CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM M&O CONTRACTOR

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Concurrence:

M&O Systems Integration Manager

For Bob Morgan
M&O QA Manager

Approvals:

MGDS Systems Engineering Manager

MGDS Development Manager

M&O Nevada Site QA Manager

M&O Nevada Site Manager

Civilian Radioactive Waste Management System
Management & Operating Contractor

M&O MGDS Design Control Improvement Plan

Introduction

This plan has been developed in order to coordinate and document corrective actions planned in response to Quality Assurance verification and deficiency documents dated from January 1993 to the present. In addition, various areas have been self-identified where process improvement is desirable. These items are also included in this plan. The purpose of these actions is to:

(a) provide immediate response to open Corrective Action Reports (CARs);
(b) ensure that conditions immediately adverse to quality (if any) are identified and corrected;
(c) provide for the development of a series of improvements to the design control process to preclude similar future incidents; and
(d) increase the confidence of external agencies and DOE in the M&O's ability to properly control our design procedures and processes.

The plan itself is not a direct response to any particular CAR, and does not supplant any CAR responses. Rather it is an effort to document these responses, review design-control-related issues to coordinate their resolution, and arrest any long-term problems (whether identified through CARs or by self-inspection) before they result in adverse impacts to the quality of our design products. Revision 1 to the plan modifies the original action items based on comments from DOE Yucca Mountain Site Characterization Project Office and QA representatives as well as other informal comments.

Background

Since January, a number of Corrective Action Reports (CARs), have been generated which are associated with M&O design control procedures or processes being employed for design of the Exploratory Studies Facility (ESF). As a result of these CARs, the M&O has committed to developing an action plan for addressing these issues. This plan has been generated as a result of that commitment, and serves to document immediate and longer-term actions and the parties responsible for implementing these actions. Subsequent to the initial drafts of this plan, CAR YM-93-070 was issued against the M&O for repetitive deficiencies. Elements of this plan will be used as part of the response to that CAR.

Actions identified in response to CARs that are still open, as well as those to improve the design control process, are documented in the form of tables as a part of this plan. The tables indicate the problems identified by the CARs and related discussions, the proposed solutions, the responsible parties, and the anticipated dates of completion.

The problems listed in the following tables are intended to not only respond to various CARs, but to allow for a thorough review of our design control process in general, to identify any weaknesses or shortcomings. By identifying these weak areas and taking steps to resolve these issues in advance, we will prevent additional future problems which might not be reflected in existing findings.

Action Items

The problems and action items identified in this plan are divided into three areas: near-term or immediate actions; longer-term, broader process improvement actions; and improvement verification or confirmation actions. The action items described herein are intended as a summary of the concerns identified at the time of the generation of this plan. It is the clear intent of these action items, however, to provide for a broad review of the entire MGDS design control process to identify weaknesses and resolve them in order to prevent future problems. It is also the intent of MGDS Development to maintain close communication with other OCRWM system elements (i.e., MRS MSA, Transportation, etc.) to allow for implementation of any changes which will resolve generic system problems.

These sections reflect action items resulting from systematic evaluation of CARs and self-identified problems associated with the design control process in general. It is anticipated that completion of these action items, including root cause analyses, may identify other needed corrective actions.

Near-Term Response Actions

The response actions found in the "Immediate Corrective Actions" section of the action plan (Table 1) are those necessary to provide prompt assurance that any conditions immediately adverse to quality are identified and corrected. These problems include primarily procedural errors and inadequate M&O control over some specific elements of design control.

Process Improvement Actions

The corrective actions found in the "Process Improvement Actions" section (Table 2) are somewhat broader in scope, and imply a longer-term approach to improving the overall design control process for MGDS. The issues addressed in this section include: resolution of conflicts between the systems engineering/configuration management control and design control processes; enhanced understanding of and personnel training in the appropriate processes; improvement of our design products and associated procedures; and promotion of constructive attitudes toward the design control and other QA processes. The activities discussed in this section will take place over the next several months.

Verification/Confirmation Actions

The "Verification/Confirmation Actions" section (Table 3) is intended to explicitly document the effectiveness of the plan and its associated action items in addressing all appropriate concerns. These action items provide for a systematic review of the problems discussed in the plan, an identification of the associated root causes, and an evaluation of the effectiveness of the completed actions in correcting these problems and preventing recurrence.

