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EFFECTIVE MANAGEMENT OF REGULATOR RI/FS COMMENTS

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EFFECTIVE MANAGEMENT OF REGULATOR RI/FS COMMENTS

ABSTRACT

This paper describes a successful strategy that facilitates regulatory approval of CERCLA documents required by compliance agreement and CERCLA, based on the experience of Operable Unit 1, Waste Storage Area, of the Fernald Environmental Management Project (FEMP). This strategy, which has become the site standard at the FEMP, was instrumental in obtaining regulator approval of the OU1 RI and FS, and early approval of the Record of Decision during a very tight compliance agreement-driven schedule. This strategy can be applied at any DOE Superfund site, especially where there is need to recover lost schedule, an incentive to meet milestones early, a need to improve the relationship between the DOE and the regulators, or where the regulatory agencies have historically provided a large volume of comments on CERCLA documents.

The strategy focuses on early identification and resolution of issues relating to draft RI/FS documents, as raised in regulatory agency review comments. This pro-active strategy has the potential for schedule and cost savings, as well as for improved communication between DOE and the regulators. The strategy includes preparation of a separate comment response document, integration of comment responses with RI/FS documents, development of a database of agency comments and their resolution, and sharing lessons learned with preparers of subsequent RI/FS documents.

The paper provides background on the FEMP and describes the FEMP comment response strategy; DOE and regulator interface; the Sitewide Comment Database; networked electronic file management; the process for classifying, analyzing, and responding to comments; integration with base RI/FS document(s); and a conclusion.

1. FEMP FRAMEWORK

SITE DESCRIPTION: The 1,050-acre Fernald Environmental Management Project (FEMP) is located in southwestern Ohio, approximately 18 miles northwest of Cincinnati. Former uranium processing operations at the FEMP (which ceased in 1989) were limited to a fenced, 136-acre tract. The remaining FEMP areas consist of wooded and pasture lands. The western portion of the property lies within the 100- and 500-year floodplain of nearby Paddys Run Creek.

CERCLA HISTORY: A limited site investigation under CERCLA began in 1986. The FEMP was named to the National Priorities List in 1989. CERCLA activity at the FEMP was initially governed by a Federal Facilities Compliance Agreement between DOE and the U.S.

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Environmental Protection Agency (EPA) in 1986, which has since been superseded by a Consent Agreement (also referred to as "the 1990 Consent Agreement") on June 29, 1991, and by an Amended Consent Agreement (also referred to as "the Amended Consent Agreement," or ACA) signed on September 20, 1991, which remains in effect today and includes references to the CA. The Ohio EPA (OEPA) is an "interested party" to these agreements and retains an informal review and comment role over all FEMP documents issued under these agreements.

The 1990 Consent Agreement divided the site into five operable units (OUs). This paper focuses on the regulator interface strategy that was devised to reach approval on Remedial Investigation (RI) and Feasibility Study (FS) reports for OU1 in a faster and least-cost manner. OU1 is a well-defined, 37.7-acre area containing eight waste pits in Waste Storage Area in the northwest quadrant of the FEMP. Various chemical and metallurgical processing operations generated large quantities of liquid and solid wastes, and these wastes were stored or disposed of in six waste pits and the Clearwell or burned in the Burn Pit. These waste units contain radiological, organic, and inorganic contaminants associated with the wastes that were placed in the waste pits since 1952. OU1 was the second FEMP operable unit to produce CERCLA documents under the terms of the ACA. The OU1 RI was approved on August 4, 1994; the OU1 FS was approved on September 29, 1994, and the OU1 Record of Decision was approved in February 1995. The ROD calls for excavation of the waste pit contents, waste processing and treatment by thermal drying, and off-site disposal at a permitted commercial disposal facility.

While developing the OU1 RI Report, the US EPA provided approximately 600 comments on two revisions of the 3,500-page report. Preparation of all responses for the OU1 RI Report, FS Report, and Record of Decision were managed using this strategy.

Several factors regarding the DOE-EPA relationship specific to the FEMP made it essential for DOE to develop a comprehensive strategy for regulator interface. Some of these factors include: (1) a historically poor relationship with the regulators, resulting in a lack of trust and a need for DOE to provide solid documentation of compliance with the CERCLA process; (2) compressed ACA schedules for CERCLA documents, with portions of both the OU1 RI and FS being developed on parallel paths; and (3) EPA disapproval of the first draft RI Report, resulting in a major change in technical approach; all three required an efficient strategy for timely issue identification and resolution.

