DOE F 1325.8
(12-84)

United States Government **Department of Energy**

memorandum

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'87 JUN 25 P3:27

DATE: June 24, 1987

REPLY TO ATTN OF: RW-24

SUBJECT: DISPOSITION OF STATE, TRIBE AND NRC COMMENTS ON THE OGR QA PLAN

TO: STATE, TRIBE, AND NRC REPRESENTATIVES (LIST ATTACHED)

Attached is a listing of all the comments we have received on the OGR QA Plan from the States, Tribes, and NRC. Also shown is the disposition of these comments that is being proposed. The dispositions noted in the attachment have not yet been submitted to OGR management for review or approval. Before having a management review we would like to be sure that we have understood and properly considered each of the comments received on the OGR QA Plan.

Please review the attached tabulation of comments to be sure that we have correctly stated your comments and that we have not overlooked any. When we present our proposed disposition to OGR management for action, we want to be sure that all comments are accurately portrayed. We also solicit your response to the dispositions we are proposing. We want OGR management to know of any concerns you have with the way we are proposing to handle your comments.

We look forward to hearing from you during the workshop at the QACG Meeting in July.

Carl Newton

Carl Newton, Chairman
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Office of Geologic Repositories
Office of Civilian Radioactive
Waste Management

WM Record File 102.7 — WM Project 11
Docket No.
PDR ✓
× LPDR ✓ (N)

Distribution:
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(Return to WM, 623-SS) — EDM
To: Kennedy — Eddie

8712100138 870624
PDR WASTE PDR
WM-11

88152621
WM Project: WM-11
PDR w/encl
(Return to WM, 623-SS)

WM Record File: 102.7
LPDR w/encl

1507

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RECORD OF CORRESPONDENCE CONCURRENCE AND DISTRIBUTION

SUBJECT: DISPOSITION OF STATE, TRIBE, AND NRC COMMENTS ON THE OGR QA PLAN

FROM: NEWTON, RW-24

TO: STATE, TRIBE AND NRC REPRESENTATIVES

PC CODE: CN137 (MARIE ADAMS' IBM)

ORIGINATOR: CARL NEWTON, 6-5059

DISTRIBUTION

QA FILE # L5
OCRWM CCRU, RW-13 (5)
OCRWM ARCHIVES (2)
ORIGINATOR'S CHRON: NEWTON
OGR READING FILE
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S.Kale, RW-20
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S. Echols, GC-11
R. Poe, EH-32
L. Barrett, RW-33

D. Siefken, Weston
L. Skoblar, Weston
G. Faust, Weston
J. Kennedy, NRC

CONCURRENCES:

Carl Newton 6/24/87
Carl Newton, RW-24

Comments	Proposed Disposition
NEVADA	
1. Section 1, Page 2. NQA-1-1983 should be revised to NQA-1-1986.	1. To be Incorporated
2. Section 3, Page 8. Figure 3.1 indicates that the OCRWM QA Manager is not a direct-line management Role to the Director of OCRWM. It appears that the QA Manager is responsible to the Director of Policy and Outreach who may in fact evaluate the QA Managers job performance.	2. To be Incorporated - Footnotes will be added to figure 3.1 clarifying solid line and dotted line. Also, responsibility of Director of Policy and Outreach will be provided in text.
3. Section 3, Page 9. The organizational structure does not provide the OGR QA Manager adequate access to top management. This structure provides little confidence that QA problems will be adequately considered.	3. To be Incorporated - See #2 Above
4. Section 3, Page 12. Section 3.2.6.2 (a)(11) should be revised to add "and affected States and Tribes."	4. To be Incorporated - A new Subsection to be added to Section 3.5 describing Interaction between affected States and Tribes.
5. Section 3, Page 13. Section 3.2.6.2 (F) should be revised to indicate that the quarterly and annual QA Status Reports will be documents available to the Public.	5. Not to be Incorporated - the new Section described in #4 above will provide availability of these documents to affected States and Tribes. However, although they are available to the public also, it is DOE's position that OGR/B-3 is not the appropriate place to state this.
6. Section 3, Page 15. Section 3.5.2 should be revised to recognize the lawful requirements of the DOE to interact with affected States and Tribes also. This interaction should include State/Tribal participation in all Audits.	6. To be incorporated - See #4 above.

Comments	Proposed Disposition
7. Section 4, Page 17. Section 4.2, In the development of QA Programs, who at DOE-HQ will be responsible for ensuring consistency between the project offices.	7. Not to be Incorporated - Responsibility is already covered in text, reference Section 3.2.6.2. Subsection d explains how this is accomplished.
8. Section 4, Page 21. Section 4.5, Affected States and Tribes and the NRC should be included in the list of those entities receiving information.	8. To be Incorporated - See comment #4.
9. Section 5, Page 24. Section 5.3.2, Affected States and Tribes and the NRC should also be included for receipt of documents from the project offices.	9. To be Incorporated - See Comments #4. Note, this Section explains Project Office submittals to HQ-OGR.
10. QIP 2.0, Page 2. Section 7.0, Retention period of 5 years is inadequate, given the long term frame of the project. What is the NRC position on Retention period for non-technical QA Records? This comment on the five year Retention period is also applicable to other QIPs which identify Record Retention for five years.	10. To be Incorporated - We agree, the Retention period of 5 years is to be re-evaluated.
11. QIP 16.0. The Corrective Action Report does not identify the Corrective Action Plan and Schedule required by Section 6.5 and the analysis and approval for that Plan and Schedule. How are comments on the Plan and Schedule resolved and by whom?	11. To be Incorporated - Appendix A, Section B.6 is to be revised to provide for when, as well as how the Corrective Action will be completed. Note that Section 6.5 does provide for the evaluation of the response for adequacy and timeliness.
12. QIP 18.3. This Procedure requires that a technical Specialist also be a trained auditor. If in the Context of an audit, a Technical Specialist is only utilized to provide technical expertise to the audit team, then auditor training is not necessary. This requirement should be deleted.	12. Not to be Incorporated - We agree that this is not required by any codes or standards, however, it is HQ-OGR's position that this requirement be maintained. A technical specialist who is genuinely familiar with the entire audit process will be that much more beneficial throughout the performance of the audit.

