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

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NRC/DOE Technical Exchange and Management Meeting on Licensing Process Topics

Enclosure 4

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

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Introduction to Licensing Process Topics

Presented to:
NRC/DOE Technical Exchange and Management Meeting on Licensing Process Topics

Presented by:
April V. Gil
Acting Director, Regulatory Authority Office
Office of Civilian Radioactive Waste Management
Department of Energy

September 13, 2007
Las Vegas, Nevada

Opening Remarks

- Discussions today will focus on licensing process issues associated with the submission, docketing, and review of the Yucca Mountain Project license application (LA)
- The LA will be submitted on or before June 30, 2008
- Purpose of today's meeting is to discuss and clarify the processes to be used to facilitate NRC's LA review

NRC/DOE Interactions

- **Interactions completed in 2007**
  - **Two Management Meetings**
    - **March 27**
    - **June 14**
  - **Four Technical Exchange Meetings**
    - **Layout and Operations – May 30**
    - **Quality Assurance – June 26**
    - **Physical Protection, Material Control and Accountability, and Emergency Planning – June 28**
    - **Pre/Postclosure Criticality – August 16**

NRC/DOE Interactions (Continued)

- **Interactions completed in 2007 (Continued)**
  - **Seven Appendix 7 Meetings**
    - **Safeguards and Security – February 22**
    - **Preclosure Criticality – March 28**
    - **Facility Layout and Operations – March 28-29**
    - **Emergency Planning – May 24**
    - **Human Reliability Analysis – June 5**
    - **Colloids, In-Package Chemistry, Multiscale Thermohydrologic Models, and Near-Field Environment – July 11-12**
    - **Unsaturated Zone Testing – August 22-23**

Agenda

8:00 AM	Introductions	All
8:10 AM	NRC Key Messages	NRC
8:20 AM	Introduction to Licensing Process Topics	DOE (A. Gil)
8:30 AM	Interactions Protocol During LA Review	NRC (B. Benney) DOE (A. Gil)
9:15 AM	Break	All
9:30 AM	License Application Content	NRC (B. Benney) DOE (R. Warther)
11:00 AM	Organizational Structure	NRC (B. Benney) DOE (A. Gil)
11:30 AM	Future Interim Staff Guidance	NRC (B. Benney) DOE (J. Williams)
11:45 AM	Lunch Break	All
1:00 PM	Sensitive Information in the LA	NRC (B. Benney) DOE (D. Crawford)
1:45 AM	Key Technical Issues	DOE (W. Boyle) NRC
2:00 PM	License Specifications	DOE (W. Spezialetti) NRC
2:15 PM	Timing of 10 CFR 63.44 Applicability	DOE (M. Williams) NRC
2:30 PM	Electronic Information Exchange	DOE (R. Warther) NRC
2:45 PM	Public Comments	All
3:00 PM	Caucus	NRC / DOE
3:30 PM	Closing Remarks	NRC / DOE
3:45 PM	Adjourn	