Implementation of Design Control Improvement Plan

Among the first steps in this action plan is approval of the plan itself. This plan is approved by the responsible managers from Systems Engineering, MGDS Development, M&O Nevada Site QA, and the M&O Nevada Site Manager; the M&O Systems Engineering Manager and M&O QA Manager provide concurrence.

The MGDS Development Manager has overall responsibility for ensuring that the improvement process described is properly executed in order to ensure that acceptable design control practices are in place for MGDS design activities. The MGDS Systems Engineering Manager has been designated the responsible manager for monitoring progress on the tasks detailed in this plan as well as ensuring that additional activities are undertaken if any are identified as necessary.

As part of the immediate corrective actions, a management steering committee will be established to ensure that a long term commitment to verbatim compliance with QA requirements is maintained. This steering committee will be supplemented by a working level QA committee.

The working level committee will be comprised of responsible individuals from the engineering and interfacing organizations. This working committee will principally be responsible for ensuring that self-identification of procedural compliance problems is achieved by identifying procedural ambiguities or inadequacies, and recommending appropriate revisions to the procedures. As the representatives of the direct users of the procedures, these individuals will be uniquely qualified to ensure that the procedure set is sufficient to control the work activities. The working level committee will report, on a regular basis, to the steering committee, who will in turn have authority to enact recommendations provided by the working level committee.

Note (Revision 1): The format of the action item tables has been changed somewhat in Revision 1 to allow for the incorporation of various comments. The original reference indicators (e.g., A1, A2, B1, etc.) are consistent with Revision 0. The only changes made to the content are the addition of clarifying language or substeps, or the appending of the table with additional steps (e.g., steps P and Q). Various dates have also been updated to reflect current expectations for completion. The revised format lists each resolution action step, followed by any related CARs in [ ] brackets, followed by the responsible person and status or anticipated due date.

Table 1 - Immediate Corrective Actions

A. Problem/ Discussion: MGDS Development is experiencing continuing difficulties complying with QA requirements, as indicated by the relatively high number of design process related CARs received in the recent past few months. Although no clear trend in a particular area has been identified, M&O management (Foust and Sandifer) directed that a plan be developed for coordinating CAR-related and other self-identified improvements needed for the design process. Immediate corrective actions must reinforce to the design organization the importance of complying with QA requirements and responding to deficiencies identified by various CARs. Longer term corrective actions shall be directed toward ensuring that a culture is established and maintained where verbatim compliance with quality assurance requirements is second nature at all levels.

Solution(s): Address immediate compliance issues by reinforcing among MGDS staff the importance of 100% compliance with QA requirements and procedures.

A1. Provide immediate "importance of QA" briefing for MGDS Development. [YM-93-070 and self-identification] *Foust, Sandifer (Complete)*

A2. Establish a Management Steering Committee to monitor progress toward resolving issues. [YM-93-070 and self-identification] *Foust (Completed - Committee established on 8/6/93 and is meeting regularly)*

A3. Establish a QA Working Committee to act as a focal point for ensuring that necessary procedure enhancements are put in place on an ongoing basis. All affected line organizations shall be represented. This committee will ensure that M&O employees at the working level have access to a local resource who will be available when QA compliance or procedural problems arise (also see item L2). [self-identification] *Foust (Completed - established 8/6/93, meeting regularly)*

A4. Develop and distribute for concurrence the action plan for the near-term and long-term corrective actions. [YM-93-070 and self-identification] *Sandifer, Geer (Complete - Revision 0 issued 8/13/93; Rev. 1 issued 9/15 incorporating DOE & QA comments)*

A5. Reinforce CCB Secretary's responsibility (at both Level 2 and 3) for ensuring completeness of change documentation. [YM-93-074, YM-93-075, and self-identification] *Geer (Complete)*