Comments	Proposed Disposition
13. Supplement 3, Page 6. Section 3.3, Retrieval will probably occur because the Repository is not performing as anticipated and the waste must be removed before further environmental degradation occurs. Items, equipment, and activities necessary for retrieval may be quite different from emplacement, and thus should be on a separate Q-list.	13. Not be to Incorporated - while we agree that the items, etc. for retrieval may be different from those of emplacement, it is HQ-OGR's position that the same criteria will be used for Q-level classification for both emplacement and retrieval (if necessary). What's important is that the assigning of Q-levels is accomplished consistently.
14. Supplement 7, Page 2. This office has commented in the past that peer reviewers must be independent of both the technical work under review and the organization performing the work. That comment is still applicable to Section 5.0.	14. Not to be Incorporated - It is HQ-OGR's position that the reviewer be independent of the work being performed, not necessarily independent of the organization. There is no requirement for this.
15. Supplement 8, Page 2. Section 5.0 requires that each project review and assign quality levels to items and activities. Who at DOE-HQ will be responsible for evaluating the consistency of assignments among the projects? What criteria will be used in that evaluation?	15. Not to be Incorporated - HQ-OGR Review and Approval of Project Office QA Plans and specific procedures for assigning Quality levels is the method by which consistency will be maintained. Also, HQ Review of the SCP will ensure Q-list consistency.
16. Supplement 8, Page 6. Section 5.3.2.2, It is our understanding that any items or activities related to radiological health and safety should be Quality level 1. Items or activities with a potential impact on occupational health and safety, such as OSHA and MSHA, could be considered Quality Level 2. Also, define those field and Laboratory investigations considered under Quality Level 2. In our view, most provide data for licensing the Repository, thus should be considered Quality Level 1.	16. Not to be Incorporated - By definition Quality Level 1 Items and Activities are those that are directly important to safety or waste isolation...As defined in 10 CFR 60. This section is in reference to those Quality Level 2 items and and Activities that are neither important to safety nor waste isolation, however, are involved with "Protection Against Radiation" as is described under 10 CFR 20.

Comments	Proposed Disposition
	Not be to Incorporated - The title of Section 5.3.2 is "Quality-Level 2". We agree that some of these activities provide data for Licensing-those will be considered Quality level 1, and are not covered here. This Section deals with those lesser Activities identified, as per definition, as Quality Level 2.
17. Supplement 9, Page 2 Section 5.2, In our view the independent reviews stated can only be accomplished by appropriately qualified technical reviewers not associated with DOE or its contractors.	17. Not to be Incorporated - It is HQ-OGR's Position that an effective Review can be accomplished by Reviewers associated with DOE. If the data generates controversy among the Reviewers then provisions can be made to initiate an independent Peer Review.
TEXAS	
1. a. on page viii, the Revision/change board refers to CCBD/BCP numbers B-119 and B-126. How do these documents relate to OGR/B-3 and DOE/RW-0095	1. a. B-119 and B-126 are OGR internal control numbers for the preparation and approval of OGR Baseline Documents, See page vii which will reference you to DOE/RW-0068.
b. Section 1.4, page 2. NQA-1-1983 Should be revised to NQA-1-1986. How will this new version affect the OGR QA Plan	b. To be Incorporated - NQA-1-1986 will not have any affect on OGR/B-3.
2. a. Figure 3.1 The OCRWM QA Manager is not in direct-line to the Director OCRWM	2. a. To be Incorporated - Footnotes will be added to figures 3.1 and 3.2 clarifying solid line and dotted line.
b. Figure 3.2, the Organization Structure does not provide the OGR QA Manager Adequate Access to Top Management.	b. To be Incorporated - See #2a above.

Comments	Proposed Disposition
c. What is the Relationship between the OGR QA Manager and the OCRWM Manager, i.e. who is in charge of what?	c. To be Incorporated - The OCRWM QA Manager is responsible for the establishment and overview of the overall OCRWM QA program policies and requirements, while the OGR QA Manager is responsible for the OGR and Related Project Office QA Program requirements and Activities.
3. Page 7: OGR Associate Director responsibilities should include ensuring adequate staffing of QA personnel in all areas of the OCRWM QA program	3. Not to be Incorporated - This responsibility has been delegated. Reference Section 3.2.3 b.
4. Section 3, Page 12. Section 3.2.6.2 (a) (11) should be revised to add "and affected States ad Tribes."	4. To be Incorporated - A new Subsection to be added to Section 3.5 describing Interaction between affected States and Tribes.
5. Section 3.3, Page 13. The Project Manager does not have the degree of independence necessary to be responsible for the QA Program and at the same time be responsible for the implementation and execution of the project. The PM may have the responsibility for establishing the Program, however, its implementation must be carried out does with a proper level of independence.	5. Not to be Incorporated. The Project Manager is designated as having the ultimate responsibility for the implementation of the QA program. The implementing itself however, is carried out by the QA organization which does have a separate reporting chain and degree of independence.
6. Section 3.5.2, Page 15 should be expanded to include notice to and participation by affected States and Tribes	6. To be Incorporated - #4 above.
7. a. Section 4.2, Page 17. In the development of QA programs, who will be responsible for ensuring consistency between the project offices?	7. a. The OGR QA Manager is responsible. Reference Section 3.2.6.2 Subsection d explains how this is accomplished.

