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

February 4, 2000

Mr. Dwight Shelor, Acting Director
Program Management and Administration
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT REPORT NO. OAR- 00-03, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-002"

Dear Mr Shelor:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-00-03 of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD), audit of the Biosphere Process Model Report (PMR) activities performed by the OCRWM Management and Operating Contractor (M&O). The audit, M&O-ARP-00-002, was conducted on November 15-19, 1999, at the M&O facilities in Las Vegas, Nevada.

This audit was limited in scope and evaluated the effectiveness of the implementation of the OCRWM QA Program described in the Quality Assurance Requirements and Description (QARD) and its implementing procedures for selected analysis model reports (AMRs) supporting the Biosphere PMR.

The NRC staff determined that this audit was effective in identifying deficiencies and recommending improvements in the AMR process. During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis reports, and software within the scope of the audit to confirm that it was properly qualified. The NRC observers determined that: a) the software supporting the AMRs had been properly qualified; and b) certain data categorized as "accepted data" were determined to be controlled in accordance with established procedures and properly categorized as "accepted data."

The NRC staff generally agrees with the audit team conclusions, findings, and recommendations. However, as noted in Section 4.7 of this report, the NRC staff expressed a concern about the adequacy of the process controlling the preparation and use of procedures for the AMR process. Further, as discussed in various sections of this report, the NRC staff is concerned about the lack of data qualification activities for the AMRs reviewed during this audit and the two previous audits. Accordingly, this condition appears to be a condition requiring DOE's management attention.

As discussed in Section 4.7.1 of the attached report, the NRC observers generated two audit observer inquiries (AOIs) questioning the process used for the validation of analysis and models, and concerning documenting the resolution of a reviewer's comments Also, we would

like to point out that we have not received a response to an AOI, dated September 22, 1999, which addressed the qualification status and use of the waste stream profiles

A written response to this letter and the enclosed report is not required. However, we do expect OQA to provide replies to the open AOIs. If you have any questions, please contact Larry L. Campbell of my staff at (301) 415-5000.

Sincerely,

Reg Stableen
for

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

Enclosure: NRC Observation Audit Report No. OAR-00-03, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-002"

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U S NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-03

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-002

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1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management and contractors from the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD) audit of the Biosphere Process Model Report (PMR) activities performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-002, was conducted on November 15–19, 1999, at the M&O facilities in Las Vegas, Nevada.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, by reviewing selected analysis model reports (AMRs) supporting the Biosphere PMR. During the audit, selected AMRs were subjected to a technical review as well as review to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC staff objective was to gain confidence that the M&O and OQA are properly implementing the provisions contained in the QARD and the requirements contained in Subpart G, Quality Assurance, to Part 60, of Title 10 of the Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the site recommendation (SR) in November 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting SR are properly qualified; and 2) reviewing the progress being made by DOE and its contractors in meeting the qualification goals for SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of AMR development.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit M&O-ARP-00-002 was useful, effective, and conducted in a professional manner. Audit team members were independent of the activities they audited and appeared to be knowledgeable in the QA and technical disciplines within the scope of the audit. The audit team members' qualifications were reviewed and the members were found to be qualified in their respective disciplines.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. Seven deficiency documents were generated during the audit. Two deficiencies were documented on deficiency reports (DRs) and four were documented on deficiency identification and referral (DIR) documents that add the conditions identified in this audit to those previously identified in currently open corrective action requests (CARs) or DRs. One deficiency was corrected during the conduct of the audit. Eight recommendations were offered for improvements and enhancements to the AMRs and to the procedures controlling various elements of the AMR process.

The NRC staff determined that this audit was effective in identifying deficiencies and recommending improvements in the AMR process. During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis reports, and software within the scope of the audit to confirm that it was properly qualified. The audit team and the NRC observers determined that the software supporting the AMRs had been properly qualified. The audit team and the NRC observer's also determined that certain data, categorized as "accepted data," were controlled in accordance with procedures and properly categorized as "accepted data."

The NRC staff generally agrees with the audit team conclusion's, findings, and recommendations. However, as noted in Section 4.7 of this report, the NRC staff expressed a concern about the adequacy of the process controlling the preparation and use of procedures controlling the AMR process. Further, as discussed in various sections of this report, the NRC staff is concerned about the lack of data qualification activities for the AMRs reviewed during the audit and the two previous audits. This appears to be a condition requiring DOE's management attention.