Table 1 - Immediate Corrective Actions

B. Problem/ Discussion: The RSN BFD has not been evaluated to determine if changes are necessary as a result of M&O-generated Package 1A design changes. Immediate corrective actions should ensure revision of the RSN BFD where necessary to comply with approved design changes; long-term corrective actions should ensure that the relevant content of the RSN BFD is incorporated into the M&O BFD so that a clear flowdown of requirements to the implemented design is available for the entire ESF design (see O).
Solution(s): B1. Complete ILP for revising RSN BFD. [93-QL-C-008, YM-93-073] *Buckey (Complete)* B2. Tabulate and collect copies of all change requests (CRs) or Field Change Requests (FCRs) processed against Job Package 92-020, the ESF Baseline, or Package 1A drawings or specifications. [93-QL-C-008] *Cruz (Complete)* B3. Review all CRs/FCRs for potential impact to the BFD; document results of review and categorize as to change impact (e.g., no change required, editorial change recommended, or technical change required). [93-QL-C-008] *Engwall, Naaf (Complete)* B4. Provide redline version of BFD incorporating the changes required and recommended by item 3. [93-QL-C-008] *Naaf (Complete)* B5. Submit Baseline Change Request per QAP-3-4 to request changes. [93-QL-C-007, 93-QL-C-008] *Naaf (Complete)* B6. Complete the revision of RSN BFD and baseline the new document. [93-QL-C-005, 93-QL-C-007] *Naaf (10/8)*

Table 1 - Immediate Corrective Actions

C. Problem/ Discussion: Change Request 93/405 resulted in a hand-written "TBV" being dropped from a drawing; problems with completeness of CR submittals (see item A5 also).
Solution(s): C1. Review all current drawings and specifications against original Job Package 92-020 products and subsequent CRs & FCRs for similar error; document review and results as part of CAR response. [YM-93-072] *Engwall, Naaf (Complete)* C2. Process necessary changes to resolve any findings as a result of review. [93-YM-072] *Engwall, Naaf (Complete)* C3. Provide additional dedicated resources to review change request paperwork prior to processing until such time that assurance exists that preparers are fully compliant with the governing procedures. Review all CRs for procedural compliance prior to issuing the change request (see also J1). [self-identification] *Jackson (Ongoing)*

Table 1 - Immediate Corrective Actions

D. Problem/ Discussion: There is no M&O procedure for formal documentation and tracking of TBVs/TBDs on design inputs/outputs. Such a mechanism is necessary to ensure that proper verification is performed prior to releasing components for their intended function.
Solution(s): D1. Complete the ILP for documenting and tracking TBDs/TBVs and begin tracking activities. [YM-93-040 and self-identification] *Taipale, Cruz (Complete)* D2. Implement the M&O TBD/TBV tracking system prior to releasing the first M&O design package to ensure appropriate controls are in place. All existing Package 1A TBVs/TBDs must be included as well as new items generated by the new design packages. [YM-93-040 and self-identification] *Cruz, Leitner (9/30)*

Table 1 - Immediate Corrective Actions

E. Problem/ Discussion: There is no process for documenting interdisciplinary (ID) design reviews.
Solution(s): E1. Evaluate the need for an MGDS implementing line procedure based on the new QAP for documenting ID reviews. [YM-93-040] *Engwall, Naaf, Jackson, SI rep. (Complete - NLP was developed to ensure documentation of MGDS ID reviews.)*

Table 1 - Immediate Corrective Actions

F. Problem/ Discussion: QA requirements are described in specifications, but QA classification is not shown on drawings.
Solution(s): F1. Ensure that QAP-2-3 is completed and approved for use on the MGDS. Acceptance of this procedure by the OCRWM Office of QA is required prior to implementation of this procedure by the M&O. [Self-identification and 93-QN-C-025] *Hastings (QAP-2-3 has been approved by the M&O. Acceptance by DOE QA is expected by 9/30.)* F2. Develop ILPs or QAP revisions for identifying QA classification on design outputs (including drawings and specs which contain QA and Non-QA components) in accordance with DIE results and QAP-2-3. Consult with MRS and Vienna on methodology. [Self-identification and 93-QN-C-025] *Engwall, Naaf, Hastings (9/30)* F3. Implement QAP/ILPs prior to final verification for 1B & 2A. [Self-identification and 93-QN-C-025] *Engwall, Naaf (10/15)* F4. Begin incorporating into package 1A as design outputs are revised. [Self-identification and 93-QN-C-025] *Engwall, Naaf (9/30)*

