



## Department of Energy

Washington, DC 20585

QA: N/A

APR 04 2000

C. William Reamer, Chief  
High-Level Waste and Performance  
Assessment Branch  
Division of Waste Management  
Office of Nuclear Material Safety  
and Safeguards  
U.S. Nuclear Regulatory Commission  
Two White Flint North  
Rockville, MD 20852

### U.S. NUCLEAR REGULATORY COMMISSION (NRC) AUDITOR OBSERVER INQUIRIES

As a result of the performance-based quality assurance (QA) audits, initiated since the start of fiscal year 2000, the NRC has generated a number of QA Audit Observer Inquiries. These inquiries were submitted by NRC observers, Larry L. Campbell, Robert Brient, Theodore H. Carter, Gerry L. Stirewalt, and William L. Dam. The responses provided to Mr. Stirewalt's and Mr. Carter's comments have already been resolved and are considered closed.

Because the inquiries were technical in nature, the U.S. Department of Energy (DOE) requested that its Civilian Radioactive Waste Management System Management and Operating Contractor evaluate these inquiries and provide a response to each of the remaining inquiries.

Please find two different enclosures, dated March 15, 2000, and March 16, 2000 respectively, which address the inquiries. The first enclosure addresses Mr. Campbell's comments and the second enclosure encapsulates the responses to the four remaining observers. DOE has reviewed these responses and find them to be satisfactory.

It is anticipated that the responses provided herein will be acceptable to your staff. If you have any questions or desire further information, please contact me at (702) 794-5583.

Robert W. Clark, Director  
Office of Quality Assurance

OQA:RWC-1067

#### Enclosures

1. Ltr, 3/16/00, Beckman to Clark, w/encl
2. Ltr, 3/15/00, Beckman to Clark, w/encls



NIMSS07

APR 04 2000

cc w/encls:

W. L. Belke, NRC, Las Vegas, NV  
J. N. Bailey, M&O, Las Vegas, NV  
Donald Beckman, M&O, Las Vegas, NV  
E. P. Opelski, OQA/QATSS, Las Vegas, NV  
R. P. Hasson, OQA/QATSS, Las Vegas, NV  
S. H. Horton, OQA/QATSS, Las Vegas, NV  
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Records Processing Center = "17"

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Safety Systems Inc.

1211 Town Center Drive  
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702.295.5400

**TRW**

QA: N/A

Contract #: DE-AC08-91RW00134  
LV.R&L.DAB.03/00-033

March 16, 2000

Mr. Robert W. Clark  
Acting Director  
Office of Quality Assurance  
U.S. Department of Energy  
Yucca Mountain Site Characterization Office  
Office, M/S 523  
P.O. Box 30307  
North Las Vegas, NV 89036-0307

Dear Mr. Clark:

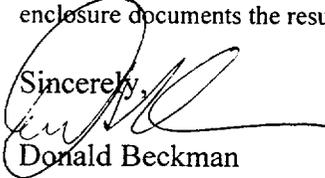
Subject: Response to OCRWN Audit Observer Inquiry from the U.S.  
Nuclear Regulatory Commission During OCRWM-ARC-99-015

Reference:

1. CRWMS M&O 1996. *Design Basis Waste Stream for Interim Storage and Repository*. A00000000-01717-0200-00036 REV 00. Vienna, Virginia: CRWMS M&O. ACC: MOV.19990630.0002
2. OCRWM Audit Observer Inquiry During OCRWM-ARC-99-015 By Larry Campbell of the U.S. Nuclear Regulatory Commission, September 22, 1999.

The potential use of data from *Design Basis Waste Stream for Interim Storage and Repository* (Reference 1) directly as the design basis waste stream, as question in the OCRWM Audit Observer Inquiry (Reference 2), has been investigated. The *Design Basis Waste Stream* report was properly used as an input to the selection of the design basis waste stream but did not constitute the design basis waste stream in and of itself. The report was revised this year (1999) to better reflect the fact that the information it contains is to be used as inputs to the design basis waste stream.. The enclosure documents the results of our investigation.

