



Lessons Learned from Recent Licensing Experience

Brian Benney
Quarterly Management Meeting
14 June 2007

Overview

- Purpose – Review recent lessons learned from NRC licensing reviews
- Desired Outcome – Share insights where the NRC and DOE can benefit

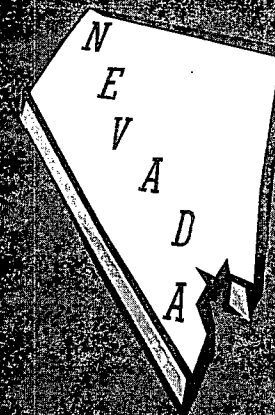
Recent Licensing Actions

- Fuel Cycle
 - Mixed Oxide Fuel Fabrication Facility: Construction Authorization 3/05
 - US Enrichment Corporation Centrifuge Plants: Licenses issued 2/04 and 4/07
 - LES National Enrichment Facility: License issued 6/06
- Spent Fuel
 - Private Fuel Storage: License issued 2/06*
- New Reactors
 - Early Site Permits



Caveat

- High-Level Waste Repository License Application is different
 - Different location and stakeholders
 - Different regulations
 - Different national and international significance



Lessons

- Identify novel and controversial issues upfront; flag for NRC's attention and describe basis in advance
- Identify sections where information may be updated; flag and describe your schedule to provide the information
- Justify key assumptions and conditions

Lessons - 2

- Familiarize LA authors with NRC's review plan
- Consider conducting a "murder board" prior to submittal – Put yourself in NRC's shoes

Lessons - 3

- Walk the NRC through the application
- Ensure all communications are through the designated NRC Project Manager(s)
- Provide prompt and high-quality responses to Requests for Additional Information

Lessons - 4

- “Rules of Engagement” – Open, public processes
- Communicate, communicate, communicate

Summary

- Recent licensing experience can be useful in gaining helpful insights
- General processes apply - Openness
- Communicate often and early
- Specifics may vary



Safety Evaluation Report and Requests for Additional Information (RAIs)

Brian Benney

Quarterly Management Meeting

14 June 2007



Safety Evaluation Report

- 5 Volumes
- 50 Sections
- Regulatory Requirements
- Technical Evaluation
- Safety Finding/Conclusion
- 18 - 24 Months

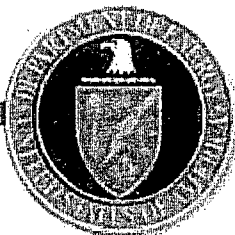
Requests for Additional Information

- Developed during the writing of the SER
- Electronic Delivery – Docketed
- Phone call to discuss
- Followed by a formal letter – Docketed
- 30 to 45 days to respond



Summary

- SER Process
- RAI Process
- RAI Cover Letter

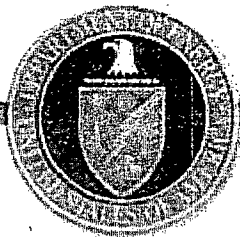


U.S. Department of Energy
Office of Civilian Radioactive Waste Management

www.ocrwm.doe.gov

DOE/NRC Quarterly Management Meeting

June 14, 2007
Las Vegas, NV



**U.S. Department of Energy
Office of Civilian Radioactive Waste Management**



www.ocrwm.doe.gov

LA Submittal and Review Process

**Presented to:
DOE/NRC Quarterly Management Meeting**

**Presented by:
Mark H. Williams
Regulatory Authority Office
Office of Civilian Radioactive Waste Management
U.S. Department of Energy**

