Mr. Steven Brocoum , Assistant Manager
for Licensing and Regulatory Compliance
Yucca Mountain Site Characterization Office
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
P. O. Box 30307
North Las Vegas, NV 89036-0307

June 1, 2000

Subject: MINUTES OF THE MARCH 8, 2000, TECHNICAL EXCHANGE ON CLASSIFICATION ANALYSIS AND GRADED QA MEETING

Dear Mr. Brocoum :

Enclosed are the minutes of the March 8, 2000, Technical Exchange on Classification Analysis and Graded QA Meeting between the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) concerning discussion of DOE's site characterization programs at Yucca Mountain, Nevada. Also enclosed are the meeting agenda, a list of attendees, the briefing material, and the clarification of NRC letter (Reamer to Brownstein).

Other organizations were also represented at the meeting via teleconferencing. These were the Center for Nuclear Waste Regulatory Analyses, DOE's Management and Operating Contractor, and the Nuclear Energy Institute.

The meeting resulted in a good exchange of information and views between DOE and NRC. No response to this letter is required. If you have any questions regarding the enclosed information, please contact Manny Comar at 301-415-6074.

Sincerely,

C. William Reamer, Chief
High-Level Waste and Performance
Assessment Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosures: 1-A. Minutes
1. Agenda
2. List of Attendees
3. Briefing Material
4. Clarification of NRC Letter

cc: See attached list

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 1, 2000

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cc: See attached list

Letter to from dated: June 1, 2000

cc: R. Loux, State of Nevada
S. Frishman, State of Nevada
L. Barrett, DOE/Wash, DC
A. Brownstein, DOE/Wash, DC
S. Hanauer, DOE/Wash, DC
C. Einberg, DOE/Wash, DC
D. Shelor, DOE/Wash, DC
N. Slater, DOE/Wash, DC
R. Dyer, YMPO
S. Brocoum, YMPO
R. Clark, YMPO
C. Hanlon, YMPO
T. Gunter, YMPO
G. Dials, M&O
J. Bailey, M&O
D. Wilkins, M&O
M. Voegele, M&O
S. Echols, Winston & Strawn
B. Price, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
D. Bechtel, Clark County, NV
E. von Tiesenhousen, Clark County, NV
A. Kalt, Churchill County, NV
H. Ealey, Esmeralda County, NV
L. Fiorenzi, Eureka County, NV
A. Remus, Inyo County, CA
B. Duke, Lander County, NV
J. Pitts, Lincoln County, NV
J. Wallis, Mineral County, NV
L. Bradshaw, Nye County, NV
M. Murphy, Nye County, NV
J. McKnight, Nye County, NV
N. Stellavato, Nye County, NV
B. Ott, White Pine County, NV
D. Weigel, GAO
W. Barnard, NWTRB
R. Holden, NCAI
C. Williams, NIEC
R. Arnold, Pahrump County, NV
J. Lyznicky, AMA
R. Clark, EPA
F. Marcinowski, EPA
R. Anderson, NEI
R. McCullum, NEI
S. Kraft, NEI
J. Kessler, EPRI
R. Wallace, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
J. Curtiss, Winston & Strawn

Enclosure 1-A

Minutes of the March 8, 2000, DOE/NRC Technical Exchange on Classification Analysis and Graded QA

Minutes for the DOE/NRC Technical Exchange on
Classification Analysis and Graded QA
Rockville MD - 3/8/2000

Staff from the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) held a technical exchange on March 8, 2000 in the NRC offices at White Flint. (See Attachment-1 for a copy of the Agenda and Attachment-2 for the list of Attendees.) The purpose of the meeting was to explain the basis for the Quality Assurance (QA) Classification Process and Grading Program being proposed by the DOE. The DOE presentation topics were: (1) Previous Meeting Summary - Historic Perspeetive (Paul Harrington - DOE), (2) Risk-Informed Classification Process, (Don Beckman - Management & Operating Contractor (M&O)) (3) Hazards Analysis and Accident Sequence Development (Ken Ashe - M&O), (4) Design Basis Events (Ken Ashe - M&O), (5) QA Strategy for Site Characterization (Don Beckman - M&O), and (6) Quality Assurance Requirements Document (QARD) Concerns on Classification (Ram Murthy - DOE). (See Attachment-3 for a set of briefing charts used during the meeting.) The main focus of the meeting was on the Risk-Informed Classification Process presentation and considerable progress was made in gaining mutual understanding of the classification process and the graded QA approach being proposed by the DOE. As agreed upon in the closing statements, the presentations made the Classification process transparent and the NRC gained confidence that all applicable criteria from the 18 Appendix-B criteria will be applied to each Quality Level.

Specific items discussed during the meeting were:

1) As a result of the discussions during the meeting, the DOE agreed to review the procedure controlling the classification process for Structures, Systems, and Components (SSCs) Important to Safety and Engineered and Natural Barriers Important to Waste Isolation. DOE agreed to make necessary modifications to the procedure to reflect what was presented during the Technical Exchange.

2) DOE agreed that several slides in the presentation material did not clearly agree with the verbal descriptions provided during the meeting. The specific examples are as follows:

   - Second presentation (Beckman), slide 21, the second sub-bullet of the second bullet indicated grading of design codes when in fact it should have stated selection of design codes.
   - Second presentation, slide 23, the QL-2 criteria discussion did not explicitly state that the SSC being evaluated has already gone through the determination that it is not QL-1. This appeared to allow SSCs to be classified as QL-2 yet still have an impact on QL-1 systems. In the verbal discussions it was made clear that for any SSC to be classified QL-2 it would have already been determined that it was not QL-1 (by either being beyond design basis $< 10^{-6}$ or the resulting dose would be less than the regulatory limits). This was also discussed in relation to QL-3 SSC versus QL-1 and QL-2 SSCs (slide 26).
   - Second presentation, slides 25 and 31, the material on the slides discussed multiple failures as potential QL-2 SSCs. This created confusion until it was

clarified that multiple failures are beyond design basis and are included only as a result of defense in depth.

Any minor discrepancies in presentation materials will be superceded by formal project documentation. It is expected that the NRC will use formal project documentation to evaluate the adequacy of the classification and grading processes and that this project documentation will form the basis for any NRC decisions. DOE also agreed that revisions to project procedures and programs would be provided to the NRC as necessary.

3) During the meeting discussions, it was not clear that items that are identified as Quality Level (QL) 2 had already gone through the procedural steps for determination that they were not QL-1. The discussion implied that QL-2 SSCs could have a direct impact on QL-1 systems. However, the discussion should have stated that the impact was not significant enough to cause the QL-1 system to fail and ultimately the dose criteria to be exceeded. DOE agreed to review the wording in the procedure to ensure clarity in the procedural steps to arrive at the appropriate classification. This will ensure that no SSC would be classified as QL-2 if it has the possibility of preventing a QL-1 system from performing its functions under a postulated credible event scenario, such that the dose criteria are exceeded.

4) NRC noted that in the DOE classification process, worker safety requirements are distinct from public safety requirements. NRC acknowledged that 10 CFR Part 20 allows higher annual doses to workers than the annual exposure permissible to the public. However, NRC expressed a concern that a generic QL-3 classification for all Part 20 activities was not adequate. Particularly, the rationale provided by DOE for classifying monitoring systems as QL-3 was weak in the absence of a convincing calculation of risk significance. In an effort to reduce the NRC's concern, the DOE pointed out that the classification procedure (QAP-2-3) determines the classification of items (e.g., system, structure, or component) based on their safety significance (i.e., the item's role in meeting safety requirements). Therefore, based on an item's safety significance, appropriate design criteria, codes & standards, and QA controls can be identified to provide reasonable assurance that there is no adverse impact to the health and safety of the public and/or workers. For items classified as QL-3, based on industry experience, it is expected that the safety focus will be on programmatic controls (e.g., radiation protection program, ALARA committees, worker training, administrative procedures) that will be present and there will be less focus on the actual SSC. In addition, the worker will be trained to recognize the radiological hazards present and to respond appropriately to alarms. The worker will also be using procedures that will require the worker to stop operations, assess the situation and take appropriate actions if an SSC identified as important to radiological worker safety is not present or operating properly. These are all industry tested and proven concepts for protecting the worker from radiological hazards. In addition, to the procedural controls discussed, it is expected that the DOE will include more restrictive administrative

limits on the workers in order to minimize the potential of exceeding the 10 CFR 20 limits. In most cases, worker exposure is the result of chronic exposures rather than one acute exposure. Therefore, as part of the facility radiation protection program, the workers will be required to verify the amount of regulatory (and administratively) allowed exposure remaining for the year, before entering an area where the worker may receive any additional dose. Regardless of the quality level, there will be an appropriate balance between SSC controls and activity controls. Classifying an item as QL-3 does not suggest the Project thinks that worker safety or monitoring systems are not important. As was discussed during the presentations, QL-3 is important to safety and the appropriate QARD criteria will be applied.

5) DOE believes that the Quality Level categorization approach proposed for the YMP is risk-informed and generally consistent with the intent of the NRC regulatory guides (RG. 1.174 and RG. 1.176). However, DOE is not committing to adopting these RGs. and NRC said that it did not expect such a commitment.

6) DOE stated that the LA design would reflect greater design details for those SSCs categorized as QL-1 and sequentially less for those categorized as QL-2 and QL-3. DOE anticipates eventually developing all necessary design details and providing details on the grading controls that will be applied.

7) NRC staff stated that it understands the DOE categorization process, but needs to further evaluate the criteria and advise DOE if it agrees with the risk measures (based on dose as indicators of risk) for the three quality levels identified by the DOE during the meeting.

8) NRC discussed its expectations that the DOE QARD would need to be revised should DOE decide to apply graded QA to design, construction, or pre-closure activities. The NRC believes a revision would need to address, at a high level, the elements of the graded QA process such as: the risk categorization process, the risk categorization levels, the graded controls applied to the different levels, provisions for corrective action and feedback, etc. DOE agreed that the QARD would be revised at a high level, after agreement is reached with the NRC.

9) NRC stated and DOE agreed that all applicable criteria from the 18 criteria of Appendix-B would need to be applied to the SSCs identified as important to safety and barriers important to waste isolation categorized under the three quality levels, namely, QL-1, QL-2 and QL-3.

10) DOE stated that the QA controls for waste isolation barriers would not, at this time, be classified into the three quality levels. Barriers would be classified as either important to waste isolation or not important to waste isolation. However, the DOE may consider further classification of waste isolation barriers at a future date and provide the necessary rationale for such classification..

Minutes for the DOE/NRC Technical Exchange on
Classification Analysis and Graded QA
Rockville MD - 3/8/2000

11) DOE stated it is not grading the QA controls related to the current design activities, performance assessment and site characterization. DOE has an approved process that applies to preparing and reviewing reports, developing models, and conducting analyses, regardless of the risk significance of such activities.

12) DOE stated that data used to support its safety case for SR and LA will be qualified in accordance with the QARD. Data qualified prior to June 1999, however, will be subject to the following re-verification: (a) Data related to the seven principal factors or the disruptive events in the Repository Safety Strategy (RSS) will be re-verified under the category VL-1 (higher risk significance); and (b) Data related to other RSS factors is being tagged as VL-2 (lower risk significance) and is being used "as-is" subject to continued low failure rates of VL-1 data verification efforts. VL-2 data will only be re-verified if high VL-1 failure rates are encountered as described in the Data Management Development Plan. This process has been subject to previous and ongoing evaluation by the NRC staff.

13) A clarification was presented regarding the NRC's recent acceptance of the DOE QARD, Revision 9. (See Attachment-3 for the text explaining the clarification).

14) DOE clarified its position with respect to the preclosure period. For all probability of occurrence calculations, a preclosure period of 100 years will be used. If an extension is sought for keeping the repository open for any additional period, it is expected that a request for license amendment will be made and NRC will consider all available and pertinent information before granting an extension.

15) DOE agreed to share Q-List updates, as they become available. DOE also assured the NRC that they would be provided opportunities to review DOE's supporting analyses and provide feedback as required.

4/14/00

Mysore S. Nataraja
Division of Waste Management
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission

4/14/00

Timothy C. Gunter
Yucca Mountain Site
Characterization Office
U.S. Department of Energy

ATTACHMENT-1

AGENDA

NRC/DOE Technical Exchange
Classification Analysis and Graded Quality Assurance
NRC Headquarters, Rockville, MD
Room O4B6
March 8, 2000
8:30 a.m. to 4:30 p.m. (EST)

8:30 - 8:50	Introduction/Opening Remarks	All
8:50 - 9:20	Previous Meeting Summary - Historical Perspective 10 CFR 63 Requirements Safety Analysis Process Compliance Discussion Period of Pre-Closure Performance	Paul Harrington
9:20 - 9:30	Break	
9:30 - 11:30	Risk Informed Classification Process Criteria Basis Iterative Process How we Determine Classification Items Important to Safety/Items Important to Waste Isolation vs. Owner Imposed Q List Update/Activities Examples (QL-1, -2, -3, CQ)	Don Beckman
11:30 - 12:30	Lunch	
12:30 - 1:15	Hazards Analysis and Accident Sequence Development Internal External Examples (QL-1, -2, -3, CQ)	Ken Ashe
1:15 - 2:00	Design Basis Events Categorization Consequence Examples (QL-1, -2, -3, CQ)	Ken Ashe
2:00 - 2:15	Break	
2:15 - 3:15	Site Characterization Procedural QA Philosophy (Waste Isolation, Classification) Monitoring and Data Qualification Procedure Architecture Implementation Experience	Don Beckman
3:15 - 3:30	QARD	Ram Murthy
3:30 - 4:30	Path Forward / Closing Comments	All

ATTACHMENT-2

LIST OF ATTENDEES

QA: N/A

LIST OF ATTENDEES

NRC/DOE Technical Exchange on Classification Analysis and Graded QA
NRC Headquarters, Rockville, MD
Hillshire, Las Vegas, Nevada (via telephone)
CNWRA, San Antonio, Texas (via telephone)
March 8, 2000
8:30 a.m. to 4:30 p.m. (EST)

NAME	ORGANIZATION	TELEPHONE
PAUL HARRINGTON	USDOE/YMSCO	702-794-5415
DAVE DANCEA	NRC/DWM	301-415-6618
RAM MURTHY	DOE/RW-3	702-794-5549
MYSORE NATARAJA	NRC/DWM	301-415-6695
Banad Jagannath	NRC/DWM	301-415-6653
Dennis Galvin	NRC/DWM	301-415-6256
JOHN TRAPP	NRC/DWM	301-415-8063
John Olquet	OCRWM M&O	702-295-3943
Douglas ORVIS	OCRWM M+O	702-295-4137
Tom Dunn	OCRWM M&O	702-925-5557
Ken Ashe	OCRWM M+O	702 295-5563
Don Beckman	OCRWM M&O	702-295-4352
DENNIS R. WILLIAMS	USDOE/YMSCO	702-794-5526
TIM GUNTER	USDOE/YMSCO	702-794-1343

QA: N/A

LIST OF ATTENDEES

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NRC Headquarters, Rockville, MD
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CNWRA, San Antonio, Texas (via telephone)
March 8, 2000
8:30 a.m. to 4:30 p.m. (EST)

NAME	ORGANIZATION	TELEPHONE
David Esh	US NRC DWM	(301) 415-6705
SHUNICHIRO HITA	US NRC ASSIGNEE	(301) 415-8087
GARY SERQUEIRA	BOOZ ALLEN & HAMILTON/DOE	(702) 794-1413
Russ Dyer	DOE/YMSCO	(702) 794-1300
King Stablein	NRC/DWM/HLWB	(301)-415-7445
TED CARTER	US NRC/DWM/HLWB	
Pete Davis	Jason Technologies	(307) 683-2577
JAMES THORNTON	DOE/M&O	704 382 8552
Sidney Crawford	Consultant (Self)	301 216 3080 scrwfrd@erols.com
Rod McCullum	NEI	202-739-8082
LARRY L. Campbell	US NRC/DWM	301 415-5000
James Smith	US NRC/IMNS/RLB	301-415-6459
Deal is Gwyn	OCRWM M&O	702-295-3964
Wesley C. Patrick	CNWRA	210-522-5158
TIM McCartin	NRC/DWM	(301) 415-6681
William Belke	NRC/EDSR by	phone.

