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DOE ORDER# 5700.6
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Wentzen, V.	XX	
Wright, R.	XX	
Wrights, M.	XX	
Wright, S.	XX	
Wright, T.	XX	
Wright, U.	XX	
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Wright, X.	XX	
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Wright, Z.	XX	
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September 9, 1994

94-RF-08983

Dero W. Sargent
Standards Performance & Assurance
DOE, RFFO

RESPONSE TO LEVEL 1 ENVIRONMENTAL EVALUATION AUDIT REPORT (07006) -
SGS-465-94

GENERAL RESPONSE

The audit referenced above was performed by the Department of Energy, Rocky Flats Field Office (DOE, RFFO) on the Environmental Restoration Program Division (ERPD) Ecological Evaluation (EE) Program from May 9-27, 1994 and included several Operable Units (OUs). The audit team recorded three issues and three observations. The issues are addressed in this response. The observations addressed positive aspects of the program and warrant no comment.

The audit addressed Environmental Evaluations and Environmental Restoration (ER) programmatic issues. The issues were concerned largely with ecological records and systems to ensure traceability and defensibility of data collected. The bases for the issues identified in the audit report consisted of the following types of project-related deliverables and processes:

- Records completion
- Records management and turnover
- Document control
- Technical and quality reviews of deliverables
- Oversight (independent and/or management)

Although the formal response to this audit is submitted through an extension to the original response due date, it should be emphasized that the Management and Operating Contractor (M&O) Ecology and Watershed Management Division, formerly Ecology and NEPA Division, initiated implementation of the corrective actions identified in Attachment 1 both prior to the audit, based on internal knowledge of the problems, and after preliminary results of the audit were verbally communicated by DOE. Operating procedures were modified to improve technical bases and quality records completion and turnover; a new data form was produced for the explicit purpose of quality control of field data; the plan for digital uploading of critical EE data was proposed for Fiscal Year (FY) 95; and data qualifiers will be assigned to critical parameter values based

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ADMIN RECORD

SW-A-003488

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on the EG&G administrative procedure 8.02 "Evaluation of ERM Data for Usability in Final Reports" (EG&G, 1994b).

Future work in the EE arena will be further corrected with Corrective Action Plans (CAPs) for each issue. Work plans for future sampling will follow appropriate guidelines. Self-evaluations will be initiated to assess performance of sampling and disposition of records.

In light of the current findings, as well as findings noted in previous DOE, RFFO audits, we suggest that designation of a DOE, RFFO point of contact for ER programmatic quality matters would improve M&O services and deliverables. In particular, quality issues open to liberal interpretation, ranging from document control to data quality, could be discussed and resolved before audits, thereby reducing subsequent findings and corrective actions. Regardless of shortcomings in organizational interfaces, we realize our responsibility for identifying and correcting our deficiencies through the self-assessment process and it is our goal to improve this process.

SPECIFIC RESPONSE

The Issues are restated from page 2 of 10, part B. "Audit Summary" of the DOE Audit Report.

ISSUE I.1 "ERM has not implemented the Quality Assurance Program Description or revised the Quality Assurance Project Plan (QAPjP)."

RESPONSE TO I.1

It is agreed that certain aspects of the Quality Assurance Program Description (QAPD) and QAPjP have been poorly implemented, especially with respect to ecological data generated in the field. However, the ultimate "quality" of the data is relative to the purposes(s) for which the data are used: the current disposition of the EG&G EE subject matter expert (SME) is that the majority of the data forms exhibit miscellaneous quality problems in an absolute sense; however, because the data is qualitative and equivalent to Level I quality (Levels I through V are defined by EPA, 1987), its quality is adequate to accomplish the primary data quality objective for the initial phase of the ecological evaluation, i.e., to define species lists for the various OU and buffer zone areas of interest as defined in the Work Plans. Throughout the environmental restoration process, oversight of ecological evaluations has been implemented consistent with a "graded" approach advocated by DOE: the vast majority of quality control has been implemented on processes and deliverables directly related to Levels 3, 4, and 5 data. Many of the corrective actions proposed in this response will raise the degree of oversight and quality control of Level 1 data (in EEs) to that of higher data quality levels.

