking about here.

MEMBER REMPE: I am a little confused because I thought earlier, you told me -- told us that the international community actually was amazed the U.S. is only thinking of up to 10,000 years, they went further overseas --

MR. ESH: Right.

MEMBER REMPE: -- to longer time periods.

MR. ESH: Right. The ones that do not set some sort of limit --

MEMBER REMPE: Go for longer time periods --

MR. ESH: -- generally, they just analyze out for much longer time frames.

MEMBER REMPE: And for uncertainties, basically, no, they don't try and think about uncertainties and differences in seismic or weather changes, they take the conditions the way they are today and do some uncertainties, but they run the calculation longer --

MR. ESH: Well --

MEMBER REMPE: -- is that the answer?

MR. ESH: No, I would not generalize like that, and if I gave you that impression, it is incorrect.

They -- it can vary from program to program, but generally, any of these that are doing the technical analyses, they are trying to do the best estimate they can of the expected performance in the future, so if they believe -- many of them will -- will look into climate change --

MEMBER REMPE: Okay.

MR. ESH: -- for instance. We say look at natural cycling of the climate, but that anthropogenic climate change, who knows where it's

going to end up and how exactly you should assess it. That is kind of a, okay, if it does in fact need to be revisited in the future, we will revisit that aspect of the assessment, but by considering natural cycling of the climate, you should be encompassing most of the effects of the anthropogenic changes in the climate because the natural cycling of the climate from the planetary motions and everything is so large, you know, you get glaciation and that sort of thing eventually at some locations.

But the -- the anthropogenic changes will occur earlier, but right now, it does not -- I would not say that they are going to cause effects on the order of the planetary motion types of effects from the climate cycle.

So anyway, internationally, though, they do consider all those sorts of process -- features, events, and processes in their analyses, but it can vary substantially from program to program. So some of them are much more mature than others, and some are earlier in their development in terms of the complexity of their technical analyses.

MEMBER REMPE: Okay.

CHAIR CHU: Dave, a lot of what you describe on how to, you know, apply the FEPs and all that, is it in the guidance document? Are all these things --

MR. ESH: Right. So in the guidance document in Chapter 2 is where we go through a process of how to develop the scope of your analyses, so what should be in it, and what should be out of it, and there's kind of two approaches, either top-down or bottom-up.

And one is based on identifying the safety factors or safety functions of your system and then building kind of the processes and events that may affect those safety functions, so that is pretty much the top-down. The bottom up is you start with a database or a list of all the features, events, and processes that you could anticipate at any site, and then you determine the subset of those that may apply to your particular site, and then you go through a process of taking a subset of those to develop into your models to evaluate your particular site.

So it is -- it is pretty lengthy, though, that part on the -- the FEP process, so I'll warn you ahead of time. Let's see, where were

we here on time frames? I think we can go to the next slide.

Also, one other thing on the time frames, the -- it isn't just in the Agreement State space that these 10,000 year analyses were used. I think this was a question earlier, but the Department of Energy has used the 10,000 year analyses in a variety of decisions that have been made, so in their incidental waste determinations for the Saltstone Disposal Facility at the Savannah River Site, for tank closure at the Savannah River Site, for tank closure at Idaho, at Idaho National Laboratory, and in process for tank closure at the Hanford site, all of those sites have analyzed -- or done 10,000 year analyses for those various decisions.

And the incidental waste problem is one where it is material that had resulted from the weapons program, basically, and some of the material that -- the residuals that remains in the system, if you went strictly by definition, it would be high-level waste because in the U.S., we're not very smart with how we define our waste classes, and Lisa will smack me for this, but they are based on words in legal definitions instead of

by necessarily engineering and that sort of thing.

So yeah, so the problem is that some of that material by definition could be considered high-level waste, but then the Department of Energy goes through this waste incidental processing, waste determination process to determine that some of it could be managed as -- with -- as low-level waste, or similar to low-level waste, and for the Savannah River Site and Idaho, they used the criteria in 10 CFR Part 61.

That material is much more similar to kind of the situation for some unique waste streams where you have long-lived -- significant amounts of long-lived radioactivity than it is most of the traditional commercial low-level waste, so it makes sense to use that there, and with our proposed requirements, I think -- I can't guess how it would fall out, but my guess is they would continue to be using the 10,000 year evaluation for those incidental waste determinations, but there may be situations in DOE's inventory in waste where they could determine if it were incidental waste that it does not have significant quantities of long-lived radionuclides, and then they would use 1,000 year analyses.

So that's another data point of you had asked about, you know, numbers and who uses what. Maybe it was over here, I think you asked numbers and who uses what, so let's see here.

Significant quantities, so the way this approach is set up now is that you determine your compliance period based on if you have significant quantities of long-lived radionuclides, and how does one determine though if you have them? And what we're advocating is that you start simple and introduce more complexity to make this decision if necessary.

So the simplest approach is to look at your inventory. The inventory is the thing you know best in -- in probably this performance assessment process. Even the inventory has uncertainties, but you know what you want to put into the system, so you can design a disposal facility with say minimal long-term barriers because you only want to take short-lived waste. That would be smart. I would do that as an engineer.

If I was trying to dispose of long-lived waste, I would design a much different facility than if I am trying to take short-lived

waste. So we thought, well, can't we structure this analyses to kind of go in that same direction? And in the -- the previous -- the most recent ACRS letter that we received, they said -- or you said use a site-specific approach, don't define the period of performance or compliance period in the regulation.

So the challenge we faced was, though, that many stakeholders had told us to define the compliance period or the performance period -- period analyses in the regulation. We heard that early on in the process when we had workshops in 2009. They said yes, yes, yes, we all want a number in the regulation. Of course, nobody can agree with each other, but they all wanted a number in there.

So -- so we -- you know, we listened to you, and we know the existing regulation has -- does not have a compliance period in it, and as I stated earlier, originally, that did result in a pretty big variance in the values that people used.

The other challenge with not putting a number in there, but doing it purely based on a site-specific analysis, is we think there could be negative incentives from a policy standpoint. So

if you have a very good site, then maybe your peak dose is not until 100,000 years or longer. So -- and then say if you had an underperforming site or a poor site, maybe your peak dose happens in 500 years. So should the poor site only need to analyze 500 years while the good site needs to analyze 100,000 years? That -- I mean, in my mind, it probably should be the other way around, as you want to have more confidence in what is going on with the poor site, and you can -- you can -- can rely on simpler analysis for the better site.

So without defining the period of performance, we kind of -- and -- we thought you could run into that, and the practical experience from what has happened in our Agreement States looks like that kind of is the fact. So like Texas, that has a very robust site and, whether you believe their calculations about infiltration rates and that sort of thing, potentially very long travel times, or even no travel times to -- to groundwater, that was a site that analyzed the longest.

And so we didn't want to have that disincentive to choosing good sites because if you're going to raise this argument that it is

extremely burdensome to do the long-term analyses, and it causes me all sorts of problems, well then why would you ever choose a good site that is going to force you to do this long analyses with this burden and all these problems? As an engineer, I would choose the one that I think is a lot easier, which would be the poorer-performing site.

So we -- we talked about that and tried to say, well, we think we need to put some numbers in here, but then if we're smart about it, we can do the part which you also wanted, which was to make it basically site-specific, so we started off and we said, okay, this is going to be waste-specific, but then maybe you look at inventory and you say gee, based on my inventory, I'm not sure whether I have significant quantities or not. Well then, you do site-specific screening analysis and see, okay, based on my physics and chemistry of my site, is the amount of inventory that I have likely to cause me a long-term problem or not?

So that's another way, as you step through this process, of defining whether you have significant quantities or not, is to consider the actual site-specific characteristics or do a full

site-specific analysis as indicated in number 3 here on a case-by-case basis, but the -- what I would say, though, is if you're needing to get into this really complicated argument for why you're doing 1,000 years, you should probably just be doing the 10,000 years because that means that you're in such an area that you're going to ask for all sorts of problems associated with if you truncate the analysis, especially if the impacts are much bigger after 1,000 years, kind of like your example, Dr. Chu, with the depleted uranium.

If you're really worried about managing the material, I think you'd want to know what is going on throughout the whole hazard profile of the material. You might make different decisions as to how you design your facility and how you make your arguments about protecting health and safety, but you definitely want to know what is going on for the waste that you're disposing of, you know, irrespective of what the regulatory requirements might be.

And so this approach with the -- kind of looking at the inventory, looking at the simplified dose assessment and then maybe doing some more complicated we feel is going to allow

people to do -- to tailor the analyses based on the waste that they have and to make smart decisions and make sure that the analysis is appropriate for the material and the site that they're analyzing. It doesn't get all the way where you would recommend it in your letter of don't define it at all in the regulation, but as I explained, there are reasons why we felt we could not do that. So next slide, please, Gary.

Here is an example that's similar to what is in the guidance, not identical, and I'm not necessarily going to go through this in detail here, but it's there in your slides, you can look at it, and we can -- you can ask about it, we can talk about it if you'd like --

MEMBER BROWN: What's SOF?

MR. ESH: SOF is the sum of fractions.

MEMBER BROWN: Okay.

MR. ESH: So yeah.

MEMBER BROWN: Thank you.

MR. ESH: So yeah, so in the -- in the context of the -- of where this came from, that would make sense. I see now that that is not identified in the example. It's a little hard to understand. But so in -- in low-level waste, when

you have a mixture of radionuclides, when you compare each radionuclide to its concentration limit to get -- you get a fractional value, and then you sum all those up, and that is called the sum of fractions, right, okay. All right, all right.

You can just tell me to shut up if I am --

MEMBER BROWN: No, no.

(Simultaneous speaking.)

MEMBER BROWN: -- Charlie Brown.

(Laughter.)

MR. ESH: The performance assessment is one of the main components of the technical analysis that you use in the 10 CFR Part 61. It is not a new requirement, though. The existing 10 CFR Part 61 has requirements for technical analyses. The words are different, the analyses is essentially the same.

So the existing analyses in Part 61 for demonstration of compliance with 10 CFR 61.41 is a performance assessment. This is just modernizing the terminology because in 1982, they didn't call it performance assessment, now we do. The definition that is shown up here, though,

basically, you identify the features, events, and processes that could affect the disposal site performance, so that's getting the scope of the analyses correct, and then you estimate the impacts associated with those, including the uncertainties.

Some of the new requirements under 61.13 that support the performance objective are new, but I will talk about those on the -- on the next slide or the slide after. Those requirements are we believe implicit in the existing regulation. They're kind of mom and apple pie things when it comes to performance assessment, so you need to have support for your calculations, you need to get the scope right, you should consider uncertainty and variability. Those are all things that the modern technical analyses should do, and so we don't believe those are burdensome.

Even if they're not listed in the regulation, if a performance assessment came in to me at NRC that wasn't being done under an Agreement State and it was lacking on any one of those things, they would be getting lots of RAIs on it, and maybe I wouldn't approve their application, because those are fundamental components of the performance assessment, and they aren't necessarily

-- well, they can involve effort, so -- but they should be part of any performance assessment, existing or in the future.

There is a requirement to update the performance assessment enclosure. That is an important requirement because, as Gary indicated, or was indicated previously, some of these facilities may operate for a substantial period of time, 50, 60 years. A lot of things can change in 50 or 60 years: our knowledge about various scientific and technical things, the -- what's going on socioeconomically in the environment of the disposal facility, so the requirement to update the performance assessment at closure is good science, and we think it is good policy because when you get to the point of closing the facility and the pass-off occurs from the licensee to the entity that is going to be doing the institutional control, they want to have confidence that the facility is going to continue to meet the requirements.

So without updating the performance assessment, there -- there may be some questions about that. If the licensee was smart and introduced significant margin or enough margin in

their analyses when they did their initial licensing basis, then the amount of updating that they might need to do at closure could be minimal, so they could make the argument that I've already accounted for everything that we observed in this time period while we operated.

The other thing in the performance assessment area is that we modified the siting characteristics, consistent with the disposal of long-lived waste. So this one is a little bit tricky if you're not familiar with Part 61. The siting characteristics are in 61.50, and they have -- there's requirements in there that are exclusionary or need to be present for a site, and they don't indicate basically the time frame that you're talking about that that characteristic might need to be present or need to be excluded.

So an example would be the facility cannot be located in a 100 year flood plain, okay? So what is the 100 year flood plain now? What is the 100 year flood plain 1,000 years from now? Those can be different answers, and the one is much harder to estimate than the other. You can do a pretty good job estimating the 100 year flood plain today; much more challenging to estimate the 100

year flood plain 1,000 years from now.

So we looked at that and said, okay, Part 61 when it was developed with the waste tables and these other criteria were envisioning not significant quantities of long-lived waste, but they were looking at mainly short-lived activity that would make sense to say, okay, you don't want to put the facility in a 100 year flood plain where it's flooding today because if it's flooding today, you're likely to have a lot of instability tomorrow.

So -- but the idea is that at longer time periods, when the short-lived activity, which you can only tolerate a small amount of that getting into the environment, has decayed away, the long-lived activity, then you can use a what we would call risk-informed performance-based approach to consider those siting characteristics, and what that means is whether you can meet the 61.41 or 42 performance objectives.

So for the first 500 years, we stuck with the language in Part 61 that says, for instance, you can't cite a facility in a 100 year flood plain. After 500 years, if you have a 100 year flood plain or you project that you're going

to have flooding in that area, then you can look at it in terms of whether it impacts the performance objectives or not.

Otherwise, say there's a requirement in there like the waste can't be disposed in the zone of water table fluctuation. Well, if you applied that for 10,000 years, you would have to look at, well, can I demonstrate that this waste is never going to be in the zone of water table fluctuation for the next 10,000 years? That seems to be an intractable problem technically. But you can probably better estimate if it does fluctuate, what's the impacts that I might see from it, so the modified siting characteristics, that's how we went about it. Next slide, please.

MEMBER KIRCHNER: May I ask just a question of clarification? So you have 500 years for the site characteristics versus 1,000 years for the compliance period, so how do you reconcile those?

MR. ESH: Yeah, the site characteristics language is existing in the regulation. It says consider the site characteristics for 500 years or the indefinite future. I don't remember, let me get the language

straight for you here.

So, okay, here, it is "In choosing a disposal site, site characteristics should be considered in terms of the indefinite future and evaluated for at least a 500 year time frame," so at least a 500 year time frame. If you evaluated the site characteristics for 500 years and you're analyzing for 1,000 --

MEMBER KIRCHNER: Yes.

MR. ESH: -- you're not going to be -- something is not going to occur -- like with confidence, you're not going to be able to say something occurs in the 500 to 1,000 year time frame that is significant that you couldn't also argue should be part of the site characteristics you consider in the 0 to 500. Now as long as you're in the same ballpark of what you're analyzing, I think that is what we're trying to achieve.

Since the regulatory language is pretty broad in how it could be interpreted, then we chose to address that in the guidance of how to -- how to consider the site --

MEMBER KIRCHNER: So you didn't --

MR. ESH: -- characteristics.

MEMBER KIRCHNER: -- go back and change it from 500 to 1,000?

MR. ESH: No. I think we still reference 500, but we also say -- we talk about the concentrations of the waste and say based on the concentrations of long-lived waste that you're dealing with, here's the time frames you might want to consider in terms of site characteristics.

MEMBER KIRCHNER: Thank you.

MR. ESH: Yes. So this is the figure of the performance assessment process, and what should be stressed is it is a learning process. The outer stuff on the pentagon is collecting data, developing the conceptual models, developing your numerical models, combining the models, and estimating the effects, while considering the site characteristics of the design and the waste form. That process is normally iterative in a performance assessment.

If the site is very complex, maybe you have a lot more iteration. If the site is simple, maybe it is once through, and -- and you are content with the results, but the performance assessment technical analysis is -- is iterative.

The requirements that were added in

this rulemaking are around the outside here, just to show how they fit into the overall performance assessment. So as I indicated, the three on the bottom there, or the one on the right and the two on the bottom with 61.13, that's scope uncertainty and the basis for your models. Those are kind of fundamental things to performance assessment. We did receive comments on it, but if you aren't doing those things in your performance assessment, you're -- you're probably not doing a good job with your performance assessment.

MEMBER SKILLMAN: David, you mentioned it's a continuous process. How often or how frequently is that circuit enacted?

MR. ESH: It depends on like in this, since these are in the Agreement States, it depends on the particular Agreement State. So I know in Texas they do an annual update to their performance assessment. Texas looks at that as one way to manage the facility and understand the performance and uncertainty and that sort of thing.

So they ask for an annual update. That's not a requirement in the regulations to do an annual update. To be on a -- I'm sorry Gary. Do we have a -- do you know, do we have a

requirement for an update frequency in the regulation?

MEMBER SKILLMAN: That's why I asked the question. I'm looking for it and I don't see it here.

MR. COMFORT: Yeah, I'm not sure that we do.

MEMBER SKILLMAN: Why wouldn't you ask that?

MR. ESH: Well, we have a requirement to update it when you get to the point of closure, so ideally though, if you've done a good analysis when you establish your licensing basis, there may not be a need to do many updates as you operate the facility. It depends apparently also on the complexity of the site and the type of waste that you're receiving.

So the update period that may be appropriate for one might not be appropriate for another. We'll have to look and see here. Maybe we can. If Gary can look if I'm talking, if we added anything for that. But that was kind of the thinking behind should we put an update period in or not. The one thing we wanted to achieve is that when you get to that final decision point of saying

okay, I'm going to move to closure, you do an update then.

So that takes into account everything that may have happened during operations. A good operator is probably going to update before that, because they want to know ahead of time what they might be looking at, you know, but that's not a requirement. As long as you can demonstrate that you're safe at closure. Whether you have problems to address when you get to the closure point, the way it's structured now I believe that would be up to the licensee.

MEMBER SKILLMAN: But that almost flies in the face of the idea that you don't know what you don't know. If you're not taking a look periodically, you may very well be surprised?

MR. ESH: I think the reality is that all of them do take a look. So all of them periodically update their analyses to reflect their new inventory and the understanding on the site based on observations they might have, and I don't know. Maybe we'll hear once we get to the comment period. Any of the individuals in the room can elucidate what they do --

MEMBER SKILLMAN: What you're saying is

it's simply not required at this point in time.

MR. ESH: I don't believe so, but Gary's looking. So this next slide here on performance assessments, a visual representation of what a PA is and what it entails. You have to build all of this regardless of the compliance period. That's something I was stressing earlier.

So if you start on the upper left-hand side, you have a real site. You're going to develop a conceptual model for the site. Then from the conceptual model, then a performance assessment. There's lots of what I would describe as models within a model.

So you might have a model for the hydrologic performance of the site. You might have a model for the geochemistry of the site and a waste form performance. All of those things feed into the overall radiological dose assessment. So if you have 1,000 year compliance period or a 10,000 year compliance period or some other number, you have to do all of these things to develop your models to evaluate your site.

As you go out in time, there may be unique features, events or processes, especially with lower frequency events that could come into

play. But that's part of the -- part of the Part 61 approach to managing the uncertainties associated with low level waste disposal is the siting characteristics.

So you're supposed to consider the likelihood for seismicity and volcanism and erosion and subsidence and all those ologies that can stress your system and result in releases or impacts. Those are to be part of your performance assessment analyses, or a consideration of your site characteristics and then if necessary part of your performance assessment analyses.

So this idea that the burden is significantly different depending on the compliance period doesn't agree with our experience and it didn't agree with many of the other practitioners that we talked to. The main point that I would associate with the performance assessment is that the quality of the work, both in terms of the analyses but then in the actual operation of the site is what's going to determine whether public health and safety is protected, not necessarily the number that's spit out of the computer program.

So I mean that can't be lost on -- we spent a lot of this time talking about the

technical analyses and debating the requirements for it. But the other parts of Part 61 that are used by the regulator to evaluate the actual operation of the facility and to inspect against, those are the primary drivers of whether the facility is achieving its performance goals, not necessarily what may be going on inside a computer model.