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Robert Brient	Team Leader	CNWRA
Kien Chang	Technical Specialist	NRC
Larry Campbell	Senior QA Engineer	NRC (Part time audit observer)
Patrick LaPlante	Technical Specialist	CNWRA

3.2 OQA Audit Team

Donald Harris	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Kenneth McFall	Auditor	OQA/QATSS
Larry Abenathy	Auditor	OQA/QATSS
Harvey Dove	Technical Specialist	OQA/QATSS
Brenda Bowlby	Technical Specialist	Management and Technical Services(MTS)
Chag-Hsiung Tung	Technical Specialist	M&O

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of the M&O was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Performance/Deficiency Reporting." The NRC staff's observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

4.1 Scope of the Audit

The audit team conducted a limited scope, performance based audit of activities and processes related to the development of the AMRs supporting the Biosphere PMR. AMRs, software, and data were evaluated during the audit process. The audit included review of the programmatic controls governing the AMRs and technical requirements contained in the AMRs. The following procedures and AMRs supporting the Biosphere PMR were reviewed by the audit team and the NRC observers during the audit:

Procedures

a) AP-2.13Q, "Technical Product Development Planning," Revision 0, with Interim Change Notice (ICN) No. 1

b) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 0

c) AP-3.15Q, "Managing Technical Product Inputs," Revision 0, with ICN No. 1

d) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 0

e) AP-3.10Q, "Analysis and Models," Revision 1, with ICN No. 0

f) AP-2.14Q, "Review of Technical Products," Revision 0, with ICN No. 0

g) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0

h) YAP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 1

i) QAP-SIII-1, "Scientific Investigations", Revision 3

Analysis Model Reports

a) ANL-MGR-MD-000008, "Transfer Coefficient Analysis," Revision 00

b) ANL-MGR-MD-000002, "Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods," Revision 00

c) ANL-MGR-MD-000003, "Disruptive Event Biosphere Dose Conversion Factor (BDCF) Analysis " (Draft)

4.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team demonstrated a sound knowledge of the applicable M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate ongoing Biosphere PMR activities. However, the audit team was unable to confirm that data supporting the AMRs had been properly qualified because no qualification

activities had been initiated by M&O for this data. The NRC staff considers the lack of data qualification activities during this audit and the two previous PMR audits to be a condition requiring OQA management attention. The NRC staff suggests that OQA management evaluate the need to conduct audits specifically to evaluate the qualification of data.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management (with the NRC observers present) were held each morning to discuss the current audit status and preliminary findings.

4.3 Audit Team Qualification and Independence

The qualifications of the audit team leader and the OQA audit team members were found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by the NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they audited. In addition, training, education and experience records for audit team members were reviewed and found acceptable.

4.4 Examination of Quality Assurance Elements

The OQA programmatic and technical audit activities were conducted simultaneously using sub-audit teams consisting of a technical specialist and a QA auditor. The limited scope audit focused on the QA elements closely associated with the development of the AMRs. The NRC observation team evaluated the audit team's review of the following QA elements.

4.4.1 AP-2.13Q "Technical Product Development Planning"

The auditors reviewed technical development plans (TDPs) and work product planning sheets (WPPS) applicable to the subject AMRs. A deficiency in the implementation of planning was identified regarding electronic management of data not being addressed in the TDP and a TDP with content not meeting specified requirements.

4.4.2 AP-SI.1Q "Software Management"

GENII-S Version 1.485 is the computer software that will be used for many of the Biosphere AMRs, including those AMRs subject to this audit. The auditors reviewed its qualification documentation which was determined to meet the requirements of the software management procedure. This software had also been re-verified after general software qualification concerns were identified in the previously issued CAR-006. The NRC observers agreed with the audit team that the GENII-S software had been properly qualified.

4.4.3 AP-3.15Q "Managing Technical Product Inputs"

Each of the AMRs examined included document input reference sheets that list the inputs to and references cited in the AMR. The document input reference sheets also identify the status of the input, (e.g., qualified, to be verified (TBV)). At the time of the audit, the TBV status had not been removed for any of the Biosphere AMR input documents.