	Comments	Proposed Disposition
	b. Section 4.4, Page 21. This Section needs more elaboration. How will management perform these assessments? Will additional guidance be issued for the objectives and implementation of the assessments?	b. To be Incorporated - We agree with your comment, additional guidelines are under development and will be forthcoming.
8.	a. Page 21, Section 4.3.2 (h): Who is responsible for verifying the QA programs for the various subcontractors?	8. a. Ultimately HQ is responsible, however, this authority has been delegated to the Project Offices per Section 5.3.1.a. Verification that the QA programs of Contractors are sufficient is provided by the Review and Approval of their plans/procedures, audits, surveillances, etc.
	b. Page 21, Section 4.5: The affected States and Indian Tribes should be included in the list of those receiving information, along with POs, contractors, and OCRWM.	b. To be Incorporated - See comment #4
	c. Page 24, Section 5.3.2 (b): The affected States and Indian Tribes should be included as recipients of this information.	c. To be Incorporated - See comment #4
9.	a. QIP 2.0 states "The procedures may be approved...etc." Section 6.1.2 states "The QA Plan will be ...etc." Why is the wording different?	9. a. To be Incorporated - Section 6.2.2 will be revised to "will be...".
	b. QIP 2.0, Section 7: Retention Period of five years is not long enough.	b. To be Incorporated - We agree, the Retention period of 5 years is to be re-evaluated.
	c. QIP 2.0, Appendix A: The QA manual evaluation checklist does not require the reviewers to be identified.	c. To be Incorporated - Appendix A will be Revised to provide for identification of the Reviewer.
10.	a. QIP 2.1, Section 7.1: Retention period of five years is not long enough.	10. a. To be Incorporated - See #9b above.

Comments	Proposed Disposition
b. All handouts and copies of visual aids used in training sessions should be included in the records.	b. To be Incorporated - Section 7.1 of QIP 2.1 will be revised to add 7.1.7 that will add this material. Note-only materials that are feasible to be retained as records will be. Such things as videos, etc. will not.
11. a. QIP 5.0, Section 4.1.1: This Section has a typographical error. The word "of" has been omitted.	11. a. To be Incorporated.
b. QIP 5.0, Section 7.1: Retention period of five years is not long enough.	b. To be Incorporated - See #9b above
12. a. QIP 16.0: Retention period of five years is not long enough.	12. a. To be Incorporated. See #9b above.
b. The Corrective Action Report form does not require a schedule for the completion of the Corrective Action. The procedure in Section 6.5 does require a schedule.	12. b. To be Incorporated. Appendix A, Section B.6 is to be Revised to provide for <u>when</u>, as well as, how the Corrective Action will be completed.
13. QIP 17.0, Section 4.5: As stated this could lead to the destruction of some documents that are not required at the five year period, but could possibly be needed at some later date.	13 To be Incorporated. See #9b above.
14. QIP 18.0, 18.1, 18.2: Retention period of five years is not long enough.	14. To be Incorporated - See #9b above.
15. a. QIP 18.3: Procedure states that technical specialist must be a trained auditor Provision should be made to allow technical personnel not qualified as auditors to assist and observe the audit team. Term "Technical observer" would probably satisfy this.	15. a. Not to be Incorporated - We agree that this is not required by any codes or Standards, however, it is HQ-OGR's position that this Requirement be maintained. A technical Specialist who is genuinely familiar with the entire Audit Process will be that much more beneficial throughout the Performance of the Audit.

Comments	Proposed Disposition
b. Is the term audit team leader synonomous with Lead Auditor?	b. Note that the term Lead Auditor is not referenced in this procedure. To answer your question, however, yes an Audit Team Leader may be synonomous with Lead auditor. An Audit Team Leader would have to be certified as a Lead Auditor, however, a certified Lead Auditor may be participating in an audit in a capacity other than Audit Team Leader.
c. Does the Lead Auditor Examination, as administered by DOE, fulfill the requirements of Section 6.1.5 for Auditor qualification?	c. There is no "Lead Auditor examination". The current program requires that one written exam be administered and this exam fulfills the requirements of Section 6.1.5. Based on additional experience/education/training, as outlined in the procedure, one can become certified as "Audit Team Leader".
16. Supplement 2, Section 5.4: The first sentence lacks a verb.	16. To be Incorporated.
17. a. Supplement 3, Page 1: The first sentence of the first quote in the middle of the page reads "...important to safety not waste isolation". This should read "...Nor waste isolation" to be consistent with 10 CFR 60 and other NRC regulations.	17. a. To be Incorporated.
b. Page 5: A truly conservative approach at the SCP design stage would be to include all site characterization activities on the Q list.	b. Not to be Incorporated. Yes, this would be truly conservative, however, not practical. As is described in the text, this decision will be based on sound technical judgment.

Comments	Proposed Disposition
c. Page 6: Retrieval of waste cannot be considered to be just the reversal of emplacement. Therefore, items and activities necessary for retrieval should be on the Q-list separately.	c. Not to be Incorporated - while we agree that Retrieval of waste cannot be considered to be just the reversal of emplacement, it is HQ-OGR's position that the same criteria will be used for Q-level classification for both emplacement and retrieval (if necessary). What's important is that the assigning of Q-levels is accomplished consistently.
18. a. Supplement 4: The list of records for lifetime storage should be expanded to include the records commented on previously regarding the five year retention limit.	18 a. To be Incorporated - See comment #9b
b. Section 5.5 and 5.6: since no licensed repository has ever been designed or constructed, it is improper to refer to "typical" records. In addition, the presented lists should not be considered limiting, and a statement to that effect should be included. The recognition of nonpermanent records and still available" point up earlier comments about records retention time.	b. Not to be Incorporated - The intent of this supplement is to establish overall OGR Policy guidance. The Project Office QA Programs will be required, as part of the program to identify the specific records to be maintained and controlled. Eventually there will be "typical" records.
19. Supplement 5: Research is often a combined effort by several people. This supplement implies that only one project notebook would be generated. This would not be the case where several groups develop input into a single report. The Activity Plans developed and approved for each activity will satisfy many of the requirement of this supplement, and perhaps the Activity Plans should be referenced in the document.	19. Not to be Incorporated - Section 5.1 requires that documentation of experiments and research be prepared using logbooks (plural) or other suitable means. It is not implied that only one notebook would be generated. The intent of this supplement is to provide the minimum requirements for experiment and research documentation. Detail will be provided by the Project Office Specific Implementing Procedures.