ATTACHMENT-3

SET OF BRIEFING MATERIAL

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

Previous Meeting Summary - Historical Perspective

Presented to:
DOE/NRC Technical Exchange
on Classification Analysis and Graded QA

Presented by:
Paul Harrington
Department of Energy

March 8, 2000

YUCCA
MOUNTAIN
PROJECT

Meeting Objective

- Describe the risk informed QA classification process used at Yucca Mountain
- Resolve open questions previously raised by the NRC
  - Use of risk was not transparent
  - Separation of QL 1, 2, 3 with respect to risk
  - Inclusion of items that are not important to safety or waste isolation on the Q-List
  - Preclosure duration

Agenda

- Summary of previous interactions
- Proposed 10CFR63 requirements
- Integrated safety analysis process
- Compliance discussion

Previous Related Meetings

- October 8, 1998 - Las Vegas
- December 10, 1998 - Rockville
- March 31, 1999 - Rockville
- November 16, 1999 - Las Vegas

Proposed 10CFR63 Requirements

- **Important to Safety***
  - **Structures, systems, and components whose function is:**
    - **"To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of 63.111(b)(1) for Category 1 design basis events"; or**
    - **"To prevent or mitigate Category 2 design basis events that could result in doses equal to or greater than the values specified in 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site"**
- **Important to Waste Isolation***
  - **"...Engineered or natural barriers whose function is to provide reasonable assurance that high-level waste can be disposed without exceeding the requirements of 63.113(b)"**

10 CFR 63.2

Proposed 10CFR63 Requirements

(Continued)

- **Category 1 Design Basis Events***
  - **"Those natural and human-induced events that are expected to occur one or more times before permanent closure..."**
- **Category 2 Design Basis Events***
  - **"Other natural and man-induced events that have at least one chance in 10,000 of occurring before permanent closure..."**

10 CFR 63.2

Proposed 10CFR63 Requirements

(Continued)

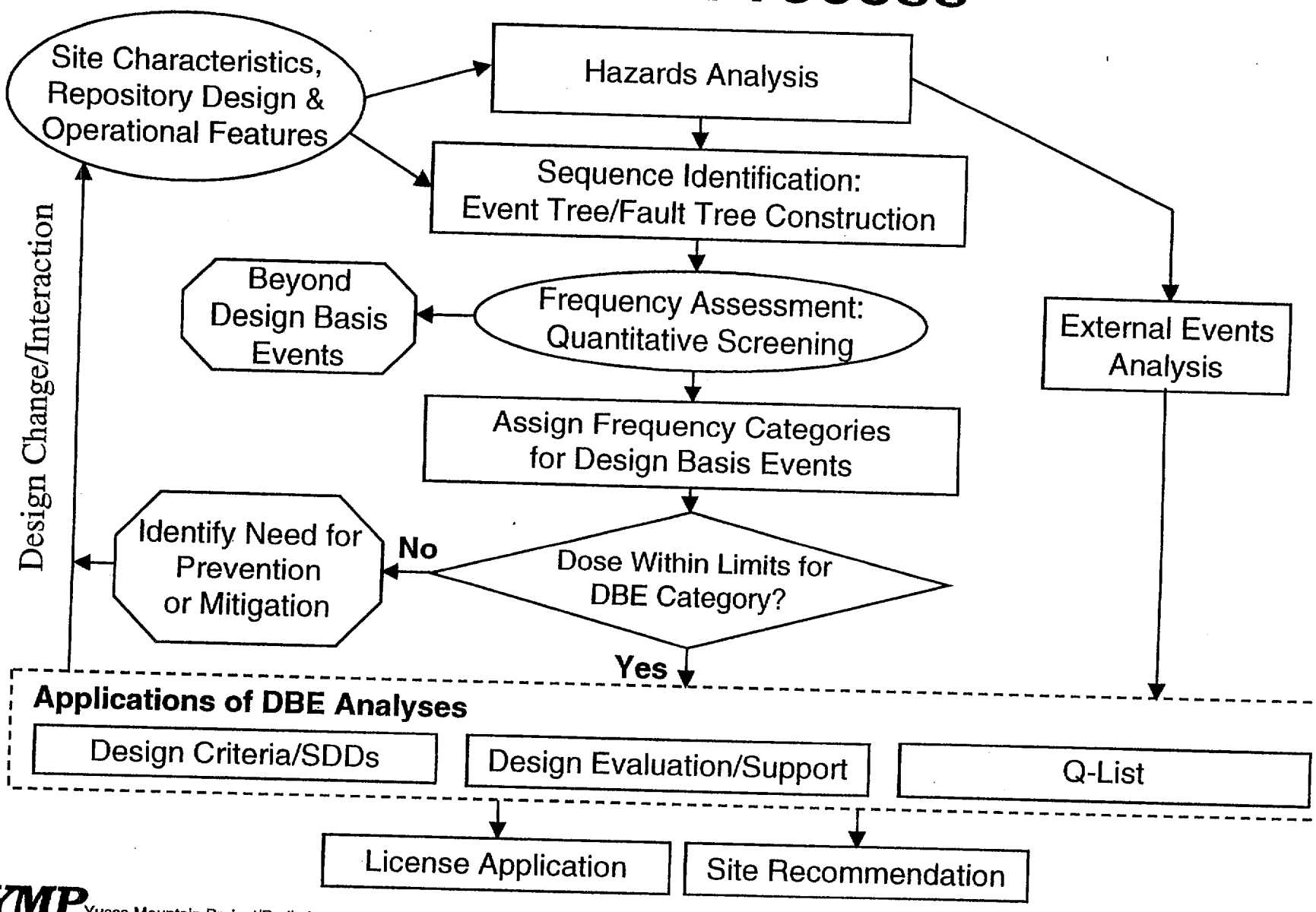
- **10CFR63.111(b)(1)**
  - **"...radiation exposures an radiation levels... will be maintained within the limits specified in paragraph (a) of this section"**
  - **10CFR63.111(a)(1) "The geologic repository operations area shall meet the requirements of Part 20 of this chapter"**
  - **10CFR63.111(a)(2) "During normal operations, and for Category 1 design basis events, the annual dose to any real member of the public, located beyond the boundary of the site shall not exceed a TEDE of 0.25 mSv (25 mrem)"**
- **10CFR63.111(b)(2)**
  - **"... No individual located on, or beyond, any point on the boundary of the site, will receive the more limiting of a TEDE of 0.05 Sv (5 rem), or the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem)..."**

Proposed 10CFR63 Requirements

(Continued)

- **10CFR63.113(b)**
  - **"The engineered barrier system shall be designed so that, working in combination with natural barriers, the expected annual dose to the average member of the critical group shall not exceed 0.25 mSv (25 mrem) TEDE at any time during the first 10,000 years after permanent closure, as a result of radioactive materials released from the geologic repository"**

Integrated Safety Analysis - Iterative Process



Compliance Discussion

- **Integrated safety analysis**
  - **Systematic hazards assessment**
  - **Design basis event screening**
    - **Screens out beyond design basis events**
  - **Design basis event categorization**
    - **Category 1 or 2**
  - **Design basis event evaluation**
    - **Design criteria, technical specifications, administrative controls**
  - **QA classification**
    - **Determine quality level of SSCs**
  - **Iterative process**
    - **The process will iterate on revisions to repository design, operational features or site characterizations as appropriate**

Preclosure Operating Period

- License application will be based on 50-125 year* preclosure operating period
- Integrated safety analysis
  - Currently based on nominal 100 year period
  - Conservative and appropriate for design phase
  - Will be based on operations that are appropriate the LA preclosure period
  - Include Design Basis Events appropriate for the LA preclosure period

** Reference: Monitored Geologic Repository Project Description Document, B00000000-01717-1705-00003 Rev 00 DCN 01*

Summary

- **Process meets proposed 10CFR63 requirements**
- **Supporting presentations**
  - **Classification Process**
  - **Hazards Analysis**
  - **Design Basis Events**

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

Risk-Informed Classification Process

Presented to:
DOE/NRC Technical Exchange
on Classification Analysis and Graded QA

Presented by:
Don Beckman
CRWMS Management & Operating Contractor

March 8, 2000

YUCCA MOUNTAIN PROJECT

Objective

- Background
- Overview of the MGR classification process
- Present classification process and rationale
  - Maximize application of risk-informed approach
  - Justification for deterministic and risk-based criteria
- Regulatory scope
- Illustrate risk-informed classification implementation
- Present examples of applications

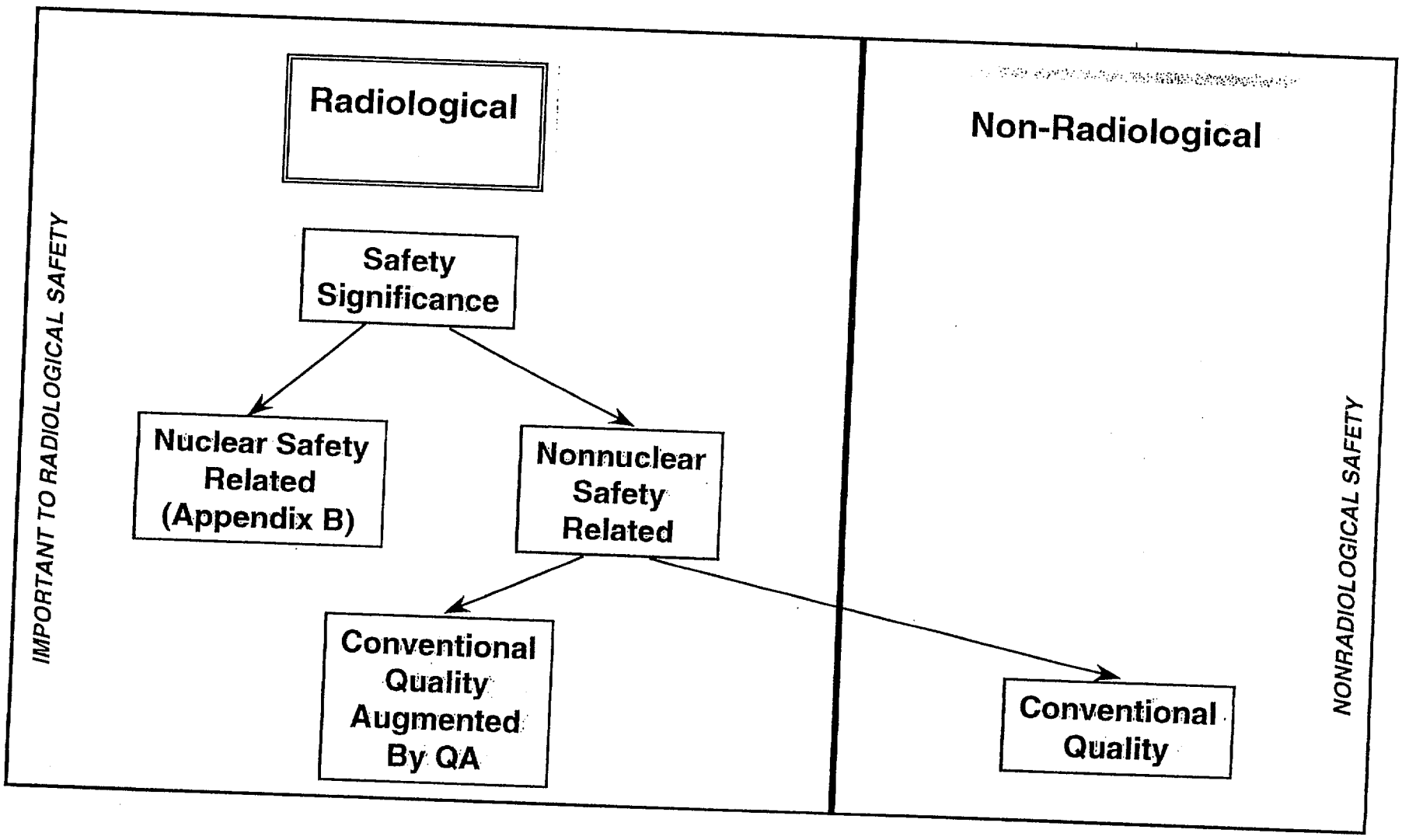
Historical Safety Approach

Radiological
(NRC, EPA)

- 10CFR50 invokes Appendix B for safety-related structures, systems, and components
- Safety related SSCs are those SSCs that are relied upon to remain functional during and following design basis events to assure
  - The integrity of the reactor coolant pressure boundary
  - The capability to shut down the reactor and maintain it in a safe shutdown condition
  - The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in 50.34(a)(1) or 100.11 of this chapter, as applicable

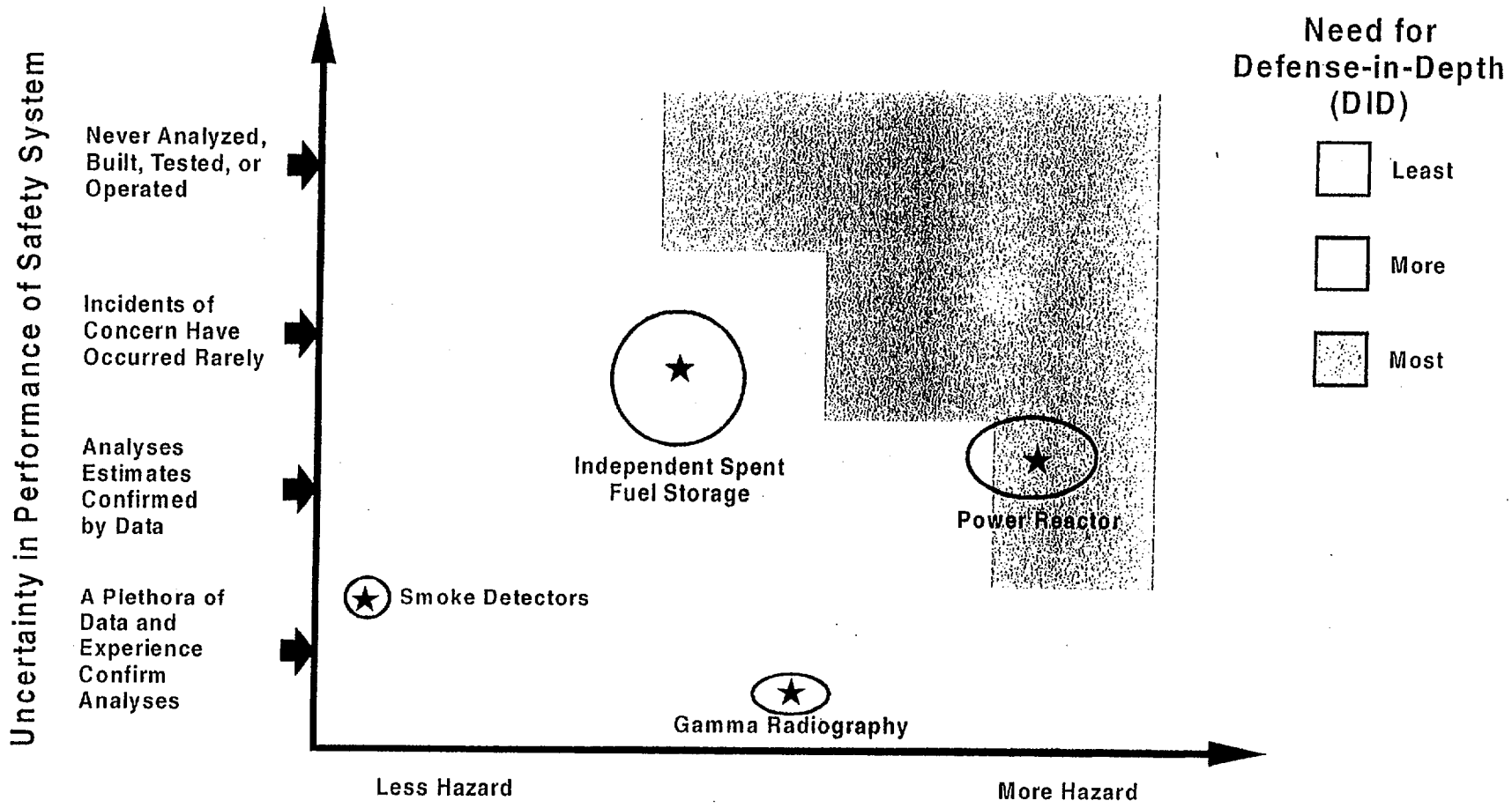
Nuclear Safety Related (Appendix B)

Safety Evolution



Risk - Probability & Consequences

Reactor	YMP
• High energy, volatile	• Low energy, nonvolatile
• Complex, active safety response to events	• Basically passive, limited safety response to events
• Risk-informed evaluations – Large release potential – Many systems may impact core damage frequency – PRA does not include fuel handling events	• No major risk equivalent – Handling events – Few systems impact events
• Licensing basis – Design criteria based evaluations – Assumed requirements	• Licensing basis – Risk-informed criteria – Initiating events – Event sequences – Consequences – Functional risk measures



Example of how need for defense-in-depth can be related to: (1) the uncertainty in the performance of the safety system and (2) the potential hazard posed by the system. Note: the positions of the various systems involves uncertainty on both axes.

