



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 21 2008

OFFICE OF
AIR AND RADIATION

Dave Moody, Ph.D., Manager
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Dear Dr. Moody:

The Environmental Protection Agency (EPA) performed a Waste Isolation Pilot Plant technical inspection November 27 to 28, 2007 in Carlsbad, New Mexico. The purpose of this inspection was to gain an understanding of the Department of Energy's (DOE) document development and review process. This inspection was the result of our concerns about the overall quality of some reports and calculations submitted as part of the documentation which accompanies some DOE requests for operational or performance assessment changes. For example, DOE's documentation for the magnesium oxide safety factor reduction analysis contained several deficiencies that required the Agency to spend a disproportionate amount of time and resources to review the planned change request.

As a result of this inspection, EPA has identified a number of process improvement recommendations in Section 5.0 of the attached inspection report, such as:

- Documenting that calculations are correct (5.1.1);
- Capturing informal review results in the formal review (5.1.2);
- EPA will confirm comments by formal letter as well as email (5.2);
- DOE and DOE's contractors need to provide more complete and clearer explanations for assumptions and conclusions (5.2); and,
- Verifying that assumptions and logic are clearly stated.

Many of these recommendations were provided by DOE, Sandia National Laboratory, and Los Alamos National Laboratory staff, who we commend for their support during the inspection. We believe that these and other process improvement suggestions, if implemented, can enhance product quality and ultimately conserve resources that can be employed to better program priorities.

UNIQUE #	DOE USE	DATE RECEIVED	ADDITIONAL COMMENTS
080047M	230000	MAR 03 2008	See list on the back

We look forward to working with your office as well as Sandia National Laboratory, and Los Alamos National Laboratory staff to address these recommendations. If you have any questions on this topic, please contact Tom Peake at (202) 343-9765.

Sincerely,



Juan Reyes, Director
Radiation Protection Division

Enclosure

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EPA Docket

DOCKET NO: A-98-49
Item: II-B3-103

**Document Review Process
Technical Inspection Report**

**EPA INSPECTION No. EPA-WIPP-7.11-27
OF THE
WASTE ISOLATION PILOT PLANT
November 27 – 28, 2007**

**U. S. ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation and Indoor Air
Radiation Protection Division
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February 2008

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1.0 EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA or the Agency) conducted an inspection of the U.S. Department of Energy (DOE) and DOE's support contractors in Carlsbad, New Mexico, from November 27 to November 28, 2007, in accordance with EPA regulation 40 CFR 194.21. EPA routinely reviews various DOE technical documents from the Carlsbad Field Office (CBFO), Sandia National Laboratory (SNL), and Los Alamos National Lab (LANL) in support of EPA's regulatory oversight mandate. The primary purpose of this inspection was to review how these three organizations produce, review and verify the reports and documents they provide to EPA. EPA examined selected activities, such as document development, project analyses, verification of calculations, and final approval activities.

EPA concluded that, for formal review, all of the groups (DOE, LANL, and SNL) interviewed during the inspection have a reasonable and appropriate process, but improvements can be made. For activities falling into the informal review realm, the process is not standardized nor well documented. Yet, the informal reviews are important because they are where the most constructive evaluations may occur.

EPA believes that process improvements need to be initiated to assure high-quality work products are provided in DOE submissions to EPA. If judiciously implemented, more transparent and complete internal reviews by SNL, LANL, and DOE should lead to enhanced confidence, resource savings, and decreased review time by EPA.

2.0 INSPECTION PURPOSE AND SCOPE

The scope of this technical inspection activity was to verify that DOE ensures that Waste Isolation Pilot Plant (WIPP) performance assessment related computer calculations, data input, documentation, and results are adequate and representative of the repository. EPA verified that DOE complies with 40 CFR 194.22[data], 40 CFR 194.23(a)(3)(i)[conceptual models], and 40 CFR 194.23(c)(4)[data].

A focus of this inspection was the documentation used to support DOE's planned change request (PCR) (April 10, 2006 and subsequent submissions) to reduce the quantity of magnesium oxide (MgO) (MGOPCR) from 1.67 to 1.2 times the amount of emplaced carbon in the repository. Review of calculations performed was also conducted. EPA interviewed individuals in the production and review of documents and activities. A sample of other documents and activities were reviewed, such as shielded container development work products at LANL.

EPA verified that the DOE, including Carlsbad Field Office (CBFO), LANL, and SNL, generally provides sufficient technical review and verification of documents and other activities used to support WIPP technical submissions to the EPA for most formal reviews.

2.1 EPA's REASONING FOR HAVING THIS INSPECTION

It is our operating principle that any decision or approval made by the Agency must have the highest quality technical accuracy, and well founded assumptions supporting it. Therefore, EPA thoroughly examines all submissions made by DOE as part of our deliberations to approve requested changes. Recently, EPA expressed concerns about the completeness and accuracy of reports and calculations submitted by DOE. The most significant example is the Magnesium Oxide Planned Change Request (MGOPCR) submitted in 2006 and updated in November 2006 in response to questions asked by the Agency.