Next slide, Please. So the inadvertent intruder assessment, it has always been part of the Part 61 framework. As I indicated previously, it was analyzed by the NRC, by us the regulator, and that analysis was not site-specific and it was not risk-informed, because we had to make certain assumptions about the site, such as that it's a human site. You had make certain assumptions about the waste that's going to go into it.

So the resultant waste classification tables are completely tied to the assumptions that the NRC put into the analyses, especially about the waste. So when we were faced with the issue of depleted uranium disposal, it basically represents an unanalyzed safety condition.

So if you've disposed of depleted uranium and you have not done an intruder

assessment, then you could potentially have a safety impact associated with that, because depleted uranium was not included in the waste classification tables. I don't know whether that was -- you could say that's NRC's fault, responsibility for not making that clear, or it's the implementer on the other side that didn't understand that issue.

But the fact of the matter is that the source terms that were analyzed were very well described in the environmental impact draft and final documentations. So if you, if I was a licensee and I was looking at disposing of new material, I could easily do a comparison to see whether okay, does this material fit in the box that, the regulatory box that was developed or not.

In the revised regulation, this is the main change, even though a lot of debate goes on about the time frames and a few other pieces, when this issue came up of whether we needed to change the regulation, I naively said that yes, we do. We only need to add the requirement to do an intruder assessment and it should only take three months. So I was a little bit off.

(Off mic comment.)

MR. ESH: A little bit humbling. So in the revised regulation, the intruder assessment is now site-specific, which we think is much more powerful and much more flexible.

It also creates some ancillary burden or effects especially on regulators. The site-specific intruder assessment allows the consideration of the actual waste, the site conditions and the expected receptor scenarios for that site.

So one of the comments ACRS gave us in this area previously was you don't need to do this intruder assessment. You can just consider the durability of the waste and the stability of the site. Yes, the durability of the waste and the stability of the site are important considerations, but how do you know what durability or stability you need if you don't consider the source of the material that you've put in the facility?

So the intruder assessment is one way to calculate how much of a particular type of salt waste stream or concentrations of radionuclides that your facility can take, at least from a protection of the inadvertent intruder.

We also felt that it was much more

difficult to design and justify the performance of a durable barrier, especially a durable barrier from the perspective of intruder protection, than it is to do the intruder dose assessment. The intruder dose assessments are usually much more simple than the performance assessments.

They represent on the order of, you know, ten percent of the effort of a performance assessment. So the intruder assessment yeah, while you could argue that what's the validity or policy reason for including the intruder. Part of that was derived from when Part 61 was developed, was around the time that like Love Canal, where you did -- people did dispose of waste and then it got disturbed and caused some health impacts.

So that was kind of the mentality at the time. It ended up in part 61, and even though it is a regulatory analysis, we do think it has a good purpose because it is a check and balance in the system. So if you combine -- if you think of defense-in-depth, this is kind of defense-in-depth of regulatory analysis, combining the intruder analysis with the 6141 type of analysis gives you a type of defense-in-depth from the regulator's perspective.

Next slide, Please. Now one of the important considerations, and this detailed charter or table here that on the left-hand side you have on your CD. So don't worry about trying to read this right now.

It's the intruder, inadvertent intruder receptor is a very important topic, because the dose impacts associated with the inadvertent intruder can be driven by the types of activities that occur and especially how one may occur and how much disruption is associated with them.

What we've done in Part 61 is we followed the Commission direction of course, and the language associated with the intruder is shown in the draft final rule. But basically we say the intruder will potentially undertake normal activities such as dwelling, construction, agriculture, drilling for water, or other reasonable foreseeable activities consistent with the activities in the vicinity of the site when the assessment is development.

So the direction that we received from the Commission prior to this was at site closure, to consider the activities in the vicinity of the site. Well, if a site operates for 50 or 60 years,

we felt that could be difficult for some and maybe draw them into, for instance, a legal argument as to how well they can project what the particular activities are 50 or 60 years in the future as compared to when now, in the present day.

If you have a requirement to update the analysis at closure, well that's when you should reflect if something different is going on at the facility, than rather trying to project it today what you think is going to be going on 50 or 60 years from now. So that's -- you can look at that language as a slight deviation between the last version of the proposed regulation and the draft final regulation.

Next slide, Please. This is a figure of some of those types of what we would consider normal activities, normal from the standpoint of people are always going to look for some place to live and they need to eat and they need to drink water. Those are things that people do today.

Now where they get their water from can vary substantially. What they live in can vary substantially and where they get their food from can vary substantially. So but we also would say that while you can and should consider the

site-specific characteristics, you should also perceive with caution in defining your receptors, because on one hand you want to argue that there's enormous uncertainties that make the results unusable.

But on the other hand, then you turn around and say but I can accurately define what my receptors are and what they're doing. Those two things are kind of diametrically opposed. You choose one or the other.

So and if you think you have imagination with developing intruder receptor scenarios, wait until you interact with your stakeholders and see the intruder receptor scenarios that they may propose to you.

So that is a slippery slope. The flexibility is afforded there. The intruder is a regulatory construct. It's not a risk calculation, and it is used effectively on low level waste disposal, both on the commercial side and DOE, both entities do this intruder assessment.

And of course I guess looking at these figures, these are obviously not just scale unless we have like 12 feet tall people in the future.

So next slide, Please. Site-specific

scenarios, I just talked about that a little bit. We think you should consider them, and they can be used to constrain the exposure pathways for the normal activities or for reasonable foreseeable activities, and it's much better to base that on physical information, things that might be durable over time such as that the water is not potable and it's going to remain not potable, rather than cultural information such as well, there's no housing development there today. Therefore, there will never be a housing development there.

If the environment is such that it's very unlikely to support a housing development, well that's one thing. But you know I still get pulled back to that Las Vegas example. I think that challenges me from relying too heavily on cultural information.

Next slide, Please. Site stability is the third component of the technical analysis. It's an important part of the safety strategy. The original regulation said stability is a cornerstone of disposal. We are not backing away from that. We still believe stability is the cornerstone of disposal.

Part of that arose from the early

problems that occurred in low level waste facilities. There were a lot of stability issues with the facilities that were developed prior to Part 61. And even more recently with one of the existing facilities had an event or incident associated with what I would call stability issues, the Beatty facility in Nevada.

We did revise in response to public comment the stability definition, because the stability definition was somewhat circular than the existing regulation. Stability is structural stability. So we tried to provide a better definition for stability in this final version of the regulation.

Next slide, Please. Site stability. The guidance in Chapter 5 provides a lot of detail on this. It's also somewhat of an iterative process starting with site characterization, what are your hazards, what are your disruptive processes both natural and anthropogenic, doing some sort of either technical analysis or technical assessment combined with engineering design.

It's pretty much two different approaches or a combination of the two that can be used to demonstrate stability. For instance,

there's an appendix to the guidance document that has examples both for the stability analyses that was done for decommissioning at the West Valley site, which is one of the most challenging sites with respect to stability.

And then there's an appendix that has a technical evaluation report from uranium mill tailings management, where in that area usually design-based approaches are used to develop erosion protection. So those are based on determining that PMF, probable maximum flood from the probable maximum precipitation, and then from that designing your erosion protection systems, the sizing of your ripwrap (phonetic) and your drainage channels and all those sorts of things.

Now there's a TER with some information around it in there that we gave examples about the technical approach and the modeling approach. Then you combine that with the evaluation and monitoring.

Next slide, Please. So the site stability should consider the temporal and spatial scales. The temporal and spatial scales associated with the site stability analysis should be a function of the waste. So we -- if you have

primarily short-lived waste, and you're primarily looking at the waste at the site itself and the disposal trenches and whether you can ensure the stability of those.

When you start moving out to longer-lived waste in higher concentrations, when that is tied, of course it triggers when you might need to do a longer-term analyses, and a longer-term analyses means the scope of your stability assessment and how you're bringing in the geomorphological considerations becomes a larger area that would be important to consider. But some of that can be seen in the examples that we provided in the guidance document.

So that's pretty much the end of the technical analysis part, and now we'll transition into waste acceptance criteria. The technical analysis may feed the waste acceptance criteria depending on the approach that's selected by the licensee.

The licensees must review their waste acceptance program at least annually, and this is the primary mechanism that you ensure that the waste that is sent and received and disposed is going to meet the technical criteria based on the

analysis that you performed to license the facility.

So the three components to the waste acceptance requirements are characterization, the criteria themselves and then the certification, and the first thing that I'll talk about is the criteria.

Next slide, Gary. So the waste acceptance criteria are made up of the allowable limits on radioactivity, the waste form characteristics and container specifications and then any restrictions and prohibitions. The last two bullets here are really lumped together in 6156 in the regulation under waste characteristics. So that lists the types of restrictions and prohibitions and the characteristics that the waste may or may not have.

The allowable limits on radioactivity may be on a package basis, or they may also be on the overall facility. The waste form characteristics and container specifications include things like it can't be disposed of in a cardboard box. You have solidify liquids. You can't dispose of explosives. You can't have waste that's pyrophoric or it contains chelating agents.

They're all things that are important things from a performance standpoint.

As an engineer when I look at the waste characteristics and the prohibitions and restrictions, I think that's a much -- one of the most effective risk management components of the regulation, regardless of all the technical analyses and everything else. If you put pyrophoric material in a facility, you're asking for trouble, right.

So the requirement that prevents pyrophoric material from going in is a very important requirement to ensure the longer term performance or performance of the facility after closure.

Next slide, Please. So in this draft final rule, as within the previous version, there's flexibility to develop site-specific waste acceptance criteria. So you can use the 6155 limits. You can use the results of technical analyses or a combination of both to develop your criteria.

So either way though, the licensee must demonstrate that the criteria will demonstrate the performance objectives will be met. So the

important point in this is that the licensees have considerable flexibility, and generally you would be considering the concentration and the inventory.

So even in the existing Part 61, there's language that references the consideration of the inventory of the material you're disposing of, in addition to the waste classification tables. So long-lived mobile isotopes, there was an identification in the early 1980's that you might need to develop inventory limits for those isotopes, technetium, iodine, technetium-99, iodine-129, tritium and carbon-14.

The reason why a licensee and you might be thinking to yourself well why does the licensee need to do this third bullet if they're doing the other things, or especially if they're using the 6155 concentration one. It's because of the problem I talked about earlier.

The 6155 concentration limits were developed for a specific waste. So if your waste is outside the envelope of what was considered when they were developed, you basically have an unanalyzed safety condition there potentially.

So that's why this requirement to meet the performance objectives must be demonstrated,

even if you're using the 6155 limits.

As I indicated earlier, three of the four existing sites on the commercial side have already analyzed intruders, and in the DOE practice it's part of their requirements to analyze intruders.

So the next slide, Please. The allowable limits from 6155. This is what the process looks like. It looks complicated but it really isn't. The part I just talked about on the previous slide is really top two boxes on the diagram. After that, it's everything else you're doing to meet the requirements associated with the waste.

So the determination of the limits is rather straightforward, whether it's based on the concentrations and the sum of fractions or you need to develop some sort of inventory limits. The other requirements take up most of the diagram.

Next slide, Please. So if you were developing allowable limits from analyses, this is how it might look like, something like this. Of course this is the flexibility that provides you the ability to look at the site-specific characteristics. It's very powerful.

But then that power also then triggers the need for a thorough review by a competent regulator, because if you're basing what the facility can take on the analyses, you have to ensure that the proper quality and valuation was done of that analyses, that the results are correct.

This was a concern for a number of stakeholders. They described it as putting the fox in charge of the hen house I think, which was kind of a good layman's way of describing it. I said no, you're not putting the fox in charge of the hen house but if you are, the regulator is the farmer. So I mean you still have somebody that's supposed to mitigate or evaluate and make sure that the decision is going to be safe.

MEMBER BLEY: Dave, I have a question. If we have reg guide and we have the SRP, I know how that works. If we have a NUREG as the guidance, does that serve both functions? Is that the guidance for reviewers as well, or are you going to have an SRP on this?

MR. ESH: Right. We have an SRP for 10 C.F.R. Part 61 that was developed based on the existing regulation.

MEMBER BLEY: Right.

MR. ESH: And it is quite voluminous, and we looked at that and we said ideally, we would like to develop an SRP that would go along with the new regulation.

But at the time, I think there was a decision that supplementing existing guidance by putting in discussion in areas that were new was the appropriate way to go for this rulemaking because it was supposed to be a limited scope rulemaking, right.

So you know, I mean you laughed at that. It was supposed to be a limited scope rulemaking. So that made sense to supplement the guidance rather than wholesale revising it. Now my personal opinion is just like we did in decommissioning, with doing a whole-scale revision of the guidance there and consolidated the guidance of what I think Derek participated in before his life here.

(Off mic comment.)

MR. ESH: Yes. That would be a useful activity to undertake in the low level waste area, but it would be very resource intensive and considering the climate with Project Aim and agency

resources, I just don't know whether they would devote the resources to --

MEMBER BLEY: Well, let me push that a little. I know somebody else wants to talk, but just a minute. The old SRP can't, I can't expect that it would be appropriate here. But I could expect, depending on what we see in this document, that it might be complete enough and clear enough that it would serve the purpose as guidance for a reviewer as well.

And on the other hand, if we don't have good guidance because we don't want to spend the money to get it, we might pay a hell of a price and so might the licensees when the reviews come around.

MR. ESH: Right, and I don't want to give that impression because the existing SRP, I think, provides a lot of guidance for the areas of the regulation that were not touched in this rulemaking. There are a lot of areas that aren't touched in this rulemaking. I mean a lot of the language changes in say 61.7. 61.7 does not provide requirements.

It's just basically the concepts of setting the stage for how everything fits together.

So you know, we received a lot of comments about our changes to that section, but the reality is that really doesn't mean anything in terms of compliance with requirements in the regulation.

In the areas that we did change, that's where we hope this guidance document comes into play, to provide information in the areas that we did change. So Chris, I don't know if you had a comment.

MR. McKENNEY: Chris McKenney from the -- Branch. The one that's also in front of the Commission right now is a programmatic assessment for the low level waste program, and one of the actions -- one of the possible actions within the next five years is a consolidation of all of our guidance, to try to revise our older guidance and bring it -- and bring the guidance that is necessary into a consolidated set of guidances.

There's a couple of options there of guidance for operators and possibly guidance for generators, and of course resource requirements for that. And as Dave mentioned, for this guidance compared to NUREG-1200, this would only be like part of Chapter 6 of NUREG-1200, because even Chapter 6, which is the technical types of

analyses, had also accidents and everything else and stuff which during operations, which this doesn't even cover those sort of things.

This guidance still does cover a number of things that the reviewers could use in that analyses for -- NUREG-2175 does cover a number of things, and with our reliance on our previous analyses in NUREG-1573, which is the previous low level waste guidance on performance assessment, which we put out in 2000, which was also written for both reviewers and the license community.

Again, was a combined sort of mixture of SRP and guidance to the community, not an SRP but not a -- just a pure guidance document.

MEMBER BLEY: Right, okay. It kind of all sounds reasonable to me. One question. After the rule becomes a rule, how soon do you anticipate staff would begin receiving analyses that they need to review in this area?

MR. ESH: Well, the short answer to that is not any time soon because they would all be received in Agreement States. So all the facilities are in Agreement States. The Agreement States would have a period of time after our rule becomes final to make the corresponding changes in

their regulations and make them final, and then they would have, receive the updated analyses in their Agreement States, which they -- the language is, I think --

MR. COMFORT: Five years or the next renewal.

MR. ESH: Five years or the next renewal.

MR. COMFORT: Whichever's earlier.

MR. ESH: So it would depend on when their rule got final and then when the next renewal was.

MEMBER BLEY: And the states that are not, our staff would review?

MR. ESH: They would, and just like always, we're available to help them or provide input to them. We have two different versions. We have one that's kind of a less detailed input to their process, and then one that's a more formal or more detailed input to their process, where I believe they reimburse the agency for our time if it's the latter one. If it's the former one, then we supply that voluntarily.

MEMBER BLEY: Okay, and then these areas, this reg guide would provide them guidance

as well as the licensees?

MR. ESH: Right.

MEMBER BLEY: Okay.

MR. ESH: So allowable limits.

MEMBER SKILLMAN: David, let me ask this please. Here are five assessments, and you mentioned a key word which is quality, and I look at the red line strikeout and I see quality identified as a concept. I'm just wondering what the vision is for the quality that is acceptable for these analyses. What is it that you use to ensure that you're getting a durable and responsible product?

MR. ESH: Right. So in the regulation, I believe we had a requirement for, associated with quality assurance of the analyses, because we felt that was important, and then in the guidance document, we've added -- and that's in the area where, one of the areas where I would say you should take a look at.

We added material associated with the quality assurance of developing models, data, all the components of the technical analyses. We put material in there referencing various quality assurance procedures and documents.

MEMBER SKILLMAN: Thank you.

MR. ESH: Next slide, please, and I'll try to hustle through these so we aren't too far behind. Waste characterization is the -- waste characterization and waste certification are the other two pieces to the waste acceptance requirements. The licensees must specify acceptable methods for characterizing the waste.

Now detection methods have improved significantly, but there's still a source of uncertainty associated with what exactly the inventory is, especially for the long-lived mobile isotopes, because they're generally hard to detect, especially if in the presence of some other isotopes that are -- confound their identification.

We have new guidance associated with that, that allows the use of scaling factors and also indicates that say for performance assessment, in some cases a practice was that if a measurement was done and the isotope was at the lower limit of detection, then a value of zero was assigned in the inventory for the performance assessment.

Well, if the lower limit of detection, if it's below the lower limit of detection, you know it's below that, but it doesn't necessarily

mean it's below zero. The challenge is that when you assign a lower limit of detection, even if the lower limit of detection it was causing some performance issues in some analyses.

So that's where the consideration of scaling factors and some other approaches that developed the inventory may come into play and may be useful. So we hope that that's a reasonable approach to deal with this issue of inventory uncertainty.

The waste characterization is to ensure that knowledge of the waste characteristics is commensurate with the assumptions and approaches used to develop the waste acceptance criteria, and sufficient to demonstrate that the waste acceptance criteria are met.

Next slide, Gary. The characterization methods may be -- I talked about this some -- direct or indirect, such as materials accountability, characterization by source or scaling factors. Data quality comes into play here, quality of the technical analysis we just talked about, and also the documentation of the responsibilities for characterization, quality assurance of procedures and records.

The guidance that has been developed addressing data quality and documentation. So if you want to rely on technical analyses to develop your waste acceptance criteria, then you need to ensure that those analyses are transparent and traceable, and they should be publicly available to your stakeholders.

You know, you should be able to weather the storm of the criticism that you might get and be able to answer the questions that the stakeholders might have about your analyses. What's shown here on the right of the characterization methods slide, there's one way to go about characterizing data using like a data quality objectives process.

First, you develop your data quality objectives, then you obtain the data, then you evaluate the data and you iterate if necessary. So it's plan, implement, assess, decide.

Next slide, please. Waste certification is the third piece to the waste acceptance requirements, and that's the program to certify that the waste meets the acceptance criteria prior to receipt at the disposal facility. So this has been modeled after DOE's program. They

do this in their facilities because for quite some time now they've used site-specific analyses to develop their waste acceptance criteria at their sites.

The waste certification process can be important for the generators and the operators, and if people aren't used to using that, I'm sure there will be some growing pains to get that implemented.

Next slide, please. So now a few slides about the guidance. The guidance changes that we've made are generally in support -- well, the guidance is in support of the regulations, and we've developed guidance for the licensees and Agreement State regulators to provide approaches that the NRC finds acceptable to meet the regulatory requirements.

Of course Agreement States and licensees may come up with their own methods to satisfy the regulatory requirements, as long as they can demonstrate that the requirements are met. The guidance that we developed we hope is useful to licensees and the Agreement State regulators.

If we were evaluating an application, that's the document, combined with many others, that we would use. It is around 500 pages or so.

It's not all words though, so you'll have to be the judge whether it's a good sleep aid to you or not if you need that sort of thing.

There are many examples provided, and some figures and that sort of thing. So hopefully it's not just reading all dry regulatory text. We do have in there suggested references, screening tools and case studies, a variety of other information. One important thing to note about the guidance is, and I can't make this enough -- can't make this point enough times is that guidance does not provide requirements.