Created by: Joseph Holonich, NRC
Norman A. Eisenberg, NRC

Chart 1.cdr

RG 1.176, An Approach for Plant Specific Risk-Informed Decisionmaking: Graded Quality Assurance

- **RG 1.176 endorses several fundamental principles**
  - **Graded QA should be applied to maximize licensee's focus and resources on items most risk significant**
  - **Graded QA programs should have 4 essential elements**
    - **A reasonable and consistent significance determination process based on traditional engineering and probabilistic evaluations**
    - **Implementation of QA controls appropriate to safety function and safety significance**
    - **An effective root cause analysis and corrective action program**
    - **A feedback process for re-assessing SSC safety significance and adequacy of controls through operating experience**

Yucca Mountain Approach to Risk Informed Decision Making

- RG 1.176 is based on different set of risks than exist at Yucca Mountain
- The YMP Program meets the intent of RG 1.176 for engineering analysis and significance determination consistency and reasonableness

Yucca Mountain Approach to Risk Informed Decision Making

(Continued)

- **The engineering analysis techniques applied by RG 1.176 exist in different but equivalent form on the Project**
  - **YMP analyses include**
    - **Event sequence determinations**
    - **Quantitative frequency assessment for each event or group of events**
    - **Quantitative dose assessment for each event**
    - **Identification of preventing or mitigating safety function**
    - **Analysis that are commensurate with relative risk and consistent with 10 CFR 50 treatment of fuel handling and storage activities**
    - **Criteria used for risk measures directly extracted from regulatory requirements**

Yucca Mountain Approach to Risk Informed Decision Making

(Continued)

- Reactor analyses include:
  - Address a singular end state or condition, based on a summation of all sequences leading to the end state or condition, i.e., core damage
  - Readily support further incremented risk measures from either an analytical or cost-benefit perspective at this Project stage

Yucca Mountain Approach to Risk Informed Decision Making

(Continued)

- **The YMP Program also contains each of the remaining elements of RG 1.176**
  - Implementation of controls
    - QAP-2-3, "Classification of Permanent Items" determines the classification via a quality level determination which feeds the Q-List
    - Current Scientific, PA, Procurement, and Design procedures (except data) are applied only at highest level of rigor; grading will be considered for future activities
    - Procedures to identify controls for items will be developed for construction and operations phases

Yucca Mountain Approach to Risk Informed Decision Making

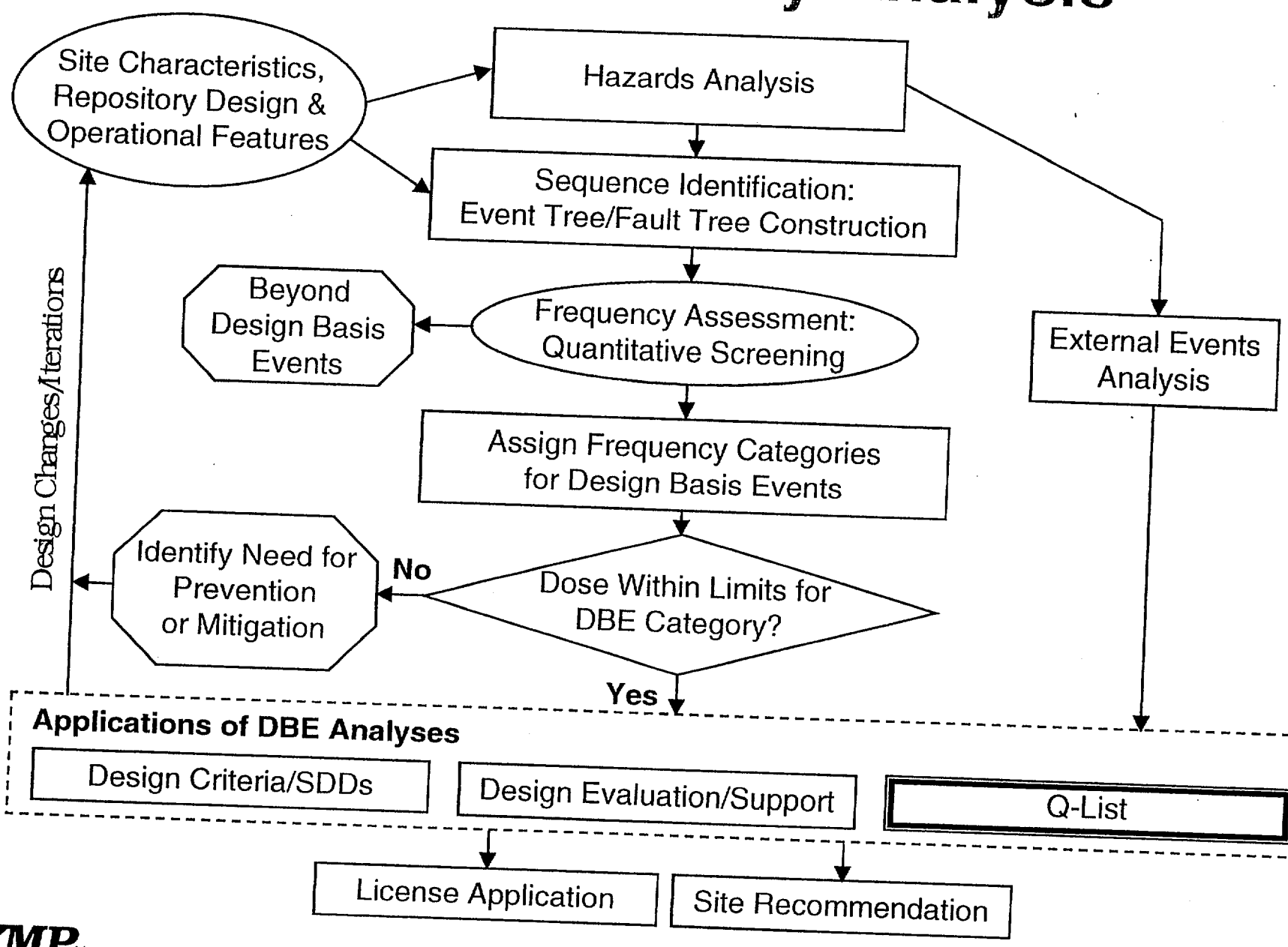
(Continued)

- Corrective action program and root cause determination - AP-16.1Q, "Management of Conditions Adverse to Quality" and AP-16.4Q, "Root Cause Determination"
- Feedback - AP-16.3Q, "Trend Evaluation and Reporting", captures "conditions." Additional guidance will be needed during construction and preparations for the operational phase to evaluate equipment performance, failure rates, etc.

Yucca Mountain Approach to Risk Informed Decision Making Conclusion

- **The YMP Program is risk informed**
  - Risk is addressed at an appropriate level of rigor
  - Includes key elements of RG 1.176
  - Results in identification of safety functions and design bases (criteria) analogous to reactor programs and consistent with RG 1.176
  - Will evolve as design develops to provide further detail below systems level
- **The Project will continue dialogue with the NRC to ensure current knowledge of program is maintained**

Integrated Safety Analysis

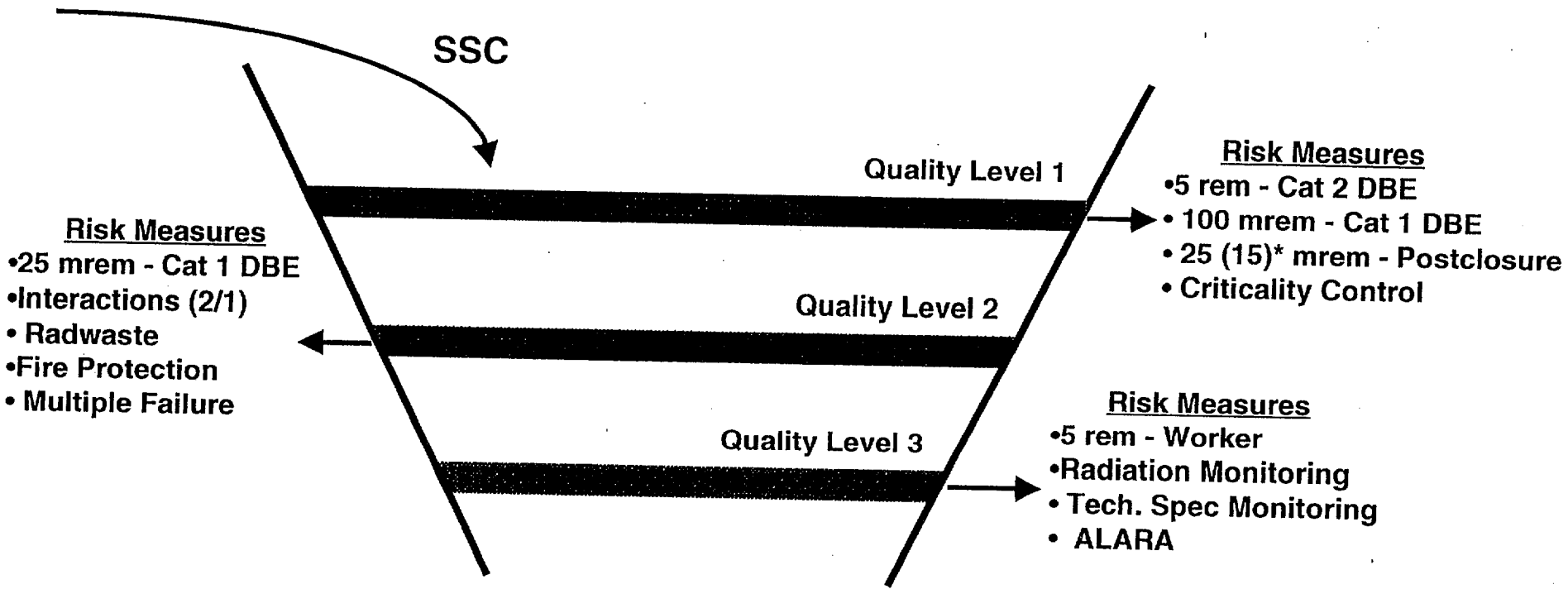


Overview of Classification Structure

- **Important to safety classification consistent with 3-tier NUREG/CR-6407* approach**
  - **Quality Level 1 - Major role in offsite safety or waste isolation**
  - **Quality Level 2 - Minor role in offsite safety or waste isolation**
  - **Quality Level 3 - Potential role in offsite safety or onsite radiological safety**
- **Conventional Quality (i.e., non-QA)**

* *"Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety"*

Classification Process



Conventional Quality

** EPA proposed limit is 15 mrem*

Classification Process Rationale

- **Process consistent with risk-informed philosophy**
  - Ensures that risk insights will be used in a manner that complements traditional deterministic approach
  - Employs 10 CFR 63 risk criteria
- **Risk-Based criteria relied upon most heavily in QL-1 where controls and standards are most stringent**
  - QL-1 - Relies most heavily on risk-based criteria
  - QL-2 - Potentially allows more items to be classified using deterministic criteria than QL-1
  - QL-3 - Includes mainly deterministic criteria; risk-based criteria for items related to onsite worker radiological safety

Classification Process Rationale

(Continued)

- **Accommodates design, licensing, construction, and operational phases of project**
  - Quantitative risk and detailed design data is gradually developed over design and licensing phases; i.e., classification process accommodates an iterative design approach
  - Classification structure should promote seamless grading:
    - License Application level of detail
    - Application of procurement & construction standards
    - Operational controls, maintenance & surveillance programs
- **Promote application of controls and standards consistent with facilities of comparable radiological risks**

Quality Level 1 Criteria

- **Deterministic Criteria**
  - Item whose failure could directly result in loss of waste package containment or criticality control for the SNF, high level wastes, or other radioactive materials received for emplacement at the MGR
  - Item forming part of the natural barriers or engineered barrier system
- **Rationale**
  - Minimizes scope of deterministically imposed classifications
  - Limited to criticality control, Waste Package containment features, and natural or Important to Waste Isolation (ITWI) engineered barrier system items

Quality Level 1 Criteria

- **Risk-Based Criteria**
  - Items required to prevent or mitigate a Category 1 DBE that could directly result in offsite doses in excess of 100 mrem/yr TEDE
  - Items required to prevent or mitigate a Category 2 DBE that could directly result in offsite doses in excess of 5 rem TEDE
  - Items directly credited in Performance Assessment (PA) to demonstrate compliance with the post-closure exposure limit of 25 mrem/yr TEDE (EPA proposed limit is 15 mrem)
- **Rationale**
  - Dose: Items providing the capability to prevent or mitigate offsite dose from a Category 1 DBE below § 20.1301(a)(1), or a Category 2 DBE below § 63.111(a)(2) for preclosure or § 63.113(b) for post-closure (or proposed 40 CFR 197)
  - Probability: § 63.2 definition interpretations; DBEs classified as Category 1 for sequence frequencies $F_i \geq 10^{-2}$ and DBE Category 2 for sequence frequencies $10^{-2} > F_i \geq 10^{-6}$. DBEs with sequence probabilities $F_i < 10^{-6}$ treated as beyond-design-basis

Quality Level 2 Criteria

- **Deterministic Criteria**
  - Items performing site-generated radwaste management function
- **Rationale**
  - Radiological release control functions are credited in Category 1 offsite and worker radiological exposure evaluations
  - QL-2 designation will allow grading of design codes and standards, consistent with 10 CFR 50 practice

Quality Level 2 Criteria

(Continued)

- **Deterministic Criteria**
  - Items performing fire protection functions for QL-1 items
- **Rationale**
  - Fire protection systems and programs typically credited in DBE identification (i.e., potentially significant fire initiated DBEs deemed incredible due to presence of fire protection systems and programs)
  - QL-2 designation allows grading of design codes and standards, consistent with 10 CFR 50 practice (i.e., comparable fire protection standards typically required for life safety purposes)

Quality Level 2 Criteria

(Continued)

- **Deterministic Criteria**
  - Items not performing QL-1 functions, but whose failure could prevent QL-1 items from performing their intended safety or waste isolation function
- **Rationale**
  - Indirect impact items credited in preclosure or postclosure radiological exposure evaluations; examples include items that could interact with QL-1 items during a seismic event, protect a QL-1 item from high energy missile impact, or otherwise maintain a QL-1 item within analyzed design basis parameter (e.g., g-load following drop)
    - QL-2 allocation confirmed by Integrated Safety Analysis (ISA) (preclosure) or PA (postclosure)
  - QL-2 designation allows grading of design codes and standards, consistent with 10 CFR 50 practice

Quality Level 2 Criteria
(Continued)