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License Application Content

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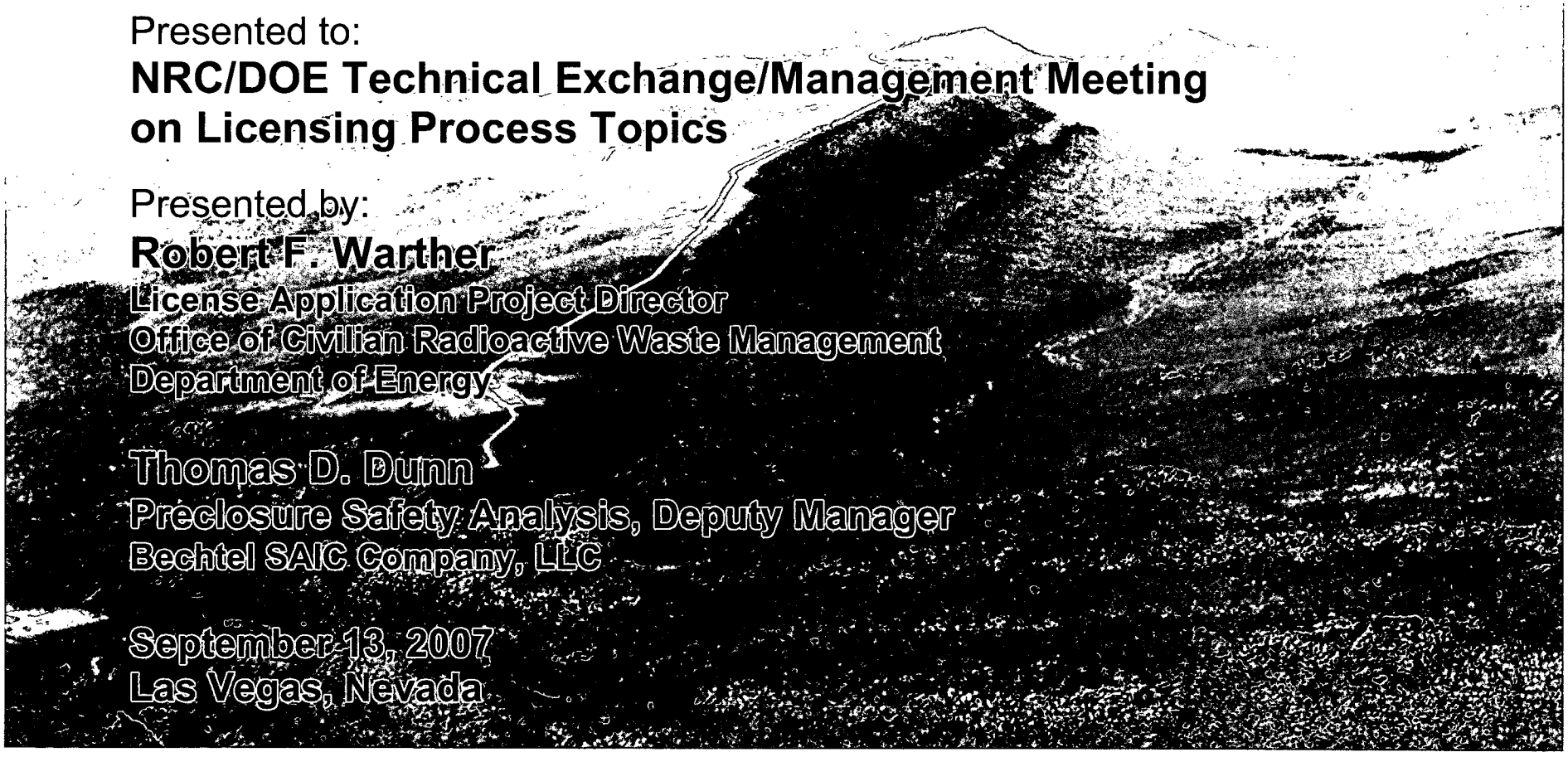

Presented by:
Robert F. Warther
License Application Project Director
Office of Civilian Radioactive Waste Management
Department of Energy

Thomas D. Dunn
Preclosure Safety Analysis, Deputy Manager
Bechtel SAIC Company, LLC

September 13, 2007
Las Vegas, Nevada

Outline

- License Application (LA) Regulatory Requirements
- License Application Plans and Programs
- Quality Assurance Requirements and Description (QARD) Document
- License Application References
- Preclosure Safety Analysis (PCSA) Information in the License Application

License Application Regulatory Requirements

- **10 CFR 63.21 contains LA content requirements**
  - **General information**
  - **Safety analysis report**
  - **Complete as possible in the light of information that is reasonably available at the time of docketing**
- **NUREG-1804, *Yucca Mountain Review Plan*, contains LA content regulatory guidance**
- **A mapping to the regulations and NUREG-1804 is being prepared**

License Application Plans and Programs

- The LA will contain a description of each plan or program that is responsive to the regulations and NUREG-1804 at time of LA submittal
- Final plan and program submittals
  - Physical Protection Plan – 180 days after CA
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  - Emergency Plan – approximately six months prior to license application to receive and possess
  - Operational Radiation Protection Program – available for NRC review prior to submittal of the license application to receive and possess

Quality Assurance Requirements and Description Document

- **QARD, Rev. 20 will be submitted to NRC prior to LA submittal**
- **LA Section 5.1 will reference the QARD, Rev. 20 submittal**

License Application References

- **Two Types**
  - **General references**
    - **Provide additional supporting information**
      - » **Codes and standards**
      - » **Underlying engineering and science products**
      - » **Regulatory guidance documents**
      - » **Published scientific and technical literature**
    - **For design oriented sections, general references will include upper tier documents such as Project Design Criteria and Basis of Design documents**
    - **For the preclosure and postclosure sections, numerous general references will include the underlying documents containing the detailed analyses**

License Application References (Continued)

- **Two Types (Continued)**
  - **Material incorporated by reference**
    - **Topical reports**

PCSA Information in the License Application

PCSA Information in the License Application

- **Approach**
  - **Level of design detail sufficient to demonstrate compliance with 10 CFR Part 63**
  - **Description of methods**
  - **Results of analyses and calculations**
  - **Additional information on the assessment of a key initiating event (e.g., failures leading to a transport, aging, and disposal (TAD) canister drop)**
  - **General references will include supporting calculations and analyses**

PCSA Information in the License Application (Continued)