2. OVERVIEW OF COMMENT RESPONSE STRATEGY

OBJECTIVES: The objectives of this process are: (1) to engender regulator confidence in the technical approach used in the OU1 RI as demonstrated in the document revision process; (2) to ensure complete and consistent rationale reflected in both the Comment Response Document and the original document (in this case, the OU1 RI Report) that are responsive to agency

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concerns; (3) to develop a systematic approach to a comprehensive comment response process that minimizes "omission opportunity" and maximize a well-rounded approach to issue identification and resolution; and (4) to create a self-standing accounting of the comment response process. Reaching the objectives of the FEMP OU1 comment response strategy was based on: (1) a formal approach to documenting, categorizing, and responding to all formal regulator comments; (2) early and frequent communication between the DOE and its contractor(s), and between the team (consisting of DOE and its contractor[s]) and the regulatory agencies; and (3) a broad focus at the beginning of the process that continually narrows to focus on reaching consensus on unresolved issues.

TOOLS: OU1 used several tools to implement this strategy; these included: (1) a detailed task schedule; (2) a PC environment, with network, word processing (featuring use of a macro to standardize comment documentation), and database capability; (3) a sitewide comment response database; and (4) interaction with the regulators that includes faxes, face-to-face meetings and DOE presentations to resolve difficult issues.

STAFFING: It is important to define responsibilities for both RI Report development and Comment Response Document preparation. The key positions include: (1) the DOE Environmental Manager who participates in developing the technical approach, approves both the schedule and the document, and maintains communication with the regulators; (2) the DOE contractor OU1 Environmental Manager who oversees the entire RI effort and provides other support as needed; (3) the DOE contractor RI Manager who is responsible for overall development, including regulatory and legal reviews; (4) the DOE contractor Comment Response Coordinator who works closely with the RI Manager, manages and tracks the entire comment response process, and participates in meetings with DOE and regulators; (5) DOE contractor RI Report Section Leads who develop the technical approach and write their sections of the RI Report, and who seek regulator and legal review of their work; (6) DOE contractor Word Processing Coordinator who supervises the support staff and maintains control of all RI Report and electronic and hard copy files; and (7) the DOE contractor Technical Editor who ensures consistency between the RI Report and the Comment Response Document.

SCHEDULING: Development of a working schedule becomes important in situations similar to that of OU1 at the FEMP, where the RI and FS were developed on nearly parallel paths and where tight schedule constraints were imposed by the ACA. The schedule must identify relationships between the Comment Response Document and the RI Report revision cycles. For example, each comment response includes an action statement that specifies changes that will be incorporated into the revised RI Report. Scheduling the final approval of each change, the finalization of the Comment Response Document, and the production time needed to incorporate the changes into the revised RI Report is demanding. Progress must be monitored closely as

final revision of both documents nears to avoid having to enter changed text more than once and to ensure that all changes are incorporated into the revised RI Report.

3. DOE AND REGULATOR INTERFACE

DOE/CONTRACTOR INTERFACE: DOE and its site contractor must agree quickly on the path forward, technical approach, comment resolution strategy, schedule, communication strategy with the EPAs, key staffing, budget, etc. In the case of OU1, the contractor prepared the OU1 RI Report for DOE review. At the FEMP, both the DOE-FN and Headquarters staff provided written comments. This is the second strategic point in this comprehensive comment response process -- use of a word processing format, called a "macro", for providing comments. (See Figure 1.) In OU1's experience, most DOE commentors provided comments using this macro. Use of this macro supports electronic comment transmission and eliminates the need for duplicate data entry; and allows comment classification, review, and evaluation to begin almost immediately upon receipt of comments, resulting in schedule and labor savings. In fact, both U.S. and OEPA provided their comments about OU1 documents to the DOE-FN electronically, using the macro. (See Section 4 for a description of comment classification.)

After the contractor has evaluated and developed draft responses, the DOE contractor Section Leads present response strategies (and in some cases, actual individual responses) to DOE in a working session. A detailed discussion ensues, resulting in agreement on revisions to both individual comment responses and parallel revisions to the RI Report. OU1 held one large working session with several "mini" sessions held subsequently, until all issues were resolved. The contractor then revises the comment responses and issues the Comment Response Document to DOE. This is called the "gold copy". Once DOE approves the final "gold copy", the contractor revises the base document (the RI Report) that will be issued to the regulators.

REGULATOR INTERFACE: The DOE followed steps for interface with the regulators that were similar to those described in the previous paragraph. This approach allowed for communication with the regulators that is "early and often". The utility of this approach was learned very early in the OU1 CERCLA process, through lessons learned on previous documents (only OU4 preceded OU1 in the document approval cycle). In fact, the OU1 managers were able to revitalize a formalized and stifled commenting and response cycle that had been unproductive historically at the site. The regulator's old paradigms had to be changed, not only for the success of OU1, but also for the success of the FEMP as a whole. There was a noticeable shift among the DOE/contractor OU1 team in its realization that the customer for these documents was, in fact, the EPA.