- **Risk-Based Criteria**
  - Items required to prevent or mitigate a Category 1 DBE that directly could result in preclosure offsite doses in excess of 25 mrem/yr TEDE
- **Rationale**
  - Dose: Items providing the capability to prevent or mitigate offsite dose from a Category 1 DBE below § 63.111(a)(2) [ITS]; this risk-based criteria is consistent with deterministic allocation of radwaste systems as QL-2

Quality Level 2 Criteria

(Continued)

- **Risk-Based Criteria**
  - Items required, in conjunction with an additional item or control, to prevent or mitigate a Category 1 DBE that could result in offsite doses in excess of 100 mrem/yr TEDE
  - Items required, in conjunction with an additional item or control, to prevent or mitigate a Category 2 DBE that could result in offsite doses in excess of 5 rem TEDE
- **Rationale**
  - Indirect impact criteria provided to allocate as QL-2 items identified by Integrated Safety Analysis (ISA) as Important to Safety (ITS) per 63.112(e)
  - Dose: Items credited, in conjunction with an additional item or control, to prevent or mitigate a Category 1 DBE that could result in offsite doses in excess of § 20.1301(a)(1), or a Category 2 DBE that could result in offsite doses in excess of § 63.111(b)(2)

Quality Level 3 Criteria

- **Deterministic Criteria**
  - Items performing radiation monitoring functions
  - Items monitoring variables for technical specification compliance
- **Rationale**
  - Monitoring systems that function to monitor radiological conditions and controlled variables perform a significant role during normal operations and DBEs
    - Recording direct radiation exposure, radiological releases, and data useful in compliance verification and system performance monitoring (i.e., trending)
    - Alert operators to adverse conditions

Quality Level 3 Criteria
(Continued)

- **Deterministic Criteria**
  - Items providing data that support emergency response functions
  - Items providing data that support post-DBE release assessments
- **Rationale**
  - Information provided to emergency response personnel by monitoring devices may be useful in mitigating DBEs or otherwise reducing offsite or onsite impacts by directing actions with accurate knowledge of existing conditions
  - The ability to perform accurate and timely assessment of releases resulting from DBEs assists in long term recovery activities

Quality Level 3 Criteria

(Continued)

- **Deterministic Criteria**
  - Items performing offsite radiological release ALARA functions
- **Rationale**
  - Items providing ALARA benefits are identified to document function as ALARA compliance related, as distinguished from radioactive waste management systems that are credited in demonstrating compliance with QL-2 offsite risk criteria

Quality Level 3 Criteria

(Continued)

- **Risk-Based Criteria**
  - Items required to limit onsite worker exposure from normal operations and Category 1 DBEs, including recovery, to less than 5 rem/yr TEDE
- **Rationale**
  - Dose: Items required to limit onsite worker exposure from normal operations and Category 1 DBEs, including recovery, to within 10 CFR 20 annual dose limits for workers

QAP-2-3 and QARD Crosswalk

Quality Level 1			
QAP-2-3 Criteria	QARD Section	10CFR63 (ITS, ITWI) without ISA	with ISA
1.1 – Containment & Criticality Control	2.2.2 A.1, 2.2.2 A.2	X	X
1.2 – Prevent or mitigate Cat 1 DBE > 100 mrem	2.2.2 A.1	X	X
1.3 – Prevent or mitigate Cat 2 DBE > 5 rem	2.2.2 A.1	X	X
1.4 – Waste Isol function required for 63.113(b) – natural or engineered barrier req'd for 63.113(a)	2.2.2 A.2	X	X
1.5 – Waste Isol function required for 63.113(b) – meet 25 mrem for first 10,000 years	2.2.2 A.2	X	X

QAP-2-3 and QARD Crosswalk

(Continued)

Quality Level 2			
QAP-2-3 Criteria	QARD Section	10CFR63 without ISA	(ITS, ITWI) with ISA
2.1 – Radwaste control	2.2.2 A.3		X
2.2 – Fire protection for QL-1 SSCs	2.2.2 A.4		X
2.3 – Interaction with QL-1 SSCs	2.2.2 A.5		X
2.4 – Required to meet Cat 1, 25 mrem	2.2.2 A.1	X	X
2.5 – Multiple failure to meet Cat 1, 100 mrem			X
2.6 – Multiple failure to meet Cat 2, 5 rem			X
2.7 a – Failure affect QL-1 engineered barrier	2.2.2 A.5	X	X
2.7 b – Failure results in changes to hydrological characteristics	2.2.2 A.5	X	X
2.7 c – Failure results in fluids/mat'ls that could adversely affect geo-mechanical characteristics	2.2.2 A.5	X	X
2.7 d – Failure compromises natural barriers	2.2.2 A.5	X	X

QAP-2-3 and QARD Crosswalk

(Continued)

Quality Level 3			
		10CFR63	(ITS, ITWI)
QAP-2-3 Criteria	QARD Section	without ISA	with ISA
3.1 – Radiation monitors	2.2.2 A.1, 2.2.2 A.3 2.2.2 A.6		X
3.2 – Tech Spec monitors	2.2.2 A.1, 2.2.2 A.3 2.2.2 A.6		X
3.3 – Monitor DBE consequences	2.2.2 A.1, 2.2.2 A.3 2.2.2 A.6		X
3.4 – DBE release or dispersion monitor	2.2.2 A.1, 2.2.2 A.3		X
3.5 – Offsite ALARA feature	2.2.2 A.1, 2.2.2 A.3		X
3.6 – Required to meet worker 5 rem	2.2.2 A.6	X	

Quality Level 1 Regulatory Scope

- **Deterministic Criteria**
  - Items identified as ITS based on criticality control functions considered within regulatory review scope per § 63.112(e) [ISA]
  - Waste Package containment considered within regulatory review scope per § 63.112(e) [ISA] and § 63.113(b) [ITWI]
- **Risk-Based Criteria**
  - Items identified as Important to Safety or Waste Isolation based on these criteria are all within regulatory review scope per § 63.111(b)(2) [ITS] and § 63.113(b) [ITWI]

Quality Level 2 Regulatory Scope

- **Deterministic Criteria**
  - Items identified as ITS based on radwaste management function considered within regulatory review scope per § 63.111(a) [ITS] and § 63.112 [ISA]; confirmed when Category 1 offsite dose analysis completed
  - Items identified as ITS based on fire protection function considered within regulatory review scope per § 63.112 [ISA]; confirmed when ISA complete
  - Items identified as ITS interaction protection functions considered within regulatory review scope per § 63.112 [ISA]; confirmed when ISA complete
- **Risk-Based Criteria**
  - Items identified as ITS based on these criteria are all within regulatory review scope per § 63.111 [ITS] and § 63.112 [ISA]; items identified based on indirect credit are confirmed ITS when ISA complete

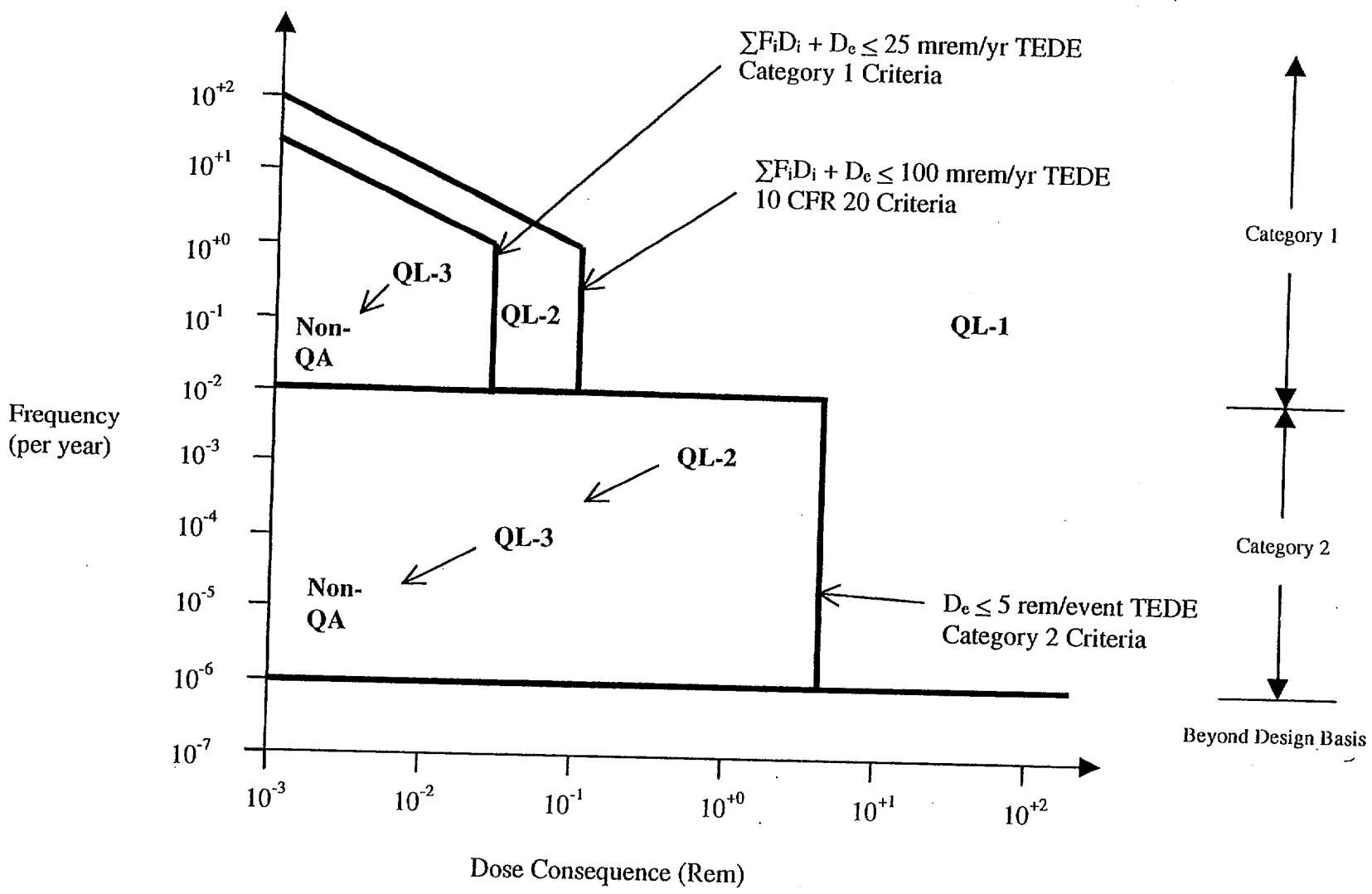
Quality Level 3 Regulatory Scope

- **Deterministic Criteria**
  - **Items identified as ITS and confirmed when ISA completed:**
    - **Radiation monitoring alarm functions considered within regulatory review scope per § 63.112(e)(7) [ISA]**
    - **Technical specification variable monitoring functions considered within regulatory review scope per § 63.112(e)(13) [ISA]**
    - **Emergency response or DBE assessment functions considered within regulatory review scope per § 63.112(e)(10) [ISA]**
  - **Items identified as ITS based on 10 CFR 20 ALARA compliance function; confirmed when Category 1 offsite dose analysis completed**

Quality Level 3 Regulatory Scope
(Continued)

- **Risk-Based Criteria**
  - **Items identified as ITS based onsite worker exposure criteria are all within regulatory review scope per 10 CFR 20 and § 63.112(e)(1-7) [ISA]**

Offsite Dose Classification Criteria



Example

- **Waste Handling Building Ventilation System**
  - **Functions include filtration of bare fuel handling area exhaust flow**
    - **Reduce routine releases**
    - **Mitigate Category 1 and Category 2 DBEs**
  - **Initial assessment of limiting Category 1 DBE indicated limiting annual dose to be < 1 mrem with HEPA and 18 mrem without**
- **Preliminary Classification Conclusions**
  - **HEPA filter not required to satisfy QL-1 risk criteria**
  - **QL-2 classification justified based on radioactive waste management function and potential to exceed QL-2 risk criteria pending final analysis**

Example
(Continued)

- **Waste Package**
  - Functions include containment of radionuclide inventory in preclosure and postclosure
  - Preclosure safety analysis takes credit for waste package integrity in Category 1 and Category 2 DBEs
  - Postclosure safety analysis takes credit for waste package integrity in TSPA
- **Preliminary Classification Conclusions**
  - **Waste Package is classified as QL-1**

Example
(Continued)

- **Stack Radiation Monitor**
  - Functions include monitoring of radioactive releases from surface facility operations
  - No Category 1 or Category 2 DBE assumes termination of release in order to demonstrate compliance
  - Normal operations assessment based on projected releases due to facility operations
  - Monitor would alert operators such that release would be minimized
- **Preliminary Classification Conclusions**
  - Stack radiation monitor is QL-3

Example
(Continued)

- **Waste Emplacement System - Transporter/Locomotives**
  - Functions to transport waste package from surface facilities to emplacement drift
  - Braking/governor limit potential of runaway transporter
  - Shielding to limit worker dose
- **Preliminary Classification Conclusions**
  - Features to limit potential transporter runaway are QL-1
  - Shielding is QL-3
  - Remainder of transporter/locomotives is CQ (assuming no safety impact from fire event)

Q-List Update

- **Q-List Revision 5**
  - Based on old QA classification system
- **Q-List Revision 6**
  - Based on QAP-2-3 Rev 10
  - Scheduled for approval in March
- **Process Improvements**
  - Combine QAP-2-3 and YAP-2.7Q
  - Electronic Q-List

Summary

- Classification process meets proposed 10CFR63 requirements
- Combination of risk-informed and deterministic criteria
  - Appropriate for Yucca Mountain facility
  - Facilitates classification early in the design process
- Risk levels consistent with existing industry classification and procurement practices
- Consistent with items required to be identified via Integrated Safety Analysis

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

Hazard Analysis and Accident Sequence Development

Presented to:
DOE/NRC Technical Exchange
on Classification Analysis and Graded QA

Presented by:
Ken Ashe
CRWMS Management & Operating Contractor

March 8, 2000

YUCCA MOUNTAIN PROJECT

Hazards Analysis Objective and Purpose

- **Objective**
  - Explain Hazards Analysis (HA) process with examples of output
  - Illustrate identification of accident sequences and frequency categories
- **Purpose**

  Provide a systematic method of identifying potential initiating events and credible accident sequences as part of an Integrated Safety Analysis consistent with proposed 10 CFR Part 63.112

Hazards Analysis Definitions

- **Proposed 10 CFR Part 63.112(b) states the Integrated Safety Analysis of the geologic repository shall include:**

  "An identification and systematic analysis of naturally occurring and human-induced hazards..."