- **LA will contain level of design detail sufficient to demonstrate compliance with 10 CFR Part 63**
  - **Identification of initiating events**
  - **Categorization of event sequences**
  - **Identification of important to safety (ITS) structures, systems, and components (SSCs), nuclear safety design basis, and procedural safety controls**
  - **Estimation of worker and offsite doses aggregated for normal operation and Category 1 event sequences, and offsite dose for each Category 2 event sequence**
  - **Prevention and control of criticality**
  - **Demonstration of compliance to 10 CFR Part 63 preclosure performance objectives**

PCSA Information in the License Application (Continued)

- **LA will contain a description of the methods used in the PCSA**
  - Initiating event selection
  - Fault tree development
  - Historical data usage
  - Estimation of SSC failure probability or reliability (passive and active)
  - Construction of event trees
  - Categorization of event sequences
  - Screening of event sequences
  - Estimation of uncertainties
  - Human reliability analysis
  - Seismic fragility analysis
  - Criticality screening
  - Source term development
  - Worker and offsite public dose analysis

PCSA Information in the License Application (Continued)

- **PCSA Results**
  - **Discussion accompanied by result tables listing identified internal and external initiating events**
  - **Discussion accompanied by result tables listing identified event sequences for all facilities**
    - **Event sequence frequency, categorization, dose, event sequence identification**
  - **Discussion and result tables**
    - **ITS SSC identification**
    - **ITS SSC reliability**
    - **ITS SSC procedural safety controls**

PCSA Information in the License Application (Continued)

- **LA will provide additional information on the assessment of a key initiating event (e.g., TAD canister drop) to illustrate the application of PCSA methods**
  - **Master logic diagrams, event sequence diagrams, and event trees**
  - **Supporting fault trees and data usage**
  - **Human reliability assessment within the fault tree**
  - **Supporting passive component fragility assessment**
  - **Supporting event tree uncertainty assessment**

Summary

- LA will meet regulatory requirements and support the NRC's safety evaluation report
- LA will contain a description of each plan or program, with the final plan or program to be submitted later
- QARD, Rev. 20 will be submitted to NRC prior to LA submittal
- LA will contain two types of references; general references and material incorporated by reference
- LA will describe PCSA methods and results

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Key Technical Issues

Presented to:
NRC/DOE Technical Exchange and Management Meeting on Licensing Process Topics

Presented by:
William J. Boyle
Postclosure Group Lead
Office of Civilian Radioactive Waste Management
Department of Energy

September 13, 2007
Las Vegas, Nevada

Key Technical Issues (KTIs)

- The license application (LA) will address still relevant technical topics, as appropriate
- The LA will not use key technical issue (KTI) nomenclature
- DOE will map open Additional Information Needs (AINs) to the LA or supporting documents, as appropriate, and transmit to NRC in correspondence at LA submittal
- DOE will map KTIs to the LA, and transmit to NRC in correspondence at LA submittal

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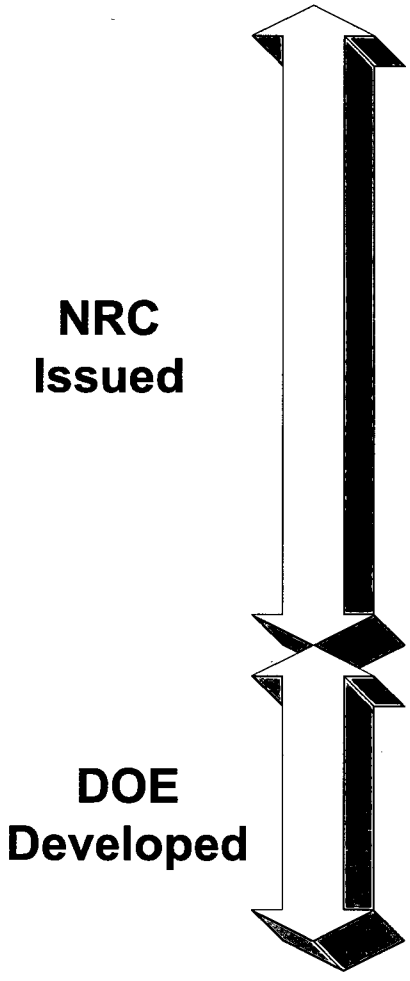
License Specifications

Presented to:
NRC/DOE Technical Exchange and Management Meeting on Licensing Process Topics

Presented by:
William R. Spezialetti
Office of the Chief Engineer – Engineering Design
Office Civilian Radioactive Waste Management
Department of Energy