Comments	Proposed Disposition
20. a. Supplement 6, Section 4.1: The term "adverse impact" needs clarification and "A quality problem that possesses generic traits..." needs better definition.	20. a. To be Incorporated - change "have an adverse impact on" to "hinder the progress of"; change "possesses generic traits applicable" to "is common".
b. Section 4.2: Define the "various participants".	b. "various participants" - is defined as HQ-OGR, the Project Offices and the numerous major contractors involved in the Repository Program.
c. Section 5.2: Does the Project QA Manager of each office have sufficient knowledge of the overall program to be able to determine quality problems generic to all offices? The OGR QA Manager should be responsible for issuing generic QAAS.	c. HQ-OGR feels that the Project Office QA Manager does have sufficient knowledge of the overall program, as a result of the continuous interaction between the Projects. As is explained in this Section, the fast relaying of information between the Project Offices assures that the QA Managers will be aware of the overall picture.
d. Define "fast relaying". Is there a specific length of time that correlates to this term?	d. "Fast Relaying" - can be interpreted as meaning within one working day.
e. Section 6.1: How will deteriorating quality conditions be identified by the project personnel?	e. Deteriorating quality conditions are identified by Project Personnel, as described in Section 5.3 of this supplement, by regularly reporting to their immediate supervisor. Section 4.5 of OGR/B-3 also requires that lines of communication between Project Offices and their contractors be maintained for the purpose of dissemination of information regarding significant quality problems. And, also Project Office specific implementing Procedures deal with identifying Quality problems.

Comments	Proposed Disposition
f. In condition (d), define the term "remarkable experience/innovations".	f. To be Incorporated - Change "Remarkable experience/innovation" to "improved development"
g. Section 6.2.2 (a): If "other means of communication" are used for the "fast relaying of QAAs, then there should be a requirement that the formal written transmittal of the QAA should follow the initial communication within some definite time span, i.e., 3 days.	g. To be Incorporated - Add last sentence to 6.2.2 (a) - "If initial communications is accomplished by any of these means, then the formal written transmittal of the QAA shall be initiated within 3 working days".
h. Section 6.2.2 (d): Who assigns the unique tracking/identification number to the QAA and, if it is done at the Project Office level, how will the different Project Offices keep track of the numbers used by different offices?	h. The intent of this Section is that each Project Office maintain their own separate QAA Tracking Log, providing uniqueness within each office.
21. Supplement 7, Section 5.2: Peer review panels should require the inclusion of at least one person independent of DOE and its contractors.	21. Not to be Incorporated - It is HQ-OGR's position that the reviewer be independent of the work being performed, not necessarily independent of the organization. There is no requirement for this.
22. a. Supplement 8, page 1, Section 3: Define how the term "economic considerations" is used in this section.	22. a. "Economic considerations" - is defined as "cost".
b. Supplement 8: Assignment of Quality levels by the different projects could lead to inconsistencies between projects and affect the decision process.	b. Not to be Incorporated - HQ-OGR Review and Approval of Project Office QA Plans and Specific Procedures for assigning Quality levels is the method by which consistency will be maintained. Also, HQ Review of the SCP will ensure Q-list consistency.

Comments	Proposed Disposition
c. Attachment B indicates that all records that support licensing activities are Quality Level 1. Records such as qualification of personnel, audit findings, and corrective actions might be part of the licensing activities. Therefore, taking the conservative approach, these documents should have a considerable retention period, it not lifetime.	c. To be Incorporated - See comment #9b.
d. Page 5, Section 5.3.1.2: The statement that "Activities covered under Quality Level 1 include: ... site characterization." implies that <u>all</u> aspects of site characterization are covered under this level. Is this true?	d. No, all Activities (important to safety or waste isolation) <u>essential</u> to adequately characterize the site will be Quality level 1.
e. Page 6, Section 5.3.2.2: Definition is needed for which field and laboratory investigations are covered under Quality Level 2. If these investigations have to do with site characterization, shouldn't Quality level 1 apply?	e. Not to be Incorporated - The title of Section 5.3.2 is "Quality levels 2". We agree that some of these investigations provide data for licensing-those will be considered Quality level 1, and are not covered here. This section deals with those lesser activities identified, as per definition, as Quality Level 2.
f. Why are items and activities with potential impact on <u>public</u> and occupational health and safety only Quality Level 2?	f. This section is in Reference to those Quality level 2 items and activities that are neither important to safety nor waste isolation, however, are involved with "Protection Against Radiation" as is described under 10 CFR 20.
23. <u>Supplement 9</u>, Section 5.2: Independent review panels should require at least one reviewer not associated with DOE or its contractors.	23. Not to be Incorporated - It is HQ-OGR's position that an effective Review can be accomplished by Reviewers associated with DOE. If the data generates controversy among the Reviewers then provisions can be made to initiate an independent Peer Review.

Comments	Proposed Disposition
24. a. Supplement 11, Section 1.0: For waste that is to accepted in the repository, the waste must have been processed under a QA program that complies with 10 CFR 60, Subpart G, not the OGR QA Plan.	24. a. The waste producers QA program will comply with both. They will comply with OGR in the sense that their program will be subject to OGR overview. Their program will require compliance with 10 CFR 60, subpart G, and OGR HQ program will verify this compliance (i.e., audits).
b. Section 5.1.1: The QA program must comply with 10 CFR 60, Subpart G, not to 10 CFR 60.2 which does not even address any requirements.	b. Not to be Incorporated - This Section states that "safety and waste isolation" is defined in 10 CFR 60.2, not the QA program.
c. Section 5.2(a): If the DOE HQ-OGR does not intend to review the technical procedures for processing the waste, will audits of the program include audits of the technical procedures and, if the procedures as determined to preclude the waste from being accepted by the repository, how will this be resolved?	c. Yes, audits of the program will include audits of the technical procedures. If the procedures are determined to be unacceptable and preclude waste from being accepted, they would be required to be revised until approved.
d. Section 5.4: Direct NRC QA involvement is required in regards to defense waste facilities. DOE overview themselves is unacceptable.	d. The NRC has stated that DOE overview of Waste Producers QA Program may be sufficient.
25. a. Supplement 12: This supplement does not belong in the QA Plan. It is more of a policy statement.	25 a. Concur. Per agreements reached in the April 23, 1987 QACG Meeting, DOE will issue a draft Policy Guidance Letter on the subject of observers on DOE audits. This letter will be distributed for review and comment.