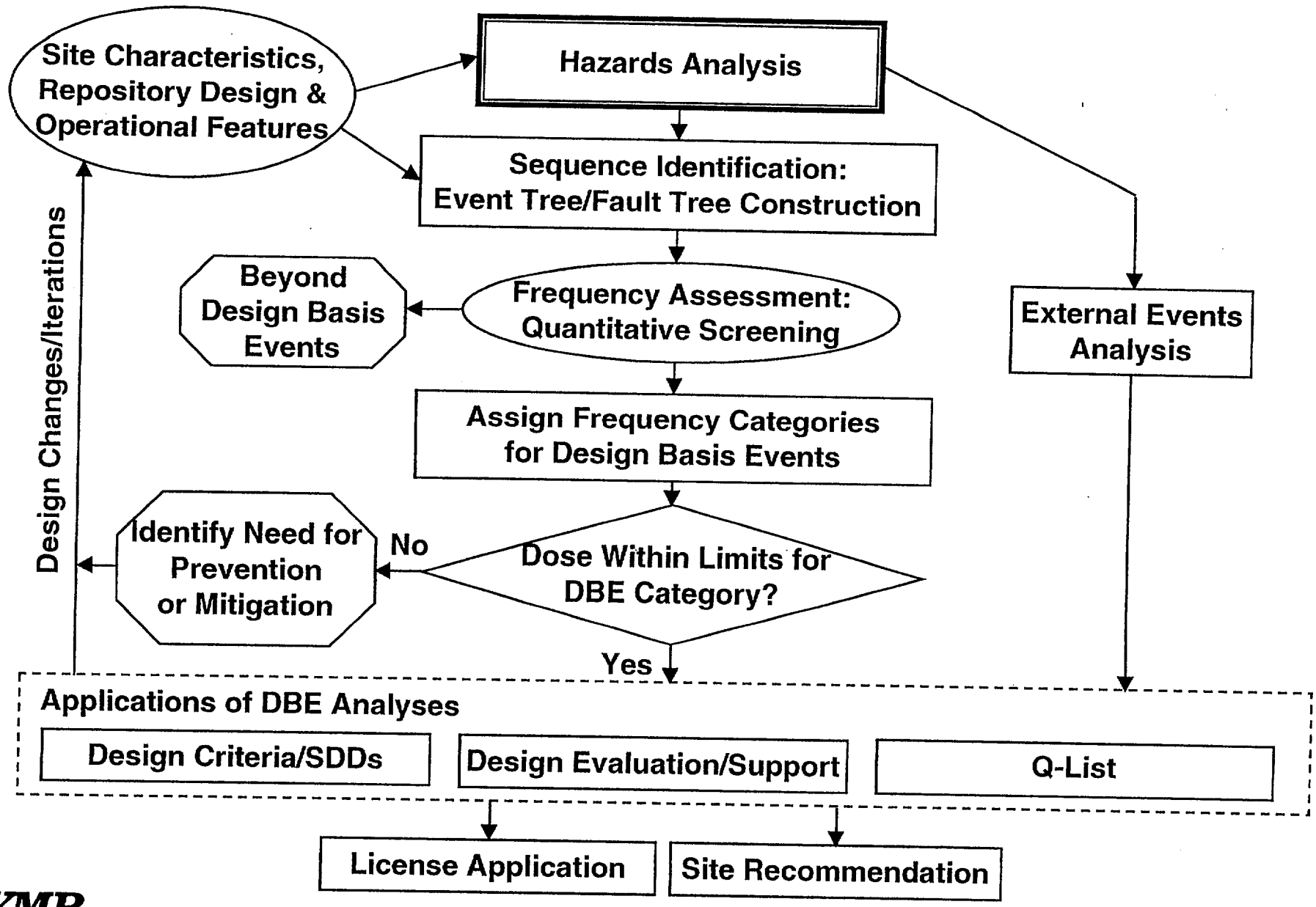
- **Hazards Analysis**

  Hazard Identification method employing any one of a number of systematic hazard evaluation techniques

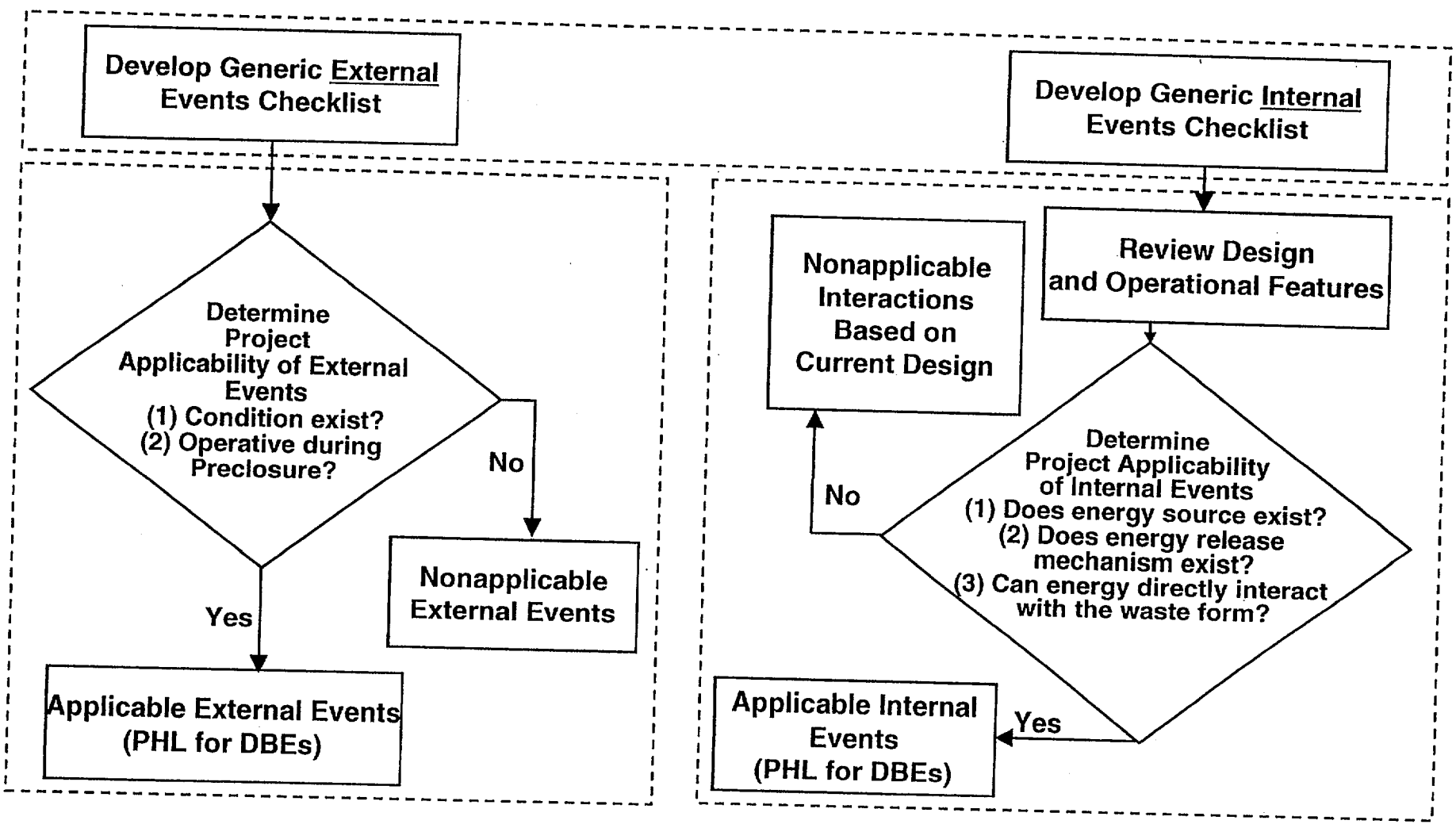
- **Preliminary Hazards List (PHL)**

  Output of HA in the form of a set of potential hazards or initiating events

Integrated Safety Analysis



Hazards Analysis Process Flow



Procedure for Identifying External Events

- Generation of a list of potential external initiating events is a 2-step procedure that uses the HA methodology
  - Step 1: Develop generic list of potential external events and phenomena utilizing best practices/guidelines in the safety field - procedure identical for external and internal events
  - Step 2: Determine applicability of each potential initiating event

Step 1

- **Utilize best practices/guidelines in the safety field**
  - NUREG-1513. Integrated Safety Analysis Guidance Document
  - ISA Requirements per NUREG-1520. NUREG-1701, NUREG-1702,Standard Review Plan(s)
  - Guidelines for Hazard Evaluation Procedures (AICHE)
  - Guidelines for Chemical Process Quantitative Risk Analysis (AICHE)
  - System Safety Analysis Handbook
  - NUREG/CR-2300, PRA Procedures Guide
  - NUREG/CR-6410, Nuclear Fuel Cycle Accident Analysis Handbook
  - DOE Standard 3009-94, Basic Methods for Hazards Analysis, Accident Analysis, and Technical Safety Requirements Derivation
  - YMP Project & National laboratory safety & risk studies
  - Licensed facilities' documents such as ISFSIs, SARs, and WIPP SARs

Step 2

- **Determine applicability - external event is not applicable if:**
  - **The phenomenon does not exist at the site**
  - **The phenomenon is not operative during preclosure because:**
    - **Process is too slow to affect preclosure in terms of radiological hazards**
    - **Initiating event frequency is less than 10^{-6}/year .....otherwise event is considered in the design basis**

Examples: Phenomena Does Not Exist

- Avalanche (e.g., heavy snow)
- Dam Failure
- Hurricane

Example: Process Not Applicable to Preclosure

- **Erosion**
  - Definition: Wearing away of soil and rock by weathering, mass wasting, and the action of streams, glaciers, waves, wind, and underground water
  - Required Condition: Soil and rock
  - Potentially Applicable to Preclosure: No
  - Conclusion: Studies determined erosion at Yucca Mountain is minimal for the 10,000-year time frame and can be considered negligible during the preclosure period - Long-term hill slope erosion rates for Yucca Mountain determined to be 0.19 cm/1000 years; therefore, although condition exists at Yucca Mountain, not applicable for consideration during preclosure period because process too slow to cause a radiological hazard

Preliminary Hazards List (for external events)

- Aircraft Crash
- Extreme Wind
- External Fire (Range)
- Flooding (including rainstorm and river diversion)
- Inadvertent/Intentional Human Intrusions
- Landslide/ Debris Avalanche
- Lightning
- Loss of Onsite/Offsite Power
- Industrial Activity Induced Accident
- Military Activity induced Accident
- Seismic Activity, Earthquake
- Seismic Activity, Subsurface Fault Displacement
- Seismic, Surface Fault Displacement
- Tornado

Reference: MGR External Events Hazards Analysis ANL-MGR-SE-000004 Rev00

Procedure for Identifying Internal Events

- **Generating a list of potential internal initiating events is a three-step procedure**

  Step 1: Develop generic list of energy sources as potential internal events and phenomena

  - **Collision/Crushing**
  - **Chemical Contamination/Flooding**
  - **Explosion/Implosion**
  - **Fire**
  - **Radiation/Magnetic/Electrical**
  - **Thermal**
  - **Human Factors**

Procedure for Identifying Internal Events
(Continued)

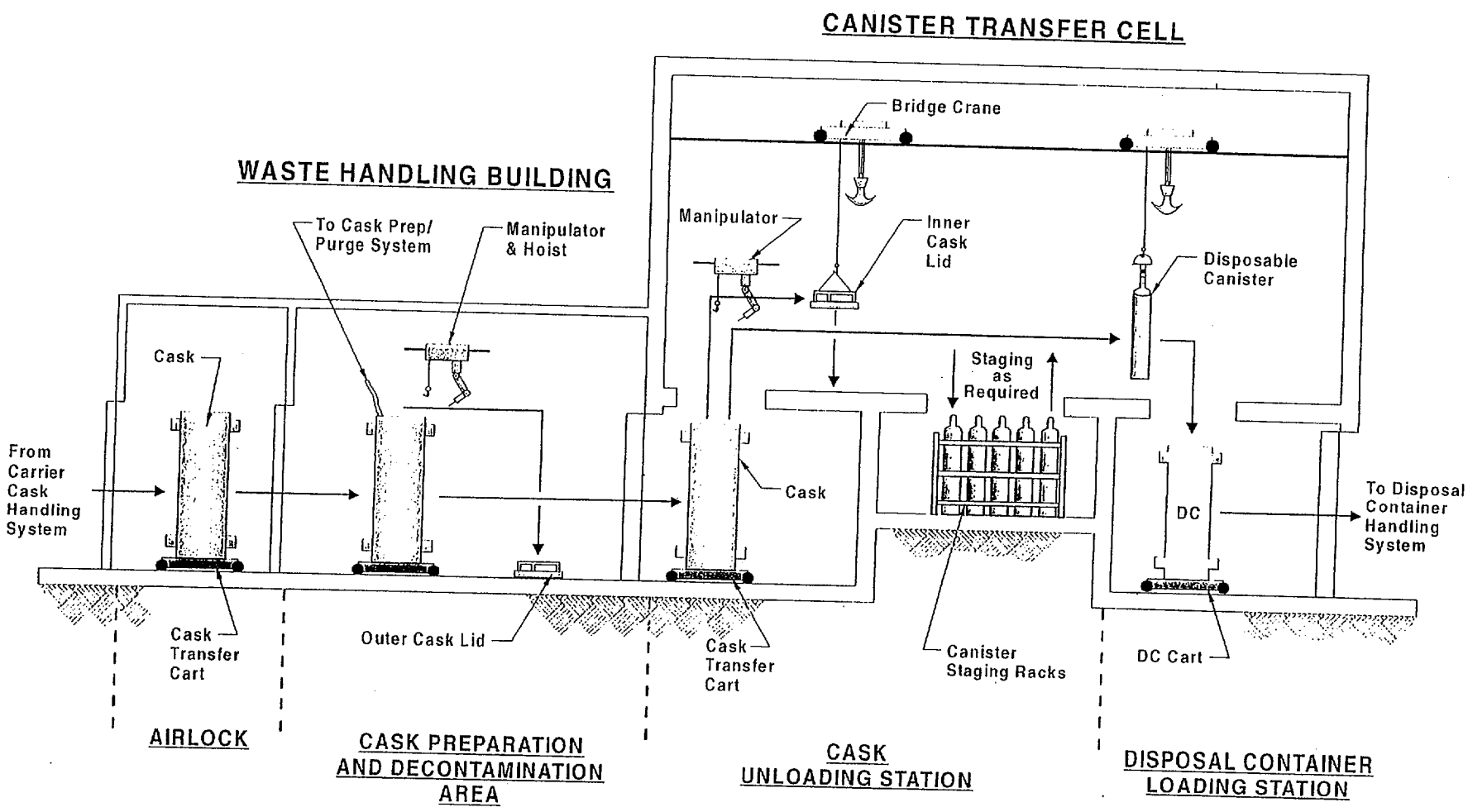
Step 2: Review design and operational features

Step 3: Determination of Applicability

- Does the energy source exist?
- Does an energy release mechanism exist?

  Example: Fire - energy source is fuel and oxygen; release mechanism is an ignition source
- Can energy directly interact with the waste form?

Preliminary CTS Design



DC - Disposal Container

CANISTER TRANSFER SYSTEM

Example 1: Canister Transfer System

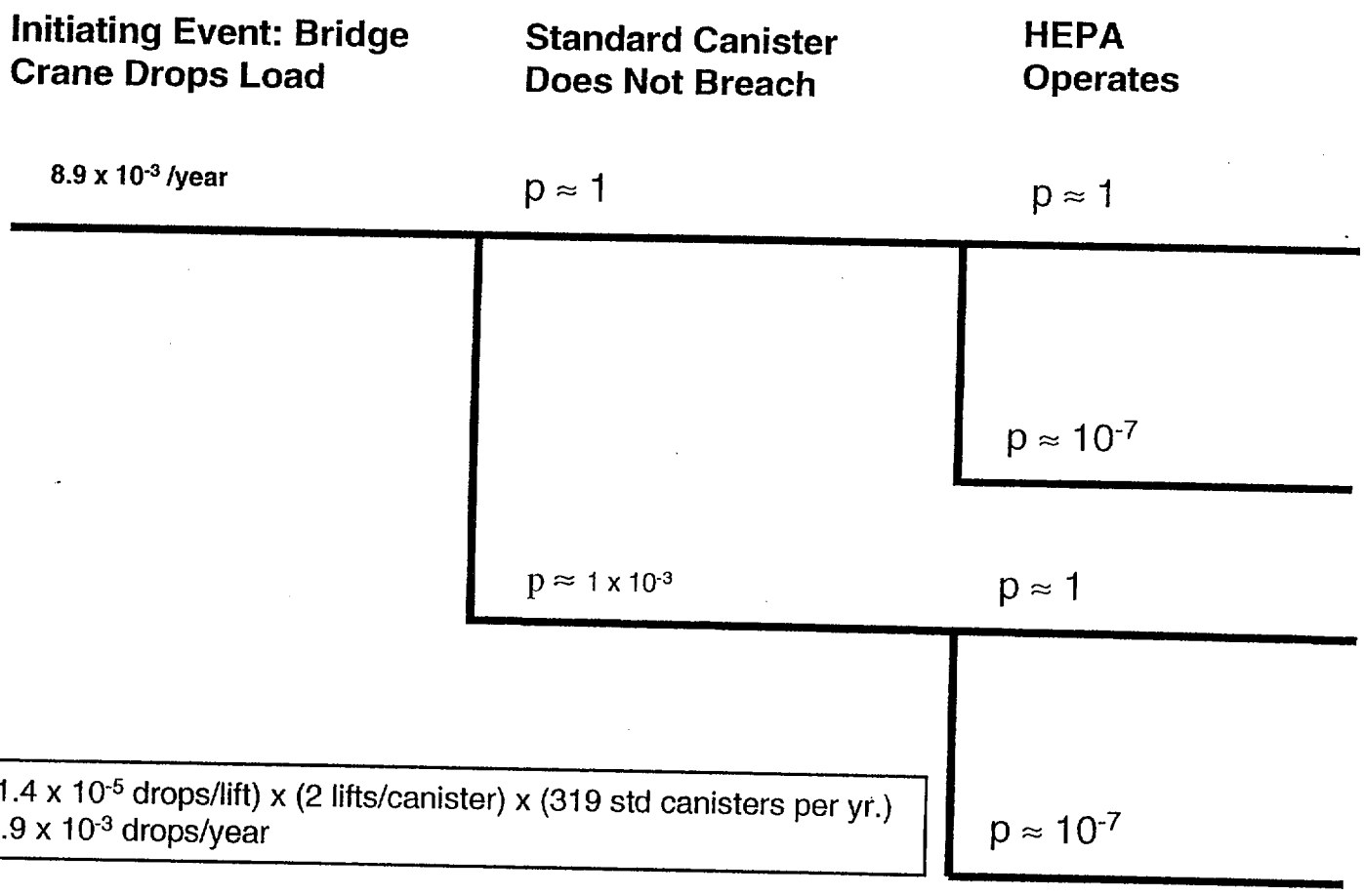
Area Description: Shipping cask moves through airlock and the contents (i.e., waste canister) is transferred to a disposal container (DC). The empty shipping cask is decontaminated and removed.