Documents cited as references or as corroborating data were given the status of not applicable along with a brief explanation. However, AP-3.15Q does not have provisions for this. The AMR developers consulted with the author of AP-3.15Q and came up with the N/A designation. During the audit, M&O staff initiated a change request to AP-3.15Q to attempt to clarify the use of references that are not directly used as inputs.

The auditors noted that one reference was inadvertently omitted from the document input reference sheets for the draft AMR for disruptive event BDCF analysis. This deficiency was corrected during the audit.

The status of the input documents for the three AMRs is summarized as follows:

a) Transfer Coefficient Analysis: Most of the documents were classified as unqualified corroborating data (N/A). One input is classified as TBV because it is unconfirmed after a CAR cast uncertainty about the qualification status of data. A TBV tracking number (3059) has been assigned to this document as required by AP-3.15Q.

b) Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods: Several documents listed in the document input reference sheets are classified as N/A, used for reference only. One document is classified as 'Accepted,' its source being a Federal Guidance Report issued by the U.S. Environmental Protection Agency (EPA). A document tracked by TBV tracking number 3059 was used in this AMR.

c) Disruptive Event Biosphere Dose Conversion Factor Analysis: All of the inputs used in this AMR are from other Biosphere AMRs, most of which have not been issued. These inputs are classified as TBV Several references are identified and given the N/A classification.

4.4.4 AP-SIII.2Q "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data"

Requests to qualify two reports concerning food consumption surveys had been initiated. At the time of the audit, no data qualification had been completed. The audit team confirmed that two sets of data from EPA Federal Guidance Reports used in the biosphere AMRs have completed the process for "accepted data" in accordance with AP-SIII.2Q. "Accepted data," as defined by the QARD, are data considered as established fact (e.g., engineering handbooks, density table, gravitational laws, or other physical constants) or data generally accepted by the scientific and engineering community and found to be technically defensible by those using it. The NRC observers agreed with the audit team that the subject data had been properly categorized.

4.4.5 AP-3.10Q "Analysis and Models"

The three AMRs evaluated during this audit are considered analyses. AP-3.10Q provides control for both analysis and models. The development and technical checking processes described in AP-3.10Q have been completed for the Transfer Coefficient Analysis and Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods AMRs. The Disruptive Event Biosphere Dose Conversion Factor Analysis AMR was in review and comment resolution during the audit.

None of the three AMRs had been subjected to model validation at the time of the audit. An interview with Biosphere PMR management indicated that they were not certain when or if model validation was necessary. The audit team identified the lack of model validation as a deficiency and recommended that AP-3.10Q be revised to clarify the criteria for determining if an activity is an analysis, a model (therefore requiring validation), or both. The NRC observers initiated an audit observer inquiry (AOI) to the audit team to assure that the NRC staff is aware of the resolution of this issue (see Section 4.7.1 of this report). The NRC staff believes that to properly support licensing decisions, calculations must be performed using validated model(s) as well as qualified data and software.

The two completed AMRs had been subjected to the technical checking process. While described as checking, the review and reviewer criteria suggests that this activity represents the substantive review by a subject matter expert. The audit team noted that AP-3.10Q requires only that the checker document comments on a "check copy" of the document. AP-3.10Q does not require that the resolution of comments be documented except for the checker's signature. While responses were provided for some comments in the "check copy," many were not responded to.. In several cases, the auditors could not trace the checker's comment through to a revision in the document being reviewed. This condition was identified as a deficiency and the audit team made a strong recommendation that available comment resolution forms be used. The auditors also found one occasion where the checker failed to address one of the specified review criteria and the document was issued despite failing to meet the objective of its development plan.

The audit team determined that the AMR author had not included sufficient detail in the justification of technical judgements in the Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods AMR. This was included in the deficiency concerning AP-3.10Q.

4.4.6 AP-2.14Q "Review of Technical Products"

The AMRs reviewed were subjected to the technical review process. The AP-2.14Q technical reviews are performed by organizations that are external to the organization that prepared the AMR and serve primarily as interface reviews.

AP-2.14Q allows several options for documenting comments and their resolution. For the AMRs in this audit, all used a markup of the document rather than requiring comment resolution. The audit team strongly recommended the use of the OCRWM comment sheet. The NRC staff concurs with this recommendation.

4.5 PRIORITIZATION OF QUALIFICATION ACTIVITIES

During the observation of the Biosphere PMR audit, the NRC observers met with DOE and M&O in order to obtain information on the process being used to prioritize the qualification of data, software, and models supporting its site recommendation (SR).