One document, COB-T2007-2, "Consumption of Carbon Dioxide by Precipitation of Carbonate Minerals Resulting from Dissolution of Sulfate Minerals in the Salado Formation in Response to Microbial Sulfate Reduction in the WIPP", was troublesome to EPA. We summarized these concerns in a note (COB-T2007-11), "Specific Comments Related to Previous MgO Submissions", which concluded that this report appeared to be rushed and incomplete in several areas. In addition, within the document there were important issues identified but not explained or otherwise resolved. Further, we believed that the process used by SNL and DOE did not capture issues that EPA identified and deemed important.

As a result, EPA decided to conduct this technical inspection to better understand the overall document and analyses development processes at DOE, SNL and LANL. EPA's goal was to explore what process improvements could be implemented to decrease the time, effort, and resources the Agency must expend to ensure DOE produces viable, sound, and defensible submissions.

3.0 INSPECTION TEAM, OBSERVERS, AND PARTICIPANTS

The inspection team consisted of two EPA staff. A partial list of inspection participants is provided in Table 1.

**TABLE 1
Inspection Participants**

EPA INSPECTION TEAM MEMBER	POSITION	AFFILIATION
Chuck Byrum	Inspector	EPA ORIA
Tom Peake	Inspector	EPA ORIA
CBFO / SNL / LANL		
Mike Gross		WRES
Steve Kouba		WRES
Russ Patterson		DOE
Lea Chism		DOE
Tim Burns		LANL
Bev Crawford		LANL
Bill McInroy		LANL
Dave Kessel		SNL
Moo Lee		SNL
Mario Chavez		SNL
Christi Leigh		SNL
Dan Clayton		SNL
Ross Kirkes		SNL
Steve Wagner		SNL
Larry Brush		SNL
John Geilow		SNL

4.0 PERFORMANCE OF THE INSPECTION

EPA inspectors held an opening meeting at CBFO on November 27, 2007 at 1:30 P.M. where we described our approach for this inspection. First, EPA inspectors wanted to understand the document and analyses development processes at each group, CBFO, LANL and SNL. EPA

also wanted to see specific examples with procedures that control the process. During the opening meeting EPA voiced its concerns about how, periodically, work products (reports and/or analyses including calculations) were not as complete or properly developed as EPA we needed for our own evaluation. EPA inspectors also added that during the “technical inspection,” they were seeking process improvements for both EPA and DOE, and not necessarily findings or concerns like a normal procedure driven inspection.

CBFO, LANL, and SNL described their document and analyses review processes. It also became clear during these interviews that there are two review processes used in each group. There is a formal process that is well controlled and highly documented and a less formal process that is not necessarily controlled, not well documented in most cases, and not archived.

At the end of the opening meeting EPA, inspectors described the interview schedule. CBFO staff would be interviewed first, then LANL staff on the November 27. The interviews with SNL staff would start the next morning. The inspection close out meeting took place at 11:30 on November 28, 2007 in DOE’s large conference room.

4.1 The CBFO Interview

At CBFO EPA inspectors interviewed Russ Patterson, Mike Gross, and Steve Kouba. Lea Chism of CBFO’s quality assurance organization observed all of the interviews. EPA inspectors asked them to describe their report review process. During these discussions they noted that most of their reviews are informal and are generally programmatic in nature (that is, they review whether the document’s concepts are consistent with DOE’s position), and act as a “sanity check;” these are usually done for every SNL or LANL document sent to EPA. CBFO does have a formal process that is controlled by procedures (CBFO MP 4.2 [COB-T2007-S2]), but this process is generally reserved for high level reports, such as WIPP Recertification documents that are considered DOE products. Many of the work products produced by LANL or SNL are informally reviewed by DOE staff or contractors. Comments are shared by email and are not archived as permanent records by CBFO.

They also noted that CBFO reviewers usually assume that calculations have been verified, that parameters have been reviewed and verified, and that technical concepts and assumptions are complete and accurate. CBFO reviewers also stated that deadlines and schedules do not control their review process and gave examples of when reviewers caused deadlines to be delayed.

4.2 The LANL Interview

Bev Crawford, Bill McInroy, and Tim Burns of LANL were the key staff members interviewed by EPA inspectors. They described the formal review processes controlled by LCO-QP9-1, Analyses (COB-T2007-S11) and LCO-QP6-2 Controlled Document Review and Approval (COB-T2007-S12) quality procedures. The Analyses procedure covers a broad range of evaluations from complex calculations to simple spreadsheet or hand calculations. The Document Review and Approval procedure appears to be designed to control development and completion of high level reports, such as the annual inventory work product produced by LANL.