Sincerely,

  
Donald Beckman  
Acting Licensing Manager  
Regulatory and Licensing Organization  
Management and Operating Contractor

TRW Inc.

**Enclosure 1**

Enclosure

cc w/encls:

R. W. Andrews, M&O, Las Vegas, Nevada  
J. N. Bailey, M&O, Las Vegas, Nevada  
M. A. Balady, M&O, Las Vegas, Nevada  
H. A. Benton, M&O, Las Vegas, Nevada  
K. K. Bhattacharyya, M&O, Las Vegas, Nevada  
Bradford Colton, M&O, Las Vegas, Nevada  
Bryan Dunlap, M&O, Las Vegas, Nevada  
H. T. Greene, QATSS, Las Vegas, Nevada  
G.W. Griffith, M&O, Las Vegas, Nevada  
K. R. Iyengar, M&O, Las Vegas, Nevada  
O. E. Lev M&O, Las Vegas, Nevada  
D. G. McKenzie, M&O, Las Vegas, Nevada  
Les Meyer, M&O, Las Vegas, Nevada  
D. S. Rhodes, M&O, Las Vegas, Nevada  
K. S. Schwartztrauber, M&O, Las Vegas, Nevada  
M. L. Scott, M&O, Las Vegas, Nevada  
D. J. Tunney, QATTSS, Las Vegas, Nevada  
R. C. Wagner, M&O, Washington, D.C.  
D. E. Watkins, M&O, Las Vegas, Nevada

cc w/o enclosures:

S. H. Horton, QATSS, Las Vegas, Nevada

**Response to  
OCRWM Audit Observer Inquiry  
OCRWM-ARC-99-015**

**Overview / Discussion of Data Qualification**

During his observation of audit OCRWM-ARC-99-015, Larry Campbell of the U.S. Nuclear Regulatory Commission (NRC) provided an OCRWM Audit Observer Inquiry regarding the *Design Basis Waste Stream for Interim Storage and Repository* report (CRWMS M&O 1996a).

Although the Audit Observer Inquiry asks four specific questions of the two waste stream reports (answers to which are provided below), the questions appear to frame an underlying question on whether the process of using unqualified data and assumptions in technical analyses was being properly and consistently executed.

The U. S. Department of Energy (DOE) on the Yucca Mountain Project (YMP) differentiates between input data and input assumptions. In this case, unqualified inputs were initially used to develop qualified outputs which were classified as To Be Verified (TBV). Subsequently, it was determined that the unqualified inputs should have been used as bases for assumptions rather than data. Based on this interpretation and the applicable procedure provisions, the qualified outputs should never have been designated as TBV. Assumptions are determined to be suitable as inputs based on appropriate supporting and corroborating information. Further background and clarification of the differentiation between data and assumptions and the treatment of assumptions in general (and in this case) is described in more detail below.

DOE's Administrative Procedures are structured to require that technical analysis inputs should indeed be qualified information if they affect the safety case. Where unqualified information is directly used as a technical analysis input, DOE has control measures in place via AP-3.15Q to assure that the information is reviewed and that proper qualification of the information is completed. Data or input which is not qualified is given a TBV designation, and the TBV data or input is eventually qualified appropriately for its use. These controls are being properly applied to the specific cases that need them.

There is one broad exception to this principle, and that is to permit the use of assumptions as inputs, provided they have appropriate support and corroboration. This position on assumptions is also consistent with commercial nuclear industry accepted practice (and is in many ways more explicitly controlled by our procedures than is typical in the industry). DOE does not intend to qualify information that is only used in the role of assumption support and corroboration, and has implemented appropriate controls via AP-3.15Q for such supporting and corroborating information.