So requirements are provided in the regulation. Guidance provides methods that you may use to satisfy the regulatory requirements. So we've received lots of comments, especially from some stakeholders that kept saying things about the requirements in the guidance, and it's just a misinterpretation of what guidance is in the regulatory approach.

We did not receive as many comments on the guidance nearly so as we did on the regulation, possibly due to length of the document. We really tried to get comments on it. We did receive some good comments from a variety of stakeholders, but

it was a bit of a challenge to get comments on it.

It will be issued at the same time as the proposed rule, so sorry, as the final rule. It will be issued the same time as the final rule. Oh, I'm sorry. I'm misreading my bullet here. The draft NUREG was issued at the same time as the proposed rule. The final NUREG will be issued at the same time as the final rule.

It was discussed in seven public meetings, including a webinar that was dedicated to it and we have the same public comment for it as we did for the rest of the regulation. The guidance such as the NUREG is easily revised or easily as defined in relation to developing a regulation.

So it still might be a bit time-consuming, but it's way easier to revise guidance than it is to change a regulation. So we expect that in the future, there may be the need to revise or supplement the guidance document, even if we don't have that need to do anything with the regulation. But that of course would depend on resources. Next slide, please.

MEMBER REMPE: Just a question, though. Like if we had a discussion of this topic at our full Committee meeting, right now the disks you

gave us are not openly available with the guidance document. Do you anticipate that you'll be done with your effort so it will be public by the first week of November?

MR. ESH: I don't believe so, because it has to be held to -- before it can be made final, we have to see what the final changes to the regulation may be. So we have to wait and align it with that, and that's primarily why it's held back.

Now the version that you got right now, if we didn't get any changes to the regulation, that would be the final guidance document. We don't anticipate any changes -- right now, we don't have any additional changes to that document. So yeah.

The comments that we received on the guidance document were mainly in alignment with the rule comments, such as in the analysis time frames. There was a lot of discussion about the protective assurance period, which Gary discussed in the three tiers that he said it's confusing and it should be eliminated.

There was comments about defense-in-depth and the requirement for analyses. So that we already covered in detail. There was

confusion on the various time frames, like I showed you that figure, a version of it that we put in the guidance document. We had questions about the site closure process, so there's more new material on that, including the development of say permanent markers to identify the site at closure, and there was some clarification on the inadvertent intruder assessment scenarios in the guidance.

MEMBER BLEY: One question about the comments. In the big package that was released, there's the summary of comments and your responses. Did you get many comments beyond those from licensees and the state regulators?

MR. ESH: You mean on the guidance document?

MEMBER BLEY: Well on both.

MEMBER SKILLMAN: On both.

MR. ESH: The comments on the rule were from a whole variety of different stakeholders, members of the public, licensees, Agreement State regulators, other trade and industry organizations, environmental groups. It was a wide smattering of groups that provided comment on it. On the guidance document, it was much more limited to some of the licensees and Agreement State regulators.

MEMBER BLEY: Okay, thanks. I hadn't seen a list of all those.

MR. ESH: Right. So all the comments are publicly available that we received on the rule. The responses for the guidance documents, the comments on the guidance document are an appendix to the guidance document. So you have that on your CD.

So the major revisions made were of course in the analysis time frame area. We eliminated the protective assurance period and we modified the compliance period discussion. We added detailed examples of how to determine if a site has significant quantities, because that drives your compliance period selection for either the 1,000 year value or the 10,000 year value.

We clarified the information on defense-in-depth. A variety of figures describing the state closure process, the time frames and the process for developing allowable limits, and as I indicated, we have the appendix for the public comments. We also had an appendix on the 10 C.F.R. Part 61 draft environmental impact statement DEIS default scenarios.

So that provides some background to

what was analyzed for the intruders, in case people wanted to analyze similar intruders in their site-specific analysis. So they have the details for how they would do that. So I guess either I would entertain questions now or turn back to Gary. He's going to do a path forward summary I think, right.

CHAIRMAN CHU: Because we're running late in the schedule, I recommend if there are any more questions we hold them until the end of the agenda, because we have still a couple of things. People are lining up, but I want to first thank you for, the two of you for your excellent and comprehensive presentations, you know. If you could stick around a little bit, there may be more questions. Now we're going to turn to the -- go ahead.

MEMBER BLEY: Well, another path forward presentation.

CHAIRMAN CHU: Oh you have another one?

MR. COMFORT: Well, it's just a real quick summary of where we're going from here. All it is basically is the Commission currently has, you know --

CHAIRMAN CHU: Oh please, go ahead, go

ahead. Yeah, okay.

MR. COMFORT: Yeah, and they're reviewing it. They'll you know presumably be receiving your letter and take that into account. My understanding is they're also talking to some other stakeholders and stuff who have been interested in the rule. They'll eventually come out with a decision on the rule, whether to go forward with it or not.

Should, you know, our expectation and hope is that they'll go forward with it. They may have changes related to that. Once they do give us direction that they do want us to move forward and publish the rule, we'd make any minor changes that they wanted us to do.

The package is then sent to the Office of Management and Budget for review under the Paperwork Reduction Act. Once we get their approval, then we publish it in the Federal Register. Under the terms of this rule, it would be effective one year after the publication of the rule itself.

Now since we don't have any licensees, that really doesn't mean a lot, unless a new licensee happened to come in. The Agreement

States who do have the licensees will have three years from the date of publication to incorporate compatible regulations. Presumably, they would use the same implementation time period that we put in our rule, which is for existing licensees.

They'd have up to five years or the next renewal to provide an update to their application on it. So likely some of these Agreement States may not see an application for seven or eight years under this time scale. That's really where -- and I was going to answer real quick the question about updating the performance assessments.

It's not specifically stated in the rule, but based on the language in the rule, they would have to update it minimally at the time of renewal, because they'll have to apply up to date information in their application, and their application has to include a technical analyses and all.

It would also be expected that in certain circumstances, such as if they were changing their waste acceptance criteria, they may have to go back and look at it and evaluate and update it to support the waste acceptance

criteria.

MEMBER SKILLMAN: Yeah. My concern was addressed by the timeliness of the one year review of the waste acceptance criteria. That took care of my real concern. Thank you.

MR. COMFORT: That's it.

CHAIRMAN CHU: Thank you. We're going to go to the next agenda item with comments from Dr. James Clarke. I hope he's still there.

MEMBER BLEY: Jim are you on the line? Try to talk to us, see if your line's open.

MR. CLARKE: I think I'm on right now.

MEMBER BLEY: Yep, you're okay. We hear you.

MR. CLARKE: Okay. Well thank you. It's a real pleasure to participate in this meeting. Let me do a sound check. I have a tendency to fade. Can you all hear me?

MEMBER BLEY: Very good right now.

MR. CLARKE: Okay and also I --

MEMBER BLEY: And your slides are on the board.

MR. CLARKE: Okay, good. I want to extend my congratulations to David Esh on his very well-deserved honor. David, congratulations.

MR. ESH: Thank you.

MR. CLARKE: Oh, you're welcome. So let me start with the first slide. I have slides that provide an introduction to CRESP. It's an mouthful of an acronym. I'll spell it out in a minute. I also have slides summarizing the comments that CRESP submitted. This organization submitted comments in 2013 and 2015.

Since CRESP didn't provide any further comments, I have a few of my own in my capacity as a member of the former -- and that should be NRC, ACMW now, and as a consultant to the ACRS. All of this material is at a very high level necessitated by the time I have, and answer any questions you might have. So I'd be pleased if it would be helpful to provide the ACRS with a more detailed report. If you'd like that, that would be great. And then I'm Jim Clarke of Vanderbilt University.

So the next slide, please. Just an introduction to CRESP. It's the Consortium for Risk Evaluation with Stakeholder Participation, and it's a university, multi-university consortium led by Vanderbilt, and I believe it goes back to Tom Grumbley (phonetic). So I think that would be somewhere in the late 90's.

The management board is shown there. I think some of you know David Kosson. He is our principal investigator. You may know Steve Krahn and Shlomo Neuman. Craig Benson I know is on the line with you folks, so you may recognize some of those names and the universities that are represented are shown there as well. Next slide, please.

MR. COMFORT: Go ahead.

MR. CLARKE: Right now, I am trying to change my own slides.

(Laughter.)

MR. COMFORT: I can't help you with that.

MR. CLARKE: Here we go. A little bit about the CRESP mission. I worked with an attorney a long time ago on a lot of merger acquisitions for corporations, and you know, she would call this happy stuff. But basically what we're all about is safe, effective publicly credible risk-informed management of existing and future nuclear waste, and you can see the rest for yourself.

We are independent. We do give advice to the Department of Energy. They don't always like it, but that's our situation.

Next slide, please. We operate under a cooperative agreement, and basically as you know, we provided comments on the 2013 and 2015 drafts.

Next slide. So I would say that we applaud and strongly support the Nuclear Regulatory Commission's risk-informed performance-based approach, and I'm a true believer of that. I remember the first time I came to an NRC meeting and somebody said risk-informed, I said "what's that." I know what risk-based is, but what's risk-informed, and you know it's truly, truly a good approach, a wonderful approach and we strongly support it.

If we took issue with anything in the proposed regulations, it was because we believe that the NRC was departing from a risk-informed performance-based approach.

Next slide, please. This is just a very brief summary of some of our comments, but several provisions in the draft rules, both in 2013 and 2015, and this quote comes I believe from our first comment in 2013. "Commendably reflect and implement a risk-informed performance-based approach. Notably provisions for site-specific waste acceptance criteria, site-specific

performance assessment and updated dosimetry in the 2013 comments."

And then the site-specific assessment to exposure to an inadvertent intruder, provisions for defense-in-depth and safety case evaluations we thought were very positive additions.

Next slide, please. However, we did express concerns that there were parts of the regulations or proposed regulations, but we didn't think that the NRC was taking the risk-informed performance-based approach, and in particular the continued incorporation of very long time frames that greatly exceed our experience and forecasting abilities.

So this is really, really the heart of my comments, these long time frames. We talked about 1,000 years, 10,000 years and beyond 10,000 years, and that's at the heart of the comments that we made, and at the ones that I will now make from a personal standpoint.

So the next slide, please. These are my comments. It appears the staff concerns that are reflected in the rule stem from the appearance of long-lived radionuclides, large quantities, from

activities that were unanticipated, and these are understandable and legitimate concerns.

However, they should be addressed through regulations in a way that's consistent with NRC's risk-informed performance-based approach, and it strikes me that I have used risk-informed performance-based probably more in these few minutes than I've heard.

Next slide, please. The draft regulations were revised to eliminate protective assurance period. This has been covered, from 1,000 to 10,000 years. However, the revision now states that the compliance period would be either 1,000 or 10,000 years, depending on the inventory and the concentration of long-lived radionuclides.

However, a compliance period of 10,000 years, I think, is neither risk-informed nor performance-based. This time period is outside our current body of knowledge, and it greatly exceeds our ability to forecast the future. My personal feeling is that our current ability would be better limited to a few hundred years. But I appreciate the 1,000 years has some standing, for example with the Department of Energy.

Next slide. With respect to the

intruder assessment, I appreciate that the staff was directed to use 10,000 years. I have the same concerns about the merits, and I think my understanding is that the Commission said to use the 10,000 years in the guidance, but I believe it's on the draft regulations.

So whether, you know, this is in other cases, should be approached on site-specific, kind of site-specific basis. So in summary, I've just got a few more here. In summary I appreciate that the appearances in large amounts of long-lived radionuclides requiring disposal in waste streams that didn't exist were unanticipated when 10 C.F.R. 61 was first promulgated.

These unanticipated events appear to be driving the regulations to positions that are neither risk-informed in my opinion nor performance-based. For example, 10,000 year compliance periods and 10,000 year intruder assessments.

Next slide. Perhaps these unanticipated waste streams, which has depleted uranium can be handled in other ways, and that's really what I'd like to suggest, possibly through guidance, but in ways that don't require

unrealistic compliance periods. I can't help but wonder what if we took long-lived radionuclides out of the main body of 10 C.F.R., perhaps they could be treated as exceptions, maybe as special waste. But they appear to be driving the regulations.

Next slide, please. So I just have a few closing comments. I know we're running short on time, but my experience with the NRC covers over 16 years, consultants to the Advisory Committee on Nuclear Waste, member of the Advisory Committee on Nuclear Waste and Materials and now a consultant to the Advisory Committee on Reactor Safeguards.

I appreciate the opportunity to tell you all that the people from the NRC with whom I've had the pleasure to work are truly extraordinary. We just heard from two of them, and indeed I hold the NRC and its staff in very high regard. We just apparently disagree over the merits of including extremely long time periods as compliance periods in enforceable regulations.

That was my last line, and I appreciate the opportunity to provide these comments, both on behalf of CRESP and me, and I'd be pleased to address any questions you might have.

CHAIRMAN CHU: Thank you Dr. Clarke.

Any questions for Dr. Clarke?

(No response.)

CHAIRMAN CHU: No? Thank you Dr. Clarke again for your presentation.

Now we're going to move to the next agenda items. As I mentioned, we have received two requests to speak at this afternoon's meeting. As is customary, we have asked these speakers to try to restrict their statements to no more than five minutes.

The first of these statements is from Doug Tonkay from the U.S. Department of Energy. Doug, are you there?

MR. TONKAY: Yes, I'm right here.

CHAIRMAN CHU: Oh you're here.

(Laughter.)

MR. TONKAY: Thank you.

CHAIRMAN CHU: Thank you.

Public Comments

MR. TONKAY: Yeah, good afternoon. I'm Doug Tonkay. I'm the Waste Disposal office director with the Department of Energy's Environmental Management Program, and I appreciate having the five minutes to talk. DOE is responsible for regulating low level waste disposal

facilities at sites across the country, and in doing so we have technical requirements for maintaining our performance objectives, as well as setting site-specific waste acceptance criteria at our disposal sites.

In addition, our directives allow utilization of commercial disposal facilities, which are directly impacted by this rule. So we have a significant interest in the changes to 10 C.F.R. Part 61. I would like to thank the Subcommittee for providing the opportunity to share the views and, as well I'd like to thank the speakers for their excellent presentations.

Please note DOE was not given an advance copy, so we have not had time to review thoroughly all of the proposed amendments and the supporting rationale, and we would appreciate the Committee's consideration of an opportunity to provide further observations at the full Committee meeting in November.

In July 2015, DOE provided comments on the then-proposed revision. We are pleased that the NRC staff considered and accepted many of the comments. I want to address three areas for which we remain concerned based on our initial review of

the Federal Register notice.

First, as we've been discussing somewhat today, the draft final rules we understand effectively proposes a default compliance period of 10,000 years for long-lived waste, with a performance objective of .25 millisieverts annual dose limit. The Commission directed and we agreed that 1,000 year compliance period be used.

Multiple Commissioners observed that using a 10,000 year compliance period in this context provides false comfort based on guesswork and subjective speculation.

We also agree with the ACRS, which stated in their letter to the Commission that introducing significant uncertainties for the performance analysis through speculation on human activities, waste and site performance, and earth processes for a millennia is unlikely to improve either our decision-making process or our understanding of the safety decisions regarding near surface low level waste disposal.

We note that the NRC regulations for materials and sites that are comparable to the near surface disposal of low level waste established compliance periods of 1,000 years at most. In

light of these considerations, we'd prefer to see a final rule with a compliance period for an annual dose limit to 1,000 years, while requiring qualitative consideration of analysis for longer time periods, up to the point of peak dose but not extending beyond the period of geologic stability.

Let me clarify Dr. Esh's statement that DOE has used 10,000 years for waste incidental to reprocessing analysis. This occurs because it is in an NRC NUREG guidance document that is used by the NRC technical staff that we are required to complete consultation with. It is not part of the DOE directive.

Our second concern is that the rule continues to include radon in the dose-based performance objectives. The inclusion of radon is inconsistent with other EPA, NRC and DOE regulations that address management of uranium containing materials.

Including radon in the calculation of annual dose imposes a limit for future exposures to a limited number of hypothetical receptors, that is significantly lower than the levels currently accepted as guidelines for residential exposures across the country today.

To establish more restrictive limitations in the context of an extended performance assessment that entails significant and irreducible uncertainties would be particularly unwarranted. Therefore, the final rule should exclude radon from dose calculations and instead include a performance objective with a flux standard for more consistency with other national requirements for disposal of waste containing uranium.

Finally, DOE suggests that a draft of the NUREG-2175 be made available for comment before the rule is finalized. The draft final rule indicates that a substantial amount of additional information ha been moved to guidance, and similarly that a large number of clarifications appear in the NUREG.

What information is included and how the regulatory provisions are interpreted can have a dramatic effect on implementation, particularly concerning the scope and conduct of performance assessment over extremely long time periods. While the staff indicated that changes could be made in the future, it could be many years if not decades before a revision to the guidance is available.

Thank you again for the opportunity to present our views, and we will continue to monitor progress of the rulemaking, and we appreciate the opportunity to provide further observations at the full Committee meeting.

CHAIRMAN CHU: Thank you very much Mr. Tonkay for your comment. We're going to go to the next comment from Roger Seitz from the Savannah River National Laboratory. He must be --

(Off mic comments.)

MEMBER BLEY: We're getting the phone line open now for you.

CHAIRMAN CHU: It's open?

MEMBER BLEY: Go ahead, yeah.

CHAIRMAN CHU: Mr. Seitz?

MR. SEITZ: Can you hear me?

CHAIRMAN CHU: Yes.

MR. SEITZ: Okay.

CHAIRMAN CHU: Yeah. Please go ahead with your comments. Thank you.

MR. SEITZ: Okay. Thank you very much for the opportunity to speak today. Again, my name is Roger Seitz and I've been a performance assessment practitioner for more than 30 years. These comments reflect my experiences over that

time.

I'd like to note that I do appreciate the efforts of the staff to address the comments, and to develop the updated materials. I previously had the opportunity to speak in detail as part of the DOE presentation for this Subcommittee, and also submitted comments.

So today, I'm just going to briefly summarize my thoughts on a few, but not all of the comments that have been provided. The first thing I would want to address is the time of compliance, and the change to 10,000 years for long-lived waste is a concern and also the fact that long-lived waste is not clearly defined in the rule.

So it's 10,000 years for long-lived waste, and then a more specific definition has been moved to the guidance. Overall, I believe 1,000 years is a reasonable time frame to have strict compliance, and that's consistent with or far exceeding time frames for other U.S. rules addressing near surface disposal, noting that for deep geologic disposal there are longer times.

I agree with the positions of the IAEA and the ICRP that time frames after many hundreds

of years involve increasingly speculative assumptions and lose meaningfulness in terms of strict decision-making. That said, I do believe that time frames after 1,000 years need to be addressed, but in an increasingly qualitative manner with an intention to build confidence that major consequences are not going to occur later in time.

For example, when we -- a number 500 millirem has been used. 500 millirem is still less than the average annual dose for someone in the United States today, and it's significantly less than average doses in some areas of the earth. So these things should be reasonable considerations as part of a qualitative assessment after 1,000 years.

The second item I will address is radon, and this is a comment that I've made several times, and I continue to be concerned that staff has departed from the well-accepted practices that exist in EPA, NRC and DOE rule. In the other rules, radon is treated as a separate performance objectives, as a flux or concentration.

I believe this was done because if you conducted dose assessments for acceptable concentrations of radon in a basement per EPA

guidance, those concentrations will easily result in doses well in excess of 25 millirem per year. So effectively staff are imposing a much more restrictive requirement for potential doses that may occur far in the future than are currently applied for exposures routinely occurring in many homes every day now.

The third thing I will address is inadvertent intrusion, and I appreciate some of the changes that helped with clarification. But I am still concerned that it's being treated as a strict performance objective. This is a departure from international recommendations that emphasize considering inadvertent intrusion in the context of optimization, rather than using a dose constraint.

I'm also concerned about the staff implication of the link between 500 millirems per year as the objective and how that accounts for likelihood in some respect. Note that 25 millirem per year is five percent of 500.