- General Functions
  - Move shipping cask to Canister Transfer System
  - Unbolt and remove shipping cask lid
  - Position cask for unloading
  - Remove canisters from shipping cask
  - Place canisters in lag storage, if required
  - Place canisters in appropriate DC
  - Replace lid on unloaded shipping cask and decontaminate

Example 1: Canister Transfer System
(Continued)

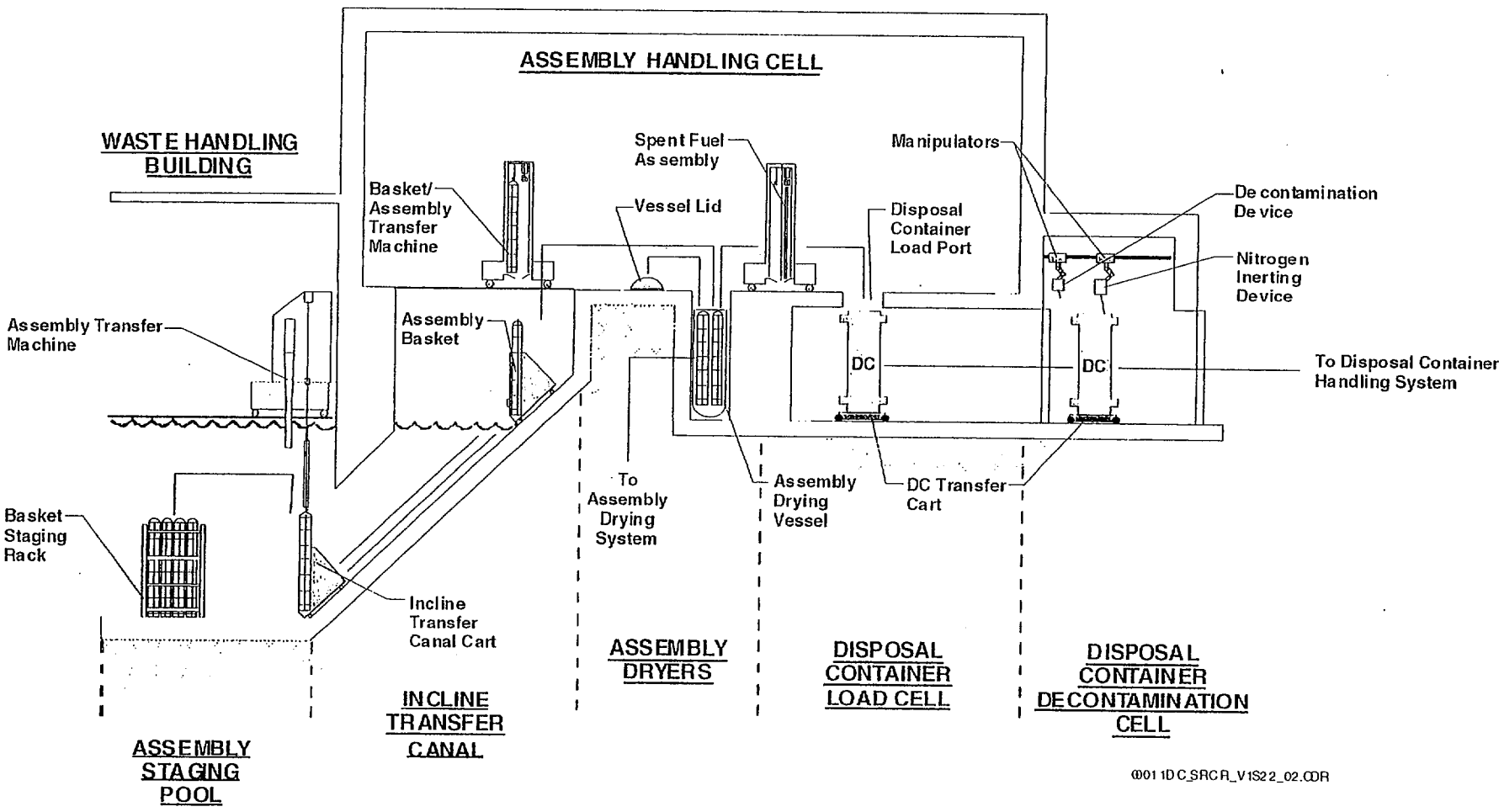
- **Generic Events Applicability (PHL)**
  - Collision/Crushing
    - Drop
    - Slap down
    - Collision
    - Drop on sharp object
  - Explosion/Implosion
    - Decontamination (or other pneumatic or pressurized) system missile due to fractured nozzle/valve stem/pneumatic device

Preliminary CTS Event Tree



Reference: Preliminary Design Basis Event Analysis of DOE SNF, ANL-WPS-SE-000001, Rev 00
Reliability Assessment of Waste Handling Building HVAC System, BCBD00000-01717-0210-00008 Rev 00

Preliminary ATS Design



DC - Disposal Container

ASSEMBLY TRANSFER SYSTEM

Example 2: Assembly Transfer System

Area Description: Spent fuel assemblies (SFAs) or Dual Purpose Canisters (DPCs) are removed from transportation casks while in the unload pool. Assemblies are placed on a transfer cart or staging rack, then transferred to the assembly cell drier, followed by transfer to Disposal Containers (DCs).

- General Functions
  - Move transportation cask to the Preparation Pit
  - Sample cask interior
  - Lid and assemblies are removed in the unload pool
  - Assemblies are placed on transfer cart/in staging rack
  - Assemblies are transferred to the Assembly Cell
  - Assemblies are dried and transferred to the DC

Example 2: Assembly Transfer System
(Continued)

- Generic Events Applicability
  - Collision/Crushing
  - Chemical Contamination/Flooding
  - Fire
  - Radiation/Magnetic/Electrical
  - Thermal

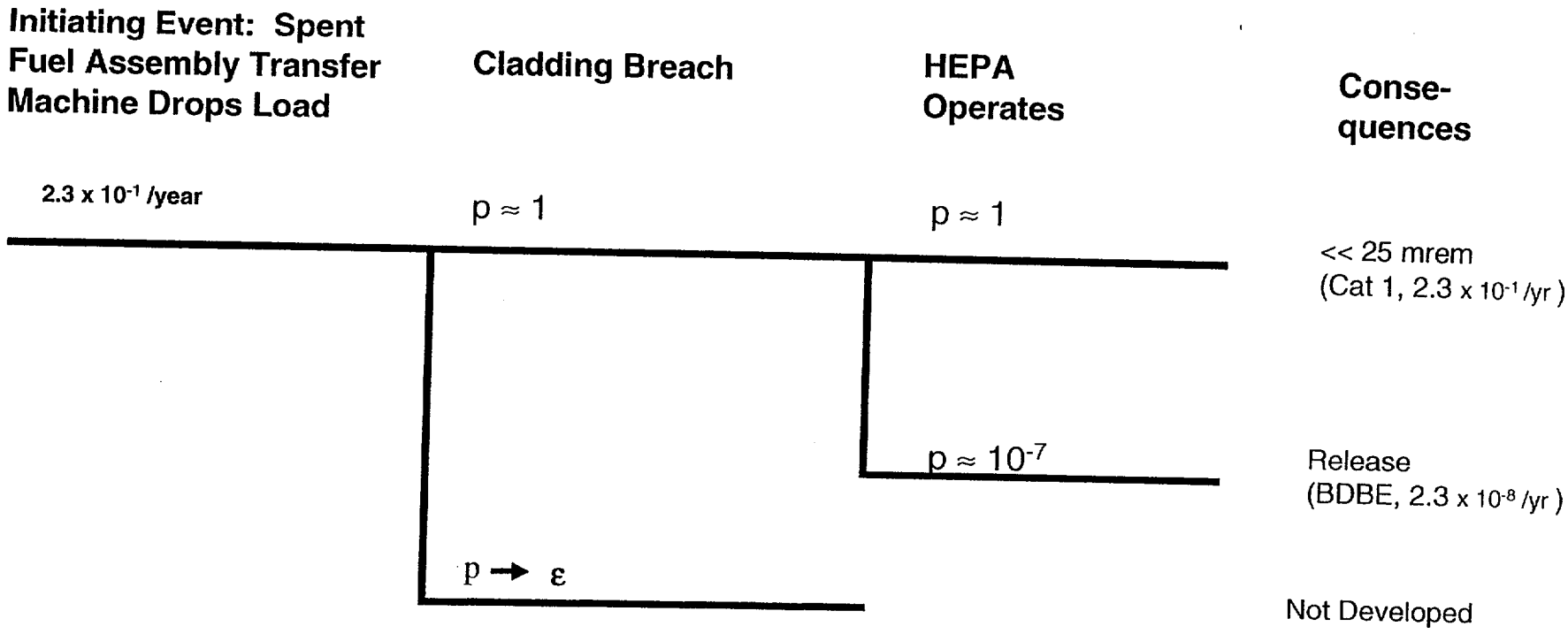
Example 2: Assembly Transfer System
(Continued)

- **Generic Events Applicability (PHL)**
  - **Collision/Crushing**
    - **Drop (Transportation Cask, SFA, and SNF)**
    - **Slap down (Transportation Cask)**
    - **Collision (Transportation Cask, SFA, and SNF)**
  - **Flooding**
    - **Uncontrolled pool water draindown/fill resulting in flooding**

Example 2: Assembly Transfer System
(Continued)

- **Generic Events Applicability**
  - **Fire/Thermal**
    - **SNF overheating/possible zircalloy cladding fire due to loss of pool water**
  - **Radiation**
    - **Radiation contamination due to pool water flooding**
  - **Fissile**
    - **Criticality from rearrangement of cask internals due to drop**

Preliminary ATS Event Tree



λ = (1.8 x 10^{-5} drops/lift) x (13,013 SFA lifts per yr.)
= 2.34 x 10^{-1} drops/year

Design Basis Event Frequency and Dose Calculation for Site Recommendation, CAL-WHS-000001 Rev 00

Summary

- Hazard Analysis provides a systematic method to identify potential initiating events
- Development of accident sequences provides framework for frequency screening and categorization
- Integral steps of Integrated Safety Analysis
- Consistent with proposed 10 CFR Part 63.112

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

Design Basis Events

Presented to:
DOE/NRC Technical Exchange
on Classification Analysis and Graded QA

Presented by:
Ken Ashe
CRWMS Management & Operating Contractor

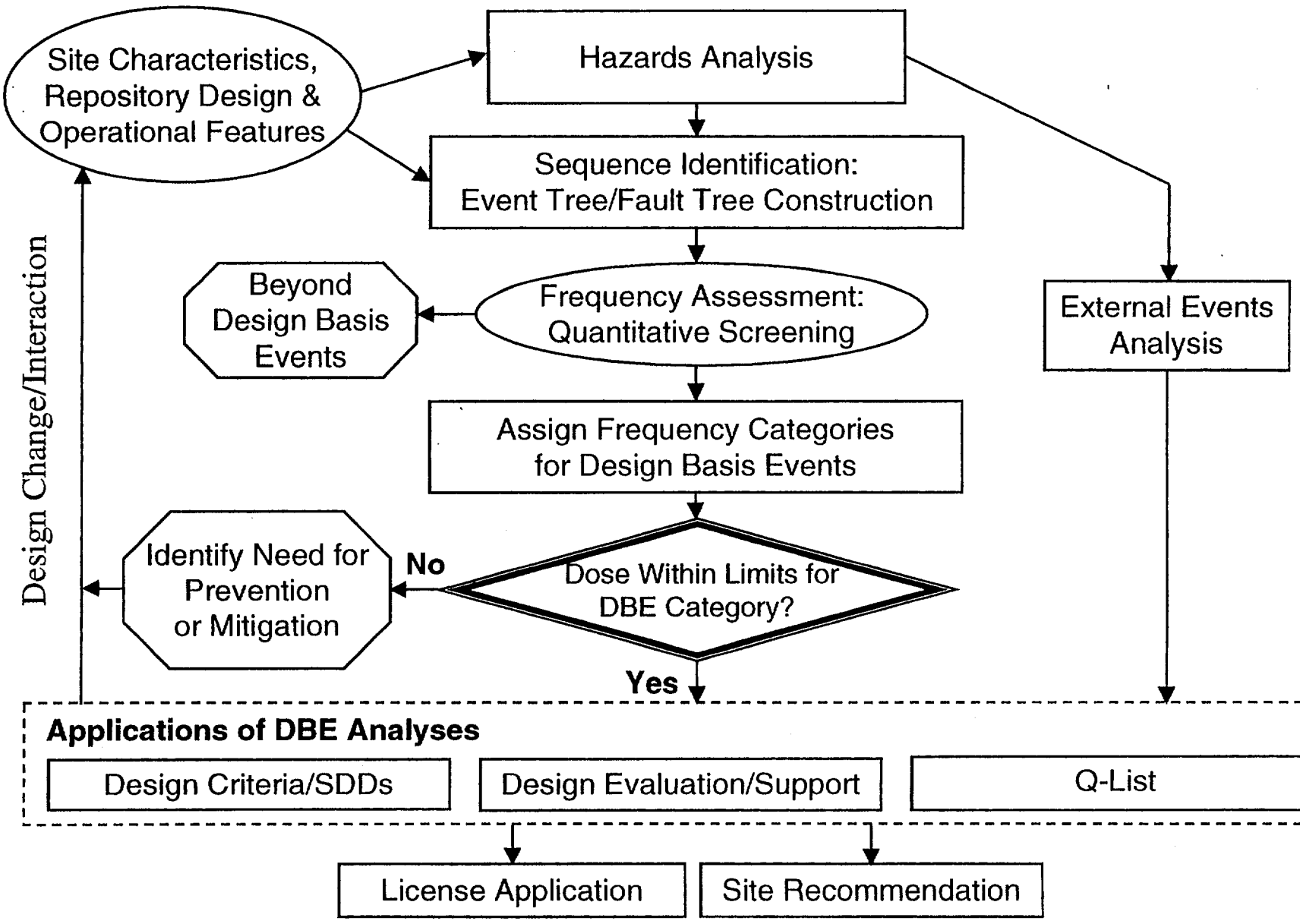
March 8, 2000

YUCCA
MOUNTAIN
PROJECT

Goals and Objectives

- **Establish basis for concurrence with 10 CFR 63 offsite dose criteria applicable to preclosure operations**
  - **DBE categorization**
  - **Offsite dose acceptance criteria**
- **Present LA approach for demonstrating compliance with 10 CFR 63 offsite public dose requirements**