**June 14, 2007
Las Vegas, NV**

LA Submittal and Acceptance Review – NRC Processes and Expectations

- **NRC Review Schedules and Key Milestones**
 - Acceptance Review – Schedule and Duration
 - Acceptance Review RAls
 - ◆ Plans for Use
 - ◆ Timing
 - ◆ Opportunities for DOE Clarification Prior to RAls
 - ◆ DOE Response Turn-around Time Expectations
- **Licensing Review**
 - Schedule and Milestones for Reviews and SER Development
 - Integration with Hearing Schedule (10 CFR 2, App. D)
 - Licensing Review RAls
 - ◆ Timing
 - ◆ Opportunities for DOE Clarification Prior to RAls
 - ◆ NRC Transmittal Approach (Rounds or Groupings, etc.)
 - ◆ DOE Response Turn-around Time Expectations
- **Development of a DOE Schedule to Assure Support of
NRC Milestones**



NRC Review Process

- **Availability of DOE Reference and Supplemental Information**
 - Content Level of LA and Approach to Supporting Documents
 - Logistics for DOE Supporting Documents for NRC Review
 - Allow DOE planning to align with NRC review support needs
- **LA Update Frequency during NRC Licensing Review**
 - Support of RAI Responses
 - Inclusion of Design and TSPA Evolution



LA Licensing Review

- **DOE Support Activities**

- **NRC Staff LA Briefing by DOE on LA Submittal**

- ♦ **Architecture and Content of LA and Supporting Documents**
 - ♦ **Cross-Walk to Part 63 and YMRP**
 - ♦ **Identification of DOE-NRC Staff Interfaces**

- » **Las Vegas, Washington, D.C. and Rockville, MD DOE Support for Emerging NRC Issues and Questions**

- **Availability of Real-time DOE Clarifications and Responses for NRC Information needs**

- **Support Needs for NRC EIS Adoption Process**

- **Meeting Practices Upon Expiration of Pre-Licensing Protocol**

- **Management Meetings**

- **Technical Meetings**

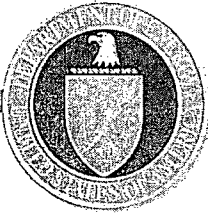
- **DOE-NRC Staff Routine Communications**



Next Steps

- **Hold NRC-DOE Staff Interactions to:**
 - Discuss approaches to topics above
 - Identify other topics that need similar treatment
- **Discuss results of staff interactions at future NRC-DOE Management Meetings**
 - Formalize agreements on approaches and interfaces
 - Determine additional actions or activities needed
 - Monitor status of future actions





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



www.ocrwm.doe.gov

Licensing Status

Presented to:
DOE/NRC Quarterly Management Meeting

Presented by:
Mark H. Williams
Regulatory Authority Office
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

June 14, 2007
Las Vegas, NV

Topics for Discussion

- **License Application Project Schedule**
- **Licensing Support Network (LSN) Status**
- **DOE/NRC Interactions**



Licensing Support Network Status

- **About 2.1 Million documents added to LSN in April 2007**
- **About 3.4 Million total documents in LSN as of April 2007**
- **Certification scheduled for 12/2007**



DOE/NRC Interactions

• Recent Interactions

- **Appendix 7 on Emergency Planning, May 24, 2007**
 - ◆ Emergency Plan will follow guidance in NUREG-1804 (YMRP)
 - ◆ Interactions with Offsite Responders
 - ◆ Technical Support Center and Emergency Operations Facility
 - ◆ Training for site workers and responders
- **Technical Exchange on Canister Receipt and Closure Facility (CRCF), May 30, 2007**
 - ◆ Site Layout Waste Handling Overview
 - ◆ CRCF and Wet Handling Facility (WHF) Layout and Operation
 - ◆ Waste Handling Control Philosophy
 - ◆ Seismic Design Considerations
- **Appendix 7 on Human Reliability Analysis, June 5, 2007**
 - ◆ Provided status and schedule of the Preclosure Safety Analysis (PCSA) human reliability analysis and hazard operations work



DOE/NRC Interactions (Continued)

- **Status of Appendix 7 meetings proposed during March 2007 Management Meeting:**
 - **Preclosure criticality: March 28, 2007 (Complete)**
 - **Facility layout and operations (Canister Receipt and Closure Facility): March 28-29, 2007 (Complete)**
 - **Wet handling facility pool and canister handling process: March 29, 2007 (Complete)**
 - **Unsaturated zone testing: April 10, 2007 (August 2007)**
 - **Emergency Planning: May 24, 2007 (Complete)**
 - **Human reliability analysis: May 31, 2007 (Complete)**