During the interviews Bill McInroy stated that his reviews are very thorough, even his informal reviews, and that he confirms equations and calculations. It was noted, however, that different staff review things at different levels of detail. Bev Crawford noted that the LANL "Inventory Team" verifies that all inventory data submitted by the sites is placed in LANL's inventory database correctly. They provided information (COB-T2007-S13 and -S15) that reviews are done and appear thorough for work produced within the scope of the formal procedures. Informal reviews appear to be adequate at LANL.

During the interview with LANL, EPA inspectors asked if schedule had impacted reviewers at any time. They said no and that reviews have not been rushed or compromised by schedule deadlines. They also stated that they believed that the reviewers have sufficient authority to resolve concerns and they said reports have been modified because of reviewer comments. They also noted that there is also an informal review process that may take place and resolve many issues before the formal well documented process is begun.

4.3 The SNL Interview

As noted in Table 1, Inspection Participants, SNL had a number of staff members participate in EPA's interview at SNL. Mario Chavez was the primary presenter for SNL (see COB-T2007-S35). He discussed the formal review process at SNL controlled by NP 6-1, Document Review Process, (COB-T2007-S22) and NP 9-1, Analysis (COB-T2007-S20) management procedures. NP 6-1 is the procedure that controls the review of many types of work products that require technical, quality assurance, and managerial review, such as all reports and analyses important to WIPP compliance or recertification, nuclear safety, waste characterization, or waste information as described in Section 1.0 of NP 6-1.

The Document Review and Comment (DRC) form (Appendix A of NP 6-1) describes requirements of the technical reviewer. The technical reviewer is to verify technical adequacy, accuracy, and completeness of the work product. The technical reviewer is also directed to verify that:

- objectives are clearly stated and fulfilled,
- the activity clearly is described,
- equations and calculations are accurate,
- the logic leads to reasonable conclusions, and
- results drawn from the data are supported by the data.

Section one of NP 9-1 describes the graded approach SNL has established for documenting and reviewing analyses and states that this procedure applies to scientific and engineering analyses. NP 9-1 specifies three grades for reviews; compliance decision (highest), programmatic decision, and routine calculations (lowest). Each requires different levels of review and justification of parameters, calculation, and reported conclusions. NP 9-1 reviewer comments are captured on the NP 6-1 DRC forms and comments are required to be resolved.

EPA inspectors examined the technical review document in DRC, COB-T2007-3, where

the SNL commenter did not have any technical comments on a MGOPCR report, COB-T2007-2, mention above in Section 2.1 of this inspection report. As noted above EPA had concerns (see COB-T2007-11) about issues that were introduced which were not reasonably concluded, results of calculations that did not appear resolved, and the apparent introduction of a new WIPP chemistry conceptual model. As a result, the Agency had to expend an inordinate amount of time, energy and resources to resolve these issues. So we were very concern that the technical review did not have any comments on the DRC form.

Before the inspection, the EPA inspectors mentioned our concerns to DOE regarding the lack of technical review comments on the MgO document DRC form. Mike Gross, contactor to DOE, investigated our concern. He learned that all of the technical comments had been resolved during the apparently lengthy informal review process. So when the final formal process was begun the technical reviewer did not have any additional comments.

The informal SNL process was discussed during the interview with SNL. From this discussion it appeared that the informal process is used extensively, especially for complex work products, and was very beneficial to achieving quality work products. The SNL staff also provided a number of DRCs (COB-T2007-S22 to -S32) as examples of the range of technical review, their level of detail, and the resolution of comments. One comment by SNL was that the positive comments are not carried forward, such as when a technical reviewer in the informal or even formal process confirms an item in the document but does not document that it was done. Thus, the verification that the item is adequate is not communicated to subsequent reviewers, be they management or the regulator.

5.0 SUMMARY OF RESULTS

5.1 EPA's Deliberations on Our Inspection

Because important issues were identified but not explained or otherwise resolved in the MGOPCR documentation, EPA believes there is a need to improve document development and review within the DOE product development process. We recognize that this example may not be typical, but it does point to the need for several corrections that are warranted. The process used by SNL and DOE did not capture issues that EPA identified and deemed important. Although interviewees stated that schedules do not affect review process, anecdotal information indicate that schedules can, in fact, affect document quality and we believe that the MGOPCR documentations reflects those pressures. DOE, SNL, LANL, and even EPA can take actions to improve the entire process.

5.1.1 The Formal Review Process

From the opening inspection discussion to the interviews, it became clear that formal work products produced by CBFO, LANL, and SNL generally follow a well-documented and well-controlled process. However, even the formal review processes can be improved. For example, a reviewer can actually verify that equations or calculations are done correctly in a report or analyses, but the reviewer may not make note of a successful outcome. In other words the reviewer may not make a note in SNL's DRC or LANL's DRF if no problems were found.