September 13, 2007
Las Vegas, Nevada

Structure of License Conditions and Specifications



NRC Issued

DOE Developed

License Conditions

§ 63.42 Conditions of License - specific restrictions located in body of license

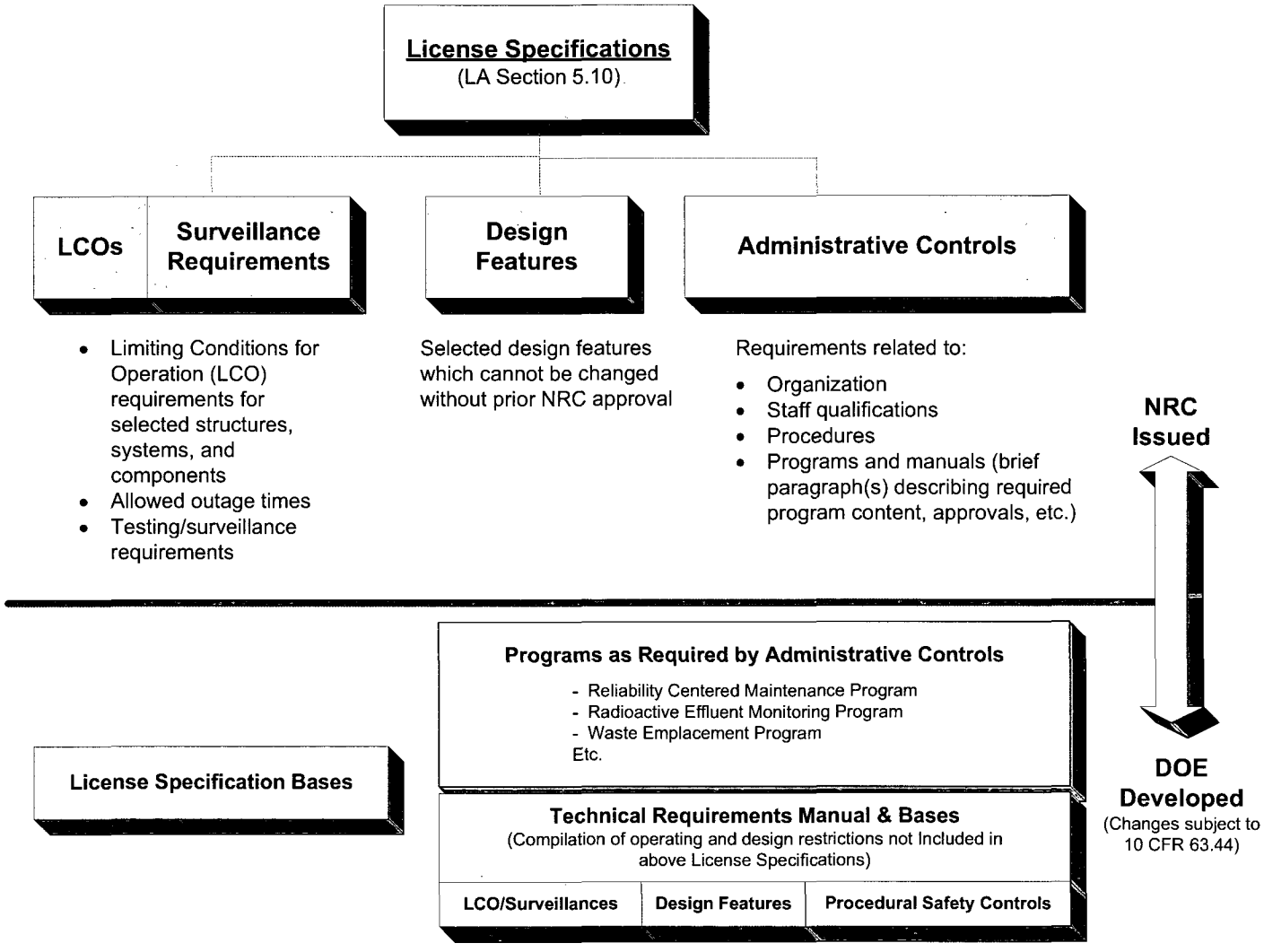
License Specifications

§ 63.43 License Specification – (similar to Part 50/72 Technical Specifications) specific subset of license conditions included as appendix to the license

Licensee Controlled Implementing Procedures and Program Documents

Technical Requirements Manual, etc.

Proposed DOE Approach for License Specifications



License Application
Section 5.10: License Specifications

- **Proposed License Specifications**
  - **Structure and format**
  - **Selection criteria/justification**
  - **Probable subjects (as required by 10 CFR 63.21(c)(18))**
- **Proposed schedule of draft License Specifications**