DOE and the regulators must agree on the path forward for development of the RI. Periodic discussions were held throughout development of the first draft RI. Then, the draft RI was

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submitted to EPA in July 1993. EPA identified critical issues regarding the adequacy of the data that would be needed to support the analysis of remedial alternatives during the FS process. As a result, DOE and the EPAs needed to agree upon a technical approach that would resolve the regulators' basic issue regarding data adequacy. This is where the establishment of a working, informal dialogue between DOE and the EPAs resulted in a new technical approach that satisfied regulators' concerns -- one that incorporated (in more detail) previously existing knowledge about the waste pits into Section 1 (title) of the RI Report.

4. NETWORKED ELECTRONIC FILE MANAGEMENT

Networked electronic file management is critical because it: (1) ensures control of all versions of the Comment Response Document; (2) allows real-time delivery of initial comments, draft responses, and draft versions of the entire Comment Response Document; (3) allows access to files by remote users. In the case of OU1, this capability became extremely useful because the DOE Environmental Manager and staff supporting the RI were located at different locations.

The FEMP electronic environment includes a local area network (LAN) which extends to all on-site and off-site users. The user has access to CC:MAIL for electronic communication of written messages and electronic files at all FEMP locations; and standard word processing, database, and graphics software needed for document development and tracking.

Managing the comment response process includes the following three steps:

STEP 1: Establishing the "paperless office" approach to comment response organization. During initial discussions with regulators, request that all comments be submitted electronically, backed up by a hard copy. Emphasize that comments will be entered into the system exactly as supplied on disk by the commenting agency. Also emphasize the efficiencies in this comment response process (no delay in text entry, so comments can be distributed internally immediately after all comments are logged). Since a word processing comment macro file forms the basis for the electronic file, provide the commentor with a disk copy of the macro, simple instructions for use, and a point of contact experienced in the use of the macro.

Once the electronic file is received, review the entire file for completeness and consecutive numbering. "Clean up" files (eliminate electronic bugs and renumber, if needed). Sort comments before distribution to Section Leads. The following "sort" categories have been useful: (1) by document section, for distribution to Section Leads; (2) by commenting agency, especially when comments are received from both the state and federal EPAs; (3) by key word, when specific issues must be identified; and (4) by individual commentor.

STEP 2: Establishing and maintaining file structure. First, the file structure and all revisions

must be controlled by the Word Processing Coordinator to ensure file integrity. All word processing staff must be trained in the document file structure. A footer must be used to identify each version. (See Figure 1.) Create a directory for each version of the document, identifying the version in the directory name (e.g., RI-CR-O, which translates to "RI, Comment Response, Original Comments". This becomes critical when the action statement from each comment response is incorporated into the parent document.

STEP 3: Tracking the comment response process. The Comment Response Coordinator also must track the status of comment response preparation. The tracking report identifies commenting agency, individual commentor, comment number, comment classification (see Section 5 for a description), individual assigned by Section Lead to develop response, issue (2-3 word statement), and status. In OU1, comments were tracked approximately twice a week early in the process and were updated daily in the final days of production. The tracking report is useful because it: (1) has been used by Section Leads to track progress on responding to the comments they are responsible for and to schedule their staff's time for RI Report and comment response preparation; (2) provided a quick reference of the comment issues; (3) identified unresolved issues that need closure; (4) proved to be an easy-to-read tool for DOE to use for tracking and for a summary of issues presented in the comments.

5. CLASSIFYING, ANALYZING, AND RESPONDING TO COMMENTS

CLASSIFYING COMMENTS: It is useful to classify comments to determine the bearing they have on the RI Report and to set priorities for comment discussions with the regulators. The commentor's use of the macro enables the commentor to classify his/her own comments. In OU1's case, the regulators classified their own comments by priority. The following comment classification is recommended: "M" identifies "major" comments; "C" identifies comments for "clarification"; and "E" identifies "editorial" comments. If comments were not classified by the commentor, use judgment based on past agency comments on other documents, on the criticality of the issue to the technical approach of the RI, or other criteria that may be appropriate. Once the classification is made, enter the classification in the "Code" section of the macro.

It is also useful to organize comments by section, issue, and type of effort required to respond. While the macro asks the commentor to identify the specific section of the document that the comment pertains to, commentors do not always complete this section of the macro, nor do they always fill it in accurately. Therefore, it is important to compare the content of the comment with the section specified to determine its accuracy. This becomes important when re-ordering the comments by the order in which they will appear in the revised parent document.