A case in point is the waste stream information addressed in the Audit Observer Inquiry. The design basis report (CRWMS M&O 1996a) provides unqualified waste stream profiles based on current utility spent nuclear fuel inventories and projections of future reactor discharges. Although the inventory information could be qualified, the projection information could not (at least not until the projected quantities have been discharged). The profiles from the design basis report (CRWMS M&O 1996a) are used as input for the *Waste Quantity, Mix and Throughput Study Report* (CRWMS M&O 1997a), which is also unqualified. The throughput report

(CRWMS M&O 1997a) established assumptions on the waste streams that may be inputs to the Total System Performance Assessment (TSPA). Technical specifications may eventually be developed based on these assumptions, and the DOE will need to demonstrate that the actual waste to be emplaced will perform as well as or better than the performance calculated using the waste stream assumptions. Parameter inputs to the TSPA models may be reasonable assumptions and need not be qualified to support repository licensing. The TSPA analyses that use such assumptions will document the use of unqualified inputs as required by AP-3.10Q. The analyses performed to demonstrate the acceptability of individual waste forms will need to use qualified waste form data and models, or will need to demonstrate through margin, bounding analyses, etc. that it is acceptable to use unqualified data (i.e., in compliance with AP-3.10Q or other applicable procedure). Where such data are available to support the TSPA, they may be used directly in the TSPA rather than being represented by assumed waste stream data.

### Answers to Specific Questions

The inquiry contained four specific questions (below with responses).

- 1. Are the data and inputs found in Reference 1 [*Design Basis Waste Stream for Interim Storage and Repository (CRWMS M&O 1996a)*] and the August 15, 1997, Study Report [*Waste Quantity, Mix and Throughput Study Report (CRWMS M&O 1997a)*] being used for Site Recommendation and/or License Application?**

Response--The *Waste Quantity, Mix and Throughput Study Report (CRWMS M&O 1997a)* is being directly used for Site Recommendation. The throughput report is currently identified as an unqualified input to the near-field environment, unsaturated zone transport, and engineered barrier system models that are being run in support of the TSPA for Site Recommendation, which has not yet been drafted. The *Design Basis Waste Stream for Interim Storage and Repository (CRWMS M&O 1996a)* is not being used for Site Recommendation and will not be used for License Application.

- 2. Is any data or inputs obtained from these 2 documents considered qualified?**

Response--The results in the *Design Basis Waste Stream for Interim Storage and Repository (CRWMS M&O 1996a)* report are not considered qualified. The *Waste Quantity, Mix and Throughput Study Report (CRWMS M&O 1997a)* properly uses waste stream profiles from the design basis report (CRWMS M&O 1996a) as unqualified inputs and not as design basis waste streams. The throughput report (CRWMS M&O 1997a) properly classifies its output as unqualified.

- 3. Have any data/inputs from these 2 reports been entered into the Yucca Mountain Project database? If yes, how is it categorized?**

Response--The data/inputs from the design basis report (CRWMS M&O 1996a) and the throughput report (CRWMS M&O 1997a) were not entered into the Yucca Mountain Project database. The waste stream inputs are projections and best estimates and are not required to be entered into the Technical Data Management System.

**4. Has any data been used from these 2 reports in support of other data or inputs? If yes, is such data classified as non-qualified?**

Response--As indicated for the throughput report (CRWMS M&O 1997a), the *Preliminary Design Basis For WP Thermal Analysis* (CRWMS M&O 1997b) report, the *Controlled Design Assumptions Document* (CRWMS M&O 1996b), and the Total System Performance Assessment for Site Recommendation, the waste stream profiles and subsequently selected design basis waste stream data are used in other analyses. These reports identify the respective inputs as unqualified.

**QARD Applicability Questionnaire**

The QARD Applicability Questionnaire cited in the inquiry (ID. No. RW-44-96-0001-1) (DOE 1996) is from HLP-2.3Q, *Quality Assurance Program Controls*. As stated in Section 2.0 of HLP-2.3Q, this procedure is applicable to OCRWM Headquarters (HQ) personnel and direct-support contractor personnel. Although this questionnaire appears to cover the identified report, it only covers data collection from nuclear utilities and software modeling activities for estimating future spent nuclear fuel characteristics and inventories, including DOE reports. The CRWMS Management and Operating Contractor is not a direct-support contractor; this questionnaire does not apply to the *Design Basis Waste Stream for Interim Storage and Repository* (CRWMS M&O 1996a) report.