DOE/NRC Interactions (Continued)

- **Status of Technical Exchanges proposed during March 2007 Management Meeting:**
 - Facility layout and operations (Canister Receipt and Closure Facility): May 30, 2007 (Complete)
 - Preclosure criticality: June 26, 2007 (Deferred – TBD)
 - Physical protection, material control and accountability, and emergency planning: June 28, 2007 ()
 - Postclosure subjects based on information gathering interactions: September 27, 2007 ()
 - Other postclosure topics: November 2007 (TBD)
 - Infiltration: (TBD)



DOE/NRC Interactions (Continued)

- **Scheduled:**
 - **Technical Exchange: Quality Assurance 6/26/07**
 - **Technical Exchange: Physical Protection, Material Control and Accountability, and Emergency Planning 6/28/07**
 - **Appendix 7 Meeting: Colloids, In-Package Chemistry, Multiscale Thermohydrologic Models, and Near-Field Environment 7/10-12/07**
 - **Appendix 7 Meeting: Drift Degradation 9/13/07**
 - **Quarterly Management Meeting 9/25/07**



DOE/NRC Interactions (Continued)

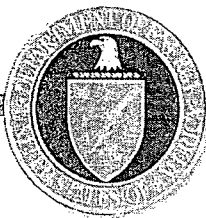
- **Recently proposed meetings:**
 - **Preclosure Safety Analysis:**
 - ♦ Hazard identification, event sequences development and categorization
 - ♦ Identification of important-to-safety structures, systems, and components
 - ♦ Source term and consequences
 - **Transportation, Aging, and Disposal (TAD) Canister System planning**
- **Planning for EIS Support**



License Application Project

- **LA Quality**
 - **Self assessments**
 - ♦ **Preclosure Criticality Event Sequence**
 - ♦ **Adequacy and Efficiency of Procedures and Desktop Information**
 - ♦ **Independent Assessment of Engineering Design Control Process**
 - **Quality Assurance audits and surveillances**
 - ♦ **QA Integrated LA Oversight Plan**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Corrective Action Program Status

Presented to:
DOE/NRC Quarterly Management Meeting

Presented by:
Paul M. Golan
Principal Deputy Director
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

June 14, 2007
Las Vegas, NV

Background

- As discussed at the March 2007, NRC Quarterly Management Meeting, numerous assessments, audits, and surveillances have found that the Corrective Action Program (CAP) was *not fully effective* and the program was *not being effectively implemented*
- Issue was further validated in a December 2006 Office of Quality Assurance assessment; Subsequently, a Level “A” condition report was issued (CR 9774) addressing CAP effectiveness
- Both immediate and long-term corrective actions are underway to address this condition and prevent recurrence



Initial Actions

- Initial actions have been focused on improving the quality, timeliness, management involvement, consistency, and trending capability of the corrective action program
- Actions have been focused in the following processes and expectations:
 - Condition Screen Team (CST)
 - Management Review Committee (MRC)
 - Trending Program
 - Management behaviors and accountability



Condition Screen Team

- **Purpose:** The purpose of the CST is to review, categorize, and assign new Condition Reports (CRs) as well as review actions and documentation taken to close existing CRs
- CST meets daily
- DOE Senior Manager assigned to lead CST
- Composition of the CST has been reformatted, focusing on line management responsibility, with oversight by the QA organization
 - Key staff reduced from approximately 30 to 12
 - Functions more effectively; meetings time reduced from 2 ½ hours to 1 hour with better results
 - CST focuses on ensuring processes are followed versus debate



Condition Screen Team (Continued)