The technical reviewer may only report errors found. Therefore the review process may not be traceable at this point. A process improvement might be to require the technical reviewer to make a note that the calculations or a sample were checked and that they were found to be correct along with verification calculations (providing the evidence in an attachment to the review comments). Another suggestion provided during the interview process was to add a note or checklist to the document review procedures for items to consider; this would especially assist those who don't have experience in the regulatory arena. These suggestions should be assessed by DOE, SNL, LANL to determine what improvements are warranted given their familiarity with the review process. The respective quality assurance organizations should review the changes to see if they are appropriate.

5.1.2 The Informal Review Process

It is also clear that the informal review process is used frequently, is part of the culture in these groups, is a valuable tool in developing reports and calculations, must continue, and needs improvement. EPA believes that the informal review process should be part of the normal working environment and work product development process. EPA itself uses informal review and interactions to assure that a project is on track and that products are on target.

However, in the regulatory framework some form of traceability of work products is needed, be they reports, analyses, or simply excursion calculations used to test or bound a concept. Therefore, we request that informal review comments, analyses, or evaluations that impact the final work product be carried over to the final formal review process, even if they are summarized comments, checks or reviews done during the informal review process that is done in such a way that still fosters freedom of comment. For example, if equations or verification calculations have been performed by the technical reviewer and they confirm the original analysis, equation, or other item, then that should be identified in the formal review process. DOE, SNL, and LANL should try to identify ways that the process can be improved without undue interference on informal reviews.

5.2 EPA Recommendations – Process Improvements for EPA and DOE

As a result of this inspection EPA found that, while DOE, SNL, and LANL have procedures in place that direct the production and review of documents, there is room for improvement, such as modifications to procedures. In addition, EPA identified process improvements that can clarify what communications come from EPA to DOE.

Based on discussions during the inspection interviews EPA has determined that it will no longer make comments to DOE by email submission only. EPA may make comments by email but will always send a letter to DOE and include DOE's Quality Assurance department at CBFO to assure that comments are properly responded too and tracked in the DOE system. It was clear during the interviews that DOE seemed to have difficulty determining the status or grade of EPA comments submitted by email, and that email comments do not get forwarded to the appropriate quality assurance staff. Therefore EPA believes it is prudent to submit comments in a formal letter.

EPA also looked at a brief history of comments the Agency has made on DOE submissions recently, for example the MGOPCR, the first recertification, and other submissions. They all have some common themes: 1) DOE did not support conclusions or assumptions adequately, and 2) logic was not clearly presented, or analyses were not sufficiently explained to allow the Agency to fully understand and review them. EPA acknowledges that questions such as these will often need further explanation or discussion, but if the submission delivered to EPA is improved, then EPA believes that our review and deliberation time will be shortened, with a commensurate reduction in cost.

Sometimes a very small amount of additional explanation is all that is needed to clarify assumptions or parameter values. During the interviews a specific example was discussed. In LANL's development of the shielded container inventory for remote handle containers, certain assumptions were made about emplacement design and material properties, such as the amount of plastic in slip sheets used to place waste containers on the waste stack. These assumptions were made because the final emplacement design for a three pack of shielded containers was not finalized at the time. The LANL Inventory Team assumed that they would use the standard seven-pack configuration of emplacement materials. However, LANL's report did not provide justification that clearly explained why this was done, or whether it was conservatively bounding or even representative. EPA used this as an example during the interview with LANL and it was clear to participants that this small explanation would have potentially facilitated EPA's review.

SNL's DRC directs the technical reviewer in Section 4 to: ensure that objectives are clearly stated and fulfilled, that the technical activity is clearly described, verify that the logic used does lead to reasonable conclusions and that the results from data supported by the data is presented. Therefore, EPA requests that DOE and its contractors document in their final/formal review these requirements. Many of these activities appear to have taken place during the informal reviews and they need to be captured in the formal review process in some appropriate way. Further considerations could include whether issues raised have been addressed, or that assumptions are clear. For example, technical review directions could be modified to ask reviewers to assure that assumptions are stated clearly and lead logically to assumptions and conclusions present in work products. The reviewers should ask themselves whether EPA could understand assumptions, logic, and conclusions sufficiently to agree.

EPA also believes, based on interviews during this technical inspection, that DOE's final reviewer for both formal and informal reviews need to be involved as early as possible--and before the documents are official contractor products-- to provide "sanity checks", completeness checks, logic checks and assumption checks and verify if the work product fulfills the intended need being addressed by the completed work. Also, as part of this enhancement process, DOE could run early approaches or work products past EPA to give us an opportunity to provide an early "reality check".

If done satisfactorily, more transparent and complete internal reviews by SNL, LANL, and DOE could lead to enhanced confidence and decreased review time by EPA.