Comments	Proposed Disposition
b. Section 3.0: Does the one observer allowed mean one observer from each interested affected State and Tribe, or one observer to be picked by DOE if more than one affected State and Tribe are interested in observing the audit?	b. See comment #25a.
c. Section 4.0: Define "certified" auditor". To our knowledge, there is no defined requirements for certification of auditors, only the requirements for certification of Lead Auditors. Have there been changes in the QA training auditors as required by NQA-1 or is this just a requirement of DOE for State and Tribe observers? If auditors are now required to be certified, does DOE plan to require their own auditors to be re-trained in accordance with these unknown requirements?	c. See comment #25a.
d. Does the DOE Lead Auditor training course qualify as training, qualification and certification of an auditor?	d. See comment #25a.
e. Section 5.1: Since this section requires 21 day written notice for observer participation in a DOE audit, we would like the requirement that 30 days written notice of scheduling of audits be given the affected States and Tribes.	e. See coment #25a.

Comments	Proposed Disposition
f. This section also states that the observer be trained, qualified, and certified in accordance with QIP 18.3. We would like the statement changed to state "in accordance with...QIP 18.3 or its equivalent.	f. See comment #25a.
g. Section 5.2: The documents sent to the audit observer should also include a list of the audit team members.	g. See comment #25a.
h. Section 6.2.2: How will possibly conflicting comments of the audit observer be resolved and who will be responsible for the resolution?	h. See comment #25a.
WASHINGTON	
1. Organizational structure in regards to who the QA Managers report to is not adequate.	1. To be Incorporated - Footnotes will be added to figures 3.1 and 3.2 clarifying solid line and dotted line.
2. The QA Plan does not address the issue of how many US DOE QA persons should be on staff to oversee contractors. At Hanford, for example, there has been an unacceptable ratio of US DOE QA persons to contractor QA persons.	2. Not to be Incorporated - The OGR QA Plan is not the document to impose such requirements. This subject is strictly a Management decision which is subject to many factors.
3. Section 2.3.1: The Mission Plan should provide an informational basis sufficient to permit informed decisions, but recent US DOE decisions regarding a second repository have severely reduced the value of the document.	3. Not to be Incorporated - There will be no change to the OGR QA Plan concerning this comment. The purpose of this section is to reference the Mission Plan as a governing document, not to evaluate its merit.

Comments	Proposed Disposition
4. Section 3.1: The statement that the "QA management functions responsibilities and authorities for OGR have been assigned by the Director, OCRWM to the Associate Director OGR" seems inconsistent with figure 3.1. clarify.	4. To be Incorporated - Section 3.1 will be revised to explain the delegation of OGR-QA Responsibilities only by the OCRWM QA Manager. He will retain all other OCRWM QA Responsibilities.
5. Section 4.3.2.d: The OGR QA Manager "overview" funding for QA activities and identified insufficient resources through the Licensing and QA Branch Chief through the SLQA Division Director to the Associate Director OGR. This appears to illustrate our concern about the level of QA personnel within the USDOE organization.	5. See Comment #1 - This will clarify that OGR QA Manager does have access to the Associate Director OGR.
6. Section 4.3.2.e.1: Project Office QA Plans and procedures should be submitted to the appropriate states and affected Indian Tribes for their review and comment.	6. To be Incorporated - A new subsection to be added to Section 3.5 describing Interaction between affected States and Tribes.
7. Section 4.3.2.e.3: The appropriate state and affected Indian Tribes should be invited to participate in project readiness reviews. The invitation should include early access to data.	7. Not to be Incorporated - The OGR QA Plan is an inappropriate place to address this subject. This concern however, has been brought to the attention of appropriate OGR-HQ management.
8. Section 4.3.2.f.6: Results of surveillance performed should also be reported to the appropriate states and affected Indian Tribes.	8. To be Incorporated - See comment #6.
9. Section 4.6: OGR QA Supplement #6 should be changed to indicate that states and affected Indian Tribes will be notified at the time significant quality problems are identified and again when resolved. Significant problem reporting and corrective action records are a significant part of the record for NRC licensing and as such should become permanent records.	9. Not to be Incorporated - Affected States and Tribes will not be notified at the time of significant quality problem identification, however, appropriate documentation/reports associated with such problems will be made available. This will be explained in a new section to the plan describing Interaction between DOE and affected States and Tribes.

Comments	Proposed Disposition
10. Section 5.3.1: The project QA Plan and/or applicable QA administrative procedures should describe a process for review and comment by appropriate states and affected Indian Tribes.	10. To be Incorporated - See comment #6.
11. Appendix A - Quality Assurance Manual Evaluation-Handling, Storage and Shipping Requirements for control of samples from collection of the sample analysis should be established and documentation for control of each sample must be provided.	11. Not to be Incorporated - This stage will be addressed in specific Implementing Procedures and HQ OGR's Review and Approval of these procedures will provide verification.
12. Supplemental QA Requirements-Supplement No. 11 1.0: Appropriations have been approved to begin preliminary design work on the Hanford Waste Vitrification Plant and criteria are being developed to determine which wastes should be vitrified. Both activities require an adequate QA program. The supplement should be amended at this time to include Hanford wastes.	12. Not to be Incorporated - We agree, however, in our opinion the Hanford Waste Vitrification Plant is in too early a phase to be included in Supplement 11 at this time.
13. Supplemental QA Requirements - Supplemental No. 12 We question whether this supplement is appropriate. Arbitrarily limiting non-DOE observers to one observer during each audit cycle is contrary to the NWPA because the states, tribes and NRC have a statutory role which allows participation. USDOE should substitute a process whereby states, tribes and NRC are encouraged to cooperate on audits and the audit team is made up of the most highly qualified personnel.	13. Concur. Per agreements reached in the April 23, 1987 QACG Meeting, DOE will issue a draft Policy Guidance Letter on the subject of observers on DOE audits. This letter will be distributed for review and comment.