- **Based on recommendations from a joint DOE, BSC, and SNL senior management team (sponsored by the Director), continued improvements in CST are planned; This may include:**
 - **New CR screening be conducted by a smaller (approx. 7 person) group consisting of senior line and quality managers in DOE, BSC, and the Lead Lab**
 - **CST fully accountable for review and approval of significance level and responsible manager assignment**
 - **Existing screening team staff will focus on closure documentation review**
 - **Line management will be held accountable for timely and effective corrective actions, overseen by the MRC using trend data**
 - **Key success criteria: quality, transparency, traceability of closure documentation, and effectiveness of corrective actions**



Management Review Committee

- **Purpose:** The purpose of the MRC is to provide senior management level oversight of the CAP
- The MRC meets weekly to review Level A and selected Level B causal analyses, corrective actions, and monitor overall CAP effectiveness
- The Principal Deputy Director leads MRC meetings and establishes quality and behavior expectations
- Improvements that are underway include:
 - Causal analysis team approach under revision
 - Performance metrics focusing on: late actions or plans, time actions take to be assigned or completed, etc.)
 - Trending
 - Modeling behavioral expectations



Management Review Committee

(Continued)

- **Based on recommendations from the Director, senior management team examined MRC functions and further improvements in the MRC are planned; This may include:**
 - **MRC function will be assigned to the same senior manager group that is responsible for the screening and evaluation function of the CST**
 - **This smaller team will be fully accountable for performing all of the current MRC functions and overall CAP performance monitoring**
 - **The team will meet weekly immediately following CST meeting**



Trending

- A Level “A” condition report on trending identified significant vulnerabilities in the trend program
- A new combined DOE/BSC/Lead Lab trend program has been developed and implemented
- The first trend report under this reconstituted program has been submitted for DOE approval
- A follow-up effectiveness review will be conducted to assure effectiveness of corrective actions



CAP Status Management Accountability

- **Principal Deputy Director regularly reviews CAP performance with all DOE, and BSC and Lead Laboratory Managers**
- **Review has focused management attention on:**
 - All Level A CRs
 - CRs greater than 365 days old
 - CRs that have late corrective actions or plans
 - Actions that have been in a step greater than 100 days
 - Actions or plans with unassigned status
- **DOE late actions and plans have been reduced from 50% occurrence to less than 5%**



Conclusion

- **Recognized issues with the CAP**
- **CAP key program success factor**
- **Focusing CAP on behaviors and accountability**
- **Improvements in CAP have been documented**
- **CAP will be a continuing focus of the management team going forward**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



LA Submittal and Review Process

Presented to:
DOE/NRC Quarterly Management Meeting

Presented by:
Mark H. Williams
Regulatory Authority Office
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

June 14, 2007
Las Vegas, NV

Objectives

- **Open NRC-DOE Dialog on Review Processes, NRC Process Support from DOE, and NRC Expectations**
- **Identify Topics for Future Communications and Clarifications**
- **Identify Plans for Future Interaction on Licensing Review Approach and Processes**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Status of Closure Schedule for NRC Onsite Representative (OR) Open Items

Presented to:
DOE/NRC Quarterly Management Meeting

Presented by:
Mark H. Williams
Regulatory Authority Office
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

June 14, 2007
Las Vegas, NV

NRC Onsite Representative Open Items

- **Procedural controls on the preparation, review, approval and maintenance of NRC Onsite Representative (OR) open item closure packages**
- **OR Quarterly Reports are reviewed to identify NRC OR Open Items**
- **Open Items are managed in the Commitment Management System (CMS) database and Condition Reports (CRs) are generated, as necessary**
- **Meet with the OR on a regular basis**



Status of OR Open Items

- **OR open items are documented in Commitment Management System and Table 1 of the NRC OR tracking report**
 - **Closure packages for 4 items have been provided to the NRC and are under their review**
 - **Schedule for providing closure packages to the NRC OR is provided in the following table**