So this leads me to think staff is implying that they believe there is reasonably a five percent chance that there will be a complete loss of control at the facility, there will be a complete loss of memory of the waste that is there.

Someone will chose to move on to the footprint of the facility. They will choose to drill a well through the facility rather than to the side of the CAF, for example. They will continue drilling in spite of cuttings that are obviously not soil, grow a garden, etcetera. I would argue that the likelihood of all those things occurring is much less than five percent. So I would recommend not referring to 500 millirem as some means of addressing likelihood.

Finally, I would like to express concern about a potential lack of transparency by publishing a substantially revised guidance as final without public review. The staff responses to comments refer to major changes being made to the guidance, and substantial information moved into the guidance.

Without seeing the substantially revised guidance, it is very difficult to understand how the staff interprets this substantially changed version of the rule. I was a bit dismayed to see the staff's position that the guidance will be issued with the rule without comment, but the public can provide input and their input would be considered when the guidance is

revised.

Considering that Part 61 was promulgated in the early 80's, and it's just now being revised more than 30 years after the original rule, I'm left to wonder how long it might be before such a revision would occur. Thank you very much for the opportunity to speak with you.

CHAIRMAN CHU: Thank you very much, Mr. Seitz, for your comments. I would like to know if there are other public members who would like to make comments?

MR. GREAVES: John Greaves --. I'd like to make a comment if I could.

CHAIRMAN CHU: Yes.

MR. GREAVES: This is -- I'll be brief. This is John Greaves. Just as background, Paul Wellhouse and I provided specific comments during July of last year during the opening of the comment period. Paul Wellhouse was a principal author of Part 61 in the early 80's. Both Paul and I were NRC senior executive managers responsible for implementing Part 61 requirements, and developing associated guidance for over two decades.

After retiring a decade ago, we both provided advice to a number of national and

international organizations on low level waste disposal.

My view is the staff has done a good job of listening to and incorporating many of the recommendations provided by us and others with expensive experience on implementing low level waste disposal regulations.

One recommendation by numerous stakeholders was a clean two-tiered approach has not been incorporated. A blended two-tiered approach has been recommended and incorporated by the staff in this proposed rule. Gary Comfort labeled it a kind of a two-tiered system, and it's not clean. It will be difficult to implement and result in unnecessary mitigation risk in my opinion.

This moving target will be a significant risk with such a subjective approach that can be argued by multiple parties either way in the future. A clean two-tiered approach with 1,000 year compliance period and a second tier from 1,000 RPG dose approach would be adequate to ensure safety to 1,000 year compliance period and that second tier analysis as the peak dose.

DOE stated a few minutes ago they used

such a two-tiered approach. This would eliminate the need for a separate, new lengthy rulemaking to address waste classification for waste streams containing larger quantities of long-lived materials.

In my opinion, requiring compliance only in a guidance document in terms of specific compliance period, whether you do 1,000 or 10,000, is not an appropriate regulatory approach and unnecessary if a plainly two-tiered system is specified.

In my view the Commission needs to make a clear final call on the one versus ten thousand year compliance period number. It's really a policy call. Thank you for the opportunity for providing these two comments.

CHAIRMAN CHU: Thank you, John for your comments. Any more online? Comment? If not, I'll turn it to the floor for comments.

MR. ARLT: I'm with the NRC staff. I just want to make a quick comment. So my name is Hans Arlt. I was the author of part of Chapter 2 of the guidance, and I just wanted to make a comment as far as like the uncertainty with regards to a site with 1,000 years and 10,000 years.

The part that's in Chapter 2 looks at that. It looks at the uncertainty of the site, and it -- it has something called scenario development and conceptual model development and so forth. All the sites do not have the same uncertainty. There are certain sites that have a lot of uncertainty. If I gave you an example, say you want to build a site on the big island of Hawaii.

I would not say that 1,000 years is adequate. You probably couldn't even judge the next 50 years or 100 years for a site like the big island. There are just too many uncertainties as far as like volcanos, earthquakes, the elevation it's at. It just would be a very, very bad site to build a repository.

Or if you're in another place, if you're like on the plains in Kansas or the desert in Chile and so forth, places that have not changed at all, the uncertainty for those areas is very, very low. Chapter 2 has a method of looking at those uncertainties.

So I just basically wanted to say there's no big magic line with the 1,000 years or 10,000 years. You really have to look at the site, and if the site has so many uncertainties, you

know, that just might not be a good place to build it.

CHAIRMAN CHU: Thank you very much. Any more comments?

MEMBER BLEY: Something's come up since before Madam Chairman, and I'd like to ask a question at this time if I might?

CHAIRMAN CHU: Sure.

MEMBER BLEY: Jim Clarke put something in my head here, and I went back and looked what I think is the last SRM, and I'm going to say how I read it, and then I'm going to ask you guys to comment if you would. They say to include a regulatory compliance period of 1,000 years.

Later they mention 10,000 years three times. Once is approving a proposal to require an intruder analysis built on the same assumptions. The second time is to do a protective assurance analysis out to 10,000 years, and the third time is to provide qualitative analysis for a performance period of 10,000 years or more.

As Dr. Esh talked earlier, the way I understood your discussion of the analysis at 10,000 years and why seeing this build up to ten percent of the daughter products, if uranium was

significant, is almost as a sensitivity study. It's not trying to model everything that's happened, but to say gee, if we build up to this amount of radon or other daughter products, is the site still well protected?

The conclusion about that could well be a qualitative approach, and the rule as it's currently stated, the 10,000 years is the compliance period if you have long-lived waste, which seems different than what the Commission suggested to you.

So if you guys would talk about that a little. It will probably come up at a full Committee meeting too, but I'd be interested in how you address that.

MR. COMFORT: Yeah. The revision, I mean the Commission provided us direction and there were a few areas from which the final rule changed. But you've got to remember that Commission direction was for the publication of the proposed rule.

We incorporated what we believe all of what they directed into the proposed rule, and then part of the Administrative Procedures Act, we've got to consider all the comments that we received,

and then we made revisions based on that to what we think both is what the Commission was aiming for, as well as, you know, addresses other public comments and all. So that was the intent that we go off to, you know. We were using the 10,000 years, but we're only applying it for the long-lived waste.

MEMBER BLEY: I have a couple more questions on this. The first is, and I think Gary you went through this earlier, I think you talked that in fact the Agreement States really urged you to have something like a 10,000 year compliance period for the long-lived waste.

Did I remember that correctly, because I haven't thoroughly looked at all those comments, but I've looked at them?

MR. ESH: They wanted to be able to preserve their approaches.

MEMBER BLEY: Okay, and some of which had that or maybe --

MR. COMFORT: Right. They didn't specify, you know, that we should have a 10,000. They wanted the flexibility by changing the compatibility category.

MEMBER BLEY: Okay. I haven't had the

opportunity yet to read the final guidance. Perhaps it makes clear that these things that happened associated with 10,000 years are of the sort I talked about, and I think that was the way I interpreted the discussion you folks offered earlier, that yeah, we want some analysis to be guideposts for making determinations of the perhaps qualitatively, perhaps quantitatively, of the capability of the site.

And I'll have to read it and see. But would you tell me that that in fact is the case?

MR. ESH: Right, yes. So the objective of those analyses is to provide the information for the regulatory decision-making about whether public health and good -- public health and safety is protected for the disposal action that you want to take. So --

MEMBER BLEY: And they're not intended to be models of the future?

MR. ESH: Well that --

MEMBER BLEY: --under all capabilities.

(Simultaneous speaking.)

MR. ESH: This is the problem. So people will talk about this process that you're doing a forecast. I wouldn't call it a forecast at

all. You are doing a regulatory analysis to justify this regulatory decision or action that you want to make, and maybe I'm splitting hairs about that. But they are not forecasts. They are not projections.

Sure, you're generating dose assessments into time. But it's not the same thing as like trying to say well, what's the population growth over the next five years, or who's going to win the election, you know? Those are true forecasts and projections.

This is an analysis over time, but it's -- we never describe or try not to ever describe them as forecasts. So and the idea that for the material that we were directed to address in this rulemaking, the depleted uranium, that you should only analyze it for 1,000 years and then cut it off, I don't know why you would describe that as a risk-informed approach.

How by not calculating what you think is going to happen is that risk-informed? I realize there are uncertainties associated with the calculations and what's happening over time. But that's the information that you should be considering as a decision-maker, not missing,

especially when the thing that you know most in these problems are the waste characteristics.

You know, I mean the decay and ingrowth characteristics. The radiation physics is the part of this that we should have the most certainty about. So if we know things about the radiation physics, then that should reflect into the approaches that we're trying to do, which is what we're doing with this tiered approach to the compliance period. We're trying to bring in the radiation physics into how we solve the problem.

MEMBER BLEY: Okay. This is starting to fit together for me, and I look forward to reading the guidance. I'd just mention, you know, if you look at Reg Guide 1.174, when it looks at things like this it has you do the best calculations you can, but talks about an integrated decision-making process. I think you're talking the same kind of thing here.

MR. ESH: Right, and I think it was maybe one of the ACRS meetings where I had some figures or slides on performance assessments and results, and you know. You can have a situation where your numerical model or calculation generates a number that's well below your limit, and as a

regulator I could still say you didn't make a safety case because it's based on the quality of the information and what went into the assessment to get you from here to there.

Likewise, you could have a situation where maybe you generate a result, a probabilistic result and some of the results are above your limit and I could say look, you've still made the criteria because you had a lot of conservatisms and this, that or the other thing that went into the calculation.

So too much is hung up on generating numbers and comparing numbers, instead of what this is about is developing all the information to build some confidence that you're making a correct decision, of which the numbers are one input to that.

Like I said earlier, you know, waste characteristics in those prohibitions and restrictions is probably much more important than whether you've analyzed 1,000 years or 10,000 years for your compliance period.

I mean if you look at the Beatty, Nevada case, they had the site catch on fire and barrels blew out of it because they apparently had

put metallic sodium in it and then they got a bunch of water that interacted with the sodium and blew the barrels out.

Okay. Maybe if they had followed the waste characteristics more closely, they could have avoided that problem. That actually is a good example because the only reason why that didn't turn into a significant impact is because in the location where that occurred, there wasn't a lot of activity remaining. If there had happened to be some long-lived waste in the vicinity of where that happened, there at least would have been an expensive cleanup to deal with, if not health and safety impacts.

I don't know. We appreciate all the input we have from the commenters, and we realize we differ from some of the commenters in the approach and the opinions.

I would indicate that I don't believe the guidance, I would call it, was revised significantly. So we did make the changes to the guidance that we needed to in response to the changes in the regulation, and other ancillary changes to the guidance.

But I certainly wouldn't characterize

it as a significant revision. The most significant thing is we dropped Chapter 6, which was the protective assurance period analyses because we took that out of the rule. So if you're talking big changes, that's the biggest change. A lot of the other material remained the same in the draft that was provided for comment.

So and many of the other comments that you heard at the end here, they're similar to the comments that were provided in writing and that we've generated responses to.

So if you're curious what our responses would be to those questions, I know we're running late tonight. Look at those between now and the final committee meeting and we'll be happy to come back to them when we get to that point.

MEMBER REMPE: If we have discussion of this at our November meeting, and this document still has not been released, will we have a closed meeting?

MR. WIDMAYER: Do you want an answer? We have been able to close certain portions of full Committee meetings. We have to check with OGC and find out if --

MEMBER REMPE: Well that's my question,

is we can't discuss it openly. If we have questions about what's in here, it's not been released to the public and I think you've said the reason it's not been released is the Commissioners want to see it because it might affect some of the rule language, and that's why it's not been released. Is that a correct paraphrase of your --

MR. COMFORT: No. The Commission doesn't actually look at it specifically. It's more because we won't want to have a bunch of variations going around, that there could be some document -- you know, people saying oh, you released this back in September or whatever. This is what I'm using. Oh, what do you mean you changed it, you know. It's just version tracking control --

MEMBER REMPE: But something in the 2125 could impact what's in the rule that might be published; is that true?

MR. COMFORT: No. The Commission could though change and direct -- change direction of what we want to do in some ways that we'd have to update --

(Simultaneous speaking.)

MEMBER REMPE: In the 2125 guidance --

MR. COMFORT: Right. Well, in our rule and then we'd have to update --

MEMBER REMPE: In the rule.

MR. COMFORT: Right.

(Simultaneous speaking.)

MR. COMFORT: Yeah.

MEMBER REMPE: Okay. That's what I thought you said.

MR. COMFORT: Right, yeah. If the Commission changes something in the rule, then we would update 2125?

MEMBER REMPE: And they might do that?

MR. COMFORT: Yeah, and if they don't make any changes, then what you see as the guidance would be going forward. And the Commission could always make the decision, I mean if they get public interest to say go release it anyways, you know. We're not going to worry about the version control issues. That's up to the Commission direction. We follow Commission direction.

MR. ESH: Yeah. Let's look at that. Let's take that back and get back to the Committee about -- so we haven't issued, released the guidance because, just as Gary's said, the rule is just the staff's proposal to the Commission. If

the Commission changes the rule, we'll have to make conforming changes to the guidance.

But I need to talk to our general counsel and our rulemaking staff. But to me, it seems like the draft guidance is consistent with the draft final rule, which is with the Commission. So I'm not sure what the pre-decisional argument would be at that point. But let us explore that and get back to you.

MEMBER BLEY: This is something we have to know about very, very, very quickly. I mean like tomorrow quickly. We have -- we're down to two weeks and a day or something like that, and we have to get our FRN out. If we should have to close part of the meeting, we have to include that. I suspect if OGC gets involved and we pursue this a little, closing a FACA meeting for pre-decisional material could get pretty dicey.

MR. WIDMAYER: Yeah. That doesn't usually happen.

MEMBER BLEY: Doesn't usually work.

MR. WIDMAYER: What we've done in the past with a similar situation is staff generated a version of the guidance document that had draft as a watermark on every page, and indicated what it

was as far as timing goes, and then it was clear that it wasn't going to necessarily be a final guidance document. The issue was whether or not the Commissioners had a chance to look at it, even in its draft form.

MEMBER REMPE: The guidance document. Not just the rule but the guidance document.

MR. WIDMAYER: Right and they, as the staff indicated, they don't typically look at the guidance. So it should be okay with the Commission for us to have the open meeting.

MEMBER BLEY: I hope you guys can really pursue this right away tomorrow and get back to us like before noon. If this thing has draft across every page, that's also a problem because I have -- some of us have trouble reading that type of -- me in particular.

MEMBER STETKAR: It's also difficult for the ACRS. If the ACRS had comments on -- well, I guess we could have comments on something that's not.

MEMBER BLEY: It's possible. It would be good to see that called final and let us look at it, even if it's not published yet.

MR. WIDMAYER: Well, it won't be final.

MR. COMFORT: Right.

MR. ESH: Right.

MR. WIDMAYER: Because we're not going to finalize the guidance until the Commission approves the rule.

MR. ESH: Right.

MR. WIDMAYER: But what we can explore is can we make that draft conforming, consistent with what was offered to the Commission, if we can make that public, and that's what I want to explore with OGC and the rulemaking staff.

MR. COMFORT: Well we're -- it's really the issue is I mean it hasn't gone through all our formal management concurrence and OGC concurrence yet, that there may be tiny little tweaks of a word here and there, but the concepts are all there, that you're going to see that nothing technical is going to change.

Whether we can discuss it in generalities I mean in a public meeting, because it supports the rule, I mean you're just really talking about the rule and how you're going to implement it and how, you know, one phase. The only thing is other members of the public wouldn't have seen it if we don't release it. And while we

can't discuss it --

MEMBER BLEY: You bring up something I was going to hold until you go around the table, but I'm going to say it now.

CHAIRMAN CHU: Okay.

MEMBER BLEY: As Chairman of the ACRS. I want to -- I know you want a letter that supports the rule and the guidance. We got the guidance today and we still have this other thing going on. In the past year, there was a case very similar to this. We wrote a letter endorsing the rule but told the Commission we could not yet endorse the guidance for different reasons.

But we did that. That's a possibility no matter what happens because we've had such short time to look at this. The other possibility is we have -- we read through it and we have a good enough full committee meeting that we feel we can include it in the letter. I was going to bring this up later but I'll bring it up now for you, Madam Chairman.

We were scheduled for a two hour full Committee meeting. Since we've not had a Subcommittee meeting on the guidance with us having had a chance to review the guidance, it seems to me

you might want to have a longer full Committee meeting. What I was thinking was we could make this the third one on the first day of the meeting, and schedule it for four hours.

If it doesn't take that long that's great, and if it does because we've got to dig into this, and as we go through the guidance, it's also possible we might have real disagreements with it. We don't know yet. I mean the way David walked us through it, it sounds pretty good. But that's not the same as reading it and thinking about it.

CHAIRMAN CHU: Dennis, you're saying in the full Committee, we spend a lot of time going through the guidance document. Is that what you're saying?

MEMBER BLEY: If the staff wants us to include review of the guidance document in our letter, I don't see how you avoid that, since we haven't -- we will not have read it until then.

CHAIRMAN CHU: Are we going to have time to write the letter, you know, 24 hours later?

MEMBER BLEY: Well, that's up to you. That's up to you.

MEMBER REMPE: But the Commission has told ACRS not just to review the rule, but also to

review the guidance, right?

MR. WIDMAYER: Yes. They encouraged you to --

MEMBER BLEY: That's almost irrelevant at this point. We will review it. Whether we review it to support a letter in November is what I'm talking about. We didn't get it a month before then, and it's going to be pretty hard to fit it all in.

(Simultaneous speaking.)

MEMBER STETKAR: I like the analogy that you brought up in that other case, where we just told them we're going to review the guidance later, and we haven't done that yet in that particular case.

MEMBER BLEY: I thought we did.

MEMBER STETKAR: Well, we wrote a letter on it. There's still open issues.

MEMBER BLEY: Oh yeah, open issues.

MEMBER STETKAR: There's still open issues. They're coming back to us some time.

CHAIRMAN CHU: But my question is --

MEMBER BLEY: What do you do?

CHAIRMAN CHU: Why write a letter in November? Can we --

MEMBER BLEY: Because the staff has asked us to. That's --

CHAIRMAN CHU: That's my question, is does it make more sense if we review the guidance documents between now and November some time, and then the full Committee actually comes in December and we write a letter in December that's comprehensive and we reviewed everything. We got all the information, you know, rather than I have 12 hours to make a decision. That's just an option that I want people to think about.

MR. COMFORT: Can I just make the point that I mean it's really not totally up to us. This document is before the Commission. I mean they can make a vote any time they want and, you know, the earlier that you provide input for that so that they can kind of assimilate that. If they're willing to wait longer, that's up to the Commission. But I just want to --

MR. WIDMAYER: Our timing right now is sensitive to the timing of the Commission. This paper is with them right now. The SECY paper is with them to make a decision whether to have the staff move forward and publish this as a final rule. The more this committee delays, the less

likely they are to have your letter in time to help with their decision.

CHAIRMAN CHU: But if we rush, we're not going to have the information in the letter.

MEMBER BLEY: Well, we can certainly write a letter on the rule.

CHAIRMAN CHU: Right, right. Is that --

MEMBER BLEY: And we can, you know, if I were you I would prepare the beginning of a letter on the rule, and have the Subcommittee help you with that. As we review the guidance, we can decide whether we'll be able to say anything positive or not about it.

MEMBER STETKAR: Why don't we -- the purpose of the Subcommittee is to bring things to the full Committee.

MEMBER BLEY: The full Committee.

MEMBER STETKAR: So why don't we go around the Subcommittee and see if we'd like to recommend to the full Committee that we postpone a review of the guidance?

MEMBER BLEY: I think at this point, you could go around the table for everything, get comments on everything.

(Simultaneous speaking.)

CHAIRMAN CHU: Yeah.

Subcommittee Wrap-Up and Discussion

MEMBER REMPE: I want to start off by thanking the staff, and I do believe that you've answered a lot of questions and that you've spent a lot of time trying to deal with this issue.