Integrated Safety Analysis



10 CFR 63 DBE Categorization

- **Category 1**
  - ***10 CFR 63.2 definition:***

    "Those natural and human-induced events that are expected to occur one or more times before permanent closure of the Geologic Repository Operations Area"
  - **Interpreted as those conditions of normal operation which are expected to occur one or more times during preclosure facility lifetime**
- **Category 2**
  - ***10 CFR 63.2 definition:***

    "Other natural and man-induced events that have at least one chance in 10,000 of occurring before permanent closure of the geologic repository"
  - **Interpreted as DBEs occurring with frequencies ranging from Category 1 to 10^{-6} per year (i.e., Category 1 > $F_i \geq 10^{-6}$/yr)**

10 CFR 63 Offsite Dose Criteria

Category 1

10 CFR 63.111(b)(1) requires that:

Radiation exposures and radiation levels ... will be maintained within the limits specified in paragraph (a) of this section

1) 10 CFR 63.111(a)(1) "The geologic repository operations area shall meet the requirements of Part 20 of this chapter"
2) 10 CFR 63.111(a)(2) "During normal operations for Category 1 design basis events, the annual dose to any real member of the public, located beyond the boundary of the site shall not exceed a TEDE of 0.25 mSv (25 mrem)"

Category 2

10 CFR 63.111(b)(2) requires that:

"... No individual located on, or beyond, any point on the boundary of the site, will receive the more limiting of a TEDE of 0.05 Sv (5 rem), or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem)"

Event Definition

- **Category 1: Summation of all Category 1 DBEs**
  - **Direct exposure and radiological release calculations performed consistent with guidance provided for power reactors in NUREG-0017[1]**
    - **Annual average**
    - **Realistic operating assumptions and engineering judgement**
  - **Sum all Category 1 direct exposures and releases over facility preclosure lifetime**
  - **Divide sum by facility preclosure lifetime to produce annual average exposure**
- **Category 2: Single Category 2 DBEs**
  - **Direct exposures and radiological releases calculated using conservative assumptions**
  - **Analysis performed for each "single" Category 2 DBE**

[1] ***USNRC, Calculation of Releases of Radioactive Materials in Gaseous and Liquid Effluents from Pressurized Water Reactors, Revision 1, 1985.***

Summary of 10 CFR 63
LA Compliance Approach

DBE Category	Dose Criteria	Analysis Basis
Category 1	25 mrem/yr†	Exposure Source Term: Best-estimate annual average Meteorology: Annual average Receptor: Nearest real member of public Dose Pathways: Direct, immersion, inhalation & ingestion
Category 2	5 rem/event	Exposure Source Term: Conservative single event Meteorology: Conservative worst case Receptor: Individual at maximum location Dose Pathways: Direct, immersion & inhalation

Notes:
† Airborne radiological effluent component limited to 10 mrem/yr by 10 CFR 20.1101(d).

Exposure Source Terms

- **Category 1: Best-estimate annual average**
  - Average waste/crud radiological source terms
  - Maximum expected annual waste receipt rate
  - Best-estimate release fractions
  - Credit for normal operational radioactive waste processing system (e.g., HEPA filters)
  - Potential for exceeding annual average in any given year addressed by facility administrative controls and limits as well as SSC QA classification evaluations
- **Category 2: Conservative single event**
  - Conservative waste/crud radiological source terms
  - Conservative release fractions
  - Mitigation system credit consistent with safety classification

Meteorology

- **Category 1: Annual average**
  - Meteorological dispersion and deposition parameters calculated based on site specific measured data
  - Based on annual average meteorological conditions
  - Parameters calculated for each specific offsite receptor (i.e., real member of public) location
- **Category 2: Conservative**
  - Meteorological dispersion and deposition parameters calculated based on site specific measured data
  - Based on 99.5th percentile conservative meteorological conditions for duration of DBE
  - Parameters calculated for maximum offsite location on or beyond site boundary

Receptors

- **Category 1: Nearest real member of public**
  - Site survey conducted to identify residences and agricultural activities in vicinity of site
  - Dose calculations performed for "real individual" locations identified by site survey
  - Dose from all applicable pathways summed for each location
  - Nearest real member of public identified based on maximum calculated dose for any location
- **Category 2: Individual at maximum location**
  - Maximum dose location on, or beyond, any point on the boundary
  - Individual assumed present for duration of event

Dose Pathways

- **Category 1:**
  - **All applicable direct, inhalation, and ingestion pathways to nearest real individual**
- **Category 2:**
  - **Dose summed for direct, immersion and inhalation pathways**

Preliminary Category 1 DBEs Contribution to Annual Dose

(Developed in accordance with NUREG-0017/01)

Type of Release	Dose (mrem/yr)
Unplanned Operational Events (Wet):	7.4E-06
Unplanned Operational Events (Dry):	5.8E-02
Normal Releases - Surface Facilities:	2.5E-04
Normal Releases - Subsurface Facilities:	2.9E-03
SUM	6.1E-02

Reference: Design Basis Event Frequency and Dose Calculation for Site Recommendation CAL-WHS-SE-000001 Rev00

Preliminary Category 2 DBEs with HEPA Mitigation

Event No.	Description	Sequence Frequency (per year)	SFAs Breached	Skin Dose (rem)	Max Organ Dose (rem)	Offsite TEDE Dose (rem)
2-01	Handling Equipment Drop onto SFA in Pool	2.93×10^{-5}	1-PWR	1.75×10^{-5}	5.02×10^{-6}	9.52×10^{-7}
2-02	Handling Equipment Drop onto SFA in Hot Cell	2.93×10^{-5}	1-PWR	1.75×10^{-5}	3.20×10^{-3}	6.54×10^{-4}
2-03	Handling Equipment Drop onto SFA Basket in Pool	2.14×10^{-5}	4-PWR	7.02×10^{-5}	2.01×10^{-5}	3.81×10^{-6}
2-04	Unsealed DC Collision	6.00×10^{-3}	21-PWR	3.68×10^{-4}	3.58×10^{-2}	8.34×10^{-3}
2-05	Unsealed DC Drop and Slapdown	8.40×10^{-3}	21-PWR	3.68×10^{-4}	3.58×10^{-2}	8.34×10^{-3}
2-06	Handling Equipment Drop onto Unsealed DC	1.35×10^{-6}	21-PWR	3.68×10^{-4}	3.58×10^{-2}	8.34×10^{-3}
2-07	Shipping Cask Drop into Cask Preparation Pit	8.68×10^{-3}	68-BWR	4.30×10^{-4}	1.08×10^{-1}	2.13×10^{-2}
2-08	Shipping Cask Drop into Cask Unloading Pool	8.68×10^{-3}	68-BWR	4.30×10^{-4}	1.35×10^{-4}	2.42×10^{-5}

Reference: Design Basis Event Frequency and Dose Calculation for Site Recommendation
CAL-WHS-SE-000001 Rev00

Conclusions - LA Approach to Demonstrating DBE Compliance with proposed 10 CFR 63

- **LA event classification approach consistent with Part 63 Category 1 and Category 2 definitions**
- **LA offsite dose acceptance criteria require different dose assessment approaches for each event category**
  - **Category 1**
    - **Annual average summation analysis and dose criteria**
    - **Best-estimate source terms and release fractions**
    - **Potential for exceeding annual average in any given year addressed by facility administrative controls and limits as well as SSC classification evaluations**
  - **Category 2**
    - **Single event analysis and dose criteria**
    - **Conservative radiological source terms and release fractions**

Conclusion - LA Compliance Approach

DBE Category	Dose Criteria	Analysis Basis
Category 1	25 mrem/yr†	Exposure Source Term: Best-estimate annual average Meteorology: Annual average Receptor: Nearest real member of public Dose Pathways: Direct, immersion, inhalation & ingestion
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Notes:

† Airborne radiological effluent component limited to 10 mrem/yr by 10 CFR 20.1101(d).

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

QA Strategy for Site Characterization

Presented to:
DOE/NRC Technical Exchange
on Classification Analysis and Graded QA

Presented by:
Don Beckman
CRWMS Management & Operating Contractor

March 8, 2000

YUCCA MOUNTAIN PROJECT

QA Philosophy for Site Characterization

Objectives:

- **Describe the basic philosophy and implementation elements of QA for Site Characterization, including**
  - **QA Classification**
  - **Grading of Control**

QA Philosophy for Site Characterization

- Only 2 QA classification categories are applied to general site characterization activities "Q" or "Non-Q"
- Conservatism aligned with NUREG 1318 principles - more rigorous control than graded programs
- Repository Safety Strategy (RSS) risk informs the classification process via determination of relative importance to waste isolation/safety
- No grading of controls except for data

QA Philosophy for Site Characterization

- Site characterization phase is largely QA "activity" oriented [QARD 2.2.3.A]
- QA program is applied to activities:
  - Affecting waste isolation
  - Scientific sample collection and analysis of data involved in site characterization
  - Waste characterization
- Project's early strategy resulted in essentially all site characterization technical products being classified "Q"...
  - Regardless of relative importance
  - Without grading

QA Philosophy for Site Characterization

- AP-2.16Q, *"Conduct of Activities,"* is used to determine if an activity is subject to QA controls (AP-2.16Q replaced QAP-2-0)
- AP-2.16Q applies to M&O and to USGS via the M&O
- Requires screening for determination of Quality Class (Q, non-Q) prior to start of activity and annually as long as activity continues

QA Philosophy for Site Characterization

- Grading is not being generally applied for site characterization
- Exception is data management
  - Data management process uses RSS to further classify the specific quality requirements applied with grading only applied to the extent of review on VL-2 data*

*Verification Level 2 (VL-2) data is an analytical input that does not support an RSS principal factor and is qualified but tagged "To Be Verified" (TBV)

Data Management
Classification and Grading

- All TBV data was originally generated as "Q"
- Essentially all TBVs were applied globally as part of CAR LVMO-9-C-006, "Data Qualification," i.e., all TBV data is from the same statistical pool
- Data is classified based on the RSS
  - RSS identifies Principal Factors and Disruptive Events "important to waste isolation" or "important to safety"
- RSS further identifies Other Factors that do not materially contribute to waste isolation or safety
- RSS provides basis for data classification and grading

Data Management Classification and Grading
(Continued)

- The data management "TBV" process is described in AP-3.15Q, "Managing Technical Product Inputs"
- AP 3.15Q provides screening process to classify data based on use in support of technical products affecting Principal Factors or Disruptive Events

Data Management
Classification and Grading
(Continued)

- **Grading is then applied to the TBV removal activity known as re-verification**
  - **If data affects an RSS Principal Factor or Disruptive Events, re-verification of applicable quality attributes per AP-3.15Q is required to remove the TBV**
  - **If data does not affect an RSS Principal Factor or Disruptive Events, additional confirmation of quality attributes is not normally required and data is tagged Verification Level 2 (VL-2)**

Data Management
Classification and Grading
(Continued)

- **Elimination of confirmation checklists for VL-2 data is based on performance**
  - Low reject rates for Principal Factor and Disruptive Events data package checklists
  - VL-2 packages are produced from same source
  - Monitoring program with trigger levels based on reject rates to initiate VL-2 evaluations

VL-2 Monitoring Program

- **Implementation of monitoring process via TBV resolution development plan**
  - **Plan administered per AP-2.13Q, "Technical Product Development Planning"**
    - **Supported by Quality Engineering**
    - **Approved by M&O line management**
    - **Overseen by Office of Quality Assurance**
  - **Plan includes explicit instruction steps and criteria for monitoring, trigger levels, and specific actions required**

VL-2 Monitoring Program
(Continued)

Specific Requirements:

- **Reject rates monitored monthly and reported to management**
- **Detailed evaluation reports and causal analysis required when "Failure Rate by Source of Data" exceeds 5%; actions if determined necessary**
- **If failure rate exceeds 10%, confirmation checklist will be performed for VL2 data from affected source or failure mode**
- **If checklists unsatisfactory, data considered unqualified**

Procedure Program Architecture

Procedure Program Architecture

Objectives

- Describe the "Design Philosophy" for current technical product procedures
- Describe the current and future quality procedure hierarchy

Procedure Program History

- PVAR strategy results
- One set of procedures for ALL technical work products at ALL locations
  - Analysis and models
  - Calculations
  - Technical reports
  - Data management
  - Software management)
- Consolidated ≈ about 80 "old" procedures into 24 new consolidated procedures

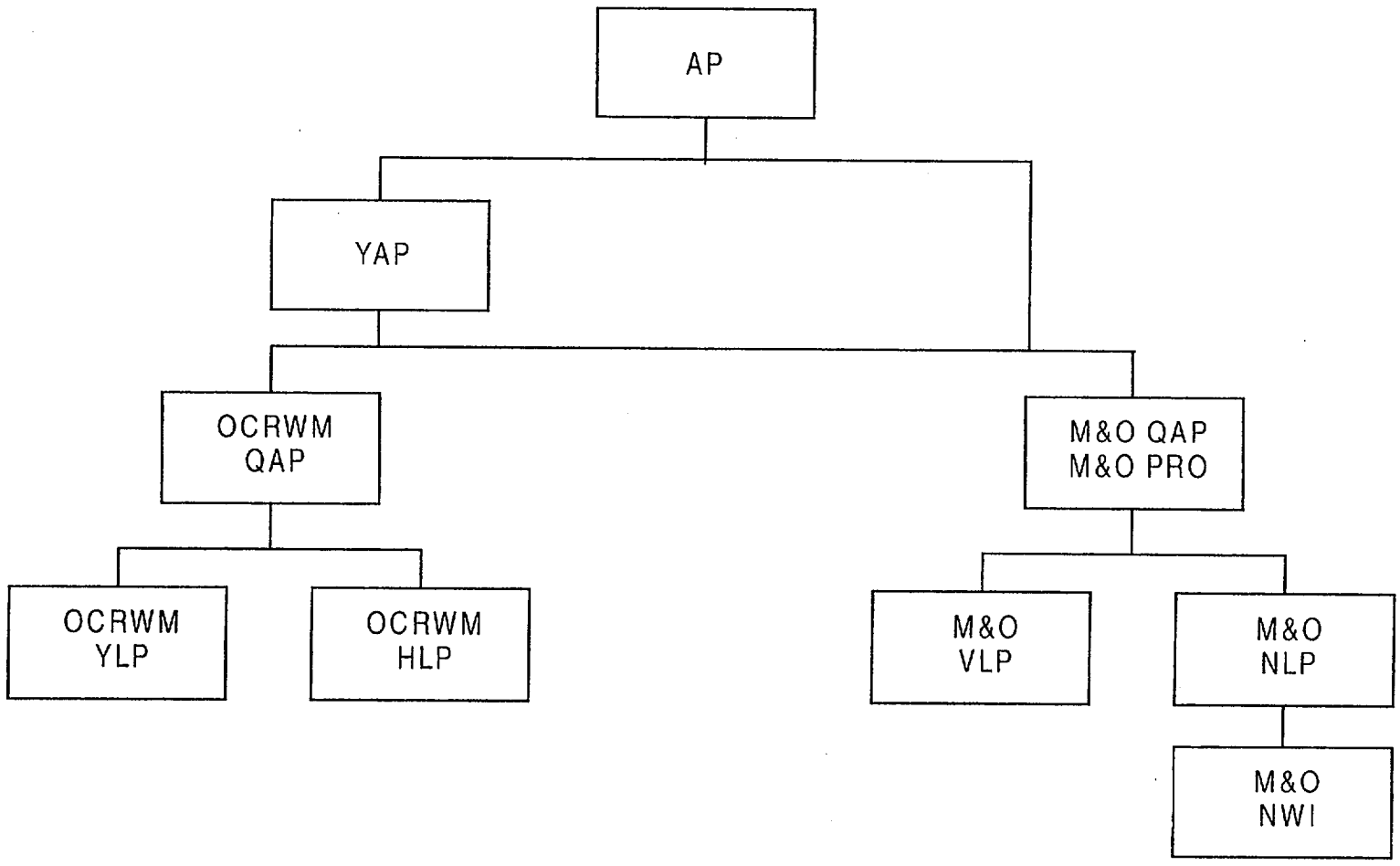
Procedure Architecture History

Procedure Hierarchy

- **APs and YAPs - - OCRWM-wide and YMSCO QA Administrative Procedures**
- **QAPs - - M&O QA Administrative Procedures**
- **XLPs, NWIs - - Line Implementing Procedure & Work Instructions (Headquarters, Nevada)**
- **PROs - - Non-Q Work Procedures**