Comments	Proposed Disposition
NRC	
1. The OGR Plan was written Prior to NRC's June 1986 draft generic technical Positions (GTPs): a.) Qualification of existing Data (Federal Register Vol. 51, No. 128, pg. 24455, July 3, 1986). b.) Peer Review (same reference as item a) c.) Items & Activities subject to 10 CFR 60 QA Requirements (Federal Register Vol. 51 51, No. 153, pg. 28643, August 8, 1986). The Plan (including supplements) should be Revised to Reflect these GTPs and differences noted and justified.	1.a,b,c. Not to be Incorporated - It is our policy that draft GTPs not be referenced, they are not requirements that must be complied with. However, when they are issued and final we will make any revisions necessary to help improve the effectiveness of our QA Program.
2. Include a list of abbreviations used in the plan.	2. To be Incorporated.
3. The September 1984 version of the OGR QA Plan stated that the Associate Director OGR, has ultimate responsibility for establishing and implementing an effective QA program for the OGR subprogram and for verifying that field project offices have established and are implementing effective QA programs. The July 1986 version does not clearly assign these responsibilities. Indicate (by position title) who now has these responsibilities. (1.1)	3. The OGR Associate Director retains these Responsibilities - Section 3.2.1.a states that he provides <u>overall</u> QA policy guidance...to ensure <u>effective implementation</u> of the OGR QA Program by all projects. Section 3.2.1.c provides that he "Approve the QA Plans and procedures of Project Offices".
4. Section 4.3.2.f of the OGR QA Plan addresses participation of OGR QA in project office audits of "major contractors". Clarify any differences between "major contractors" used in 4.3.2.f and "contractors" as defined in Section 1.4.1 of the plan. Specify the frequency of OGR audits. (1.4)	4. Major contractors are those contractors doing significant, large amounts of work on a project and may have the resources to subcontract (if necessary) some of that work. There are also a number of smaller contractors doing a lesser amount of work. The second part of your comment will be incorporated - will be revised to require that annual audits be performed on the Project Offices.

Comments	Proposed Disposition
5. Section 3.3 of the OGR QA Plan indicates that the manager of each operations office has line management responsibility and accountability for overall project implementation. Clarify the reporting relationship of the manager of the operation office and the OGR. (1.7)	5. To be Incorporated - This is explained in the Project Charters - a Revision will be made to Reference these.
6. Clarify whether the OGR QA Manager is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality and is sufficiently independent from cost and schedule. (1.10a)	6. To be Incorporated - Footnotes will be added to figure 3-2 clarifying solid line and dotted line.
7. Section 3.2 of the OGR QA plan indicates that each OGR Division and Branch will be responsible for quality achievement and assurance of quality within their areas of responsibility. Clarify that the assurance of quality (or verification of conformance to established requirements) is accomplished by individuals or group who do not have direct responsibility for performing the work being verified.	7. The purpose of Section 3.2 of this Plan is to describe the organizational responsibility for Quality Achievement and Assurance. This is not the appropriate place to include the subject of your comment. Please Reference Fig. 1.1 in the QAMPR (DOE/RW-0032) which describes Quality verification as including reviews, audits, and surveillances. Within the OGR QA Plan each of these is discussed separately, and it is here that it is documented that these are accomplished by personnel not directly responsible for the work being verified. Reference Supplement 2, Sections 5.3 and 5.4, and Supplement 7, Section 5.2.
8. The last item in Section 3.4 of the OGR QA plan indicates that OGR QA can stop, or cause to be stopped, unsatisfactory work, through established channels. The QA organization need not have authority to stop work if the individual to whom the person responsible for managing the QA program reports has this authority. Describe how stop-work requests are initiated and completed. (1.12)	8. To be Incorporated - A QIP for stop work is forthcoming that will explain these matters.

Comments	Proposed Disposition
9. Describe provisions for the resolution of disputes involving quality arising from a difference of opinion between OGR QA personnel and other OGR personnel. (1.13)	9. To be Incorporated - Revision to be made to QIP 16.0 Section 6.5.b adding the provision that disputes arising from a difference of opinion between OGR QA personnel and other OGR personnel will be elevated to the next higher level of management.
10. Section 5 of Supplement 8 addresses rationale for assigning Quality Levels. Clarify whether these rationale include system analyses and definition of numerical performance objectives and standards. Justify why not if not. Identify items and activities covered by the QA program. The staff information needs defined in the "Q-List" GTP (See comment 1.c for complete title) should be used as guidance. If items and activities important to safety or waste isolation as defined in 10 CFR 60.2 will be identified in the project offices QA plans, so state. (2.1)	10. Level 1 items and Activities will be based on direct assessment of whether the performance objectives will be met at the LA Design Stage as described in Section 3.2 of supplement 3, Attachment A; and by Engineering judgment at the SCP Design Stage as specified in Section 3.1. the reason numerical standards are not used at SCP stage is because they are not available to the extent needed to make such evaluations. Items and Activities important to safety or waste isolation will not be identified in the Plan, they will be on the Q-list and Quality Activities List Respectively (tentative at SCP, complete at LA Stage).
11. Supplement 1: a.) Section 1.0 of this supplement indicates the supplement applies to personnel performing or verifying activities that affect quality. Sections 2.0, 5.1, 5.2, 5.4, 5.4, 5.5, and 5.6 address personnel who perform activities affecting quality, omitting personnel who verify activities affecting quality. Conversely, the examples given in Section 3.0 are all verifiers. Clarify that the entire supplement applies to both doers and verifiers.	11. a. To be Incorporated - Supplement to be Revised to clarify that it applies to both doers and verifiers.