However, I am stuck on Commissioner guidance that said we need to look at the rule and the guidance. I'm stuck on the fact that the guidance was just given to us today. We didn't have a chance to go through it and implementation of the rule, which is in the guidance, could affect my thoughts about the rule.

Hence, despite the fact -- I mean I would be happy to send the Commissioners a valentine or mailgram saying we didn't get this in time. We'll talk to you next December. Why don't you wait until we get a chance to talk, to have a thorough evaluation?

So I'm with what Margaret is suggesting that -- I mean we can send them a note or we can call them and contact them. But I don't think we should be providing comments on the rule when we've not had a chance to discuss the guidance. Thank

you.

CHAIRMAN CHU: Thank you. Charlie?

MEMBER BROWN: Yeah. I don't have any other comments, other than one on this, is that I -- am I interfering? Pardon?

MALE PARTICIPANT: You're okay.

MEMBER BROWN: Okay. I have a little bit of difficulty understanding how you can issue guidance without ever having the public and the people who have utilize it even see it. That just seems to go against my sense of whatever sense I should have.

I mean I don't know why you just don't publish it and just don't put the drafts on the thing but put pre-decisional up at the top on every page, and let the public see it, and then they can see what's going on. Because right now, that's just my opinion, okay.

MR. ESH: Can I add though that the guidance was made publicly available, and it had the same public comment period as the rule? That's the -- I mean the way the process works is that was the proposed rule and the proposed guidance. So we received all the comments, make changes, and then we issue a final document, the final rule and the

final guidance.

MEMBER BROWN: That's the same that they made comments on?

MR. ESH: That's the final draft of the final guidance document.

MEMBER BROWN: But is it the same? Is it --

MR. ESH: It is not the same, but how do you ever get out of the public comment loop if you always submit something for public comment then? So if you submit that document, you're going to get new comments. Then what do you do, change the document and then you have to submit it again?

MEMBER BLEY: I'm sorry. This isn't -- this isn't a time for discussion with the staff. But the process we always see is one where the staff publishes guidance, gets comments and prepares the final that includes responses to all the comments.

That's just the way, and then they don't go out again unless there's massive changes that really upset things. In any of their guidance documents that I've been aware of since I've been here.

CHAIRMAN CHU: Jose.

MEMBER MARCH-LEUBA: Yes. Maybe you have noticed I'm not an expert of this field, so I have been mostly quiet. But I have listened to David and I have agreed with essentially every one of your arguments. I really appreciate what you said. But I sense a lot of pushback on a couple of topics. The 10,000 years and the radon.

So if you could prepare one slide or two on that for the full Committee for my education. What is the implication of doing the 10,000 year analysis? Why is people opposed to it, and what would be the rationale of taking radon as a different isotope than any of the others?

Is it because we don't have good models for it? So if you could educate me on that one in a couple of weeks, I would appreciate it.

MR. ESH: Certainly.

CHAIRMAN CHU: John.

MEMBER STETKAR: Nothing, thank you.

(Off mic comment.)

MEMBER BLEY: Not even going to help on the decision about the letter?

MEMBER STETKAR: Well, I thought --

(Off mic comment.)

MEMBER STETKAR: I thought we were

going to just go around and ask. Nobody else --

MEMBER BLEY: Charlie did.

MEMBER STETKAR: Okay. Well my recommendation would be that we bring the rule to the full Committee, and that we recommend that we did not hear anything on the guidance. If nothing else, the full Committee, as best as I can tell, isn't here and they haven't received the guidance and it's now about two weeks before the full Committee meeting, which is well under our 30 days time for transmitting material to the full Committee and expecting --

I've been told, I haven't loaded the CD, that it's several hundred pages?

MALE PARTICIPANT: 500 pages.

MEMBER STETKAR: 500 pages? There's no way that you can expect, you know, our other committee members to try to do any type of meaningful review of that material in two weeks, given everything else we have to do. So that would be my recommendation.

CHAIRMAN CHU: Dennis.

MEMBER BLEY: Yeah. First, I see no reason why we don't draft a letter on the rule. I think we not only should but we have to, to serve

the Commission in the way they've asked us to, and we've had the rule for a fair time now and we've had a very good discussion today on it.

I'm not as -- I mean there have been times in the past where we have fit in things at this late a date, but nothing with this much material in it. If we're going to -- I don't mean to ramble on here -- if we're not going to try to include the guidance in the letter and we're not going to use a couple of hours in the full Committee to have a briefing on the guidance, we'll need another Subcommittee as soon as we can to look at the guidance, some time late November or early December if possible.

But we'll have to look at what's feasible. Our Subcommittee agenda is pretty full right now. We have to look at that. We don't have the full Committee here to make a choice, but as a subcommittee I'd lean toward trying it.

But I haven't read it yet, so I won't know for a week whether that's even remotely feasible and whether the briefing we got today covers it at anywhere near the level we would have wanted to dig into it. That's the best I can do.

CHAIRMAN CHU: Well, I have voiced my

preference is to review everything, okay, the rule and the reg guide -- and the guidance document if possible. But my question is if we only write a letter on the rule, does that mean we have to write another one?

MEMBER BLEY: Yes.

CHAIRMAN CHU: So it will be another one.

MEMBER BLEY: Yeah, and if we write a letter on both, two or three things have to happen. We have to make a longer full Committee meeting, which I will do. We have room to put it in as a four hour meeting. The staff has to clarify the status of this document to support the review by tomorrow some time.

But I misunderstood you earlier. I thought you didn't want to include this guidance in the letter.

CHAIRMAN CHU: Well if we didn't review it, then we can't include it. That's my point.

MEMBER BLEY: Yeah, and our time to review it is two weeks plus the full Committee meeting.

CHAIRMAN CHU: I'm going to ask David a question. I used to do performance assessments.

So I think a lot of things are in the details, how do you implement it, and then I believe most of that is in the guidance document, right? So my point is if we don't read it, are we going to miss something important for the rule? That's what I'm afraid, okay, is say -- because they're kind of linked, you know.

The guidance tells you what the rule really asking the licensee to do, and then what kind of bothers me a little bit is say we approve the rule, but we haven't looked at the implementation. Is that okay not to look at it and then approve the rule?

MR. ESH: Well, the rule has to stand on its own merits and the technical content that's in there, along with the statement of considerations that goes along with it. So while the guidance does provide information associated with implementation, my opinion is you could look at the rule --

CHAIRMAN CHU: Independently?

MR. ESH: Independently of the guidance. You could also just take my opinion and write that the guidance is very good.

(Laughter.)

MR. WIDMAYER: That was summarily rejected.

MEMBER STETKAR: In the past, we've also taken -- well I have anyway, because it's a subcommittee meeting, the position that the rule ought to be very clear on what should be done. The guidance tells you how to accomplish it, and the rule ought not to be held hostage to the how to accomplish it part of it.

In that sense, as we did in this other kind of ongoing example right now, it should be possible for the ACRS to reach conclusions regarding the rule language, without being held hostage to the implementation guidance. I mean if the rule language is that dependent on the implementation guidance, it seems there's a problem.

MEMBER BLEY: I'm going to clarify my recommendation. I'm going to recommend that in fact at the next meeting we have a four hour session and we have at least two hours devoted to the guidance. Whether or not at that time we can decide we're ready to write or not on the guidance, we'll decide then.

We have the previous guidance. We've

had it for a long time. We reviewed it two years ago and personally I don't know how much has changed. It sounds like a lot of it's pretty similar, which would make our reviewing easier, except for some of us haven't been here for that other meeting.

MR. ESH: Crea's (phonetic) "please read me" file, that will be useful, because that focuses you on the delta from the previous version to this version.

CHAIRMAN CHU: I'm going to sort of change the subject a little bit and make a comment about 10,000 years. Personally, it doesn't bother me. Maybe it's because I just don't know how to perform this assessment.

But I look at the value is you are forcing the licensees to go through this quite rigorous or comprehensive process, to look at all the things that could possibly happen at your site and your environment, and then up until a time you feel that you have a little bit of control, because of the radioactivity, okay.

And so to me, I think it's similar to what you say. It's not the answer itself, but it is the process you go through so you know your site

well, okay. You know your engineer barriers, you know the long-term geological change that might occur. All these things that otherwise a licensee wouldn't look at it rigorously. To me that's the value.

So and then like you said, it's 1,000 year or 10,000 year, the cranking of the computer is nothing, okay. You just keep cranking for another 9,000 years. But it's looking at all the things and you have to justify what you present to the NRC, the evaluator of why you pick what you pick. That's the value I feel. So 10,000 years doesn't bother me. Just my personal opinion.

MEMBER SKILLMAN: I want thank David and Gary for a very thorough presentation. This represents a huge amount of work. Thank you. I also want to respect the four individuals that made comments. So thank you. I have nothing further to add. I'm aligned with Joy and with John. I believe we could write a letter, we could write a letter on the rule.

Until we see the guidance, I think we should be careful. A four hour meeting would allow us to creep up on that. But I think we should be very cautious before we commit to writing anything

regarding the NUREG. But I do believe we can look at the rule from the perspective of overarching guidance, as opposed to how to. Thank you.

CHAIRMAN CHU: Walt?

MEMBER KIRCHNER: Thank you. Thank the staff for their very good presentations. I think I'm in Dick's camp and several others. I think we could -- the rule should stand on its own, and therefore I think we could be in a position with the next full Committee meeting to write a letter on the rule.

I sure would like to look at the guidance of why and maybe reserve comment until everyone has more opportunity to review it thoroughly. There were a couple of areas that hopefully maybe we could ask the staff to address.

We heard comments on radon-related dose, and also I thought I understood the rationale for the 500 millirem per year dose for the intruder, but if that could be addressed again in the full Committee, I would appreciate hearing that again.

It seems to me to be an important addition to the rule, and I'm not sure I thoroughly, being new to this area, ingested the

rationale behind that. Thank you.

MEMBER BLEY: One clarification. I think Derek's going to circulate the old white paper to the full Committee, yeah.

CHAIRMAN CHU: Any other comments?

(No response.)

CHAIRMAN CHU: Thank you very much. I thought the presentations were excellent.

MEMBER BLEY: Meeting adjourned.

(Whereupon, the above-entitled matter went off the record at 5:59 p.m.)

DOE Remarks Regarding NRC Staff Revisions to Draft Final 10 CFR Part 61 (October 18, 2016) -- Revised as given

Good afternoon, I am Douglas Tonkay, the Waste Disposal Office Director with the Department of Energy's Office of Environmental Management. DOE is responsible for regulating low-level waste disposal facilities at sites across the country. In doing so we have technical requirements for maintaining our performance objectives as well as setting site-specific waste acceptance criteria at our disposal sites. In addition, our directives allows utilization of commercial disposal facilities, which are directly impacted by this rule. So, we have significant interest in any changes to 10 CFR Part 61.

I would like to thank the Subcommittee for providing the opportunity to share DOE views on the NRC staff's draft final rule. Please note that, DOE was not given an advance copy, so we have not had time to review thoroughly all of the proposed amendments and their supporting rationale. We would appreciate the opportunity to provide further observations at the full Committee meeting in November.

In July 2015, DOE provided comments on the then proposed revision. We are pleased that the NRC staff considered and accepted many of our comments. I want to address three areas for which we remain concerned based on our initial review of the Federal Register notice.

First, the draft final rule, as we understand it, <u>effectively</u> proposes a default compliance period of 10,000 years for long-lived waste with a performance objective of 0.25 mSv annual dose limit. The Commission directed, and we agree, that a 1,000-year compliance period be used. Multiple Commissioners observed that using a 10,000-year compliance period in this context "provides false comfort . . . [based] on guesswork and subjective speculation". We also agree with the ACRS, which stated in a letter to the Commission that, "Introducing significant uncertainties to the performance analysis through speculation on human activities, waste and site performance, and earth processes for millennia is unlikely to improve either our decision making process or our understanding of the safety decisions regarding near surface [low-level waste] disposal." We note that NRC regulations for materials and sites that are comparable to near-surface disposal of low-level waste establish compliance periods of 1,000 years at most. In light of these considerations, we prefer to see a final rule with a compliance period for an annual dose limit to 1,000 years, while requiring qualitative consideration of analyses for longer time periods, up to the point of peak dose but not extending beyond the period of geologic stability. Let me clarify Dr. Esh's statement that DOE has used 10,000 years for Waste Incidental to Reprocessing analysis.

This occurred because it is in NRC NUREG guidance used by NRC technical staff and we are required to complete consultation with them. It is not a DOE directive.

Our second concern is that the rule continues to include radon in the dose-based performance objectives. This inclusion of radon is inconsistent with other EPA, NRC, and DOE regulations that address management of uranium-containing materials. Including radon in the calculation of annual dose imposes a limit for future exposures to a limited number of hypothetical receptors that is significantly lower than the levels currently accepted as guidelines for residential exposures across the country today. To establish more restrictive limitations in the context of an extended performance assessment that entails significant and irreducible uncertainties would be particularly unwarranted. Therefore, the final rule should exclude radon from dose calculations and instead include a performance objective with a flux standard for more consistency with other national requirements for disposal of wastes containing uranium.

Finally, DOE suggests that a draft of NUREG-2175 be made available for comment before the rule is finalized. The draft final rule indicates that a substantial amount of additional information has been moved to guidance, and similarly, that a large number of “clarifications” appear in the NUREG. What information is included and how the regulatory provisions are interpreted can have a dramatic effect on implementation, particularly concerning the scope and conduct of performance assessment over extremely long time periods. While the staff indicated that changes could be made in the future, it could be many years, if not decades, before a revision to the guidance is available.

Thank you again for the opportunity to present our views. DOE will continue to monitor progress of the rulemaking and would appreciate the opportunity to provide further observations at the full Committee meeting.

Dr Chu, thank you for the opportunity to make comments. I will be brief. I, [John Greeves] and Paul Lohaus provided specific comments during the public comment period 7/24/2015.

Paul L. was a principal author Part 61 in the early 80's. Both Paul and I were NRC SES managers responsible for implementing Part 61 requirements and developing the associated guidance for over two decades. After retiring a decade ago we both provided advice to a number of national and international organizations on LLW disposal activities.

The staff has done a good job of listening to and incorporating many of the recommendations provided by us and others with extensive experience with implementing LLW disposal regulations.

One recommendation by numerous stakeholders for a clean two-tiered approach has not been incorporated.

A blended two-tiered analysis has been recommend and incorporated by the staff.

A "kind of a two tier system" [as labeled by Gary Comfort earlier today] is not clean; it will be difficult to implement and will result in unnecessary litigation risk. This moving target will be a significant risk with such a subjective approach that can be argued by multiple parties either way.

A clean two-tiered (i.e.; 1,000y compliance period; a tier-2 1,000y-to-peak dose) approach would be adequate to ensure safety through a 1,000 year compliance period, and second tier analysis out to peak dose. DOE uses such an approach two-tiered approach.

This would eliminate the need for a separate new lengthy rulemaking to address waste classification for waste streams containing large quantities of long lived material.

I would add, in my opinion, requiring compliance, pointing at a "guidance document" to determine a specific compliance period (either 1,000 vs. 10,000) is not an appropriate regulatory approach, and unnecessary, if a clean 2-tier system is specified.

The Commission needs to make a clear final call, on this 1 vs. 10k y compliance period number. It is a policy call.

Thank you for the opportunity to provide these few comments.

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10 CFR Part 61
"Low-level Radioactive Waste Disposal" Final Rule

Gary Comfort
Senior Project Manager
United States Nuclear Regulatory Commission

Presented to the ACRS Radiation Protection and Nuclear Materials Subcommittee

October 18, 2016

Discussion Topics

- Purpose and History
  - Overview
  - Commission Direction
  - Past ACRS Interactions
- Proposed Rule Comments
- Draft Final Rule
- Technical Elements
- Path Forward

Purpose of Rule

Problem: Ensuring safe disposal of new waste streams not analyzed as part of original 10 CFR Part 61 regulation

- Depleted uranium (DU)
- Blended wastes
- Future waste streams

Purpose of Rule

Objectives

- Specify site-specific analyses requirements
- Reduce ambiguity and facilitate implementation
- Better align with existing health and safety standards

Commission Direction

- Order CLI-05-20
  - Staff directed to consider disposal of DU
- SRM-SECY-08-0147
  - Directed rulemaking to require site-specific analysis for disposal of large quantities of DU and associated technical criteria
  - Develop supporting guidance
  - Maintain the waste classification of depleted uranium

Commission Direction

- SRM-SECY-10-0043
  - Incorporate blending into rulemaking
- SRM-COMWDM-11-0002/COMGEA-11-0002
  - Allow licensee flexibility to use ICRP dose methodology
  - Use two-tired approach with compliance period covering reasonably foreseeable future and longer period of performance
  - Allow flexibility to establish waste acceptance criteria based on site-specific technical analyses
  - Establish compatibility to ensure alignment between States and Federal government

Commission Direction

- Staff provided proposed rule to Commission in SECY-13-0075
  - Latest rule language ACRS reviewed
- SRM-SECY-13-0075
  - Directed numerous significant changes
  - Directed publication after changes made
  - ACRS encouraged to provide independent review and recommendations on the technical basis and the accompanying draft guidance

Commission Direction

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Comparison of Draft Rule in SECY-13-0075 and Published Draft Rule

SECY -13 -0075	Publication
Analysis Time Frames (2 – tier)	Analysis Timeframes (3 – tier)
Performance Assessment	Performance Assessment
Intruder Assessment	Intruder Assessment
	Explicit Description of Safety Case
	Defense In Depth (DID) Analysis
	Site Stability Analysis
Waste Acceptance Criteria	Waste Acceptance Criteria
Updated ICRP Dosimetry Modeling	Updated ICRP Dosimetry Modeling
Compatibility Category C	Compatibility Category B

= Minor change resulting from SRM Direction

= Major change resulting from SRM Direction

ACRS Interactions

Meeting Dates

Subcommittee	Full Committee
December 16, 2009	March 4, 2010
June 23, 2011	July 13, 2011
August 17, 2011	September 8, 2011
April 9, 2013	July 10, 2013

ACRS Letter Reports – Key Issues

- Risk-informed based on site-specific, realistic performance assessments with consideration for uncertainties
  - Realistic assumptions for release and fate and transport of DU
  - Realistic likelihood of intrusion
  - Range of site-specific conditions
- Use timeframes determined on a case-by-case site-specific basis rather than defining specific fixed period of performance

ACRS Letter Reports – Key Issues

- Compliance with performance objectives after institutional control period should be evaluated considering FEPs for a given site for a period commensurate with the site-specific risk
- Protection of inadvertent intruder
  - Large uncertainties associated with human intrusion scenarios will not help decision making
  - Durability and stability should be sufficient
- Previously disposed wastes should not be subject to additional compliance evaluations

Rule status

- Proposed rule
  - SRM-SECY-013-0075 issued February 12, 2014
  - Published for comment on March 26, 2015 (80 FR 16081)
  - 120 day comment; reopened August 27 – September 21, 2015

- Draft final rule
  - Submitted to Commission September 15, 2016

Public Comments on Proposed Rule

- Received 2,401 comment letters (2,300 form)
  - Extensive public outreach
  - Six workshops and webinar
- Represented:
  - Individuals
  - Public interest groups
  - Native American Tribal Governments
  - Industry groups
  - Licensees
  - State and federal agencies
- Over 800 comments binned and responded to

Examples of Public Comments

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- 3-Tier System
  - More complicated than necessary
  - 500 mrem dose goal reduces public health and safety
  - RESPONSE: Changed to new, simplified approach
- Compatibility Category
  - Reduced current health and safety provided by some States
  - Most commenters recommended "C"
  - RESPONSE: Changed compliance period definition and 61.58 to "C"

Examples of Public Comments (Cont)

- Grandfathering
  - 61.1(a) should allow existing sites to grandfather
  - Already disposed of wastes should not need to be addressed
  - RESPONSE: Staff concluded that grandfathering not appropriate and removed confusing language in 61.1(a)
- Backfit
  - Backfit analysis should be done because of impact on other licensees
  - RESPONSE: No backfit in Part 61; NRC doesn't address passed along costs

Draft Final Rule Major Changes

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The rule

- Requires a site specific analysis
- Provides a 1,000 or 10,000 year compliance period for protection of the general public
- Adds a new technical analysis for the protection of inadvertent intruders
- Adds a new post-10,000-year performance period analysis
- Adds a new requirement to update the technical analyses at site closure
- Adds a new requirement to identify DID protections
- Facilitates implementation and better aligns the requirements with current safety standards

Draft Final Rule Language – Definitions (61.2)

- *Compliance period*
  - Site closure to 1,000 years if no significant quantities of long-lived radionuclides.
  - Site closure to 10,000 years otherwise
- *Defense-in-depth*
  - Use of multiple independent and, where possible, redundant layers of defense such that no single layer, no matter how robust, is exclusively relied upon
  - Includes, but is not limited to, the use of siting, waste forms and radionuclide content, engineered features, and natural geologic features of the disposal site to enhance the resiliency of the land disposal facility

Draft Final Rule Language – Definitions (61.2)

- *Inadvertent intruder assessment* is an analysis that:
  - Assumes inadvertent intruder occupies site and engages in normal activities and other reasonably foreseeable pursuits that are realistic and consistent with expected activities in and around the disposal site at the time of the assessment
  - Examines capabilities of intruder barriers to inhibit contact with the waste or limit exposure to radiation from the disposal unit
  - Estimates inadvertent intruder's potential annual dose considering uncertainties.