Instead, QAP-2-0 Activity Evaluation, *Waste Stream Analysis*, (CRWMS M&O 1996c) applies to the design basis report (CRWMS M&O 1996a). This QAP-2-0 evaluation determined that the report is not subject to the QARD requirements. This evaluation does not make a statement similar to the QARD Applicability Questionnaire, i.e., "Not used as design basis." There is no QARD requirement that all inputs used to support the design basis must be qualified. As previously mentioned, the inputs supporting the design basis waste stream will include assumptions regarding that waste stream. DOE plans to describe the assumptions and to explain their basis in an appropriate document or documents.

**Subsequent Documents**

*1999 Design Basis Waste Input Report for Commercial Spent Nuclear Fuel* (CRWMS M&O 1999) was issued to revise the original design basis report (CRWMS M&O 1996a) based on program changes to eliminate the Interim Storage Facility and require CRWMS to be designed to accommodate all commercial spent nuclear fuel available for disposal. This new document made the same statements regarding the unqualified nature of the inputs. In Section 1, it states "representative waste streams were developed as realistic bounding cases based on considerations of the tradeoffs facing utilities and transportation contractors."

*Updated Utility Nuclear Fuel Discharge Projections From 1998* (Heath 1999) provides new projections for the commercial waste stream. The information contained is expected to prompt a revision of the 1999 design basis input report (described above).

## References

CRWMS M&O [Civilian Radioactive Waste Management System Management and Operating Contractor] 1996a. *Design Basis Waste Stream for Interim Storage and Repository*. A00000000-01717-0200-00036 REV 00. Vienna, Virginia: CRWMS M&O. ACC: MOV.19990630.0002.

CRWMS M&O 1996b. *Controlled Design Assumptions Document*. B00000000-01717-4600-00032 REV 04. Las Vegas: Nevada: CRWMS M&O. ACC: MOL.19970130.0039.

CRWMS M&O 1996c. QAP-2-0 Activity Evaluation, *Waste Stream Analysis*. A00000000-01717-2200-00091. Vienna, Virginia: CRWMS M&O. ACC: MOV.19961009.0042.

CRWMS M&O 1997a. *Waste Quantity, Mix and Throughput Study Report*. B00000000-01717-5705-00059 REV 01. Las Vegas: Nevada: CRWMS M&O. ACC: MOL.19971210.0628.

CRWMS M&O 1997b. *Preliminary Design Basis for WP Thermal Analysis*. BBAA00000-01717-0200-00019 REV 00. Las Vegas: Nevada: CRWMS M&O. ACC: MOL.19980203.0529.

CRWMS M&O 1999. *1999 Design Basis Waste Input Report for Commercial Spent Nuclear Fuel*. B00000000-01717-5700-00041 REV 00. Vienna, Virginia: CRWMS M&O. ACC: MOV.19991006.0003.

Heath, C.A. 1999. Letter report. "DE-AC08-91RW00134: *Updated Utility Nuclear Fuel Discharge Projections From 1998*, (Activity No. 3123D030, WBS 3.1.2.3)". From C.A. Heath (CRWMS M&O) to D. Shelor (DOE-RW). October 22, 1999. Vienna, Virginia: CRWMS M&O. ACC: not available at this time.

DOE [U.S. Department of Energy] 1996. QARD Applicability Questionnaire. ID. No.: RW-44-96-0001-1. July 18, 1996. Washington, D.C.: U.S. Department of Energy, Office of Civilian Radioactive Waste Management.