Comments	Proposed Disposition
b.) Section 1.0 of this supplement should be revised to be consistent with the other supplements to the OGR QA Plan.	b. To be Incorporated - The following sentence will be added to Section 1.0, "The Requirements in this supplement are to be used in conjunction with the requirements embodied or referenced in the governing QA plans and procedures."
12. Supplement 2:	
a.) Section 4.1 of Supplement 2 states that overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillance. Section 5 of the supplement should be expanded to address each of these component parts of overviews.	12. a. To be Incorporated - Section 5.0 to be expanded to address each of the component parts of overview.
b.) Section 5.2 of this supplement should require that overview procedures include the criteria for determining the acceptability of the QA program documentation. Timeliness of document review should also be addressed.	b. Not to be Incorporated - As is described in Section 4.3.2.e.1 of the QA Plan, Reviews are performed in accordance with an established procedure. The timeliness of a Review will vary depending on the program. It is OGR's position to make every effort to assure that a timely Review is accomplished.
c.) Section 5.3 of Supplement 2 requires surveillance. The qualification requirements of surveillance personnel should be specified.	c. Not to be Incorporated - As is inferred in Supplement 1, Section 3.0, Surveillance personnel will be sufficiently Indoctrinated and Trained in accordance with this supplement. Personnel qualified for surveillances will vary based on their specific training as compared to the Surveillance being performed.
12. Supplement 2:	
d.) Section 5.4 of Supplement 2 addresses external audits as part of the overview process. Clarify that both technical and QA programmatic audits are performed to:	d. To be Incorporated - Supplement to be Revised to address points 1 and 2 of your comment.

Comments	Proposed Disposition
1) Provide a comprehensive independent verification and evaluation of procedures and activities affecting quality. 2) Verify and evaluate suppliers QA programs, procedures, and activities.	
e.) Audit teams should be led by an appropriately qualified and certified lead auditor from the QA organization.	e. Not to be Incorporated - Audits will be led by qualified and certified lead audits as required by QIP 18.0 and 18.4 However, it is not required that the Lead Auditor be from the QA organization, only that he be independent of the work being audited.
13. Supplement 3:	
a.) Prior Supplement 3s addressed the control of measuring and test equipment. Identify where within the OGR QA Plan these controls are now specified.	13. a. Not to be Incorporated - Reference figure 4-1 on page 18 of the QA Plan. It is explained here that the authority for this requirement has been delegated.
b.) Section 5.0 of this supplement requires a procure for determining what is placed on each project's Q-List. Clarify that each project's Q-List will be reviewed by HQ-OGR and submitted to the NRC.	b. Each Project Office Q-list will be in the SCP which is required to be reviewed by DOE. At this time they will also be provided to NRC for comment.

Comments	Proposed Disposition
c.) The first paragraph of the summary of Attachment A of this supplement refers to items and activities "important to safety and waste isolation". Change the "and" to "and/or" or justify not doing so. This same paragraph quotes from a preliminary draft NRC document. The quotation and paragraph should reflect the draft GTP and should be revised per Comment 1, item c. For example, this section indicates that only Q-List items and activities will be subject to NRC licensing review and oversight. In addition to the Q-Listed items and activities important to safety and/or waste isolation, other items and activities will be associated with demonstrating that DOE meets all of the 10 CFR Part 60 Licensing requirements. For example, 10 CFR Part 20 requirements, which are referenced in 10 CFR Part 60, will need to be addressed in the License application. Although these additional items and activities are not covered by the 10 CFR 60 Subpart G QA requirements (which apply only to items and activities important to safety and/or important to waste isolation), assurance measures are needed to provide confidence that the requirements have been met. Certain assurance measures, such as use of written procedures, documentation of completed work, and monitoring of radiation levels, are currently prescribed in the regulations and, although not explicitly stated as quality assurance requirements, provide a basis for demonstrating compliance with the licensing requirements. Therefore, these assurance measures are also subject to NRC Licensing review and oversight. Modify this section to clarify this point or justify not doing so.	c. To be Incorporated - Change to be made to first paragraph, change "and" to "and/or". Section will also be modified to clarify your point.

Comments	Proposed Disposition
d.) The supplement on the Q-List states that DOE will utilize an annual probability value of 1X10-5 as a limit for accident scenarios for identification of the Q-List. As noted in the staff's letter to J. Knight, DOE, dated March 7, 1986, it is the staff's position that credible initiating events and accidents should not be bound by a specific probability value at this stage of the repository program until DOE and NRC have agreed on the rationale for such a limit.	d. Not to be Incorporated - At this point it is HQ-OGR's position that this value is conservative and will be used unless directed otherwise.
14. Supplement 5:	
a.) Clarify the last sentence in Section 3.0 of this supplement which states: Data... shall be conducted...". Also, from the same sentence, identify the "other applicable requirements identified in the OGR QA Plan," and/or clarify what these words mean.	14. a. To be Incorporated - This section to be revised to incorporate your comment.
b.) The signature of the experimenter and the signature of a competent technical reviewer do not appear to be adequate for Quality Level 1 or 2 data. Clarify.	b. Not to be Incorporated - These signatures are quite adequate for the documenting of data results from experiments and research. Additional requirements to control the reliability of data generated are contained in Supplement 9.
15. Supplement 6:	
a.) Prior Supplement 6s addressed the control of computer software. Identify where within the OGR QA Plan these controls are now specified.	15. a. Not to be Incorporated - will be identified in the Project Office specific procedure, in accordance with NQA-1, Supplement 3S-1.