Status of NRC Open Items

#	Open Item	Description From NRC OR's Report	Responsible DOE Manager	Status and Schedule for Resolution
1	AOI-OCRWM-OQA-05-20-02	"Revise procedure AP-3.13Q to reflect 10CFR63.21 requirements related to completeness of information necessary for LA review." [Note: issue with BSC citation of "draft" design documents.]	Paul Harrington	Procedure AP-3.13 Q <i>Design Control</i> has been revised to address issue related to BSC citation of <i>draft</i> design documents. Original closure package provided to OR's for review on 10/18/05. OR review of original package resulted in additional dialog on issue and clarification of information needed for resolution. Additional information requested was provided on 6/6/07.
2	AOI-OCRWM-OQA-05-20-01	"Procedural controls for "preliminary" classification of Engineering calculations will be revised to clearly define the designation of completed calculations suitable to support the requisite safety analysis." [Note: issue with BSC citation of "preliminary" design documents]	Paul Harrington	Procedure AP-3.12 Q <i>Design Calculations and Analyses</i> has been revised to address issue related to BSC citation of <i>preliminary</i> design documents. Original closure package provided to OR's for review on 10/18/05. OR review of original package resulted in additional dialog on issue and clarification of information needed for resolution. Additional information requested was provided on 6/6/07.
3	OR-OI-07-01	"Failure to take prompt corrective actions related to documenting Conditions Adverse to Quality in the CAP system and initiating a Root Cause Analysis in response to QA Program inadequacies identified in Level A CR 10141." [Note: issue is related to delay in entering CR's based on NEI assessment of QA program.]	Larry Newman	This issue is being addressed by CR 10534, "Delay in entering conditions into the CAP system," and CR 10535, "Failure to promptly address Significant Condition Adverse to Quality." CR 10534 is currently being evaluated for appropriate corrective action. CR 10535 is being verified for closure by Quality Assurance Closure Package will be provided to the ORs by 8/1/2007
4	OR-OI-06-10	"BSC had not implemented effective requirements management system for the Quality Management Directive sections that were reviewed during an audit, indicating inadequate corrective actions for previous conditions identified in CRs – signifying emerging adverse trends."	Paul Harrington	This issue is being addressed by CR 10285, "NRC Open Item OR-OI-06-10 regarding Requirements Management," and CR 10381, "Inadequate corrective actions to prevent recurrence for conditions related to requirements management." CR 10285 is currently being evaluated for appropriate corrective action. The plan to address CR 10381 is currently being reviewed by OCRWM (DOE, BSC and Lead Lab) management. Closure Package will be delivered to the ORs by 12/31/2007
5	OR-OI-06-09	"Based on OR review of the RCA for CR7395, it was determined that the RCA for CR7395 does not support the stated conclusions nor does it adequately address the extent of the condition and impact."	Larry Newman	This issue is being addressed by CR 9664, "Inadequate Root-Cause Analysis (RCA) for Condition Report (CR) 7395." A proposed resolution for CR 9664 was developed; OCRWM management has directed revision of the proposed approach. Closure Package will be delivered to the ORs by 8/1/2007

AOI: Audit Observation Inquiry

OR-OI: NRC On-Site Representative's Open Item



Department of Energy • Office of Civilian Radioactive Waste Management

YMWWilliams_NRC_OROpenItems_061407.ppt



www.ocrwm.doe.gov

Status of NRC Open Items (Continued)