4.5.1 Background

The latest information provided by DOE at the time of the audit on its qualification of the data, software, and models supporting the SR was that: a) the qualification and validation of inputs

for the SR will be prioritized and evaluated in order of their importance; b) approximately 50 percent of the inputs for the SR will be qualified by the end of May 2000; c) approximately 80 percent of the inputs for the SR will be qualified mid-January 2001, and d) at the time the SR is issued in proposed form for NRC review in November 2000, the most critical inputs for the SR would be qualified with approximately 20 (+) percent of the inputs not qualified. Also, DOE informed the NRC that the inputs for the SR would be the basis for the license application (LA) and that all inputs for the LA would be qualified prior to its transmittal to the NRC.

NOTE: **[Subsequent to the audit, on December 16, 1999, NRC and DOE management met and discussed a number of issues including prioritization of data used as inputs for SR. At this meeting DOE informed the NRC that it intended too only to qualify data that was initially qualified and later determined to be "suspect" data if such data was categorized as high-risk significant. Further, DOE emphasized that low-risk significant data that was initially qualified and later determined to be "suspect" data would not be subject to any additional qualification.]**

4.5.2 Qualification Methodology

The NRC observers were provided the following information by DOE and M&O:

Data, software, and models supporting SR and LA will be prioritized based on their importance to waste isolation and to safety using the broad criteria contained in the "Repository Safety Strategy (RSS)," Revision 3 (currently issued by M&O and presently under review by DOE). The RSS contains the plan for preparing the post-closure safety case to support SR and the LA. The RSS evaluated the natural and engineered barrier systems relative to their roles in preventing or mitigating the release and migration of radionuclides to the public.

The RSS identifies seven principal factors, disruptive events, and 20 other factors that contribute to the performance of the proposed high-level waste repository at Yucca Mountain (YM). The seven principal factors represent those repository performance features which provide the preponderance of waste isolation performance. The seven principal factors are: 1) seepage into drifts; 2) performance of the drip shield; 3) solubility limits of dissolved radionuclides; 4) retardation of radionuclide migration in the unsaturated zone; 5) retardation of radionuclide migration in the unsaturated zone; 6) retardation of radionuclide migration in the saturated zone; and 7) dilution of radionuclide concentrations during migration. Disruptive events include earthquakes and volcanism.

The prioritization process groups the data, software, and models into categories by their use. If data, software, or models directly support the analysis used for a principal factor or a disruptive event having waste isolation significance (e.g., related to the 7 principal factors in the RSS), it is placed in the first priority category (high priority) and the qualification of these items will be identified for first priority qualification or verification, ahead of those related to the 20 other factors.

Data Tracking Numbers (DTN) will be assigned to data once the data has been confirmed as inputs to analyses, calculations, software, and models required to support SR and LA. Because the entry of data into the DTN system continues to occur well into the analytical development

process, the actual inventory of DTNs subject to qualification and verification is dynamic and will not be finalized until near the end of the AMR and PMR completion process.

4.5.3 Completeness of Site Recommendation Qualification Activities

DOE and M&O informed the NRC observers that they expect to have 80 percent of the data, 80 percent of the software, and 80 percent of the models supporting SR fully qualified by mid-January 2001.

NOTE: **[As previously noted, DOE informed the NRC during a December 16, 1999, public meeting that only data, categorized as high-risk significant that had not been initially qualified or was "suspect" data, requiring re-qualification, would be subject to the qualification process. Further, DOE stated that this decision was based on the sample of "suspect" data re-qualified to date. At the December 16, 1999, meeting the staff stated that it would evaluate bases for DOE's decision not to re-qualify the "suspect," low-risk significant data.]**

[DOE now plans to have 80 percent of the high-risk significant data qualified by mid-January 2001.]

4.5.4 Conclusions on Prioritization of Qualification Activities

Based on the discussions with DOE and M&O, the NRC observers concluded that the prioritization process used for qualifying data, software, and models supporting SR appears to be reasonable. However, to fully understand this prioritization process, the NRC staff needs to review its implementation. The NRC staff will review the implementation of the prioritization process and document the results in future NRC staff observations of DOE audits for PMRs and through the NRC Onsite Representative's activities.