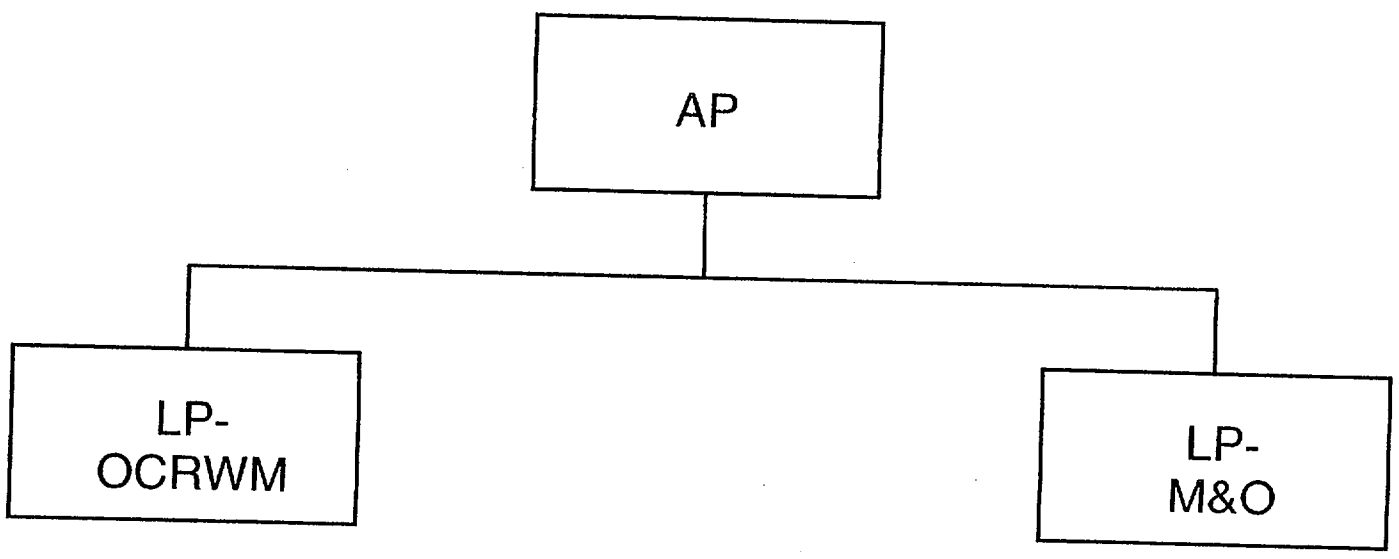
Current Architecture Model

Previous Hierarchy



Procedure Architecture History
(Continued)

Current
Hierarchy Controlled by AP-5.1Q



Transition from "old" to "new" in progress

Current Architecture Model
(Continued)

AP **– A procedure used to establish organizational interface controls and processes for activities performed by multiple affected organizations or used to establish a standard process for an activity that may be implemented by multiple affected organizations.**

Current Architecture Model
(Continued)

LP **– A procedure that prescribes specific responsibilities and processes to be used by a single affected organization or a group within an affected organization.**

Ongoing Program Evolution

- Future plans will continue development and use of RSS to support classification decisions
- RSS will refine identification of Features, Events and Processes that have non-trivial effect on dose (i.e., Principal Factors)

Procedure Performance

- Frequency of procedure changes not extraordinary
  - 3.75 Changes/Month for 27 Procedures
- Nine of the first 30 changes involved minor process changes to simplify or improve
- Nineteen others provided clarifications
- Only 2 changes corrected errors that prevented proper procedure performance

Implementation Experience

- **Results of checking and audits on "In Process" documents**
  - **Processes working except implementation of software management**
  - **Process controls and checking for input management are labor intensive but achieving adequate control**
  - **No identified impacts on technical adequacy of results**

PVAR Procedures/Revision/Time/Audits/Deficiencies

PVAR Procedure	Revision/ICN								
	JUN. '99	JUL. '99	AUG. '99	SEP. '99	OCT. '99	NOV. '99	DEC. '99	JAN. '00	FEB. '00
1. AP-2.1Q, Indoctrination and Training of Personnel	0								
2. AP-2.2Q, Establishment and Verification of Required Education and Experience of Personnel	0								
3. AP-2.12Q, Peer Review	0								
4. AP-2.13Q, Technical Product Development Planning	0					ICN 1 11/16			
5. AP-2.14Q, Review of Technical Products	0								
6. AP-3.4Q, Level 3 Change Control	0			1 9/24		ICN 1 11/17			ICN 2 2/7
7. AP-3.10Q, Analysis and Models	1				ICN 1 10/19				
8. AP-3.11Q, Technical Reports	0					ICN 1 11/24			
9. AP-3.12Q, Calculations	0								
10. AP-3.13Q, Design Control	0							1 1/31	
11. AP-3.14Q, Transmittal of Input	0								
12. AP-3.15Q, Managing Technical Product Inputs	0		ICN 1 8/31			ICN 2 11/22	1 12/15		
13. AP-3.17Q, Impact Reviews	0								
14. AP-3.19Q, Specifications/Drawings	0				ICN 1 10/22				
15. AP-3.20Q, Technical/Design Verifications	0								

PVAR Procedures/Revision/Time/Audits/Deficiencies

PVAR Procedure	Revision/ICN								
	JUN. '99	JUL. '99	AUG. '99	SEP. '99	OCT. '99	NOV. '99	DEC. '99	JAN. '00	FEB. '00
16. AP-5.1Q, Procedure Preparation, Review, and Approval	0			ICN 1 9/17		ICN 2 11/1	ICN 3 12/22		
17. AP-5.2Q, Testing Work Packages	0								
18. AP-6.1Q, Controlled Documents	3 6/30							4 1/4	
19. AP-17.1Q, Record Source Responsibilities for Inclusionary Records	1 6/30			ICN 1 9/2			ICN 2 12/17		
20. AP-AC.1Q, Expert Elicitation	0								
21. AP-REG-001, Managing Lessons Learned	0				1 10/22				
22. AP-SI.1Q, Software Management	1 5/5				2 10/15 ICN 1 10/29		ICN 2 12/15		ICN 3 2/7
23. AP-SIII.1Q, Scientific Notebooks	0								
24. AP-SIII.2Q, Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data	0					ICN 1 11/30	ICN 2 12/15		
25. AP-SIII.3Q, Submittal and Incorporation of Data to the Technical Data Management System	0			ICN 1 9/1			ICN 2 12/15		
26. AP-SIII.4Q, Development, Review, On-Line Placement, and Maintenance of Individual Reference Information Base Data Items	0						ICN 1 12/15		
Audit Performed/Date					1	2,3	4	5,6	7,8
Deficiencies Identified			0	0	2	0	2	0	1

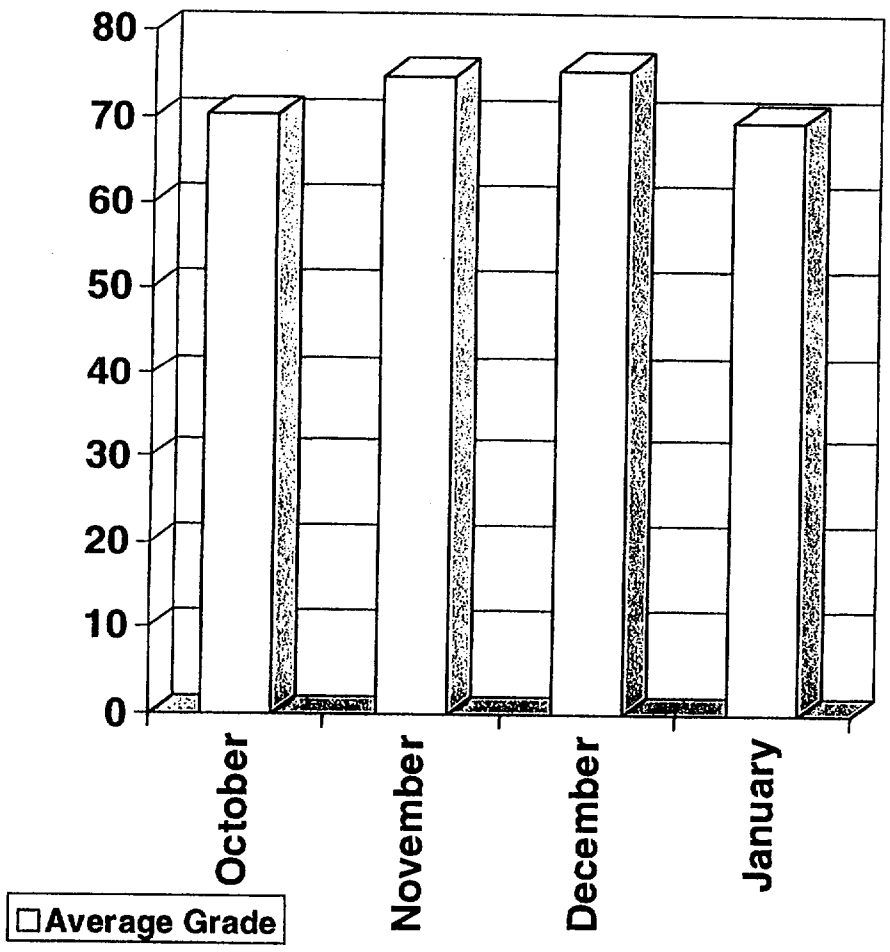
PVAR Procedures/Revision/Time/Audits/Deficiencies

Audits Performed

	Audit No.	Date	Subject	Deficiency/Issue Date	Brief Description
1.	M&O-ARP-99-09	10/11-15/99	ISM-PMR	LVMO-00-D-011/10-26-99 LVMO-00-D-012/10-26-99 DIR to LVMO-98-D-055	Not following AP-3.4Q, R. 1, ICN 0 Unqualified software used in AMRs Control of the Electronic Management of Data
2.	M&O-ARP-00-01	11/8-12/99	WP-PMR	DIR to LVMO-98-C-006	Use of unqualified software
3.	M&O-ARP-00-02	11/15-19/99	Biosphere-PMR	LVMO-00-D-021/12-10-99 LVMO-00-D-023/12-10-99	AP-2.13Q requirements not met RTN requirements not met
4.	LANL-ARP-00-03	12/6-10/99	Busted Butte		
5.	LBNL-ARP-00-04	1/10-14/00	UZ-PMR	USGS-00-D-034/2-12-00	AP-3.10Q requirements not met
6.	M&O-ARP-00-05	1/24-28/00	Waste Form-PMR		
7.	M&O-ARP-00-06	2/7-11/00	EBS-PMR		
8.	M&O-ARP-00-07	2/21-25/00	Disruptive Events-PMR		

Quality of Technical Documents

*Average Grade of Incoming Documents**



Results of Checking

- January results based on 24 documents in checking
- Slight decline a result of first significant volume of Analysis and Model Reports (AMRs) put into checking process

**This grading process is used to provide management and author feedback*

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

QARD Concerns on Classification and Grading

Presented to:
DOE/NRC Technical Exchange
on Classification Analysis and Graded QA

Presented by:
Ram Murthy
Department of Energy

March 8, 2000

YUCCA
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PROJECT

NRC QARD Concerns on Classification and Grading

- **Current QARD Requirements:**
  - QARD Rev-9, Section 2.2.2 and 2.2.3 currently defines items/activities applicable to QA Program
    - QARD Section 2.2.4 allows for grading of QA controls commensurate with functions/risk
    - Current methodology for classification (Basis for Grading) contained in QAP 2-3

Path Forward

- Continue discussions with NRC staff on the technical basis for classification and grading
- Reach agreement on approach and methodology
- Identify changes, if any, necessary to include in QARD after methodology agreed to and finalized

ATTACHMENT-4

CLARIFICATION TO NRC LETTER (REAMER TO BROWNSTEIN)
DATED FEBRUARY 16, 2000
(SUBJECT: STAFF REVIEW OF DOE QARD REV. 9)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 16, 2000

Mr. Alan B. Brownstein, Division Director
Office of Regulatory Coordination Division
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. Nuclear Regulatory Commission Staff Review Of Revision 9 Of The Office Of Civilian Radioactive Waste Management Quality Assurance Requirements and Description

Dear Mr. Brownstein:

In response to your letter dated December 22, 1999, the U.S. Nuclear Regulatory Commission (NRC) staff reviewed the changes identified in Revision 9 of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, document. The QARD was reviewed in accordance with the NRC Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions (Review Plan), Revision 2, dated March 1989.

The Review Plan is the basis for reviewing and determining the acceptability of quality assurance (QA) program documents, which are prepared by the U. S. Department of Energy (DOE) and the DOE program participants (e.g., Quality Assurance Requirements Document (QARD), Quality Assurance Program Description (QAPDs) and participant Quality Assurance Program Plans). The Review Plan also invokes, with exceptions, NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities - 1986," and contains additional review guidance.

As a result of the review, the changes incorporated into Revision 9 of the QARD document are acceptable, and the QARD is considered adequate for controlling DOE's present work activities. However, we would like to point out that certain sections of the QARD document will have to be modified in order for the QARD to be applied to design, construction and preclosure activities. These modifications include changes to sections controlling activities such as graded quality assurance, commercial grade item dedication, records and storage of records using electronic media, and audits.

If you have any questions or require additional information regarding this review, please contact Ted Carter at (301) 415-6684 or Larry Campbell at (301) 415-5000.

Sincerely,

[Original signed by:]

C. William Reamer, Chief
High-Level Waste and Performance
Assessment Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

cc: See List

Clarification:

In the third paragraph of the February 16, 2000, letter from the NRC (C. William Reamer) to DOE (Mr. Alan B. Brownstein), "U. S. Nuclear Regulatory Commission Review of Revision 9 Of The Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description," the NRC stated the following:

> "As a result of the review, the changes incorporated into Revision 9 of the QARD **[QARD refers to the DOE Quality Assurance Requirements and Description Document]** document are acceptable, and the QARD is considered adequate for controlling DOE's present work activities. However we would like to point out that certain sections of the QARD document will have to be modified in order for the QARD to be applied to design, construction, and preclosure activities. These modifications include changes to sections controlling activities such as graded QA **[quality assurance]**, commercial grade item dedication, records and storage of records using electronic media, and audits."

The following is a clarification of the intent of line two in this paragraph:

> As a result of the discussions at the NRC/DOE November 16, 1999, Appendix 7 meeting on the Q-List, it was the NRC staff's understanding that graded QA would be applied to the design process used for the high-level waste repository at Yucca Mountain. Therefore, it was the NRC staff's opinion that it would be necessary for the QARD to be revised in order to apply graded QA controls to design activities. DOE informed the NRC that its current design activities includes the safety-significance categorization of SSCs, and that it did not intend to apply graded QA controls to its current design activities.
>
> It is the NRC staff's opinion that Revision 9 of the QARD contains adequate controls for current design activities for the high-level waste repository at Yucca Mountain. However, should DOE decide to apply graded QA to design, construction, or preclosure activities subject to the provisions contained in the QARD, the QARD would need to be revised to address the graded QA process.