**Attachment A
Inspection Plan**

Technical Inspection of WIPP Performance Assessment Related CBFO and SNL Documents and Activities

Purpose: EPA will verify that the Department of Energy (DOE), including Sandia National Laboratory (SNL) and the Carlsbad Field Office (CBFO), provides sufficient technical review and verification of documents and other activities used to support WIPP technical submissions to the EPA.

Scope: The scope of this technical inspection activity (under the authority of 194.21) is to verify that DOE ensures that WIPP performance assessment related 1) computer calculations, 2) data input, 3) documentation, and 4) results are adequate and representative of the WIPP repository. EPA will verify that DOE complies with 40 CFR 194.22[data], 40 CFR 194.23(a)(3)(i)[conceptual models], and 40 CFR 194.23(c)(4)[data].

A focus of this inspection is the set of documents used to support DOE planned change request (April 10, 2006 and subsequent submissions) to reduce the quantity of MgO from 1.67 to 1.2 times the amount of emplaced carbon in the repository. Review of calculations performed will also be examined. EPA also plans to interview individuals in the production and review of documents and activities. A sample of other documents and activities will be reviewed, such as shielded container development work products.

Focal Areas for this Inspection:

- What is the process used by DOE and SNL to develop and then verify the quality of work products?
- Does SNL ever request external review (e.g., LANL) of products or activities?
- What procedures are used by DOE and SNL to control/guide the review process of program work products?
- What are the records produced during the review and approval of the reports?
- What plans have been established to address reviewers concerns?
- Do reviewers have authority to question the technical basis and conclusions of a report? If so what actions are taken?
- Are calculations and data input files independently reviewed to verify accuracy of input and reasonableness of parameter selection? What procedures cover this process? What documentation is generated? Do reviewers have the authority to make calculations to be redone correctly? Show examples and objective evidence.
- Interviews with DOE and SNL technical reviewers
- How are EPA's concerns provided to DOE and SNL (via email or formal letters) transmitted from SNL and DOE staff to their QA counterparts?

Location: This inspection will be held DOE's and Sandia National Laboratories office in Carlsbad, New Mexico. At the opening meeting DOE and SNL will describe their review processes and provide procedures that control these processes with examples.

Expected Dates: November 27-28, 2007, starting at 1:30 on the 27th.

Information Requested: Before the inspection, provide any relevant DOE or SNL procedures that control the internal product development and review processes. Provide all documents related to the review and approval of the above document, by Brush, et al.

Attachment B
Inspection Checklists

Technical Inspection of PA Related CBFO and Contractor Documents and Activities		November 27, 2007	
#	Question	Comments (Objective Evidence)	Results
DOE – CBFO Questions		DOE	
1	Do all technical work products get technical reviewed by DOE before being transmitted to EPA?	All of the groups interviewed, DOE, LANL, and SNL, stated that they have two types of internal reviews, one formal-a well controlled proceduralized review [See COB-T2007-S2, -S3, -S11, -S12, -S20, and -S22], another informal-not well controlled nor proceduralized. It appears all documents are reviewed by DOE-CBFO to some extent, however they do not appear to generally have a detailed technical review.	
2	Is there a process that guides internal DOE review of work products?	Yes for formal reviews and some routine calculations, see COB-T2007-S2, -S3, -S11, -S12, -S20 and -S22 for examples. But informal reviews do not appear to have written controlling procedures. Informal reviews are generally done by email or a non-traceable paper trail. Most of DOE's reviews appear to be done using the informal process.	
3	Are calculations that support a work product independently reviewed?	They generally appear to have not been reviewed or confirmed by DOE. DOE staff and reviewers stated they assume it was done by the work product generating organization (LANL, SNL).	
4	Do DOE reviewers have authority to change or require additional supporting calculations [or documents]?	Yes, sort of – it appear that the process is changing. It is difficult to have changes made in SNL documents once they have been placed in the SNL records center. In the past is appears that it was hard to make changes once the originating organization completed the work produce. However, the SCPA was cited as a recent example that was changed as a result of CBFO reviewer comments, moved to Revision 1, after SNL had completed its work.	
5	Have DOE schedules caused reviews to be omitted or shortened?	During the interviews we asked each group (CBFO, LANL, and SNL staffs) this question and each organization stated that the schedule was not a driver. However, it has been EPA's observation in recent years that deadlines may have influenced the level of completeness of work product review. See the inspection report Section 4.3 for a specific example	