Organization of comments by type of effort required to respond is useful in identifying the technical complexity of the comment and the related level of effort that may be required to

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prepare a response. This information is critical when the Section Lead is preparing responses to hundreds of comments while developing an individual section of the RI.

ANALYZING COMMENTS: Analysis of each comment is critical because it: (1) allows identification of any significant comments early in the process; (2) aids in understanding the completeness of the commentor's concern on a specific issue; and (3) aids in understanding the technical complexity of concerns expressed in the comments (needed to predict staffing for comment analysis and response preparation). Identify any critical issues noted in the comment transmittal letter or in minutes of meetings between DOE and the regulators. Look for supporting documentation in specific comments. Identify any such issues in the "Comments" column in the comment tracking database. Analysis of comment by issue is critical for the Section Lead to understand the depth and breadth of the commentor's concern about a particular issue. Create a file for each issue identified while maintaining the original comment file.

SITEWIDE COMMENT RESPONSE DATABASE: An initial step in the analysis of each issue for a site with multiple operable units is to compare the issues presented in the current comments with other comments made by the same agency on other documents prepared by this site. To facilitate this process, the FEMP developed the Comment Response Database.

The database integrates comments and responses to comments from the EPAs and the DOE (headquarters and the Fernald office), so comments on previously reviewed documents can be addressed in all follow-on documentation where applicable. More than 1,200 comments from the EPAs exist in the database. Database fields include commenting organization, operable unit identifier, type of document (RI, FS, Proposed Plan, ROD, etc.), and others. There are two ranking categories: (1) classification of comment — major, clarification only, grammatical; and (2) whether the comment is specific to an individual operable unit, has the potential for crossover to another operable unit, or is applicable sitewide (e.g., topic area such as risk assessment).

The database is available on the site's LAN. User access is "read only" or "read/print". Users have the option of designing a report to their specific needs. Reports are in ASCII text, and may be printed to any printer, to a screen, to a file, or imported into word processing software. The user can access the database to see if the same or similar comment was received on a preceding document, analyze the previous response and action, and accept it "as is" or adapt it with modifications appropriate to the comment being analyzed.

QUESTIONS IMPORTANT TO THE ANALYSIS: Once the technical complexity of the comments is assessed, it is useful to ask whether the commentor understood the original intent of the text being commented on. If the commentor understood it as intended, consider: Is the

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criticality of the issue central to the RI's technical approach? How severe is the issue? Will agreeing with the commentor dilute the RI's technical approach? Can part of the comment be agreed with? How does the commentor's issue compare to regulatory guidance? Will the response to the comment require stakeholder involvement?

If the commentor did not fully understand the intent of the text, acknowledgement of the commentor's concern and clarification of the issue, perhaps through further explanation of the text under discussion or by directing the commentor's attention to other sections of the RI Report where clarification is self-evident, are essential. Disagreement leaves the commentor's concerns unanswered, alienates the commentor, and ultimately prolongs the approval process.

After all comments have been addressed and action statements developed, a sensitivity analysis is essential to reveal other parts of the document -- such as tables, charts, illustrations, appendices, or additional sections requiring change by association or ripple effect. The Risk Assessment (RA), for instance, is often the last section of the document to be developed. The RA is heavily dependent on the accuracy of all data, text, and statistical analyses that were evaluated and addressed in previous RI Report sections, such as Nature & Extent of Contamination (Section 4.0) and Fate & Transport Modeling (Section 5.0). Revisions to those sections that result from a response to comment, particularly those that represent a dominant shift in the technical approach, should be cross-referenced and compared to the current text and data in the RA. Changes in the RA could also impact previous sections of the RI Report. However, in the experience of OU1, major ripple effects that resulted from responses to comments were quantitatively forward biased (i.e., revisions to Section 1.0 [Introduction] would impact the entire document while those associated with Section 5.0 would impact only Section 6.0 and those beyond). The quality of impact and the degree of reverse ripple effect into prior sections of the document were variable.

The importance of the sensitivity analysis is further complicated by the number of regulatory personnel (including subcontractors) commenting on the document. As in the private sector, the regulator has subject matter experts who assess and comment on limited sections of the RI Report. Conflicts in either technical understanding, comment quality, or personal perspective may not be detected by the agency until the final review. Recall that the DOE comment response team is composed of Section Leads who address only comments that are germane to their section of the document. As a result, conflicts in technical approach and understanding may not be detected until all comments have been addressed and compiled for resubmittal to the regulators. Further, responses to comment for one document may be synergistically aligned and still conflict with responses, action items, or general guidance principles developed through other operable units at the same site. Hence, the compiled responses should be compared not only to the current and revised text, but also to the Sitewide Comment Response Database.