The NRC staff will also continue to review the progress being made by DOE and M&O in meeting its qualification percent completion goals. This review will also be accomplished as part of the NRC staff observations of DOE audits of the PMRs and through the NRC Onsite Representative's activities.

4.6 Examination of Technical Activities

NRC staff observed the audit team technical specialists conducting detailed checks of the technical adequacy of the subject AMRs. At the start of the audit, NRC observers reviewed the technical specialists' qualifications (resumes) and found that the technical specialists had sufficient technical education, training and experience related to the AMRs reviewed. The technical specialists used a combination of technical issue probing and procedural compliance checks and verifications to thoroughly consider both the technical adequacy of the AMRs and the effectiveness of implementation of the QA program.

4.6.1 Analysis Model Report Transfer Coefficient Analysis (ANL-MGR-MD-000008, Rev 00)

The AMR for transfer coefficient analysis documents the M&O staff analyses to select transfer coefficients. Transfer coefficients (i.e., factors that determine concentrations of radionuclides in plants and animal products from radionuclide concentrations in soil and feed) are data inputs for the GENII-S Version 1.485 code used to calculate BDCFs for total system performance assessment (TSPA) calculations. Because transfer factors for plants vary with plant type and soil chemistry, wide variation exists in published values. The purpose of the AMR is to establish criteria for selection of transfer coefficients and apply the criteria to a number of data sources to select a set of transfer coefficients applicable to YM that can be qualified in accordance with procedures.

The audit of the transfer coefficient AMR included a combination of procedural and technical inquiries to verify that procedures were followed and that the technical quality of the product was satisfactory. The audit team inquired about the technical basis for the report including: a) planning and implementation of the technical approach; b) assumptions used; c) data acquisition and traceability; d) qualification of source data; e) treatment at data uncertainties; f) data selection criteria; g) rationales for data exclusion; and h) rationales for defining data as accepted. Selected key issues concerning source data analyzed to select transfer coefficients were investigated with extensive questioning and technical discussion. Discussions emphasized that data sources were summaries of available literature and these summaries constituted unqualified data. However, the selected transfer coefficients would eventually be qualified according to procedure even though the original sources would remain unqualified. After extensive discussions, the audit team and observers agreed that the selected transfer coefficients could be qualified according to procedures using the source data to corroborate the transfer coefficient selection.

In checking the collection of site-specific data associated with this AMR, auditors investigated the use of the food consumption survey results Although the audit team determined that the data from the food consumption survey has not been qualified, no problems were identified with the use of the information.

Resolution of technical comments from checkers and reviewers was assessed by auditors thoroughly reviewing a number of examples in the records package. The qualifications of the document originator and checkers were checked (resumes reviewed) by the auditors and verified by observers and all were found to have sufficient technical experience to conduct the assigned work. The records package for the AMR was extensively reviewed to confirm that checkers had provided comments, that the comments were technically adequate, and that the comments were resolved by the originator. The auditors and NRC observers noted a variety of comments that were both editorial and detailed on technical issues. At least one of the checkers was found to have provided very detailed technical comments. While the final report could be checked to determined that comments had been resolved (in a number of cases the originator provided written responses to comments in the text of the report), the auditors and NRC observers noted that formal comment/response forms were not required by the procedure. This condition made comment resolution traceability difficult for the auditors. Nonetheless, the auditors and observers verified that procedures for review had been followed correctly. The inclusion of comment/response forms for report checking was noted by NRC observers as an inquiry at the conclusion of the audit (see Section 4.7.1 of this report).

4.6.2 Analysis Model Report Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods (ANL-MGR-MD-000002, Rev 00)

The purpose of the dose conversion factor analysis AMR is to document analyses confirming the selection of internal and external dose conversion factors for use in the GENII-S Version 1.485 code as data inputs. GENII-S Version 1.485 is used to calculate Biosphere Dose Conversion Factors (BDCFs) for the TSPA. This AMR was necessary because the GENII-S code contains the dose conversion factors in binary data files that cannot be modified by the user. Because the GENII-S code was initially developed for analyses at the Hanford site in Washington State, the dose conversion factors in GENII-S Version 1.485 are based on material properties consistent with the waste materials existing at Hanford in the late 1980's. Since that time, other accepted sources of external and internal dose conversion factors have been published, for example, by the EPA in Federal Guidance Reports 11 and 12 (Environmental Protection Agency, 1988, 1993). Therefore, the AMR was prepared to address whether default dose conversion factors in GENII-S are consistent with currently accepted sources.