Draft Final Rule Language – Definitions (61.2)

- *Long-lived radionuclide* means radionuclides:
  - Where more than 10 percent of the initial activity of the radionuclide remains after 1,000 years
  - Where the peak activity from progeny occurs after 1,000 years; or
  - Where more than 10 percent of the peak activity of the radionuclide (including progeny) within 1,000 years remains after 1,000 years

Draft Final Rule Language – Definitions (61.2)

- *Performance assessment*
  - analysis to demonstrate compliance with the performance objectives
  - identifies the features, events, and processes that could affect the disposal site performance
  - estimates the potential dose as a result of releases caused by all significant features, events, and processes including the uncertainties
- *Performance period*
  - timeframe established to evaluate the performance of the disposal site after the compliance period

Draft Final Rule Language – Definitions (61.2)

- *Safety case*
  - Collection of information that demonstrates the assessment of the safety of a land disposal facility
  - Includes technical analyses, DID, and supporting evidence and reasoning
  - Also includes description of the safety relevant aspects of the disposal site, the design of the facility, and the managerial control measures and regulatory controls.

Draft Final Rule Language –

- 61.12 Specific Technical Information
  - New DID requirement added as 61.12(o)
  - Requires identification of DID protections, including a description of the capability of each DID protection relied upon to maintain safety and a basis for the capability of each DID protection
  - Not an analysis

Draft Final Rule Language –

- 61.13 Technical Analyses
  - Requires performance assessment for compliance period that:
    - Considers features, events, and processes that represent a range of phenomena with both beneficial and adverse effects on performance
    - Considers the likelihood of disruptive or other unlikely features, events, or processes
    - Provides a technical basis for models used
    - Evaluates contaminant transport pathways and processes in environmental media (e.g., air, soil, groundwater, surface water)
    - Accounts for uncertainties and variability in the projected behavior of the disposal site and general environment and in the demographics and behaviors of human receptors
    - Identifies and differentiates between the roles performed by the natural disposal site characteristics and design features in limiting releases of radioactivity to the general population

Draft Final Rule Language –

- 61.13 Technical Analyses (cont)
  - Requires inadvertent intruder assessment for compliance period that
    - Assumes inadvertent intruder occupies the disposal site and engages in normal activities and other reasonably foreseeable pursuits that are consistent with the activities and pursuits occurring in and around the site at the time of development of the inadvertent intruder assessment.
    - Is updated prior to closure to reflect any significant changes to the activities and pursuits occurring in and around the site.
    - Identifies barriers to inadvertent intrusion that inhibit contact with the waste or limit exposure and provides a basis for the time period over which barriers are effective.
    - Accounts for uncertainties and variability in the projected behavior of the disposal site and general environment.

Draft Final Rule Language –

- 61.13 Technical Analyses (cont)
  - Analyses of the protection of individuals during operations
    - Includes assessments of expected exposures due to routine operations and likely accidents
    - Must provide reasonable assurance that exposures will be controlled to meet the requirements of 10 CFR Part 20
  - Long-term stability analysis
    - Evaluates need for ongoing active maintenance after site closure
    - Based on analysis of active natural processes, infiltration, and surface drainage of the disposal site.
    - Provides reasonable assurance that long-term stability of the disposal site can be ensured for the compliance period and that there will not be a need for ongoing active maintenance
  - Performance period analysis
    - Only required if 10,000-year compliance period used
    - Assess how disposal site limits the potential long-term radiological impacts during the performance period, consistent with available data and current scientific understanding.
    - Must identify and describe features of the design and site characteristics relied on

Draft Final Rule Language –

- 61.41 Protection of the general population from releases of radioactivity
  - Compliance period
    - Limits annual dose to 0.25 milliSieverts (25 millirems) to any member of the public
    - Demonstrated through analyses that meet the requirements specified in § 61.13(a).
  - Performance period
    - Must minimize releases of radioactivity to the general environment to the extent reasonably achievable
    - Demonstrated through analyses that meet the requirements specified in § 61.13(e).

Draft Final Rule Language –

- 61.42 Protection of individuals from inadvertent intrusion.
  - Compliance period
    - Limits annual dose to 5 milliSieverts (500 millirems) to any inadvertent intruder
    - Demonstrated through analyses that meet the requirements specified in § 61.13(b).
  - Performance period
    - Must minimize exposures to any inadvertent intruder to the extent reasonably achievable
    - Demonstrated through analyses that meet the requirements specified in § 61.13(e).

Draft Final Rule Language –

- 61.58 Alternative requirements for waste classification and characteristics.
  - Specifies waste acceptance criteria
  - Requires waste certification
  - Requires annual review of content and implementation of the waste acceptance criteria, waste characterization methods, and certification program

QUESTIONS?

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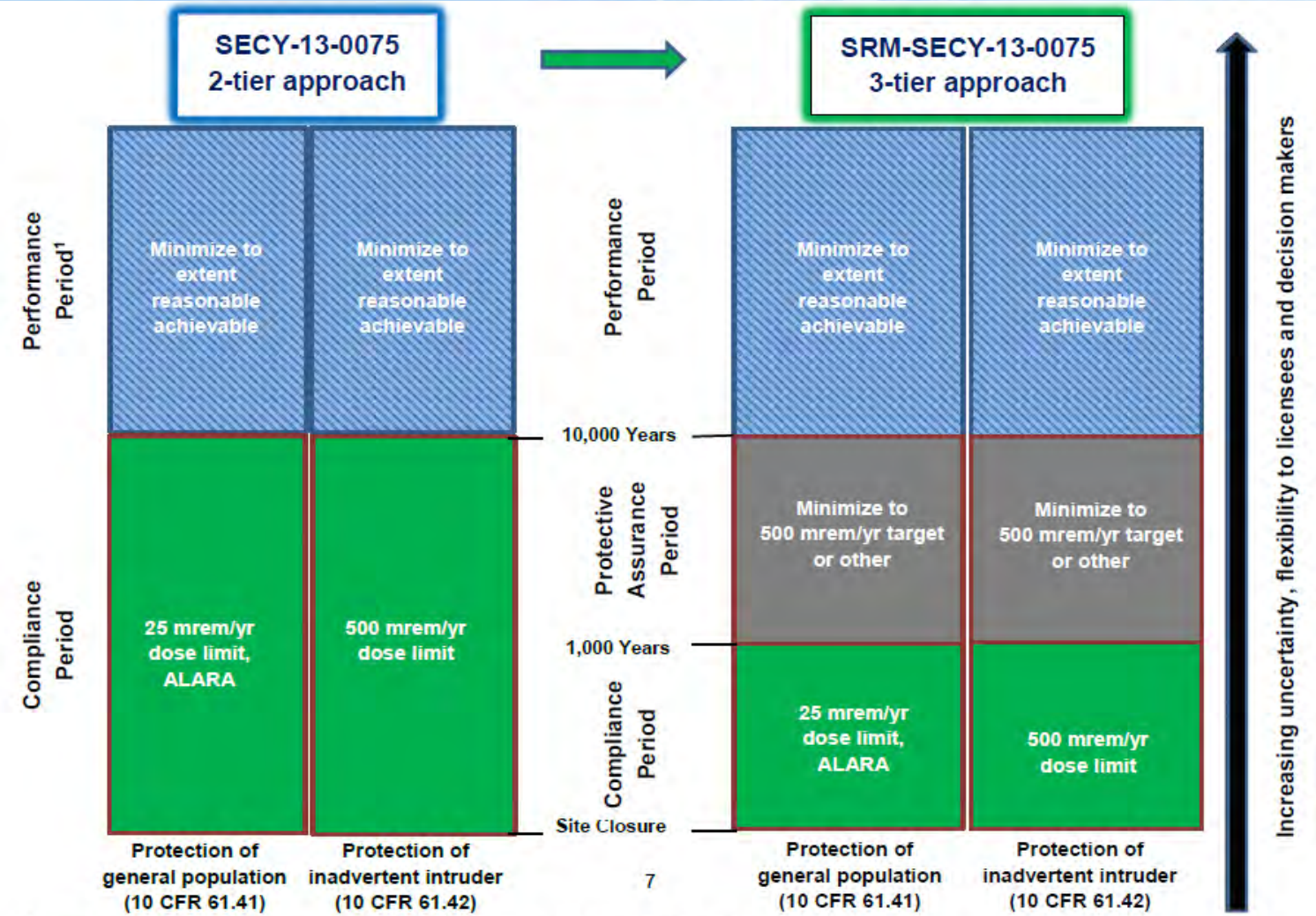
??????

Path Forward

- Commission review
- If approved for publication
  - Incorporate Commission directed changes
  - Send to OMB for review (~90 days)
  - Send to *Federal Register* for publication
- Effective date: 1 year from publication
- License updates due next renewal or within 5 years of effective date
- Agreement States have 3 years from publication to implement compatible regulations

BACKUP SLIDE

Timeframe changes



[1] Only applicable if concentrations on a facility-averaged basis are above Class A

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Overview of Major Technical Elements of 10 CFR Part 61

David Esh, PhD
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Presented to the ACRS Radiation Protection and Nuclear Materials Subcommittee, October 18, 2016

Outline

- Safety Case
- Defense-in-Depth
- Analysis Timeframes (Significant Quantities)
- Technical Analyses
  - Performance Assessment
  - Intruder Assessment
  - Site Stability
- Waste Acceptance Requirements
- Guidance (NUREG-2175)

Safety Case

- A collection of arguments and evidence to demonstrate the safety of a land disposal facility (e.g. defense-in-depth protections and technical analyses).
- Describes all safety relevant aspects of the disposal site, the design of the facility, and the managerial control measures and regulatory controls to inform the decision whether to grant a license.
- Includes the same type of information that the original 10 CFR part 61 required to be submitted as part of a license application (i.e., 10 CFR 61.10 – 10 CFR 61.16).
- The safety case will be updated over time as new information is gained during the various phases of the facility's development and operation.

Safety Case

- Plain language description of:
  - Strategy for achieving safe disposal
  - Safety arguments that highlight the main evidence that quantify and support the claim that the land disposal facility will be safe
  - The disposal site and facility
  - Information about the nature of the waste and the design and proposed operation of the facility
  - The technical analyses that demonstrate performance objectives
  - Strategy for institutional control of the disposal site
  - Licensee's financial qualifications

Defense-in-Depth

- The use of multiple, independent, and, where possible, redundant layers of defense so that no single layer, no matter how robust, is exclusively relied upon.

IMPLICIT

EXPLICIT

Note: Lifecycle timeframes not to scale

Defense-in-Depth Requirements

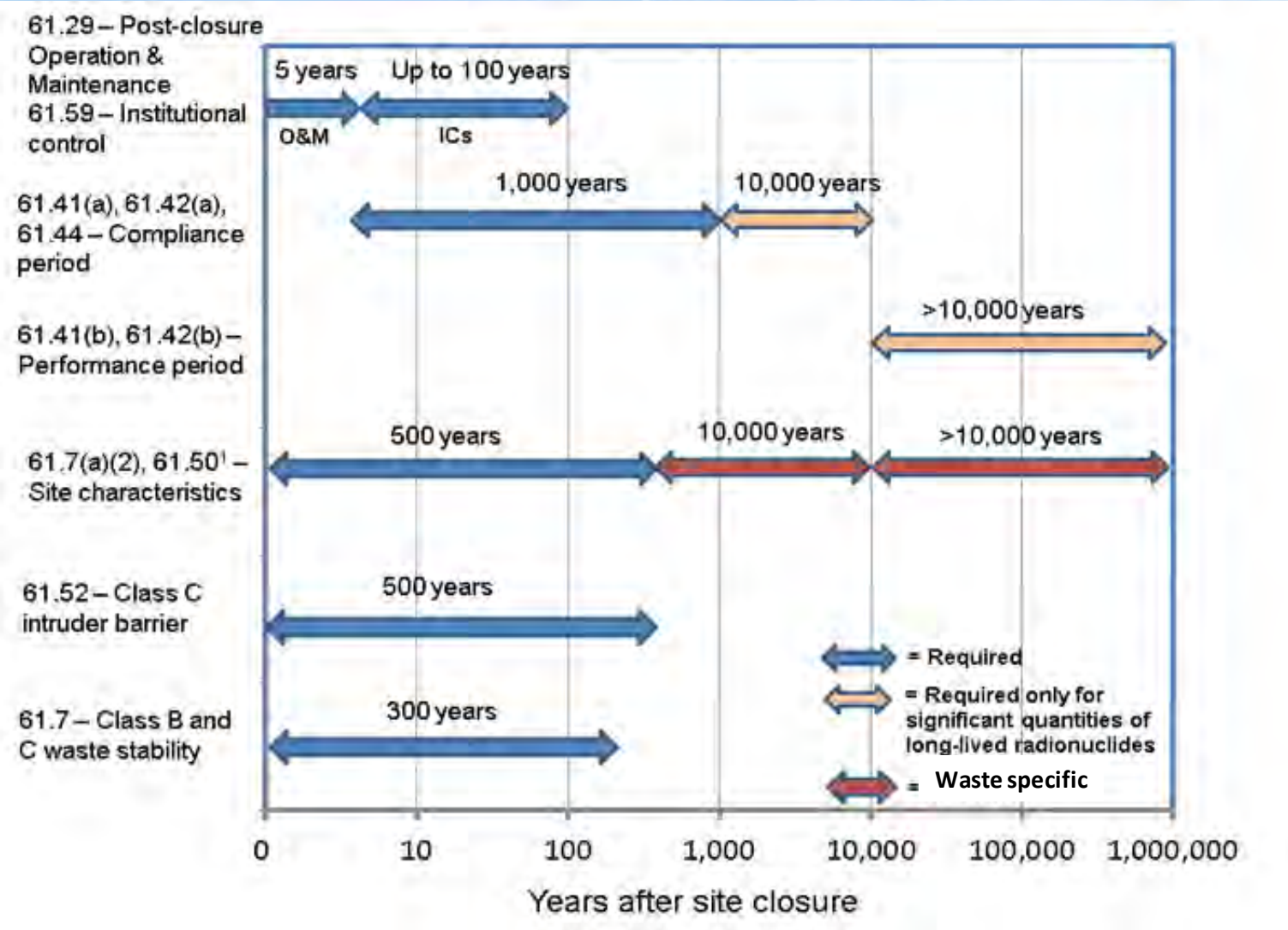
- Identify defense-in-depth protections commensurate with risks.
- Describe capabilities of defense-in-depth protections.
- Provide a technical basis for capabilities of defense-in-depth protections.

Defense-in-Depth for LLW Disposal

- Operations
  - Provide for active and passive safety systems commensurate with the hazard and complexity of the activities.

- Post-Closure
  - Disposal site is essentially a passive system, relying on both natural site characteristics and engineered features.
  - Diversity of capabilities of the components and attributes of the disposal site increases the site's resilience to unanticipated failures or external challenges.
  - Each layer of defense must make a definite contribution to the isolation of the waste.
  - Capabilities of site characteristics and engineered features over long timeframes are subject to interpretation and many uncertainties. These uncertainties can be quantified generally and are addressed by requiring the use of multiple layers of defense.

Timeframes


61.29 – Post-closure Operation & Maintenance
61.59 – Institutional control
5 years
Up to 100 years
O&M
ICs
61.41(a), 61.42(a), 61.44 – Compliance period
1,000 years
10,000 years
61.41(b), 61.42(b) – Performance period
>10,000 years
61.7(a)(2), 61.50[1] – Site characteristics
500 years
10,000 years
>10,000 years
61.52 – Class C intruder barrier
500 years
61.7 – Class B and C waste stability
300 years
= Required
= Required only for significant quantities of long-lived radionuclides
= Waste specific
0
10
100
1,000
10,000
100,000
1,000,000
Years after site closure

Timeframes

- Throughout the process, significant interest in the analyses timeframes.
- Significant comments received reflecting diverse opinions.
- Staff devoted significant effort to the formulation of the final position.
- Key features:
  - Compliance period is 1,000 years or 10,000 years depending on if the site will contain significant quantities of long-lived radionuclides.
  - Performance period only applies if the compliance period is 10,000 years.
  - Compatibility criteria is C (Agreement State may be more restrictive).

Significant Quantities

How does one determine if they have significant quantities?

- Start simple and if necessary introduce more complexity

1. Perform screening based on inventory
2. Perform screening based on simplified dose assessment
3. Site-specific analysis (case-by-case)

Significant Quantities - Example

Example A licensee wishes to dispose of waste at a disposal site that does not have a potable groundwater pathway or any credible mechanisms for release other than from disturbance by inadvertent intruders. The total volume of disposal cells for existing waste is 400,000 m^3. The inventory of waste located in the facility is comprised of: 50,000 m^3 of C-14 containing waste at 0.2 Ci/m^3, 200,000 m^3 of waste containing C-14 at 0.1 Ci/m^3 and I-129 at 0.002 Ci/m^3, and 50,000 m^3 of Tc-99 containing waste at 0.01 Ci/m^3. The uncontaminated fill and material used to construct the cells represents 100,000 m^3.

Conclusion: The licensee uses the Class A waste concentrations to calculate the volume-averaged SOF per the following equation. This equation is used to calculate the SOF for *n* waste streams containing *m* isotopes. *V* is the volume, *C* is the concentration on a volumetric basis, and *CA* is the Class A waste limit for the particular isotope.

$$SOF = \frac{1}{V_T}\sum_{i=1}^{n}\left(V_i \sum_{j=1}^{m}\frac{C_{i,j}}{CA_{i,j}}\right)$$

$$SOF = \frac{1}{400{,}000\ m^3} * \left(50{,}000\ m^3\left(\frac{0.2}{0.8}\right) + 200{,}000\ m^3\left(\frac{0.1}{0.8} + \frac{0.002}{0.008}\right) + 50{,}000\ m^3\left(\frac{0.01}{0.3}\right)\right) = 0.223$$

Because the SOF is less than 1, a 1,000-year compliance period can be used and performance period analyses are not required.

Performance Assessment

Performance assessment is an analysis used to demonstrate compliance with 10 CFR 61.41(a) and (b) that identifies the features, events, and processes that could affect the disposal site performance; and estimates the potential dose as a result of releases caused by all significant features, events, and processes including the uncertainties.