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PREPARING RESPONSES: The initial focus here is on developing the "response" and waiting until the response is finalized before developing the "action statement". OU1's experience has been that it takes two or three attempts before the response is ready for review by the Section Lead. Once the Section Lead approves the draft text, the text is electronically forwarded to the Comment Response Coordinator. The Comment Response Coordinator reviews the response, which specifies "Agree," "Disagree," or "Partially Agree" and includes a summary of the logic of the response. The regulators complimented OU1 for this straightforward approach.

After DOE and the contractor agree on the wording of the response, two approaches could be taken: (1) provide the regulators with DOE's initial disposition of the comment and rationale, identify those issues that can be readily resolved, and discuss path forward for those issues that remain; or (2) continue to develop the action statement (see next paragraph) and provide both response and action statement to the regulators. The first approach is recommended when issue resolution is anticipated to be difficult while the second approach may be more expedient when the issues raised in the comments are neither technically complex nor critical to the technical approach. Regardless of which approach is taken, the ensuing dialogue with the commenting agency is critical to resolve each issue raised.

Develop the action statement next. It is the second part of the response and provides the exact text that will be incorporated into the RI Report. It is critical to agree on the response rationale before developing the action statement in order to avoid duplication of effort. In resolution of some of the critical OU1 RI risk assessment issues, DOE and FERMCO held a series of meetings with the EPA project manager and his senior technical staff to refine the technical approach related to these issues, then followed up with conference calls until the EPA technical staff and their support contractors agreed on the final wording of each statement. This continual issue discussion was one of the key elements of the success of this approach.

After all responses and action statements are complete, finalize the Comment Response Document. It includes an introduction explaining the process and organization of the document, a modified tracking log to serve as an index of all comments, and complete comments with responses and actions statements organized by section as they appear in the RI Report.

6. INTEGRATION WITH BASE DOCUMENT

After the regulators agreed on the draft action statement, the Comment Response Coordinator coordinated incorporation of the new text into the RI Report. Incorporation of changes involves a critical interaction among the Section Lead, Comment Response Coordinator, and Word Processing Coordinator. This process includes the following steps: (1) identify the action statement by the comment number; (2) electronically copy the action statement into the RI Report by deleting the text being replaced, then copying in the new text; (3) identify the new

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text in two ways -- shade the new text (ignore text deletions) and add the comment number in the exterior page margin next to the affected text; (4) identify the page and line number of the affected text in the Comment Response Document for cross-referencing; (5) compare the text, and page and line number in the Comment Response Document to the revised text in the RI Report to ensure consistency between the two documents; (6) update the comment response tracking log to reflect the location of each revision, and include a modified version of the tracking log in the introduction to the Comment Response Document. EPA's confidence in this DOE process is a result of the accuracy and ease of use of this cross-referencing.

7. CONCLUSION

This paper described a successful strategy that facilitates regulatory approval of CERCLA documents required by compliance agreement, based on the experience of OU1 of the FEMP. This strategy, which has become the site standard at the FEMP, was instrumental in obtaining regulator approval of the OU1 RI and FS, and early approval of the Record of Decision during a very tight compliance agreement-driven schedule. This strategy can be adapted at any DOE Superfund site, especially where there is incentive to meet milestones early, where regulatory agency-driven schedules are constrained or demand parallel preparation of RI Reports and FS Reports, where DOE must work to build a relationship of trust with the regulators, or where the regulatory agencies have a history of providing a large volume of comments on CERCLA documents.

Commenting Organization:	OHIO EPA	Commentor:	Geo Trans				
Section #:	3.4.2.2	Page #:	3-25	Line #:	28-29	Code:	e
Original Comment #:	083 (OC 66)						
Comment:	Note that the Winter and Spring months are the major recharge months. Recharge is pretty much finished by the beginning of summer due to heavy ET.						
Response:	Agree that the text could be clarified to indicate that the winter is included in the major recharge period.						
Action:	Page 3-25, lines 28-29, have been revised to read: "Major groundwater recharge usually occurs during the winter and spring, which results in maximum water table elevations during the spring and early summer months.						
OUIR/DRAFT COMMENT RESPONSES/OHIO EPA/CAF01/31/94							

Figure 1. Sample of Macro (with Footer Shown)

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THE PROCESS FOR EFFECTIVE MANAGEMENT OF REGULATOR COMMENTS ON RIFS DOCUMENTS