Comments	Proposed Disposition
b.) The title of this supplement, "Quality Problem Reporting;" Sections 2.0 and 5.3; and the QAA format shown in Attachment A of the supplement are all limited to quality problems and quality problem reporting. Section 3.0, 4.2, 5.1, 5.2, and 6.1 indicate that quality improvement is also included in Supplement 6. Clarify the supplement to eliminate this inconsistency.	b. Clarification to be made to eliminate this inconsistency and include quality improvement.
c.) This supplement needs to be edited to take care of question like the following:	C. 1) To be Incorporated - Section 1.0 To be revised to sate this.
1) Are the requirements of the supplement to be used in conjunction with the requirements specified (or embodied) or referenced in the governing QA plans and procedures?	
2) Should "information" in the first sentence be "improvement?"	2) To be Incorporated - "information" is the correct word, however, sentence will be revised to to clarify this.
3) Should the text always refer to "significant quality problems" and "substantial quality program improvement?" (Underlines added)	3) Not to be Incorporated - Yes, the documentation required per this Supplement is not necessary for minor or "one time" occurrences.
4) Should "consequently" in 5.1 be "subsequently" or, rather, should it be deleted?	4) Comment not applicable - Supplement 6, Draft 3, Nov. 1986, Section 5.1 has deleted the word consequently.
5) Section 5.2 refers to the "applicable immediate supervisor" and Section 5.3 refers to the "immediate supervisor". Do these supervisors have any responsibilities that should be listed in Section 5.0?	5) Not to be Incorporated - The supervisors referenced here do not have any responsibilities in relation to the requirements of this supplement.

Comments	Proposed Disposition
6) When there is no need to expedite, does the telephone requirement of Section 5.2 still apply?	6) Per this supplement, "fast relaying" of QAA Information is required. If there is no need to expedite then it is not a QAA condition.
7) On the QAA form, does the "RECIPIENT ACTION" require feedback?	7) "Recipient Action" on the QAA form does not require feedback.
8) Are no signatures required on the form?	8) To be Incorporated - Form to be revised to provide for signature of preparer.
16. Supplement 7:	
a.) This supplement, being issued prior to issue of the GTP on peer review, should be revised to reflect the GTP. (See Comment 1, item b). For example, the definition of peer review in Section 4.1 of Supplement 7 references the NRC QA Review Plan, Appendix A, Section 3.8. It would be preferable to reference NRC's draft GTP on peer review. As noted in the definition of peer review in the draft GTP, the definitions in Section 4 of this supplement should point out that peer reviews confirm (validate) the adequacy of work whereas technical reviews verify conformance to predetermined requirements. The emphasis (underlining) on data that "go beyond the existing state of the art" should be removed as the definition is revised to reflect the draft GTP. Section IV.1 of the draft GTP addresses the applicability of peer reviews.	16 a. Not to be Incorporated - See comment #1.
b.) The records required by Section 5.4 of the supplement should include objective evidence of the independence of the reviewers. Section IV.3.b of the draft GTP discusses reviewer independence.	b. To be Incorporated - form to be provided, signed by the Reviewer stating that he is independent of performing the work that the Review was covering.

Comments	Proposed Disposition
17. Supplement 8:	
a.) Section 5.1.1 of Supplement 8 indicates that, once a quality level is selected, further grading shall be accomplished by technical and quality system personnel working as teams. Clarify who (by position title) is responsible for selecting quality levels. As noted, Section 5.1.1 refers to "quality system" personnel. Clarify that these are "quality assurance system" personnel as they are referred to in Section 5.1.2.	17. a. To be Incorporated - Section 5.1.1 to be revised to indicate "quality assurance system" personnel. However, it will not be clarified here as to who is responsible for selecting quality levels. This is covered in specific implementing procedures.
b.) The list of OGR QA Plan Supplements on page 2 of Attachment A needs to be updated to reflect the latest supplement titles.	b. To be Incorporated
18. Supplement 9:	
a.) This supplement being issued prior to the GTPs on peer review and qualification of existing data, should be revised to reflect these GTPs. (See Comment 1, items a and b).	18. a. Not to be Incorporated - See Comment #1.
b.) Section 3.0 of Supplement 9 addresses the scope of the supplement. Its scope should be extended to data collected prior to NRC acceptance of the QA program description under which the data were collected and NRC verification of acceptable implementation of the program.	b. Not to be Incorporated - Any/all Corrective Action required to resolve NRC comments or findings on the OGR QA Program will have to address, in part, the impact on all work performed to date.
c.) Section 5.2.1 of the supplement should include the qualifications of the original investigator as part of the documentation made available to the reviewers.	c. To be Incorporated - Section 5.2.1 to be revised to include qualifications of the original investigator as part of the documentation made available to the Reviewers.

Comments	Proposed Disposition
d.) The list of documentation in Section 5.2.1 of this supplement should include the list in Section 5.3.1.	d. Not to be Incorporated - the list of documentation in Section 5.2.1 (non journal) is not applicable to Journal data as defined in Section 3.c.
e.) The written reports required by Section 5.2.2 and 5.3.2 of the supplement should include the qualifications of the reviewers and objective evidence of their independence.	e. To be Incorporated - Revision to be made to include the qualifications of Reviewers. Objective evidence will consist of a form, signed by the Reviewer, stating that he is independent of performing the work that the Review is covering.
f.) Although most definitions of QA indicate that QC is a subset of QA, Section 5.2.2(d) would be more clear if it requires a description of the "quality control/quality assurance methods" rather than a description of just the "QA methods". Instead of a description of such methods that "may have been used," 5.2.2(d) should require a description of such methods that "were used". Objective evidence of the use of such quality control/quality assurance should be available.	f. To be Incorporated - Revision to be made to provide for your comment.
g.) A better description should be provided of the qualification requirements of the reviewers in Section 5.4 of the supplement. The supplement should indicate any allowable and/or any prohibited reporting relationships of these independence is given in Section 3 of the GTP on peer review. (See Comment 1, item b).	g. Not to be Incorporated - This will be covered in Project Specific Procedures as is required by Section 5.1.

Comments	Proposed Disposition
19. Supplement 11: The limited oversight role of the NRC for defense wastes described in this supplement is a concern expressed previously by the staff (see the December 11, 1986 minutes from meeting with DOE on the Defense Waste Processing Facility, DWPF). Further DOE/NRC discussions are necessary to develop an acceptable approach for NRC oversight.	19. Concur. At the conclusion of DOE/NRC discussions on this matter Supplement 11 will be ammended accordingly.