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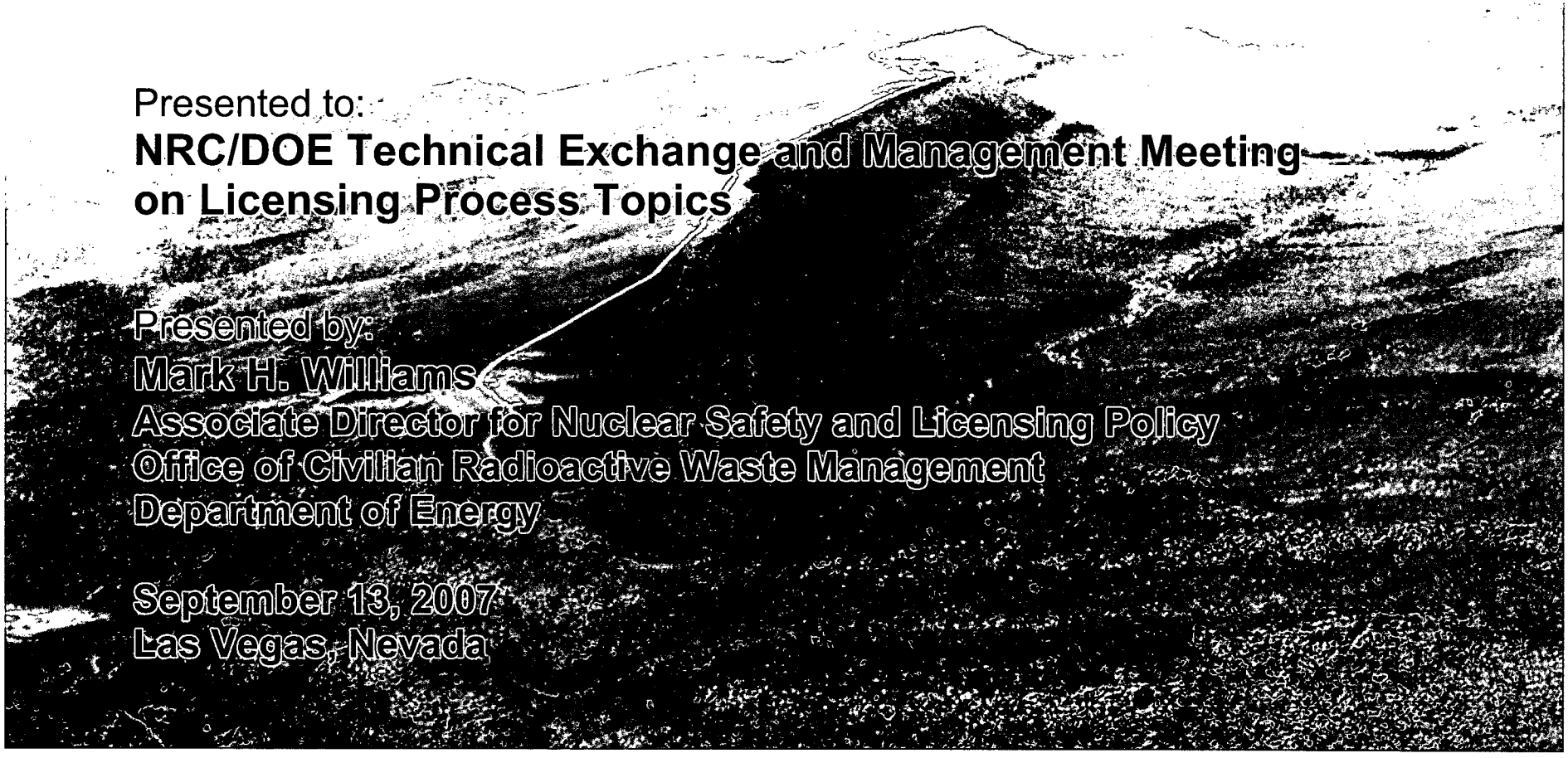
Timing of 10 CFR 63.44 Applicability



Presented to:
NRC/DOE Technical Exchange and Management Meeting on Licensing Process Topics