The audit of the dose factor analysis AMR included a combination of procedural and technical inquiries to verify that procedures were followed and the technical quality of the product was satisfactory. The audit team inquired about the technical basis for the report including: a) planning and implementation of the technical approach; b) assumptions used; c) data inputs, acquisition, and traceability; d) data selection criteria; e) rationales for data exclusion; f) software validation; and g) justification for conclusions. Upon initial inspection of the AMR report, one of the auditors commented that the bases for key assumptions needed to be stated clearly in the report. The auditor noted that many assumptions appeared to be considered common knowledge by the originator and not thoroughly explained. The NRC observers concurred that more explicit bases for assumptions would improve the report. However, it was recognized that the omissions were due to the originators familiarity with the material and were not intentional. Auditors also asked questions about the bases for selecting a limited set of radionuclides for the analysis and the decision was traced back to viability assessment conclusions. Inquiries about the sources for data clarified that most were taken from the available literature and some were unqualified but did not need TBV because of their use as corroborative evidence.

Resolution of technical comments from checkers and reviewers was assessed by auditors by thoroughly reviewing a number of examples in the records package. The qualifications of the document originator and checkers were checked (resumes reviewed) by auditors and verified by observers and all were found to have sufficient technical experience to conduct the assigned work. The records package for the AMR was extensively reviewed to confirm that the checker's comments were technically adequate and appropriately resolved by the originator. The auditors and NRC observers reviewed a variety of comments that were both technical and editorial. At least one of the checkers was found to have provided very detailed technical comments. Thus, the checker and technical reviews appeared to be adequate to ensure the technical quality of the report even though the procedures for the checker hampered traceability of comment resolutions (see discussion in section 4.6.1).

References:

Environmental Protection Agency. *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion: Federal Guidance Report No. 11. EPA* 520/1-88-20. Washington DC: Environmental Protection Agency, September, 1988.

Environmental Protection Agency. *External Exposure to Radionuclides in Air, Water, and Soil: Federal Guidance Report No. 12.* EPA 402-R-93-081. Washington DC: Environmental Protection Agency, September, 1993.

4.6.3 Analysis Model Report Disruptive Event Biosphere Dose Conversion Factor Analysis (ANL-MGR-MD-000003, Draft)

The purpose of the AMR for disruptive event BDCF analysis is to document DOE environmental pathway/dose calculations for radionuclides deposited in the biosphere following a volcanic eruption at the proposed YM repository site. The model assumes that radionuclides are released to the air and transported to the critical group location. The BDCFs are used in TSPA calculations to convert radionuclide concentrations deposited in soil to annual dose to the critical group.

The audit of the transfer coefficient AMR included a combination of procedural and technical inquiries to verify that procedures were followed and the technical quality of the product was satisfactory. The audit team inquired about the technical basis for the report; planning and implementation of the technical approach; assumptions; data acquisition and traceability; qualification of source data; data selection criteria; rationales for data exclusion; and software qualification. The planning documentation (Work Package Planning Summary) described in AP-2.15Q was in draft form. Auditors asked a number of detailed questions regarding assumptions for the work which led to a similar concern as with the dose conversion factor analysis (e.g., need more explicit rationales for modeling assumptions per AP-3.10Q). The auditors asked technical questions about assumptions. The NRC observers found these questions to be insightful and indicated that the auditors had conducted a detailed review of the material in formulating the QA checklist and were familiar with pertinent technical issues. NRC observations of the discussions about technical assumptions indicated the report originator had a comprehensive understanding of the important parameters and limitations of available data. Many of the difficult-to-determine parameter inputs were found to be the under the jurisdiction of other AMR reports. The auditors and NRC observers emphasized the importance of future audits for tracing data sources and key assumptions that support more than one AMR. Auditors tracked data successfully to its source by use of DTN and the technical document management system. Auditors requested input transmittal records for those parameters that did not have accession numbers. Data obtained from other AMR reports were tracked by auditors to those referenced reports. All software packages used for the technical analyses were checked by auditors for their qualification status.