Table 1 - Immediate Corrective Actions

G. Problem/ Discussion: Design inputs are not consistently shown on drawings and the M&O process for demonstrating traceability of requirements is not explicit.
Solution(s): G1. Review M&O BFD traceability matrix and RSN CM report to identify most effective method of ensuring traceability. [self-identification - requirement identified as part of Conformance Review directed by Art Kubo and comments received during the design reviews.] *Rindskopf, Peters, Leonard (Complete)* G2. Resolve Configuration Item/Architecture definition issues to ensure that a basis for establishing traceability exists. [93-QL-C-008, 93-QN-C-030 and self-identification - see G1] *Rindskopf, Peters, Leonard, Robinson (Complete)* G3. Revise or create procedures for implementation as appropriate. [93-QL-C-008, 93-QN-C-030] *Rindskopf, Robinson (Complete - No additional procedures were deemed necessary.)* G4. Revise the BFD provided at the 2A and 1B design reviews as necessary to demonstrate traceability, including the traceability matrix documenting allocation of requirements to specific Configuration Items and the associated BFD design criteria, calculations, drawings, and specifications. [93-QL-C-008 and self-identification - see G1.] *Rindskopf, Peters, Leonard (10/15)* G5. Revise drawings & specifications appropriately based on changes to the BFD. [self-identification - see G1.] *Engwall, Naaf (10/15)*

Table 1 - Immediate Corrective Actions

H. Problem/ Discussion: Generic procedures are used for waste isolation and test interference evaluations, but line procedures specific to these evaluations are needed.
Solution(s): H1. Develop ILP to formalize guidance on waste isolation evaluations. [YM-93-070] *Younker (Complete - approval anticipated 9/17)* H2. Develop ILP to formalize guidance on test interference evaluations. [YM-93-070] *Statton (Complete)*

Table 1 - Immediate Corrective Actions

I. Problem/ Discussion: Review all design-related CARS to ensure corrective actions are being accomplished and that this plan identifies the steps within it which satisfy various CAR corrective actions.
Solution(s):
I1. Tabulate & summarize all open and closed CARS affecting or involving the M&O design process. [Self-identification and YM-93-070] *Verdery (Complete.)*
I2. Establish MGDS point of contact for all CAR responses for MGDS Development. [self-identification] *Sandifer (Complete - Verdery is contact point)*
I3. Review outstanding actions to ensure timely completion. [Self-identification and YM-93-070] *Verdery (On-going.)*
I4. Provide revision 1 of the design process improvement plan with a cross reference of corrective action to the relevant CAR, where appropriate. [response to DOE QA (letter, Horton to Robertson, 9/2/93) and other comments] *Geer, Hastings (Complete)*

Table 2 - Process Improvement Actions

J. Problem/ Discussion: Recurrent instances of non-compliance with procedural requirements.
Solution(s): Develop "Culture of Compliance". J1. Involve M&O QA more proactively during design development by increasing consultation and surveillances. The early implementation of this item is discussed in C3 with the addition of a dedicated resource to review design products for compliance prior to release. The long-term solution will continue this as a permanently imbedded design resource, the effectiveness of which will be reviewed during additional M&O QA surveillance. M&O QA will increase surveillance in all areas, including those areas where design managers feel additional attention is needed (coordinating with the M&O plan for improving M&O QA Audit and Surveillance System). [Self-identification and YM-93-070] *Jackson, Franks (Ongoing)* J2. Invite DOE QA to review M&O design process. [Self-identification] *Sandifer (Start 8/6)* J3. Implement systems conformance reviews involving Systems Engineering, Regulatory & Licensing, QA. [YM-93-070] *Geer (FY 94)*

Table 2 - Process Improvement Actions

K. Problem/ Discussion: Perception exists that schedule pressures are impacting quality of work.
Solution(s): K1. Provide a letter to the M&O staff reinforcing management commitment to verbatim compliance with quality assurance requirements, even at the expense of schedule. [Self-identification] *Foust, Sandifer (Complete)*

Table 2 - Process Improvement Actions

L. Problem/ Discussion: Perception persists that the design procedures are overly complex and difficult to follow; not developed or maintained by those performing work; feedback mechanism (to authors) is inadequate; revisions and improvement are not easily facilitated.