#	Open Item	Description From NRC OR's Report	Responsible DOE Manager	Status and Schedule for Resolution
6	OR-OI-06-07	"Failure to process clarification related to the content and completeness of a CR record package in accordance with requirements of LP2.2Q, is identified as a deficiency. Clarification in response does not comply with the requirement." [Note: issue deals with retention of records from Correction Action Program.]	Scott Wade	This issue is being addressed by CR 9414, "Deficiency in clarification of QARD identified by NRC." [Note that DOE has directed BSC to maintain CAP records in accordance with Technical Direction Letter dated 6/5/07.] CR 9414: is being verified for closure by Quality Assurance. Closure Package will be delivered to the ORs by 6/29/2007
7	OR-OI-06-03	"Based on Audit Observation of Software control (OQA-BSC-06-10), requesting a description of DOE's remediation processes related to the approximately 35 legacy codes."	Russ Dyer	This issue is being addressed in CR 8460, "NRC OR Open Item 06-03 regarding legacy software remediation." CR 8460: corrective action has been developed, approved, and is being implemented. Closure Package will be delivered to the ORs by 8/24/2007
8	OR-OI-06-04	"Based on Audit Observation of Software Control (OQA-BSC-06-10), requesting a basis and justification for the continued use of the output from software on the baseline that has not undergone IV&V remediation."	Russ Dyer	This issue is being addressed in CR 8461, "NRC OR Open Item 06-04 regarding retesting of legacy software codes embedded in DTNs." CR 8461: resolution for this CR has been planned, approved and implemented. Implementation is now being verified. Closure Package will be delivered to the ORs by 5/21/2008
9	OR-OI-06-02	"Requirements Flow-Down and Procedure Adequacy and Audit Observation: Involved the inconsistent use of quality-affecting document designators that indicated inadequate corrective actions related to similar conditions documented in CR3448." [Note: Inconsistencies in the application of QA/QA/QA/NA and non-Q designators on Quality affecting documents]	Scott Wade	A closure package was delivered to the NRC ORs on 7/26/2006 and the latest OR Report, dated 4/30/2007, provides results of the NRC review of this item. The NRC OR Report states that "DOE failed to perform an adequate extent of condition for the conditions adverse to quality identified in CRs 7963 and 8050. Pending the resolution of this deficiency, OR Open Item 06-02 will remain open." DOE will prepare a revised response to this item addressing the ORs concerns noted in the latest ORs Quarterly Report issued on 4/30/2007. CR 10740 "Failure to perform an adequate extent of condition for CRs 7963 and 8050 will address this issue. Closure Package will be delivered to the ORs by 9/21/2007
10	OR-OI-05-01	"Inconsistencies in the root cause statements developed by the root cause analysis team, specifically the root cause related to traceability and transparency issues. Pending resolution of the apparent discrepancies in the root cause analysis for CR3235 identified in this Open Item."	Paul Harrington	The closure package was delivered to the NRC on 10/31/05. OR's are reviewing the package and will document the results in a future report.
11	OR-OI-02-10	"Pending appropriate evaluation and documentation of the design control attributes associated with requirements of 10CFR63.44 and 10CFR Part 21." [Note: 63.44 and 10 CFR Part 21 were not addressed in the readiness report]	Mark Williams	A closure package was delivered to the ORs' on 11/30/05 and has been reviewed by NRC. DOE is developing additional documentation with respect to its position on timing of applicability of regulatory requirements in 63.44 and 10 CFR Part 21 and will provide that documentation to the OR's as a supplement to the original closure package. Closure Package will be provided to the ORs by 8/31/2007

AOI: Audit Observation Inquiry

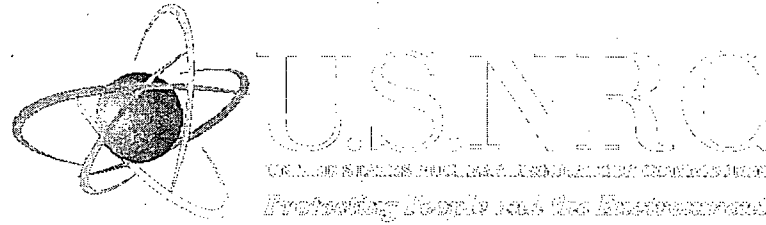
OR-OI: NRC On-Site Representative's Open Item



Department of Energy • Office of Civilian Radioactive Waste Management

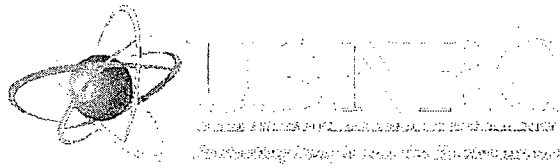
YMWWilliams_NRC_OROpenItems_061407.ppt





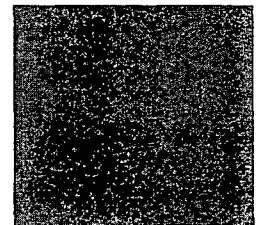
Lessons Learned from Recent Licensing Experience