The QAPjP (EG&G, 1994a) is the de facto baseline document that defines environmental restoration quality assurance requirements at the project level and is recognized not only by DOE, but by the Environmental Protection Agency (EPA) and

Colorado Department of Public Health and Environment (CDPHE). The QAPD was developed to implement 5700.6C, and the Quality Assurance Requirements and Description (QARD) because DOE directed EG&G not to revise the QAPjP. In practice, implementation of the QAPD and QAPjP are equivalent for environmental restoration processes. The major difference between the two documents is conceptual, not practical, i.e., the QAPD references EG&G Level 1 procedures while the QAPjP does not. The latest EPA guidance and comments from DOE Headquarters, specifically through their subcontractor, Hazardous Waste Remedial Actions Program (HAZWRAP) (ASG, Inc.), advises the ERPD quality control program to implement a graded approach *specific to environmental restoration activities, with emphasis on project-specific data quality objectives*. References to two controlling QA plans instead of one (i.e., the QAPD and QAPjP) and to EG&G Level 1 procedures, where ERPD procedures and work plans already exist, are contrary to this direction and only serve to confuse, and potentially degrade, the quality of the EG&G ER program objectives and performance indicators within ERPD. An independent assessment, conducted in August, 1994, based on the directive from Mark Silverman to Anson Burlingame, also concluded that too many controlling documents are brought to bear on the ER program and effectively hinder compliance and improvement.

CORRECTIVE ACTION PLAN (CAP) for ISSUE I.1

ACTION ITEM	ACTION	RESPONSIBILITY	DUE DATE
1	Issue a revised draft QAPjP to DOE for review (QAPD will be rescinded upon approval of the revised QAPjP).	M. Brooks	1/20/95
2	Qualify data used in final reports and decision-making with respect to its limitations and usability (process described in procedure ADM 8.02, EG&G, 1994b).	E. Mast ^A A. Primrose ^B B. Peterman ^C W. Busby ^D	See note ^E

AOUs 5 & 6

BOUs 3 & 11

COUs 8, 9, 10, 12, 13, 14

DOU 2

^ESame as respective draft RFI/RI report milestone dates.

ISSUE I.2 "ERM is out of compliance with RFI 5700.6 Criterion 4 (Documents & Records) and August 16, 1994 the EG&G RFP QA MANUAL Quality Requirement (QR-2A) Quality Assurance Program."

RESPONSE

The examples in the audit report focus primarily on two records management issues: records identification and turnover. Standard records-capture statements have been developed and are being incorporated into each new procedure as it is created, and into each existing procedure as it is revised. In addition, two new records management

procedures, specifically addressing these areas, have been developed: "Records Identification and Generation" and "Records Transmittal."

- "Records Identification and Generation" addresses the policy, requirements, and responsibilities for the incorporation of records-capture statements in work controlling documents to identify the records to be generated and turned over as a result of project activities. The procedure also addresses the preparation of Program documents to ensure that records acceptance criteria are met (e.g., unique document identification numbers, page numbering, etc.). Format for specific types of documents is also addressed. Project Managers are responsible for identifying subcontractor deliverables in the contractual Statement of Work.
- "Records Transmittal" addresses the policy, requirements, and responsibilities for transmittal of completed Project documents, generated or received, to the ERPD Project File Center using the Records Transmittal Form.

One new procedure, "Records Storage and Access Control" will be developed to address the policy, requirements, and responsibilities for records protection, storage, maintenance, and retrievability.

All of the above procedures apply to ERPD personnel and subcontractors performing work for the ER Project and prescribe requirements for quality, non-quality and Administrative Records (AR), including field records, generated in conjunction with Project activities.

Quality records are clearly defined in the QAPjP (§ 17.0), and turnover of QA records to the M&O (and therefore DOE) is required contractually through statements of work. Data forms, for example, are quality records by definition, and their uniqueness and version is controlled by the associated Standard Operating Procedure (SOP), which is a controlled document. Heretofore, ERPD will provide clear specifications and more detail on the quality records required for turnover in future statements of work to the subcontractors; such specifications will clarify checks on whether subcontractors have completed and submitted the minimum quality records based on the scope of work.

EG&G will not perform work to "draft" procedures. Those procedures requiring review by DOE and the regulators will be considered final when a letter of approval has been received from the regulators. If review of the procedure is not required by DOE or the regulators, the procedure will be considered final when approved by the ERPD Director and the Quality Assurance Project Manager (QAPM).

If it is imperative that a procedure be implemented prior to approval, EG&G management shall formally request and justify the procedure's use on a case-by-case basis. DOE shall grant or deny approval for interim use of the procedure in writing.

The following protocols will be followed:

- If the request is approved, the implemented draft procedure, the requesting letter, and the approval letter will be placed into the Procedure History File and archived by Document Control as a quality record. The draft procedure will be issued as a controlled "working copy" with an expiration date indicated on the cover page. Any comments received from the regulators will be incorporated into the document and an approval letter obtained from the regulators prior to the document being issued as final controlled copy. This requirement will be incorporated into ERPD administrative procedure 3-21000-ADM-6.01, "Document Control."
- If the request is denied, only the requesting letter and the letter of denial shall be entered into the Procedure History File. EG&G will not implement the procedure until approval is obtained from the DOE, RFFO. Upon approval the procedure shall be issued per current document control procedures.