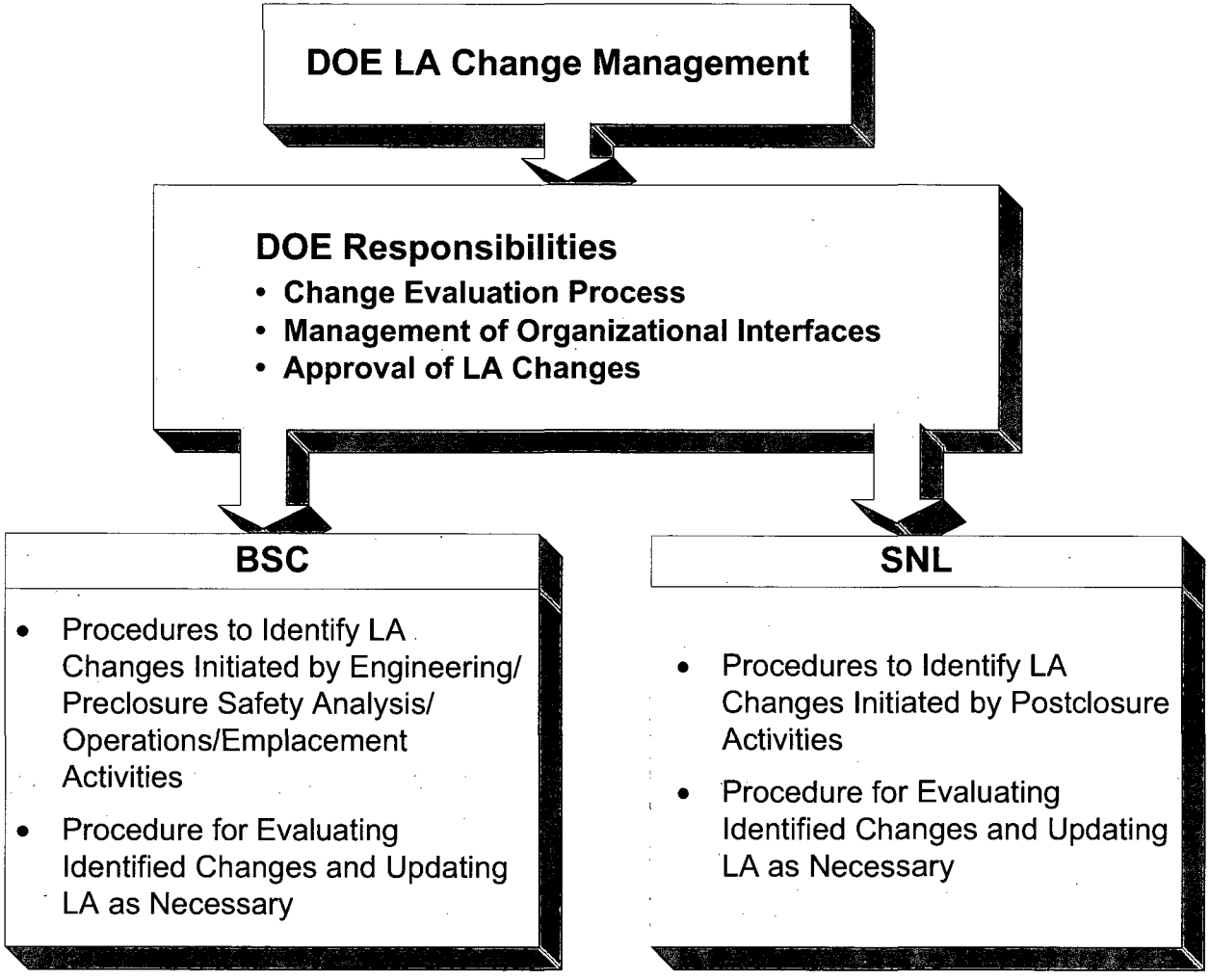
Presented by:
Mark H. Williams
Associate Director for Nuclear Safety and Licensing Policy
Office of Civilian Radioactive Waste Management
Department of Energy

September 13, 2007
Las Vegas, Nevada

LA Configuration Management

- **DOE will establish a process for license application (LA) change control prior to the Construction Authorization**
- **DOE will implement 10 CFR 63.44 at Construction Authorization**

LA Configuration Management (Continued)



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Electronic Information Exchange

Presented to:
NRC/DOE Technical Exchange/Management Meeting on Licensing Process Topics

Presented by:
Robert F. Warther
Federal Project Manager, Licensing
Office of Civilian Radioactive Waste Management
Department of Energy

September 13, 2007
Las Vegas, Nevada

Submission of the license application

- **DOE will submit the license application (LA) to the NRC per the regulatory requirements**
  - **Hard copies of the LA and environmental impact statement (EIS)**
  - **Optical storage media copies of the LA and EIS, formatted per *Guidance for Electronic Submissions to the NRC***
  - **Mail or hand delivery**

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Protecting People and the Environment

Repository Licensing Interactions

Brian Benney
NRC

September 13, 2007

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Protecting People and the Environment

Topics

Organizational Structure
Licensing Interactions
The Docketing of Information
The Acceptance Review
Interim Staff Guidance (ISG)
Submittal of Sensitive Information

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Protocol for Interactions

- Pre-licensing interactions end.
- ALL interactions are coordinated by the Project Managers.
- Informal discussions are limited to regulatory processes, schedules, generic issues – NOT technical details.
- Public meetings are noticed 10 days in advance.
- RAIs on the phone ... and public observation by bridgeline.
- Meeting summaries will be brief, and written by NRC Project Managers.