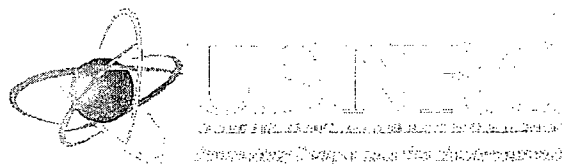
Brian Benney
Quarterly Management Meeting
14 June 2007



Overview

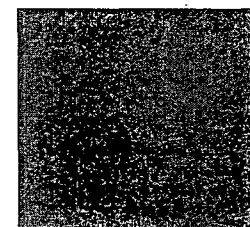
- Purpose – Review recent lessons learned from NRC licensing reviews
- Desired Outcome – Share insights where the NRC and DOE can benefit

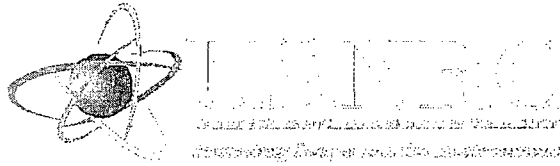




Recent Licensing Actions

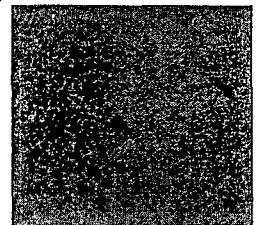
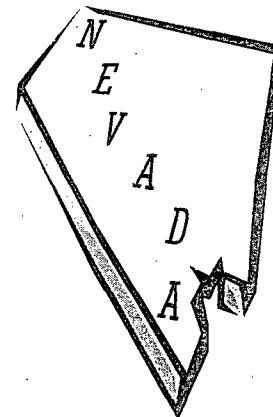
- Fuel Cycle
 - Mixed Oxide Fuel Fabrication Facility: Construction Authorization 3/05
 - US Enrichment Corporation Centrifuge Plants: Licenses issued 2/04 and 4/07
 - LES National Enrichment Facility: License issued 6/06
- Spent Fuel
 - Private Fuel Storage: License issued 2/06*
- New Reactors
 - Early Site Permits

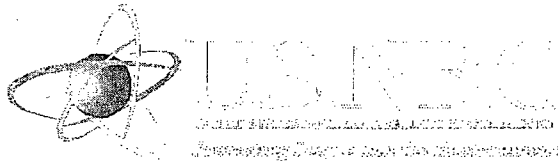




Caveat

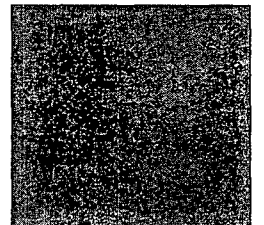
- High-Level Waste Repository License Application is different
 - Different location and stakeholders
 - Different regulations
 - Different national and international significance

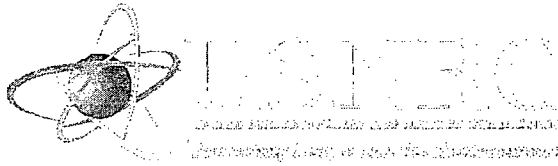




Lessons

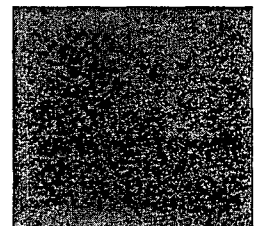
- Identify novel and controversial issues upfront; flag for NRC's attention and describe basis in advance
- Identify sections where information may be updated; flag and describe your schedule to provide the information
- Justify key assumptions and conditions