6	Have changes to work products or activities been made as a result of DOE reviewer comments? If yes, is this a common or infrequent response – please show examples?	Yes. It appears that recently DOE has attempted to respond to EPA concerns. CBFO has added a geochemist to help review chemistry work products. The CBFO Manager has verbally stated that changes need to be made to the process but there is no formal documentation of the change presently.	
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Technical Inspection of PA Related CBFO and Contractor Documents and Activities		November 27, 2007	
#	Question	Comments (Objective Evidence)	Results
DOE Contractor Questions		LANL	
1	Is there a process that guides internal development and review of work products?	As noted in DOE-1, above, for formal internal reviews the process is controlled, documented, and archived [see COB-T2007-S11 and -S12 for LANL requirements]. However informal reviews may or may not be controlled, documented, or archived in LANL records and appears to depend on the individual review's own initiative. Therefore adequacy of the informal review process is difficult to verify.	
2	Do reviewers have authority to require changes to documents, supporting work (such as calculations)?	Yes for LANL's formal review process. Section 5.3.3 of Analyses, LCO-QP9-1 (COB-T2007-S11) and Section 5.15 of Document Review, LCO-QP6-2 (COB-T2007-S12) require resolution of reviewer's comments. However, for the informal review process this requirement is less clear. During the interviews LANL staff stated that informal review was where a lot of issues are ironed out and corrected before the formal review is begun – once again it is hard to verify this because the informal reviews do not appear to always be well documented or archived.	
3	Are calculations that support a work product independently reviewed?	Yes for formal reviews, required in procedure LCO-QP9-1, Attachment 2. However, the rigor of verifying calculations, rather formal or informal, appears to depend on the initiative of the staff member. It appears that verification of calculations may be done as part of informal reviews but proof is hard to find. However, during the interview the staff stated that calculations are verified.	
4	What process is used to verify accuracy and reasonableness of parameters and computer input files.	Procedure LCO-QP9-1 requires parameters and code inputs be verified for formal reviews. However, once again, it appears that many of the reviews are done informally and may not easily be verifiable.	
5	What documentation is required in the verification of parameters, computer input files, and related products or activities?	Inventory verification has a set of procedures with reviews by site and LANL staff, LCO-QP9-1. LANL's Analysis Plan for Transuranic Waste Inventory (INV-AP-01: COB-T2007-S7) on page 5 paragraphs 2 and 3 require that generator site inventory data and calculations have independent review and be verified by the Inventory Team.	

6	Are external reviews of products or activities ever requested (excluding the NUREG 1297 process)	Yes for formal reviews. DOE's appears to review inventory data for documents that go out under DOE's name and therefore falls under DOE's formal review process [see CBFO 4.2, Document Review (COB-T2007-S2)). As noted above LANL's Inventory Staff perform an independent review of waste generator site inventory information.	
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Technical Inspection of PA Related CBFO and Contractor Documents and Activities		November 27, 2007	
#	Question	Comments (Objective Evidence)	Results
	DOE Contractor Questions	SNL	
1	Is there a process that guides internal development and review of work products?	NP 9-1 for analyses (COB-T2007-S20) and NP 6-1 for document review (COB-T2007-S22) controls SNL's formal work product review process. These appear to apply to compliance decision (CD), programmatic decision (PD), and routine calculations work products. However, even these reviews appear to be influenced by the informal review process. It appears that many work products (calculations or reports) are informally reviewed and issues are resolved informally before the formal, documented, controlled process starts. A specific example is, COB-T2007-3, the formal technical DRC related to the review of the report used for the MgO planned change request. This DRC notes that the commenter did not have any comments. EPA questioned this result. Mike Gross, for DOE, investigated the issue and found that the formal technical reviewer had been engaged informally and had worked out issues during the informal process. However, the informal process was only documented in the reviewer's private records and was difficult to review by the inspector. See Section 4.3 of this inspection report.	
2	Do reviewers have authority to require changes to documents, supporting work (such as calculations)?	Yes for formal reviews. Found in Section 2.5 of the formal review procedure NP6-1 verify the requirement for the formal process. The Document Review and Comment form (DRC, NP 6-1-1) verify the implementation requirement for the formal review process [see DRCs COB-T2007-S23 to -S33 for example). However, many comments appear to be worked out in informal reviews and the final formal review forms don't reflect issues that were resolved beforehand. Staff did say that they did have the authority to resolve issues during the EPA's interview.	