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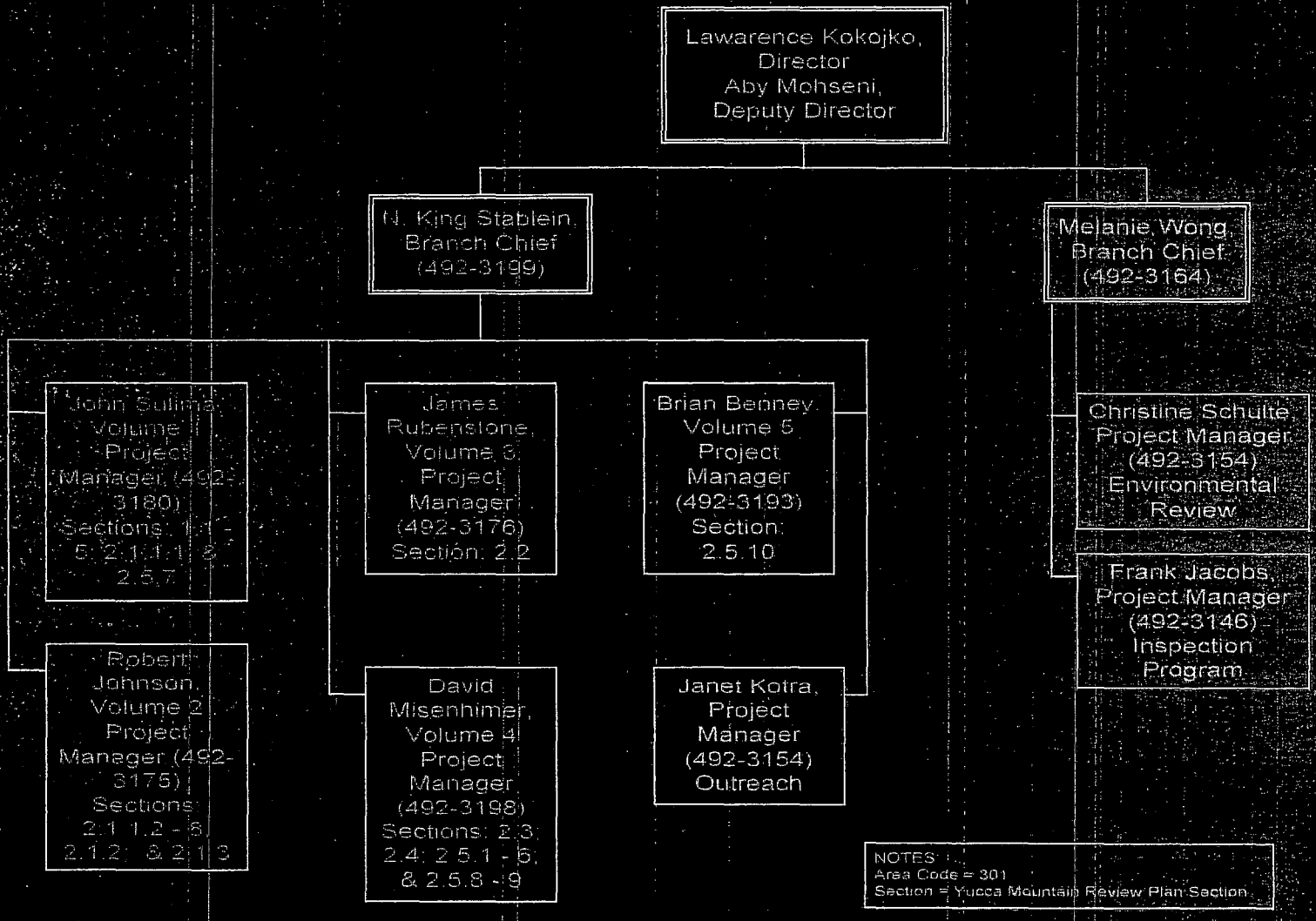

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Docketing Information

Items relied on by the NRC staff to develop a regulatory decision MUST be on the docket.

Two systems with two different purposes:

- ADAMS is the official agency record.
- LSN supports the hearing process.

The structure of the license application and its references.

Meetings or telephone calls, where information is gained that is vital to the staff's regulatory decision, must be captured.

- DOE must respond by letter.

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Acceptance Review

Develops the staff's knowledge of DOE's license application and justification for compliance.

Informs the NRC's docketing decision.

Determines if sufficient information has been developed to begin a detailed technical review.

Does not evaluate the technical adequacy of the information.

The requirements of 10 CFR 63.21 guide the acceptance review.

If LA does not adequately meet the docketing requirements, DOE will be informed.