Contract #: DE-AC08-91RW00134  
LV.R&L.NJC.03/00-029

March 15, 2000

Mr. Robert W. Clark, Director  
Office of Quality Assurance  
U. S. Department of Energy  
Yucca Mountain Site Characterization  
Office, M/S 523  
P.O. Box 30307  
North Las Vegas, NV 89036-0307

Dear Mr. Clark:

Subject: Reevaluations of Responses to Nuclear Regulatory Commission  
(NRC) Audit Observer Inquiries

Enclosed are the subject reevaluations, as requested in Office of Quality Assurance (OQA) letters (R.W. Clark to J. N. Bailey) dated January 24 & January 26, 2000. The subject reevaluations address NRC Audit Observer Inquiries associated with OQA Audits as follows:

1. Integrated Site Model Audit, M&O-ARP-99-009, of October 11 – 15, 1999, including NRC Audit Observer Inquiries M&O-ARP-99-009-01, M&O-ARP-99-009-02, and M&O-ARP-99-009-03 (Enclosure 1).
2. Biosphere Analysis and Modeling Report Audit, M&O-ARP-00-02, of November 15-19, 1999, including NRC Audit Observer Inquiries M&O-ARP-00-02-01, and M&O-ARP-00-02-02 (Enclosure 2).

Additionally, please note that NRC Audit Observer Inquiries associated with Audit OCRWM-ARC-99-015 (Yucca Mountain Division Audit of the OCRWM Headquarters Quality Assurance Program, of September 21-23, 1999) are being reevaluated separately, and will be provided to you under separate cover.

March 15, 2000

Page 2 of 2

If you have any questions, please feel free to contact me at 295-4392 or Samuel Hobbs at 295-6620.

Sincerely,



D. A. Beckman, Manager  
Licensing Dept.  
Management & Operating Contractor

NJC/lmh

Enclosures:

- 1) Integrated Site Model Audit M&O-ARP-99-009 NRC Audit Observer Inquiries
- 2) Biosphere Analysis and Modeling Audit M&O-ARP-00-02 NRC Audit Observer Inquiries

cc w/encls:

RPC = 9 pages

**Enclosure 1**  
**Integrated Site Model Audit M&O-ARP-99-009 NRC Audit Observer Inquiries**

The formal responses to M&O-ARP-99-009 audit observer inquiries as requested by the Office of Quality Assurance are provided below.

**Audit Observer Inquiry Number M&O-99-009-01**

- 1) How are the 1200-1300 DTNs supporting the AMRs prioritized?
- 2) What criteria are used to determine the significant/important DTNs?
- 3) How are the more significant DTNs being scheduled for completion?
- 4) It is our understanding that 80% of the data to be used for the LA will be available at the time of SR. Will this include all of the scientific and engineering software issues?

**Evaluation**

The OQA requested reevaluation of the original M&O response to audit observer inquiry M&O-ARP-99-009-01, new formal response as appropriate, and status (letter OQA-JB-0604 dated January 24, 2000, R.W. Clark to J. N. Bailey). The M&O response originally provided to the NRC (Ted Carter) was found satisfactory without exception as noted in e-mail correspondence (S. Horton to S. Hobbs) sent on February 15, 2000, at 2:40 PM.

Status: No change has occurred to affect the responses to questions 1, 3, and 4 of this inquiry. However, an update to question 2 of this inquiry is provided.

Original response to question 2: "Screening criteria have been developed to implement the priorities described under Question 1. These criteria are based on how the data is used in the analysis of principal factors and disruptive events. Draft criteria are currently being incorporated in our procedures and are available for review."

Updated response to question 2: The screening criteria based on how the data is used in the analysis of principal factors and disruptive events were incorporated into AP-3.15Q *Managing Technical Product Inputs*, Rev. 1, effective December 15, 1999, and remain in the revised procedure effective February 18, 2000, as Rev. 1, ICN 1.

**Audit Observer Inquiry Number M&O-99-009-02**

- 1) The ISM is developed by combining the GFM, RPM, MM. Considering that QA/QC should assure the quality and consequent usability of the final ISM product, will the ISM be reviewed/viewed during the audit as well as the separate pieces (i.e., GFM, RPM, MM)?
- 2) Assuming the ISM is a 3D property model running in EV software, is R. Clayton responsible for assembling the 3 pieces into a single ISM?
- 3) Is it not practical to determine that implementation of procedures has lead to generation of a functional ISM by examining [the] 3D model with EV software?