In response to auditor and observer questioning about the qualification and validation status of the GENII-S Version 1.485 software, the AMR originator indicated that the software had been validated according to the procedure for software qualification (AP-SI.1Q); however, there was no attempt at model validation. The software qualification documentation (that includes software validation) was extensively reviewed by the auditors and observers. The auditors and

NRC observers found that the qualification documentation conformed to AP-SI-1Q. In response to further questioning about why the model in GENII-S was not validated, the originator noted that the procedures in AP-3.10Q do not require model validation if the report is considered to be an analysis rather than a model. The auditors and NRC observers noted this as a limitation of the procedures because the procedures intended models to be validated, however, originators could bypass the requirements for model validation by selecting the option to call the report an analysis rather than a model. NRC observers presented the lack of clarity of the procedures regarding model validation to the audit team as an inquiry (see Section 4.7.1 of this report).

Resolution of technical comments from checkers and reviewers was assessed by auditors thoroughly reviewing a number of examples in the records package. The qualifications of the document originator and checkers were checked (resumes reviewed) by auditors and verified by observers and all were found to have sufficient technical experience to conduct the assigned work. The records package for the AMR was extensively reviewed to confirm that checker's comments were resolved by the originator. The checker's comments were technically sound and adequate: The auditors and NRC observers noted a variety of depth in comments (from editorial to detailed technical issues). At least one of the checkers was found to have provided very detailed technical comments Thus, the checker and technical reviews appeared to be adequate to ensure the technical quality of the report even though the procedures for the checker hampered traceability of comment resolutions (see discussion in section 4.6.1)

4.7 NUCLEAR REGULATORY COMMISSION STAFF FINDINGS

The NRC staff has determined that OQA Audit M&O-ARP-00-002 was effective in determining the level of compliance of M&O activities associated with the subject AMRs. The NRC staff agrees with the audit team conclusion that the OCRWM QA program had been satisfactorily implemented.

However, the NRC staff expressed the following concerns during the conduct of the audit:

a) There was no objective evidence that data qualification activities had been initiated for data supporting the selected AMRs for this audit and the previous two AMR audits.

b) The NRC staff questioned the adequacy of the process controlling the preparation and use of procedures for the AMR process. During this audit, OQA identified one deficiency and made five recommendations about the adequacy and clarity of the these procedures During the previous two audits of selected AMRs, ten recommendations and one deficiency identified similar conditions. The NRC staff expressed a concern that the M&O management and its senior staff responsible for the supervision and use of these procedures should have recognized the need for the more apparent procedure clarifications prior to OQA making these recommendations.

4.7.1 Audit Observer Inquiries

Two NRC audit observer inquiries (AOIs) were presented to the audit team:

1. AOI No. M&O-ARP-00-02-1

   AP-3.10Q, "Analysis and Modeling" and the QARD are not specific regarding which calculations/analyses are subject to model validation and the timing of model validation. M&O Environmental, Safety, and Regional Programs Office involved with the biosphere AMRs do not appear to have an understanding or strategy of model validation as it applies to the biosphere AMRs/PMR.

2. AOI No. M&O-ARP-00-02-2

   Documented resolution of individual comments is not required for checks of analysis 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) which requires that mandatory comments shall be documented and resolved before approving the document. Note that the audit of the Integrated Site Model (ARP-99-009) also identified several recommendations concerning the review processes of AP-3.10Q and AP-2.14Q.

The two NRC Staff inquiries follow recommendations made by the audit team. The NRC staff is interested in DOE's and the M&O's resolution of these issues because of their potential significance in licensing. These inquiries remain open at the time of this report.

4.7.2 Closure of Previous NRC Audit Observer Inquiries

AOI No. M&O-ARP-99-009-1 was closed during the conduct of this observation. This AOI questioned aspects of the data qualification process (see the discussion is Section 4.5 of this report).

4.7.3 Open NRC Audit Observer Inquires (AOIs)

The following NRC AOIs remain open:

a) AOI No OCRWM-ARC-99-015-1, dated September 22, 1999: OQA agreed to provide information to the NRC on the qualification status and use of the "Waste Stream Profiles" addressed in the "Design Basis Waste Stream for Interim Storage and Repository" and the "Waste Quantity, Mix and Throughput Study" documents.

b) AOI No. M&O-ARP-00-02-1, dated November 18, 1999: (See Section 4.7.1 of this report for a description of this AOI)

c) AOI No. M&O-ARP-00-02-2, dated November 18, 1999: (See Section 4.7.1 of this report for a description of this AOI)