Solution(s):

L1. Evaluate the process by which M&O procedures are reviewed in the field to identify potential improvements. [YM-93-040, YM-93-070, self-identified] *Hodgson, Geer, Carruth (Complete)*

L2. Procedure review team to trial run the existing procedures and upcoming revisions to ensure that the procedures are adequate and to generate the necessary revisions and/or ILPs. This review team is a subcommittee to the QA Working Committee (see A3). [YM-93-040, YM-93-070, self-identified] *Hodgson, Geer (Implementation of this solution began on 8/6)*

L3. Conduct formal training on appropriate procedures; this training will include instruction on where each procedure fits into the design process to facilitate better understanding of interfaces between procedures, etc., using guidance document established in M1. [Self-identified] *Penovich (Start 9/1)*

L4. Add J. Schmit (OQA Quality Improvement Team) to the Procedure Review Team [DOE Letter OQA:DGH-5870, 9/2/93] *Hodgson (9/17/93)*

Table 2 - Process Improvement Actions

M. Problem/ Discussion: M&O design process is not universally understood within the M&O and is not well documented from an overall standpoint.

Solution(s):

M1. Develop detailed MGDS Design Process Guidelines Manual; include policy statements on use of procedures and verbatim compliance with Quality Assurance requirements. The purpose of this manual is to provide guidelines to the engineering staff for implementing the MGDS Development design process. Work performed shall always be governed by QA procedures, rather than this guidance document, when such work is subject to quality assurance requirements. By documenting the steps in the process, as well as the rationale for various aspects of the work (e.g., configuration management, requirement traceability), the guidelines will provide an excellent tool to facilitate indoctrination of new employees as well as providing a common basis for communication with external parties. This document will also state the intention of the MGDS Development Office to prepare all design products in accordance with the appropriate QAPs (regardless of QA classification) so that uniformity of the engineering products is assured.

Include topics such as: generic schedule/process chart; Annual Engineering Plans; organization interfaces, responsibilities, and authority (SE, Design, QA, CM, DOE, REECO, QA Working Committee); requirements; CIs; BFDs; RIB, Technical Database; drawings, specifications, calculations (incl. DIEs); reviews; QA; transmittal of design outputs; changes (CRs/FCRs); non-conformance

Map design control process to DOE's process to ensure consistency. Also ensure that consistency with the new design process procedure (QAP-3-0) is maintained. Clarify resolution of CM and design processes; train all MGDS development staff to manual. [Self-Identified, YM-93-070] *Geer (1st draft due 9/30)*

M2. Interface with the informal FCR/CR working group to ensure that lessons learned, recommendations and followup actions are appropriately integrated into the guidelines manual. [YM-93-070, Self-Identified] *Pimentel (1st draft due 9/30)*

M3. Ensure manual reflects changes to CCB/CM processes when necessary. [YM-93-070, Self-Identified] *Cruz (1st draft due 9/30)*

Table 2 - Process Improvement Actions

N. Problem/ Discussion: Change Control and Configuration Management (CM) processes are overly cumbersome.
Solution(s): N1. Review OCRWM Baseline Management Plan, DOE 4700.1, and QARD for CM requirements. Ensure that the interfaces between the configuration management and design control process are properly reflected in the appropriate procedures. [YM-93-070, Self-Identified] *Hodgson, Cruz (9/30)* N2. Implement any necessary procedure changes resulting from review in N1. [YM-93-070, Self-Identified] *Cruz, Hodgson (9/30)* N3. Ensure a process exists to track required changes to impacted documents. [YM-93-073, YM-93-074] *Cruz (9/30)*

Table 2 - Process Improvement Actions

O. Problem/ Discussion: M&O needs to incorporate RSN BFD & design products into M&O baseline (see B).
Solution(s):
O1. Incorporate relevant RSN BFD sections for 1A into M&O BFD; prepare baseline change for combined BFD. [Self-identified, 93-QL-C-007, 93-QL-C-008] *Naaf, Engwall (1/31/94)*
O2. Revise drawings, specifications, calculations for new traceability; adopt fully as M&O products. [Self-identified, 93-QL-C-008] *Naaf, Engwall (4/30/94)*