Performance Assessment

- Performance assessment is not a new topic – renaming of technical analyses
- New requirements in 61.13:
  - Scope (features, events, and processes)
  - Uncertainty and variability
  - Model support
- Requirement to update the performance assessment at closure
- Modified siting characteristics consistent with disposal of long-lived waste

IMPLICIT

↓

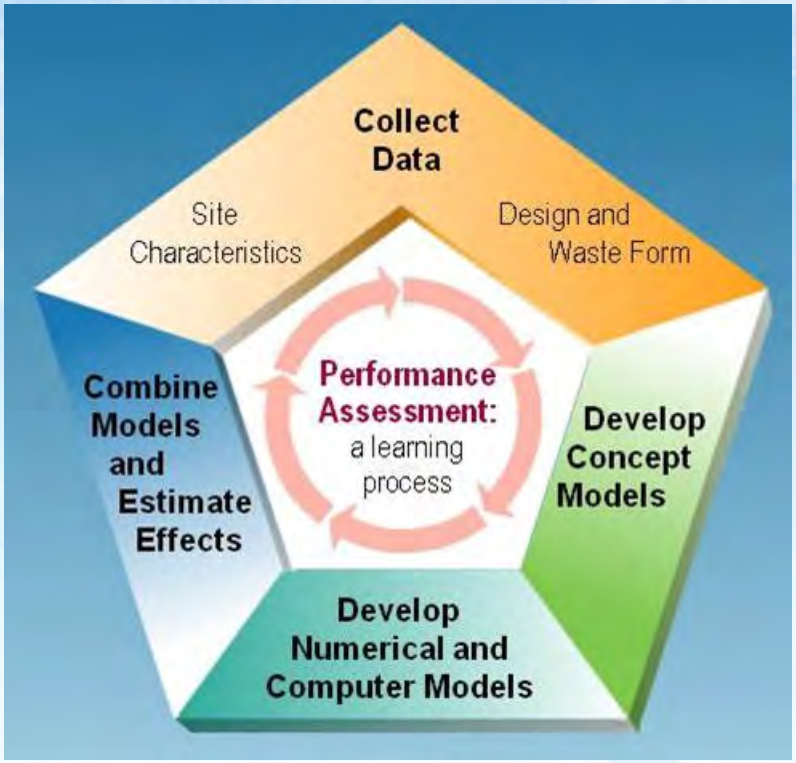
EXPLICIT

Performance Assessment

61.28: Update PA at closure

61.50: Informed by timeframes

61.58: PA results may be used to develop WAC



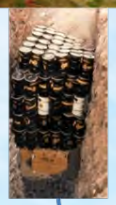
61.13: PA results considered in DID and safety case

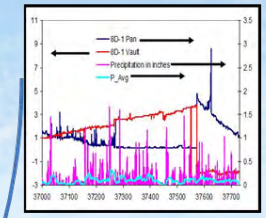
61.13: Features, events, and processes

61.13: Model support

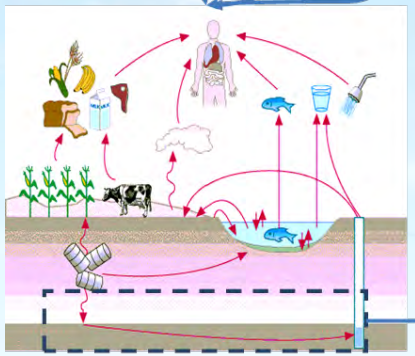
61.13: Uncertainty and variability

Performance Assessment



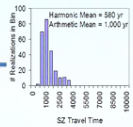


Site characterization data and other information



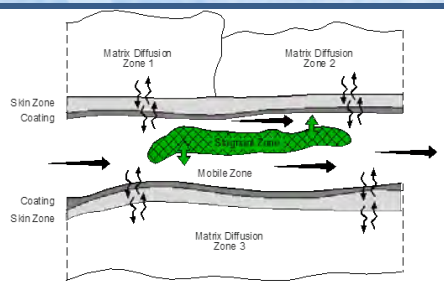
Performance assessment conceptual model development

Hydrologic conceptual model development (see next figure)

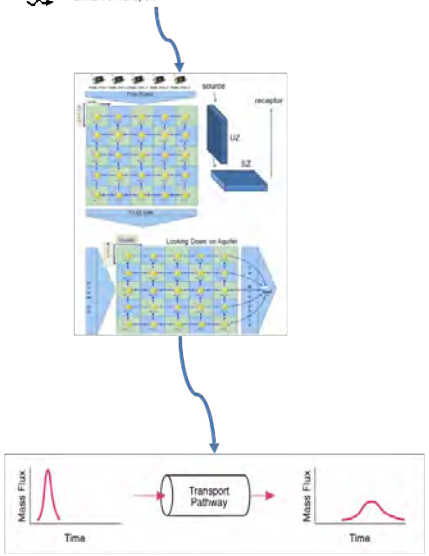


Abstracted hydrologic model

Estimated system performance



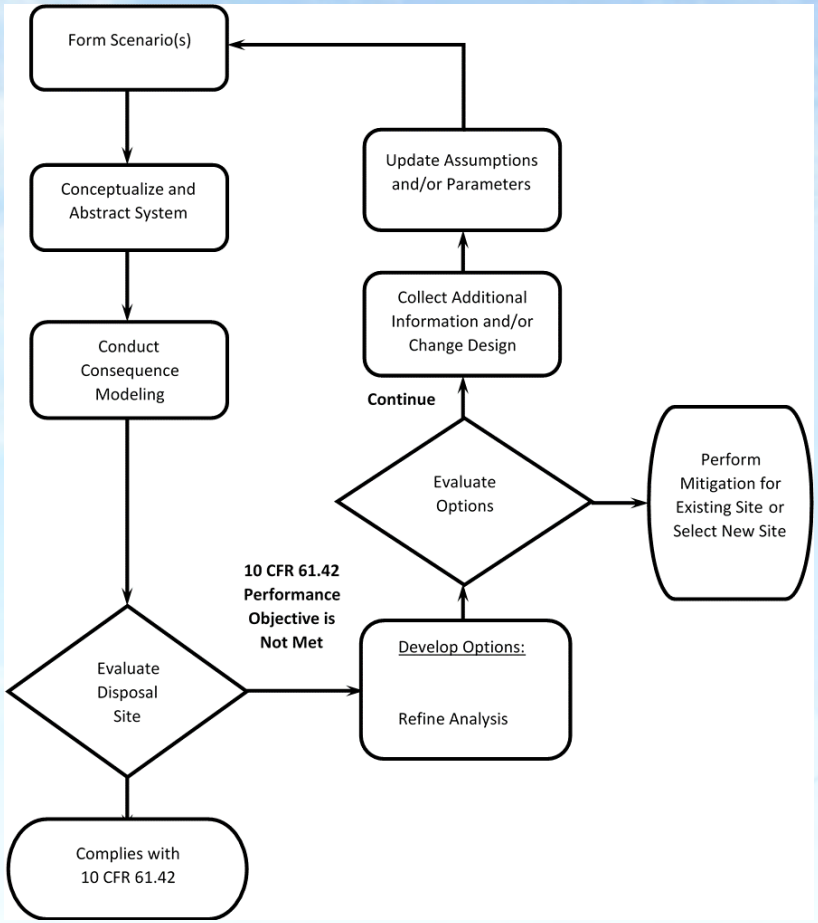
Hydrologic conceptual model



Numerical model development

$$m'_{is} = -m_{is}\lambda_s + \sum_{p=1}^{NP} m_p \lambda_p f_{ps} R_{sp} (A_s/A_p) + \sum_{c=1}^{NC} f_{cs} + S_{is}$$

Inadvertent Intrusion Assessment



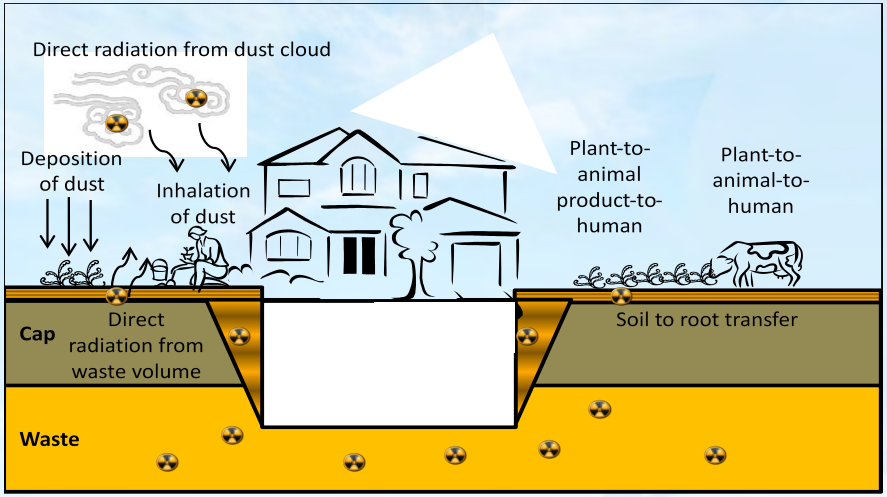
- Similar to performance assessment, except:
  - Receptor scenarios
  - Onsite exposures
  - 500 mrem/yr limit
  - Precluded during institutional control period (i.e., 100 yrs)

Inadvertent Intruder Receptor

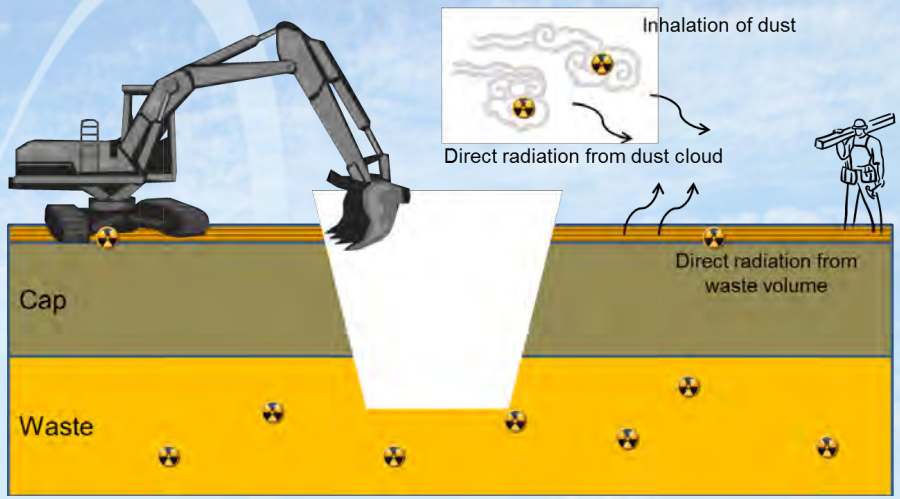
Types of Scenarios		Evaluation Purpose	Description
Plausible	Generic	All can be used to demonstrate compliance with the inadvertent intruder performance objective. Licensees should use the plausible scenario from which the inadvertent intruder would reasonably be expected to receive the greatest exposure to radiation from the waste to demonstrate compliance.	The scenarios used to inform the waste classification criteria at 10 CFR 61.55 that are consistent with normal activities including agriculture, dwelling construction, drilling for water.
	Site-Specific		A scenario developed, using site information, either from scratch or by modifying a generic scenario that is consistent with activities in and around the disposal site at the time the assessment is developed.
	Reasonably Foreseeable		Reasonably foreseeable scenarios are based on (i) normal activities and (ii) other pursuits that are consistent with activities in and around the disposal site at the time the assessment is developed. Normal activities include agriculture, dwelling construction, resource exploration or drilling for water. The NRC staff continues to believe the generic receptor scenarios associated with normal activities are plausible assuming the loss of institutional controls and the loss or significant degradation of the capabilities of intruder barriers. The NRC staff also continues to view the generic receptor scenarios as reasonably bounding over long timeframes, given the uncertainty in estimating future human activities over long time periods. However, licensees can also rely on site-specific scenarios that are consistent with activities in and around the site at the time the assessment is developed.
	Less likely, but plausible	Not analyzed for compliance, but may be used to risk-inform the decision.	Intruder activities that are plausible, assuming the loss of institutional controls, based on the capabilities of intruder barriers, site characteristics, and historical uses, but are **not** reasonably foreseeable considering normal activities or other pursuits that are different than activities in and around the site at the time of closure. These scenarios are usually site-specific.
Implausible		No analysis required.	Assuming the loss of institutional controls, intruder activities that could not occur because of persistent physical limitations of the site.

- Normal Activities
  - Dwelling Construction
  - Agriculture
  - Drilling for Water
- Reasonably Foreseeable Activities
  - Consistent with activities in vicinity of site when assessment developed

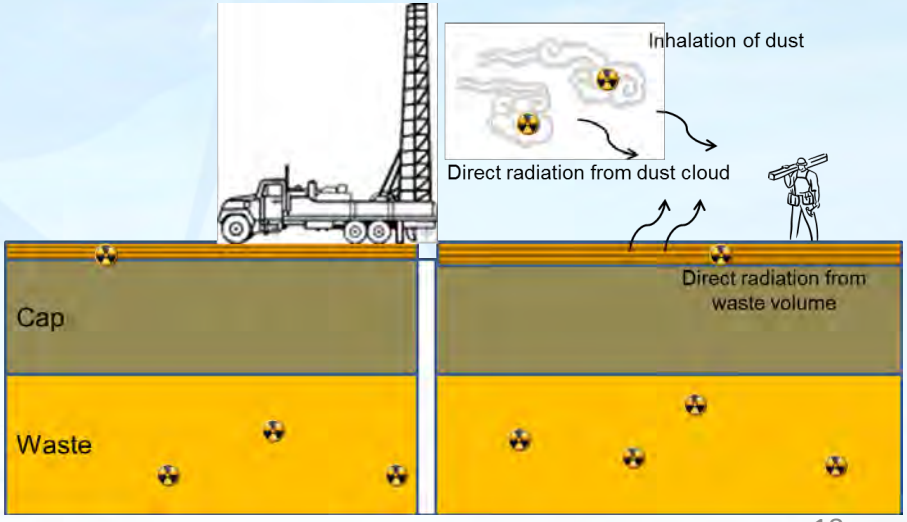
Normal Activities



Agriculture



Dwelling Construction



Drilling for Water

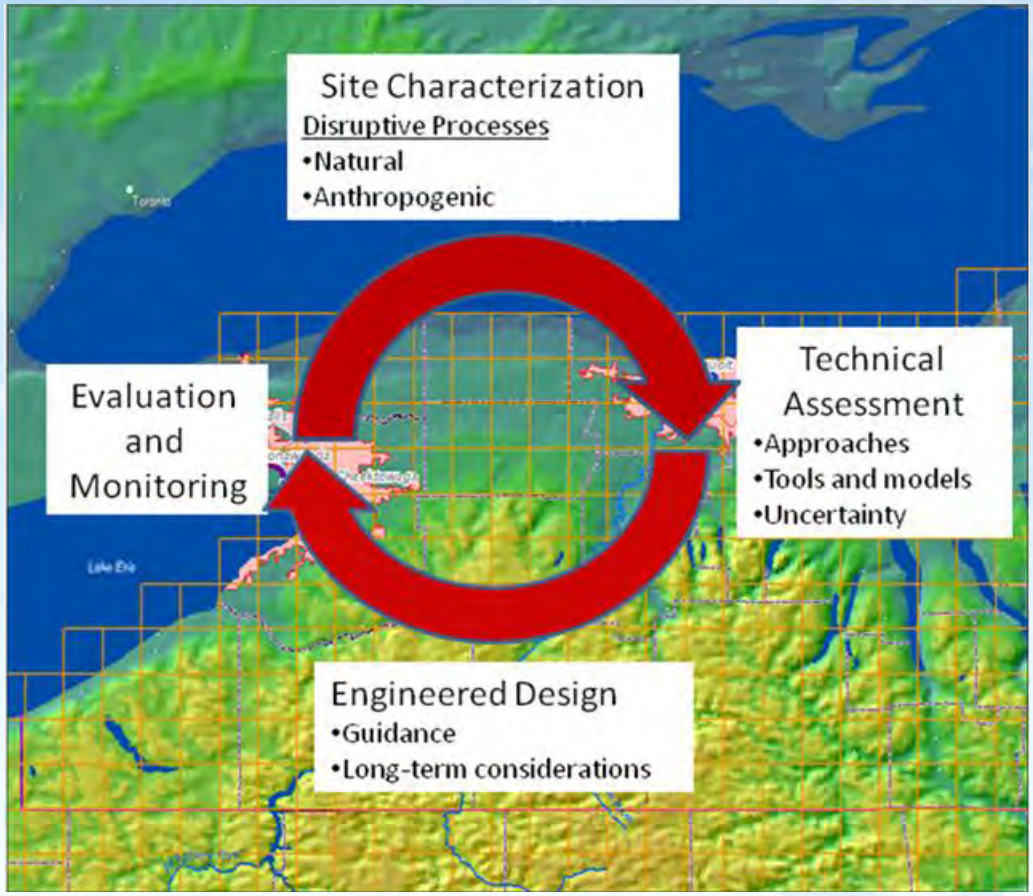
Site-specific Scenarios

- Constrain exposure pathways for normal or reasonably foreseeable activities based on:
  - Physical information
    - Waste characteristics and disposal practices
    - Disposal site characteristics
  - Cultural information (e.g. land use)

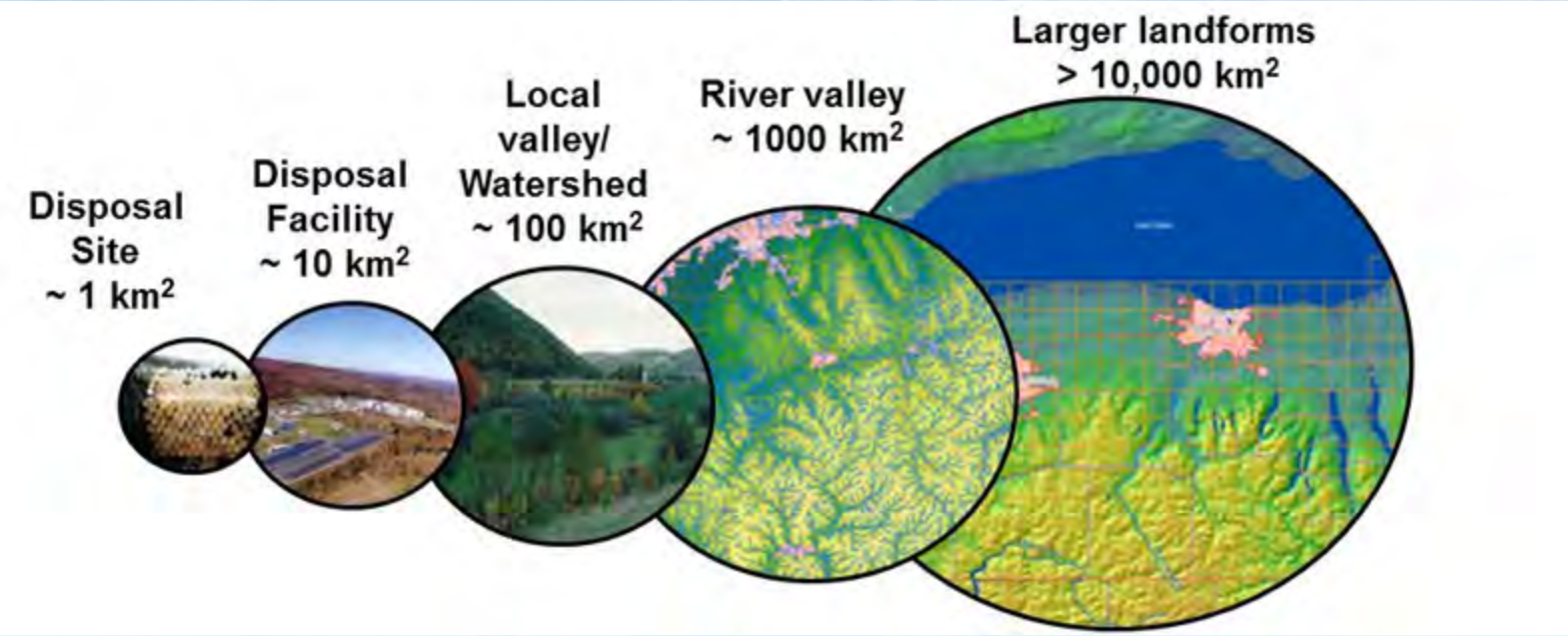
Site Stability

- Consideration of site stability is an important part of the safety strategy.
- Site stability is required for the compliance period but may be performance-based.
- Guidance describes design-based and model-based approaches.