**Enclosure 1**  
**Integrated Site Model Audit M&O-ARP-99-009 NRC Audit Observer Inquiries**

**Evaluation**

The OQA requested reevaluation of the original M&O response to audit observer inquiry M&O-ARP-99-009-02, new formal response as appropriate, and status (letter OQA-JB-0605 dated January 26, 2000, R. W. Clark to J. N. Bailey). The M&O response originally provided to the NRC (Gerry L. Stirewalt) was found satisfactory without exception as noted in e-mail correspondence (S. Horton to S. Hobbs) sent on February 14, 2000, at 11:12 AM.

Status: No change has occurred to affect the response to questions 1-3 of this audit inquiry since originally provided.

**Audit Observer Inquiry Number M&O-99-009-03**

- 1) The audit team focused on reviewing technical aspects of geophysical logs. Has other data that are used to correlate GMF lithostratigraphic contacts been audited? These data include cores, cuttings and downhole videos.
- 2) Does this data (from cores, etc.) correlate with geophysical logs?
- 3) Has porosity and mineralogy data represented in RPM & MM been used to improve or verify the horizons (or other geologic information) in GFM to full integrate ISM?
- 4) Has data from RPM & MM been restricted or removed due to limitations of GFM? A detailed list of data used (and not used) in ISM is needed.
- 5) The Calico Hills unit in GFM is represented by 2 units that are not based on vitric or zeolitic percentages. Can the data from the mineralogy model improve the representation of these vitric and zeolitic sequences within the ISM?
- 6) Has the audit team evaluated the sufficiency of data present in the 3 models? Has the ISM been evaluated by statistical methods to determine spatially varying uncertainty as was done in RPM (see p. 177 of AMR).

**Evaluation**

The OQA requested reevaluation of the original M&O response to audit observer inquiry M&O-ARP-99-009-03, new formal response as appropriate, and status (letter OQA-JB-0606 dated January 26, 2000, R. W. Clark to J. N. Bailey). The M&O response originally provided to the NRC (Bill Dam) was found satisfactory with one exception as noted in e-mail correspondence (S. Horton to S. Hobbs) sent on February 12, 2000, at 06:13 AM.

The noted exception was the response to M&O-99-009-03, question 6, part 2: "Has the ISM been evaluated by statistical methods to determine spatially varying uncertainty as was done in RPM (see p. 117 of AMR)." The response originally provided by K. Kersch (M&O) from discussion with R. Clayton (M&O) was "Statistical methods were not used."

## Enclosure 1

### Integrated Site Model Audit M&O-ARP-99-009 NRC Audit Observer Inquiries

N. Chappell-O'Neill (M&O Licensing) met with R. Clayton, T.R. Crump, and G. Nieder-Westermann, all of the M&O, to form the following response:

The *Integrated Site Model Process Model Report* (PMR) (TDR-NBS-GS-000002, REV 00, ICN 01) documents the three individual models discussed in the Analysis/Model Reports (AMRs):

- *Rock Properties Model (RPM3.1) AMR* (MDL-NBS-GS-000004, REV 00, ICN 01)
- *Mineralogic Model (MM3.0) AMR* (MDL-NBS-GS-000003, REV 00, ICN 01)
- *Geologic Framework Model (GFM3.1) AMR* (MDL-NBS-GS-000002, REV 00, ICN 01).

Geostatistical methods, if used, would not be applied to the Integrated Site Model (ISM) PMR itself; such methodology would be used in the three supporting models.

Only in the Rock Properties Model (RPM3.1) were geostatistical methods applied to developed data and used to determine spatially varying uncertainty.

In the Mineralogic Model (MM3.0) an inverse-distance calculation was the methodology used. While the AMR acknowledges that geostatistical methods could have been applied in MM3.0 to improve accuracy, a correlation between geophysical data and the sparse available mineralogic data would first have been required.