Table 3 - Verification/Confirmation Actions

P. Problem/ Discussion: Root causes need to be identified for design control problems.
Solution(s):
P1. Perform root cause analysis for each CAR related to the design control process (as part of each CAR; perform an overall analysis of the design control process relative to design control improvement. [YM-93-070] *Jackson (10/31)*
P2. Include root cause analysis documentation in any related CAR response(s) for supplemental responses. [YM-93-070] *Jackson (begin 10/31 - ongoing effort for any future CARs)*

Table 3 - Verification/Confirmation Actions

Q. Problem/ Discussion: Follow-up evaluation is needed to verify effectiveness of plan actions.
Solution(s): Q1. Concur with DOE on appropriate scope of and methodology for follow-up line organization verification activities. [YM-93-070] *Sandifer, Petrie (10/15)* Q2. Document plan and schedule for surveillance/evaluation(s). [YM-93-070] *Franks (10/31)* Q3. Implement surveillance/evaluation(s) and document results in final follow-up report. [YM-93-070] *Franks (TBD)*

M&O MGDS Design Control Improvement Plan

Appendix A
Acronym List

1A - Design Package 1A (primarily ESF surface facilities)

1B - Design Package 1B (additional ESF surface facilities)

2A - Design Package 2A (beginning of ESF excavation of North Ramp)

BFD - Basis for Design document

CAR - Corrective Action Request

CCB - Change Control Board

CI - Configuration Identifier

CM - Configuration Management

CR - Change Request

DIE - Determination of Importance Evaluation

DOE - Department of Energy

ESF - Exploratory Studies Facility

FCR - Field Change Request

ID - Interdisciplinary (as in "interdisciplinary review")

ILP - Implementing Line Procedure

M&O - Management & Operating Contractor

MGDS - Mined Geologic Disposal System

OCRWM - Office of Civilian Radioactive Waste Management

QA - Quality Assurance

QAP - QA Procedure

Appendix A (continued)

QARD - DOE Quality Assurance Requirements and Description document

REECo - Reynolds Electrical & Engineering Company, Inc. (construction contractor)

RIB - Reference Information Base

RSN - Raytheon Services Nevada

SE - M&O Systems Engineering

TBD -To Be Determined

TBV - To Be Verified

Attachment 2

Supplemental Response to QA Comments

Reference: Letter, Horton to Robertson, 9/2/93, Comment 2 and Enclosure 1

Certain comments from Enclosure 2 of the referenced letter were not explicitly addressed in Revision 1 of the Design Control Improvement Plan. The followibng supplemental responses are provided, as discussed with Richard Powe.

Comment 3b: QAP-3-4 and the letter issued to resolve Action Item A5 will be reviewed in this context as part of Plan Action Items A3 and L1-2. The comment will be forwarded to the QA Working Committee for resolution, and resolution will be documented in a subsequent status update.

Comment 4: This implementing line procedure will be forwarded to the QA Working Committee for resolution of this comment.

Comment 9: DOE involvement has been taking place informally; formal documentation of consists of the above referenced letter (indicating OQA's intended areas of involvement) along with Attachment 3 of this letter.

Attachment 3

Point Contacts from MGDS for OQA Quality Improvement Team

Reference: Letter, Horton to Robertson, 9/2/93, Comment 4 and Enclosure 2

The following personnel have been identified as point contacts for the OQA Quality Improvement Team. Issues should be addressed through these persons for resolution. If the point contact is unavailable, the backup person should be contacted.

Area of Involvement	OQA Lead	M&O MGDS Contact
QIT Lead	Richard Powe	Bob Sandifer
Design Control Process	Steve Dana	Surface: Larry Engwall (Paul Pimentel backup) Subsurface: Jerry Naaf (Paul McKie backup)
Field Control Process	Jerry Heaney	Art Watkins (Ron Ruth backup)
Procedure System	Jim Schmit	Nat Hodgson (Robert Justice for QRB)
Audit and Surveillance System	Richard Powe	Doug Franks (Audits Mgr Vienna) Jack Jackson (Las Vegas)
CAR Status	Ken Wolverton	Howard Verdery (Tom Geer backup)