Site Stability



Site Stability

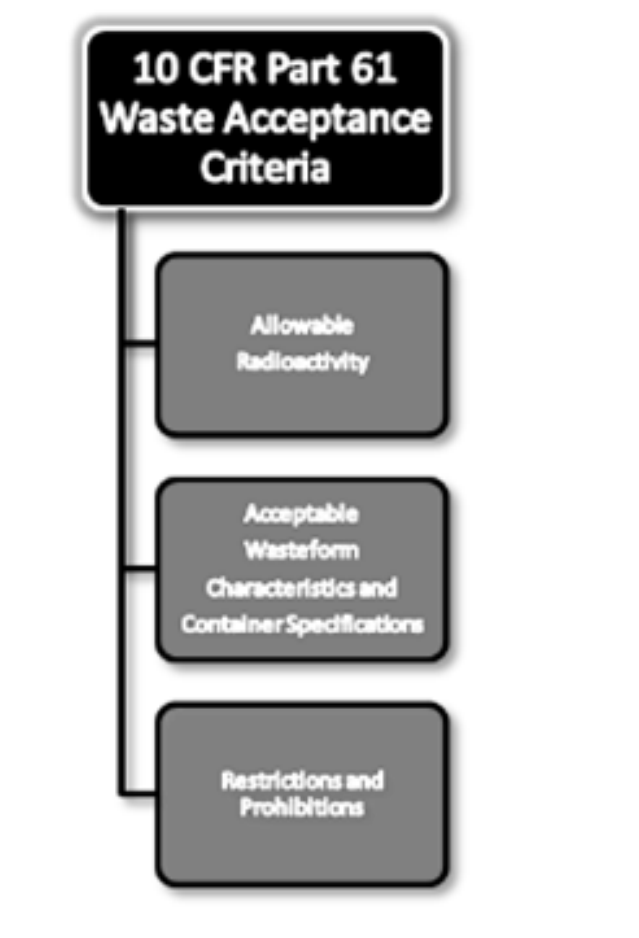


Temporal, Spatial scales = f(Waste)

Waste Acceptance Requirements

- Licensees must review their waste acceptance program at least annually
- Ensures that the program continues to be adequate and is being implemented in a way that continues to protect public health and safety

Waste Acceptance Criteria

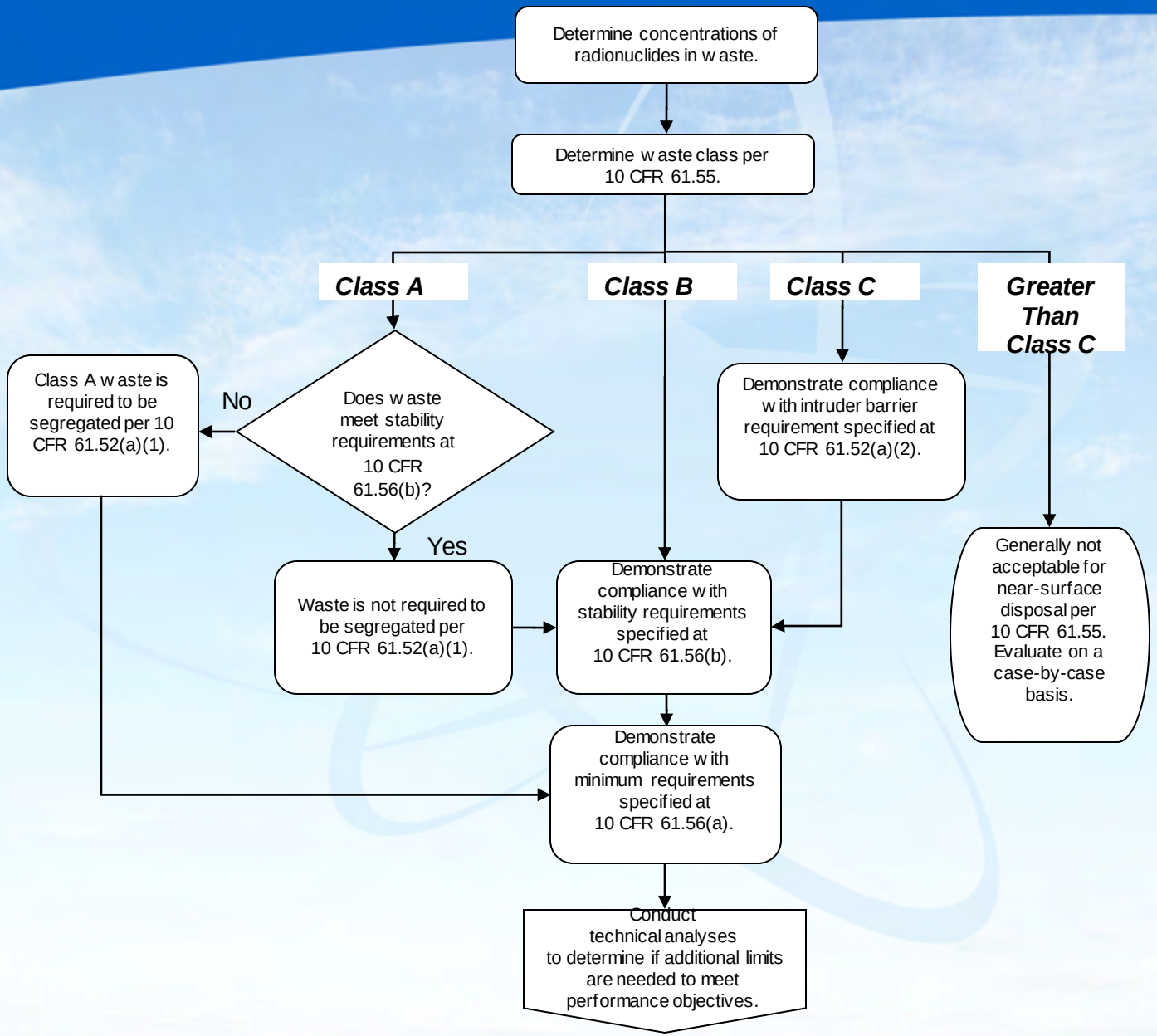


- Allowable Limits on Radioactivity
- Wasteform Characteristics and Container Specifications
- Restrictions and Prohibitions

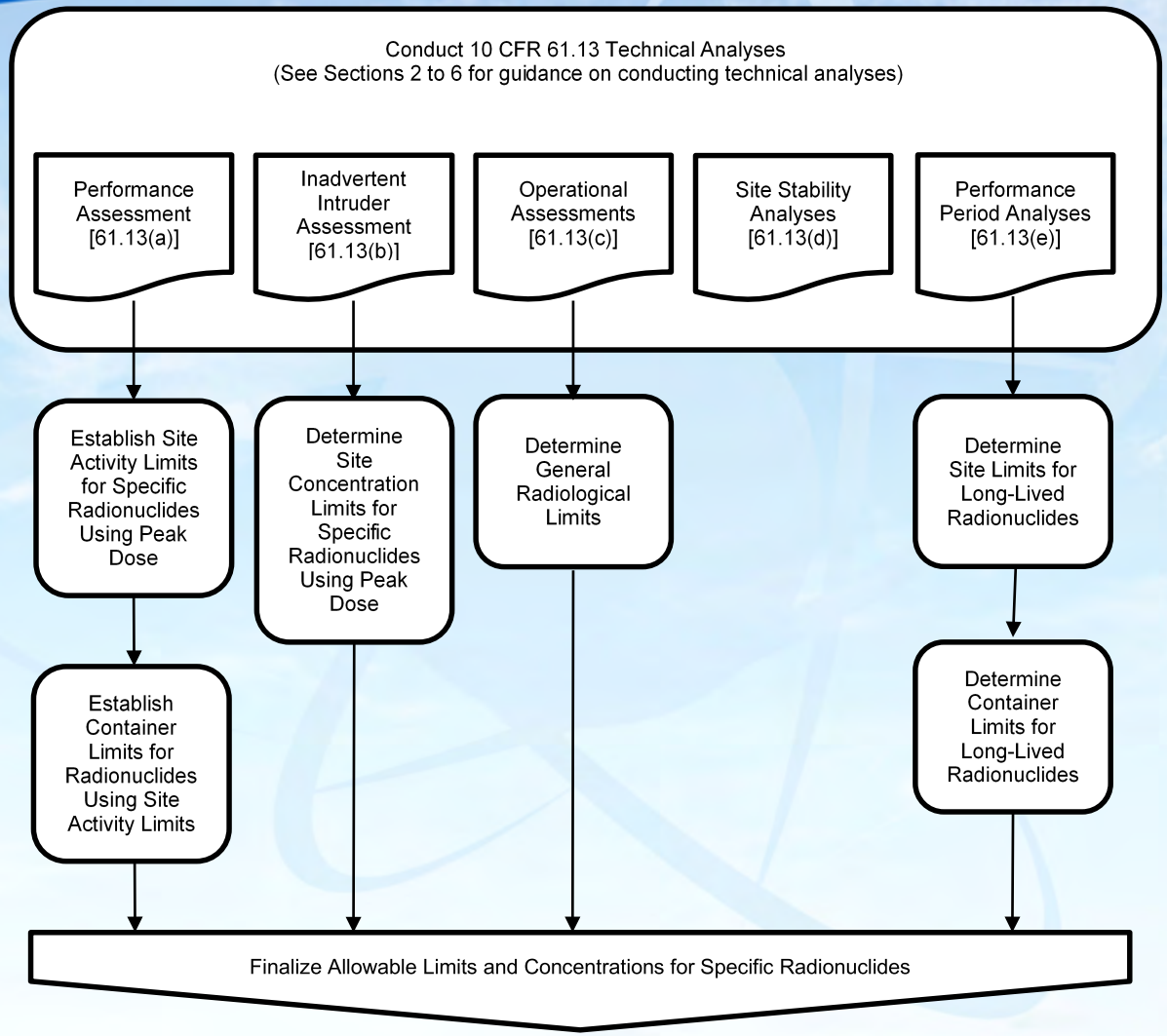
Waste Acceptance

- Flexibility to develop site-specific waste acceptance criteria.
- Use 61.55 limits, results of technical analyses, or combination of both to develop criteria.
- Either way, licensees must demonstrate that criteria will demonstrate that performance objectives will be met.

Allowable Limits from §61.55



Allowable Limits from Analyses

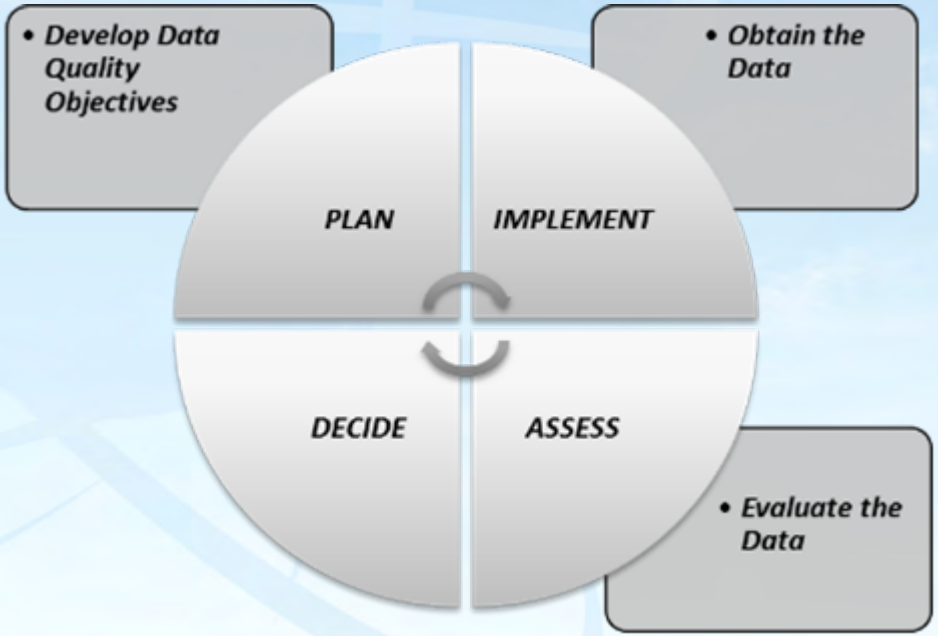


Waste Characterization

- Licensees must specify acceptable methods for characterizing waste
  - Acceptable methods to characterize waste
  - Criteria for determining an acceptable level of uncertainty in the characterization data
  - Documentation required to ensure sufficient detail is available to demonstrate that the waste acceptance criteria are met
- Ensure that knowledge of the waste's characteristics is:
  - Commensurate with the assumptions and approaches used to develop the waste acceptance criteria
  - Sufficient to demonstrate that the waste acceptance criteria are met

Characterization Methods

- Direct or indirect (materials accountability, characterization by source, scaling factors) methods
- Data quality
- Documentation
  - Responsibilities
  - QA
  - Procedures
  - Records



Waste Certification

- Program to certify that waste meets the acceptance criteria prior to receipt at a disposal facility
  - Designate the authority to certify and receive waste for disposal at the disposal facility
  - Provide procedures for certifying that waste meets the waste acceptance criteria
  - Specify documentation required for waste characterization, shipping and certification
  - Identify records, reports, tests, and inspections that are necessary to maintain and provide criteria for auditing
  - Provide approaches for managing certified waste to maintain its certification status

NUREG-2175

- NUREG-2175 (Guidance for Conducting Technical Analyses for 10 CFR Part 61) provides:
  - Flowcharts, NRC staff recommendations, and examples for how licensees can develop high-quality technical analyses
  - Guidelines for what licensees or applicants should include and what regulators should review for each type of analysis
  - Suggested references, screening tools, and case studies

NUREG-2175

- Draft NUREG-2175 (Guidance for Conducting Technical Analyses for 10 CFR Part 61)
  - Issued at same time as Proposed Rule (March 26, 2015)
  - Discussed in seven public meetings including in a dedicated webinar (May 2015)
  - Same extended public comment period as proposed rule
  - Received seven sets of comment letters
    - Individuals, public interest groups, industry, licensees, and federal agencies
- Final guidance document has been developed (in concurrence)
  - Will be issued after Commission approves Final Rule publication

Major Comments Received

- Analyses timeframes
  - Protective Assurance Period and three-tiers is confusing and should be eliminated
- Defense-in-Depth
  - Requirement for a separate “analysis” should be clarified
- Confusion on various timeframes discussed
- Questions on site closure process
- Clarification on inadvertent intruder assessment scenarios

Major Revisions Made

- Analyses timeframe
  - Eliminated protective assurance period
  - Modified compliance period discussion
  - Added detail and examples on how to determine if a site has significant quantities of LLW
- Defense-in-Depth
  - Clarified the requirement to identify defense-in-depth protections and describe their capabilities
- Added figures describing site closure process, timeframes for evaluation, process for developing allowable limits
- Appendix with responses to public comments received
- Added appendix on 10 CFR Part 61 DEIS default scenarios

CRESP Comments on Proposed Rule 10CFR61

Presentation to the NRC ACRS RP & NM Subcommittee

The CRESP Management Board
Craig Benson[8], Joanna Burger[2], James Clarke[1], Michael Greenberg[2], Kathryn Higley[3],
Kimberly Jones[4], David Kosson[1], Steve Krahn[1], Shlomo Neuman[7], Ron Rousseau[9], Richard Stewart[5]

[1]Vanderbilt University, [2]Rutgers, The State University of New Jersey, [3]Oregon State University, [4]Howard University, [5]New York University, [6]Robert Wood Johnson Medical School, [7]University of Arizona, [8]University of Wisconsin- Madison, [9]Georgia Institute of Technology

CRESP

Consortium For Risk Evaluation with Stakeholder Participation

October 18, 2016

CRESP Mission

Support safe, effective, publicly-credible, risk-informed management of existing and future nuclear waste from government and civilian sources through independent strategic analysis, review, applied research and education.

www.CRESP.org

- CRESP operates under a Department of Energy cooperative agreement awarded to Vanderbilt University. The multi-university consortium is working to advance cost-effective, risk-informed cleanup of the nation's nuclear weapons production facility sites and cost effective, risk-informed management of potential future nuclear sites and wastes.

- Members of the CRESP Management Board commented on the 2013 and 2015 drafts for 10CFR61 **LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE**

www.CRESP.org

- We **applaud** and **strongly support** the Nuclear Regulatory Commission's *Risk-Informed, Performance-Based Approach.*

- If we took issue with certain aspects of the proposed regulations, it was because we believed that the approach was **departing** from a *Risk-Informed, Performance-Based Approach*.

www.CRESP.org

- Several provisions in the draft proposed rules of 2013 and 2015 “commendably reflect and implement a risk-informed, performance-based approach”.
- Notably they include provisions for site specific waste acceptance criteria, site specific performance assessment, and the use of updated dosimetry. (2013 comments).
- Furthermore, we noted that site specific assessments of exposure to an inadvertent intruder, and provisions for defense-in-depth and safety case evaluations were positive additions, consistent with risk-informed, performance-based regulation (2015 comments)

However, we expressed concerns that there were parts of the proposed regulations where the NRC was still not taking a risk-informed performance-based approach, in particular, the continued incorporation of very long time frames that greatly exceed our experience and forecasting abilities.

Comments from Jim Clarke Consultant to the ACRS

- It appears that the staff concerns reflected in the Proposed Rule stem from the appearance of quantities of long-lived radionuclides from activities that were unanticipated when10CFR61 was first promulgated.
- These are understandable and legitimate concerns.
- However, they should be addressed through the regulations in a way that is consistent with NRC's risk-informed, performance-based approach.

Comments from Jim Clarke, Consultant to the ACRS

- The draft regulations were revised to eliminate the "protective assurance period" from 1000 to 10,000 years, however, the revision now states that the **compliance period** would be either 1000 or 10,000 years depending on the inventory and concentration of long-lived radionuclides intended for disposal.

- However, a compliance period of 10,000 years is neither risk-informed nor performance-based. This time period is outside our current body of knowledge and greatly exceeds our ability to forecast the future.

- My personal feeling is that our current ability to forecast future events would be better limited to a few hundred years, but I appreciate that 1000 years has some standing e.g., with the Department of Energy.

Comments from Jim Clarke Consultant to the ACRS

- With respect to the intruder assessment, I appreciate that the staff was directed, by the Commission, to use a 10,000 year period, but have the same concerns about the merits of putting unrealistically long time frames in regulations.

- Rather the intruder assessment, as the draft regulations support, should be approached on a site-specific and waste-specific basis.

Comments from Jim Clarke Consultant to the ACRS

- In summary, I appreciate that the appearances of larger amounts of long-lived radionuclides requiring disposal and waste streams that did not exist at the time, were unanticipated, when 10CFR61 was first promulgated almost 35 years ago.

- However, these unanticipated events appear to be driving the proposed regulations to positions that are neither risk-informed nor performance-based viz. the imposition of a 10,000 year compliance period in certain cases and a 10,000 year intruder assessment.

Comments from Jim Clarke Consultant to the ACRS

- Perhaps these unanticipated waste streams, such as DU, can be handled in other ways, possibly through guidance, that do not require the imposition of an unrealistic compliance period, rather that letting their occurrence drive the regulations.

Comments from Jim Clarke Consultant to the ACRS

In closing my experience with the NRC covers over 16 years:

- Consultant to the Nuclear Regulatory Commission, Advisory Committee on Nuclear Waste. 2000-2004
- Member, Nuclear Regulatory Commission Advisory Committee on Nuclear Waste and Materials 2005 -2008
- Consultant to the Nuclear Regulatory Commission Advisory Committee on Reactor Safeguards, 2008 to present

The people from the NRC with whom I have had the pleasure to work are extraordinary.

Indeed, I hold the NRC and its staff in very high regard.

We just apparently disagree over the merits of including extremely long time periods as “compliance periods” in enforceable regulations.

Comments from Jim Clarke Consultant to the ACRS

- I appreciate the opportunity to provide these comments on behalf of CRESP and me and would be pleased to address any questions you might have.

Questions?