The methodology used in the Geologic Framework Model (GFM3.1) was a combination of mathematical grid construction and applied interpretive constraints (algorithms and hand contouring). Uncertainties and limitations using this method are associated with data restrictions. Uncertainties in the geologic framework increase vertically below, and horizontally between, boreholes and in the less-penetrated deeper geologic formations. Geostatistical techniques were not used to estimate uncertainty because of faulting and tilting in the modeled area and the sparseness of data. Two methods (piecewise reconstruction and contouring uncertainty estimation) were used in examination of the modeling processes to determine uncertainty related to gridding, contouring, interpreting, and interpolating. Used together, the two methods provide bounds to uncertainty and additional confidence to the estimation.

R. Clayton related that, during the June 3-4, 1999, DOE/NRC Technical Exchange on the GFM3.1, the use of geostatistical methodology for the GFM was discussed as a possibility but that any such use would be in development of the next model revision. While geostatistical methodology could provide the benefit of reproducibility in the next GFM revision, no decision to include geostatistical methodology has been made at this time. This question will be addressed in Fiscal Year 2001 planning.

Status: No change has occurred to affect the response to questions 1-5 and 6, part 1 of this audit inquiry since originally provided.

**Enclosure 2**  
**Biosphere Analysis and Modeling Audit M&O-ARP-00-02 NRC Audit Observer**  
**Inquiries**

The formal responses to M&O-ARP-00-02 audit observer inquiries as requested by the Office of Quality Assurance are provided below.

**Audit Observer Inquiry M&O-ARP-00-02-01**

AP 3.10Q (as well as the QARD) are not specific regarding which calculations/analyses are subject to validation. M&O Environmental, Safety, & Regional Programs Office Staff do not appear to have an understanding or strategy of model validation as it applies to Biosphere AMRs/PMRs.

**Evaluation**

The OQA requested reevaluation of the original M&O response to audit observer inquiry M&O-ARP-00-02-01, new formal response as appropriate, and status (letter OQA-JB-0608 dated January 26, 2000, R.W. Clark to J. N. Bailey).

AP 3.10Q, "Analyses and Models," has been revised to clarify the distinction between models and analyses and the approach to validation (AP 3.10 Q, Revision 2, ICN 0, Effective 02/25/2000).

Appropriate personnel including AMR originators, checkers, leads, supervisors, responsible managers, and potential reviewers have been trained on the clarifications to model validation requirements provided in AP 3.10Q, Revision 2, ICN 0.

A team led by the Performance Assessment Group has completed an impact analysis of all AMRs that had been approved prior to 02/25/2000. This team has recommended that issues arising from the review be addressed in Revision 01 to the AMR or, in some cases, via ICNs.

**Audit Observer Inquiry M&O-ARP-00-02-02**

Documented resolution of individual comments is not required for checks of analyses and models (AP 3.10Q) and is optional for reviews of technical products (AP 2.14Q). A lack of documented resolution is inconsistent with the QARD, Section 2.2.10. (F), that requires that mandatory comments shall be documented and resolved before approving the document. Note that the audit of the Integrated Site Model (ISM) also identified several recommendations concerning the review processes of AP 3.10Q and AP 2.14Q.

**Evaluation**

The OQA requested reevaluation of the original M&O response to audit observer inquiry M&O-ARP-00-02-02, new formal response as appropriate, and status (letter OQA-JB-0607 dated January 26, 2000, R.W. Clark to J. N. Bailey).

**Enclosure 2**  
**Biosphere Analysis and Modeling Audit M&O-ARP-00-02 NRC Audit Observer**  
**Inquiries**

AP 3.10Q, "Analyses and Models," has been revised to require documentation of comment resolution (Sections 5.5.3, 5.5.4, 5.5.5 and 5.5.6, AP 3.10 Q, Revision 2, ICN 0, effective 02/25/2000) in accordance with AP 2.14, "Review of Technical Products," Revision 0, ICN 0, Section 5.3, "Comment Resolution and Concurrence."

The revision to AP 3.10Q, Section 5.5.6 requires written justification in cases where review under AP 2.14 is not required, i.e., when it is determined that an analysis, model or a revision thereto, does not impact an organization other than the originating organization.

All AMR originators, checkers, leads, supervisors, responsible managers, and potential reviewers have been trained on the revisions to AP 3.10Q, which require documentation of comment resolution.