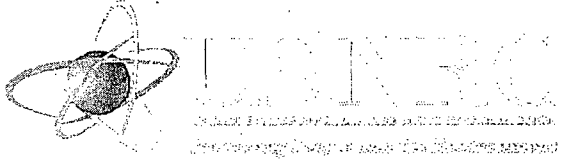




Lessons - 2

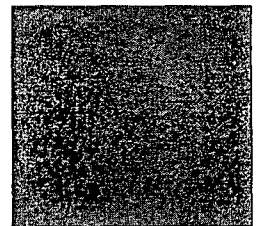
- Familiarize LA authors with NRC's review plan
- Consider conducting a “murder board” prior to submittal – Put yourself in NRC's shoes

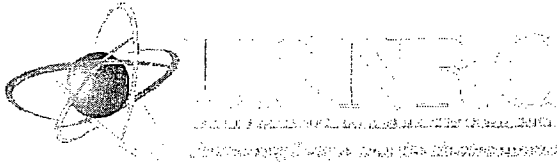




Lessons - 3

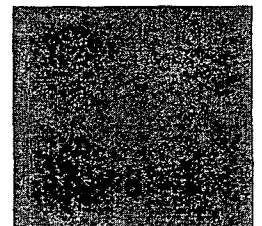
- Walk the NRC through the application
- Ensure all communications are through the designated NRC Project Manager(s)
- Provide prompt and high-quality responses to Requests for Additional Information

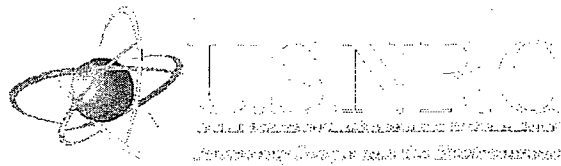




Lessons - 4

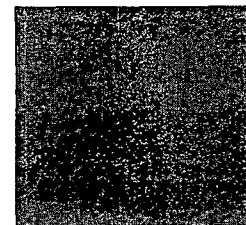
- “Rules of Engagement” – Open, public processes
- Communicate, communicate, communicate





Summary

- Recent licensing experience can be useful in gaining helpful insights
- General processes apply - Openness
- Communicate often and early
- Specifics may vary



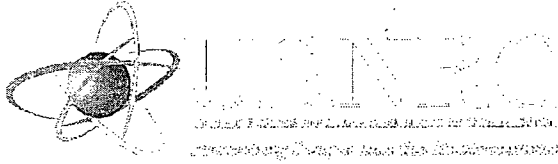


Safety Evaluation Report and Requests for Additional Information (RAIs)

Brian Benney

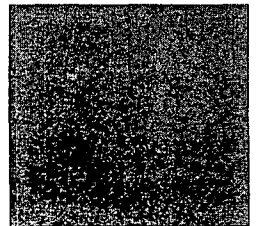
Quarterly Management Meeting

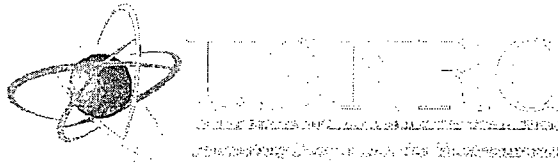
14 June 2007



Safety Evaluation Report

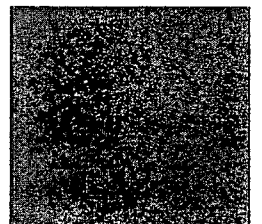
- 5 Volumes
- 50 Sections
- Regulatory Requirements
- Technical Evaluation
- Safety Finding/Conclusion
- 18 - 24 Months

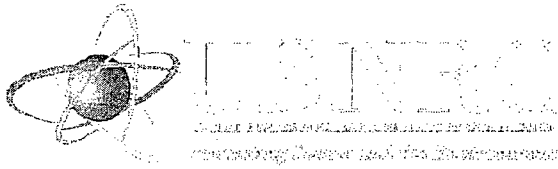




Requests for Additional Information

- Developed during the writing of the SER
- Electronic Delivery – Docketed
- Phone call to discuss
- Followed by a formal letter – Docketed
- 30 to 45 days to respond





Summary

- SER Process
- RAI Process
- RAI Cover Letter