CORRECTIVE ACTION PLAN (CAP) for ISSUE I.2

ACTION ITEM	ACTION	RESPONSIBILITY	DUE DATE
1	Define a generic list of EE records needed per OU project, based on the work plan and the latest documented Data Quality Objectives (DQOs).	E. Mast ^A A. Primrose ^B B. Peterman ^C W. Busby ^D	03/30/95 12/22/94 10/30/94 12/22/94
2	Inventory and complete/correct existing EE quality records with respect to Action Item 1. Based on contract modifications with subcontractors and/or M&O staff.	E. Mast ^A A. Primrose ^B B. Peterman ^C W. Busby ^D	03/30/95 02/28/95 11/28/94 02/28/95
3	Submit the records, from Action Items 1 and 2 to the Records Center for archival according to ADM §17.01 (EG&G, 1994c).	E. Mast ^A A. Primrose ^B B. Peterman ^C W. Busby ^D	03/30/95 03/30/95 11/28/94 03/30/95
4	Develop Procedure "Records Storage and Access Control" internal milestone in FY95 work package.	L. Tyler	2/95
5	Submit the existing draft EE SOPs to ERPD Plans and Procedures group for DOE approval.	L. Woods	10/31/94
6	Incorporate a list of the minimum types and approximate number of quality records, based on Work Plans, into ERPD statements of work.	E. Mast ^A A. Primrose ^B B. Peterman ^C W. Busby ^D	03/30/95 12/22/94 12/22/94 02/28/95

AOUs 5 & 6
 BOUs 3 & 11
 COUs 8, 9, 10, 12, 13, 14
 DOU 2

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ISSUE I.3 "ERM is out of compliance with the EG&G RFP QA Manual Quality Requirement (QR-7) Control of Purchased Items and Services."

RESPONSE

Programmatic quality controls are established for purchased items and services, both before the procurement activity and during the service and production of deliverables. Prior to procurement, the Master Task Subcontract (MTS) system is invoked to ensure that only qualified and competitive subcontractors perform ERPD work. Qualifications of the subcontractors are initially approved by consensus agreement among a selection committee including the affected OU-project managers. Any rebids on work beyond the initial task require project managers' review and approval of personnel proposed on the subcontract. The MTS is a controlled document (RFPD-59, Rev. 1, 11/91) managed by EG&G Procurement located at the Denver West business park in Golden.

Completion of quality records, such as data forms in the field, are addressed in all ERPD statements of work issued to subcontractors working on Ecological Evaluations. Because the subcontractors are contractually responsible for completion of such records, any inadequate records will be corrected by the responsible subcontractors at no additional cost to EG&G or DOE, RFFO.

During scientific investigations and production of the associated deliverables, the primary means of quality control is peer review, as described in §3.0 of the QAPjP. Independent assessments and training have also contributed to the quality controls, but to a lesser degree. Based on the findings of this audit, it appears that these means of quality control have not proven adequate, and the proposed corrective actions should remedy the problem.

The Ecology and Watershed Management Division has increased their professional staff over the past year in an effort to perform a greater level of management and field work, and provide more technical oversight of subcontractors; this should infuse a greater appreciation for DOE requirements in scientific investigations.

CORRECTIVE ACTION PLAN for ISSUE I.3

ACTION ITEM	ACTION	RESPONSIBILITY	DUE DATE
1	Ensure adequate QA requirements in Statements of Work through the Readiness Review Process.	S. Luker	09/30/94
2	Upload quantitative data to electronic database.	John Hopkins	06/01/95
3	Qualify data with respect to usability.	John Hopkins	07/01/95
4	Perform quality review checks, as evidenced by authentications, on contractual deliverables identified in statements of work from the subcontractor to the M&O contractor; checks shall be performed by the Project Manager or a designee; this includes data forms or data packages. All data beginning 10/1/94 will be addressed at a level of effort.	E. Mast ^A A. Primrose ^B B. Peterman ^C W. Busby ^D	04/30/95 See note E 02/22/95 See note E
5	Invoke stop work authority on implementation of unapproved procedures in the field.	S. Luker	Level of Effort
6	Perform assessments of subcontractor ER activities and deliverables with emphasis on quality records; ≥ 2 per unique subcontractor; upload deficiencies/findings to PATS (for enhanced visibility, subsequent follow-up, and closure).	S. Luker	9/30/95

AOU 5 & 6

BOU 3 & 11

COU 8, 9, 10, 12, 13, 14

DOU 2

E Same as respective draft RFI/RI report milestone dates.

Contact Steve Luker at extension 8625 with any questions or comments regarding this response, including references cited in the text.



S. G. Stiger, Director
Environmental Restoration Program Division
EG&G Rocky Flats, Inc.

RSL:maa

Orig. and 1 cc - D. W. Sargent

Attachments:
As Stated

cc:

D. George - DOE, RFFO
F. R. Lockhart - " "
M. N. Silverman - " "
B. Thatcher - " "

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