3	Are calculations that support a work product independently reviewed?	Yes, for the formal review process of analyses (see NP 9-1) Comments are required to be put on DRCs. However, if a calculation or equation is found to be correct, there may be no record that that verification took place and if calculations are verified informally no traceable record may exist. SNL staff stated that the informal process is often used but no documentation was presented during the inspection.	
4	What process is used to verify accuracy and reasonableness of parameters and computer input files.	NP 9-1 (Analyses) states in Section 2.2.2 that routine calculations reviews are to be conducted per NP 6-1 requirements and NP 6-1 (DRC form) Part 4 requires the technical reviewer to verify that equations are correct and that calculations are accurate. The last bullet in Section 2.1.3 of NP 9-1 states that the flow chart in Appendices B and E provides the requirements for proper review of analysis records and that they are documented on DRC forms. During the EPA interviews, SNL staff stated that they did verify the accuracy of calculations, data used, and input values.	
5	What documentation is required in the verification of parameters, computer input files, and related products or activities?	NP 9-2 (Parameters) [COB-T2007-S34] documents the development of parameters for the performance assessment, but does not specifically state that the actual value is verified as noted in Question 5, the procedure states that the value placed into the parameter database is verified. EPA assumes that parameters that are developed are rigorously verified and reviewed but NP 9-2 does not appear to specifically state that requirement. During EPA's interview Mario Chavez stated that, as part of his QA review, he will sample input files in QA surveillances. SNL NP 9-1 Appendix E is a flowchart of the record flow for an analysis. Appendix E notes that the review is based on NP 6-1 and Appendix B of NP 9-1. It appears that reviews are assumed but they do not seem to be specifically spelled out in all cases.	
6	Are external reviews of products or activities ever requested (excluding the NUREG 1297 process)	Yes. The frequency of these is not clear. SNL staff stated that external reviews are done but did not clearly specific the requirements that control there initiation and any external reviewer needs to be trained in SNL's review procedures. Recently CBFO required two external reviews of calculations related to the MgO planned change request.	

Attachment C
Documents Reviewed During the Inspection

Nov 2007 – Technical Inspection - Documents Received and Reviewed GENERAL		
Document ID	Document Title:	Source
COB-T2007-1	Copy of email from Mario Chaves, dated 11/14/2007 which includes files ERMS 544482, 544841, 544788, 544787, 544786, and 544843 attached – all listed below.	SNL
COB-T2007-2	Document Reviewed – Consumption of Carbon Dioxide by Precipitation of Carbonate Minerals Resulting from Dissolution of Sulfate Minerals in the Salado Formation In Response to Microbial Sulfate Reduction in the WIPP, 112706, (ERMS 544785)	SNL
COB-T2007-3	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 544786, 111506. Form for the technical review of ERMS 544785. (COB-T2007-2) [Reviewer had no comments.]	SNL
COB-T2007-4	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 544787, 111506. Form for the QA review of ERMS 544785. (COB-T2007-2)	SNL
COB-T2007-5	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 544788, 111706. Form for the management review of ERMS 544785. (COB-T2007-2)	SNL
COB-T2007-6	Document Reviewed - Geochemical Information for Calculation of the MgO Effective Excess Factor. 111706 (ERMS 544840)	SNL
COB-T2007-7	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 544841, 111306. Form for the technical review of ERMS 544840. (COB-T2007-6)	SNL
COB-T2007-8	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 544842, 111406. Form for the QA review of ERMS 544840. (COB-T2007-6)	SNL
COB-T2007-9	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 544843, 111406. Form for the management review of ERMS 544840. (COB-T2007-6)	SNL
COB-T2007-10	EPA table comparing documents reviewed and the DRCs for those documents, 120607. (Repeated as Table XX in this inspection report.) For reviewed documents COB-T2007-2 and –S6.	EPA
COB-T2007-11	EPA comments – “Specific Comments Related to Previous MgO Submission”. 012507 EPA comments on COB-T2007-2 (ERMS 544785) and COB-T2007-6 (ERMS 544840) developed during EPA’s MgO changes request Review.	EPA

Documents Received During DOE Interview		
Document ID	Document Title:	Source
COB-T2007-S1	Technical inspection opening meeting sign-in sheet, 112707.	DOE
COB-T2007-S2	CBFO MP 4.2, Revision 4, July 20, 2005 Subject: DOCUMENT REVIEW. DOE Management procedure that describes the formal document review process at CBFO.	DOE
COB-T2007-S3	CBFO MP 4.1, Revision 7, July 19, 2007 Subject: PREPARATION AND MAINTENANCE OF CBFO PROCEDURES. Describes the formal process used to prepare and maintain CBFO procedures.	DOE
COB-T2007-S34	Technical inspection closing meeting sign-in sheet, 112807.	DOE

Documents Received During LANL Interview		
Document ID	Document Title:	Source
COB-T2007-S4	LANL LCO-QPD-05, Revision 1, May 10, 2007 WIPP Compliance and Recertification Program Strategy Plan. Defines LANL's work scope and strategy to support the WIPP recertification.	LANL
COB-T2007-S5	LANL-CO EES-12 Organization Chart	LANL
COB-T2007-S6	LANL Activities and Quality Level Determination Chart – May 2007	LANL
COB-T2007-S7	LANL INV-AP-01, Revision 2, October 23, 2006. Analysis Plan for Transuranic Waste Inventory. Plan describes LANL activities to be done that support development of the WIPP waste inventory.	LANL
COB-T2007-S8	LANL list of key assumptions related to inventory parameters to support the shielded container performance assessment (SCPA), Draft-080207.	LANL
COB-T2007-S9	WIPP-Washington TRU Solutions, Specification E-I-474, July 30, 2007. Specification for the RH-TRU Drum Handling Bag. Used by LANL to develop SCPA inventory information.	LANL
COB-T2007-S10	Technical inspection LANL interview sign-in sheet.	LANL
COB-T2007-S11	LANL Analyses-Quality Procedure, LCO-QP9-1, Revision 2, June 20, 2005. Describes formal methods for controlling and documenting analyses done by LANL.	LANL
COB-T2007-S12	LANL Controlled Document Review and Approval - Quality Procedure LCO-QP6-2, Revision 3, January 26, 2007. Describes the formal process for reviewing and approving controlled documents at LANL.	LANL
COB-T2007-S13	LANL-CO Document Review Form (DRF) (Form QA6-2-1, R1, Attachment 1 of COB-T2007-12) Example of technical review	LANL