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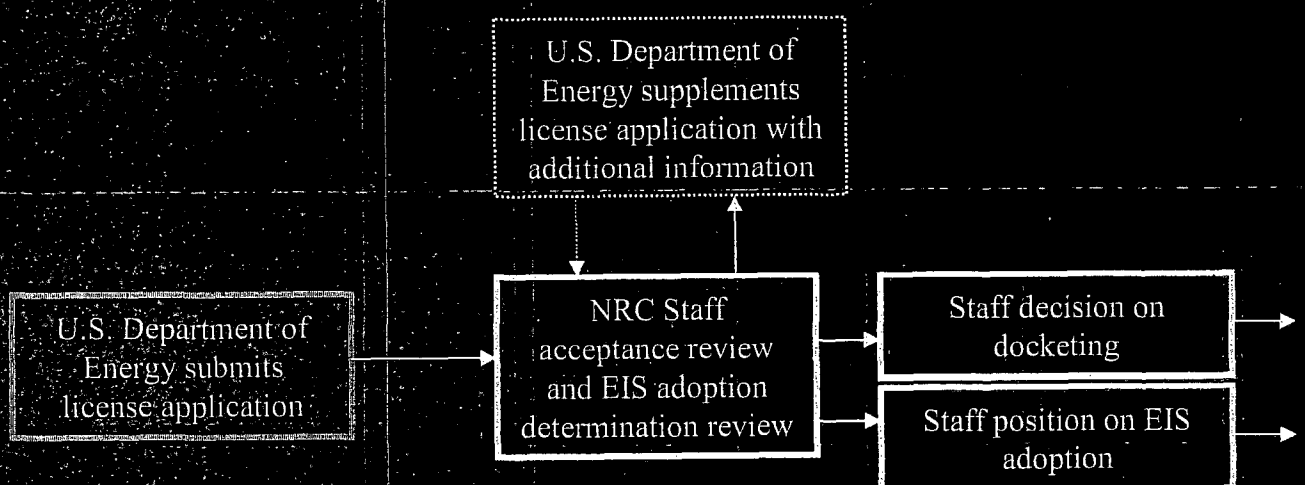
Acceptance Review



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Detailed Technical Review

If LA passes the acceptance review, it is docketed and the detailed technical review begins.

Determines whether submitted information demonstrates that regulatory requirements are met.

Relies on docketed information.

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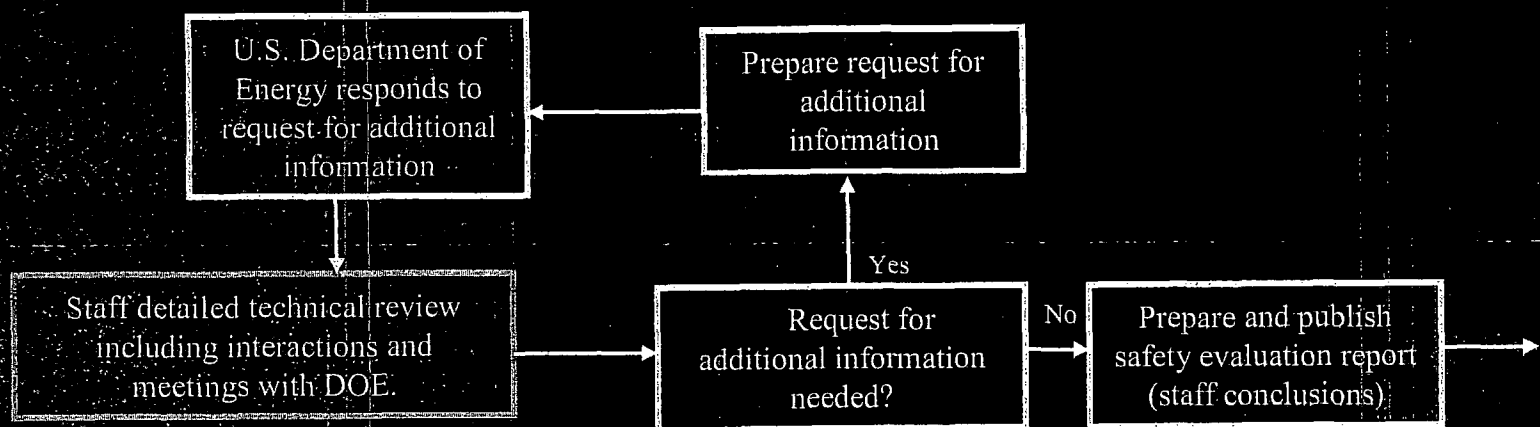
Detailed Technical Review of DOE's SAR



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Interim Staff Guidance

No new guidance is expected

If Rulemaking in any area is significant, the NRC will consider the need for additional guidance.

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Licensing Specifications or Conditions

DOE proposes license specifications or technical specifications (10 CFR 63.43).

NRC evaluates and ensures the safety and security of the public and the environment. If necessary, the NRC will place conditions on the construction authorization (10 CFR 63.32 CA).

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Application Submission

HLWRS handles the reviews

Submission requirements

Office of the Secretary (Policy)
EMILE JULIAN (301) 415-1966
REBECCA GIITTER (301) 415-1679

Office of Information Services (Document Specifications)
KENNY NGUYEN (301) 415-2046

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(BACKUP SLIDE) Proprietary Information

DOE or vendor requests NRC to withhold information in accordance with 10 CFR 2.390.

NRC makes a determination.

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