	form (INV-07-08-25-01-04) for LANL inventory report INV-SAR-08 (see COB-T2007-S16 below)	
COB-T2007-S14	LANL inventory report from the first CRA. Estimation of Cellulose, Plastic, and Rubber Based on TWBID, Rev 2.1, Data Version 4.15, January 26, 2005 (ERMS 538664, INV-0607-01-46-26)	LANL
COB-T2007-S15	SNL Document Review and Comment (DRC) Form NP 6-1-1. ERMS 538665, 012705. LANL Form for the technical review of ERMS 538664 (COB-T2007-S14)	LANL
COB-T2007-S16	Analysis of RH TRU Waste for Containment in Lead Shielded Containers, Simple Analysis Report, INV-SAR-08, 083007 (INV-07-08-25-01-01). LANL inventory report for shielded container report to support the performance assessment.	LANL

Documents Received During SNL Interview		
Document ID	Document Title:	Source
COB-T2007-S20	SNL Management Procedure – Analyses - NP 9-1, Revision 6, 082906. Describes formal methods for controlling and documenting analyses performed by SNL for WIPP.	SNL
COB-T2007-S21	Technical inspection SNL interview sign-in sheet, 112807.	SNL
COB-T2007-S22	SNL Management Procedure – Document Review Process, NP 6-1, Revision 6, 092006. Describes SNL’s formal process for reviewing documents.	SNL
COB-T2007-S23	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 547198, 102207. SNL Form for the technical review of ERMS 547358 – Analysis Report for the Shielded Container Performance Assessment. Attachment 3 of the Shielded Container submission.	SNL
COB-T2007-S24	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 541423, 101105. SNL Form for the technical review of Notebook – WIPP-MgO-CDB-6.	SNL
COB-T2007-S25	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 540573, 072705. SNL Form for the technical review of Analysis Package for PANEL: CRA-2006 PABC, Calculation, 072705.	SNL
COB-T2007-S26	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 544530, 101906. SNL Form for the technical review of a memo – Incorporation of Calcium Citrate Hydrate, Earliandite; Calcium Oxalate Monodyrate, Whewellite; and Aqueous Species of Citrate and Oxalate into the EQ 3/6 HMP Database and Its Modified Version HMY.	SNL
COB-T2007-S27	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 545989, 042007. SNL Form for the technical review of an SNL report – Evaluation of the Duration of Direct Brine	SNL

	Release in WIPP Performance Assessment.	
COB-T2007-S28	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 545756, 041007. SNL Form for the technical review of a parameter memo – Revised Porosity Estimates for the DRZ.	SNL
COB-T2007-S29	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 544569, 101606. SNL Form for the technical review of a memo – Routine Calculation for Hydration Data.	SNL
COB-T2007-S30	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 541691, 072105. SNL Form for the technical review of a notebook – WIPP-MgO-CDB-17 (pages 1-100).	SNL
COB-T2007-S31	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 545765, 041007. SNL Form for the technical review of Justification of Relative Permeability and Capillary Pressure Model Parameters for Use by BRAGFLO Version 6.	SNL
COB-T2007-S32	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 545277, 020707. SNL Form for the technical review of a memo – Incorporation of Amorphous Calcium Carbonate with Higher Solubility (CaCO ₃ (am-cpa)), Aqueous Complexes of Magnesium and Calcium with Acetate, Calcite, EDTA and Oxalate, and Aqueous Species of Acetate and EDTA into the EQ3/6 HML Database and Its Modified Version HMO.	SNL
COB-T2007-S33	Document Review and Comment (DRC) Form NP 6-1-1. ERMS 545747, 040607. SNL Form for the technical review of a memo Revised Permeability Estimates for the Disturbed Rock Zone (DRZ).	SNL
COB-T2007-S34	SNL Management Procedure – Parameters NP 9-2, Revision 1, 082906. Describes SNL's process to develop, document, control, and change parameters.	SNL
COB-T2007-S35	Presentation on document review at SNL by Mario Chavez	SNL