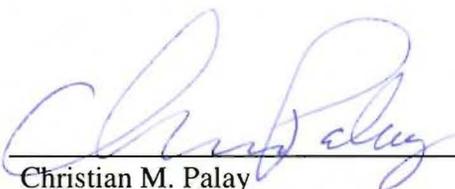


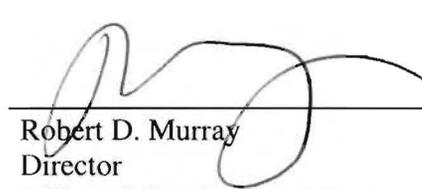


Office of Environmental Management (EM)

Subject: Preparing Implementing Documents

Administrative Procedure

Preparer:  4/26/2011
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Approved:  4-27-2011
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Concurrence:  4-27-2011
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Acting Deputy Assistant Secretary
Safety and Security Program

1.0 PURPOSE

- 1.1 The purpose of this procedure is to establish responsibilities and provide a uniform method for the preparation, review, approval, revision, and distribution of controlled documents.

2.0 SCOPE

- 2.1 The scope of this procedure is controlled documents for the Environmental Management (EM) High Level Waste (HLW) and Used Nuclear Fuel (UNF) Independent Oversight Program.

3.0 APPLICABILITY

- 3.1 This procedure applies to EM personnel and contractors that participate in quality assurance (QA) oversight activities for the EM HLW and UNF Independent Oversight Program.

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

4.1.1 Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 20

4.1.2 EM-QA-002, Quality Assurance Program Plan (QAPP)

4.2 References

4.2.1 AP-17.1Q, Quality Assurance Records

5.0 DEFINITIONS and ACRONYMS

- 5.1 Author and/or Subject Matter Expert (SME) – an individual who writes or originates the controlled document.
- 5.2 Controlled Document – a document that is prepared, reviewed, and formally approved by the Director, Office of Standards and Quality Assurance or designee. In particular, these documents are identified as Policy Statements, Program Descriptions, Plans, Administrative Procedures, Forms, and Departmental Technical Instructions. An approved controlled document describes how an activity is to be performed and the responsibility of those personnel performing the activity. The document may include methods, equipment, materials to be used, and the sequence of operations to complete the activity.
- 5.3 Departmental Technical Instructions – these instructions provide a mechanism of documenting standard departmental functions that must be followed in a consistent manner.

- 5.4 Controlled Document Coordinator (CDC) – is assigned within the EMCBC Office of Logistics Management and is responsible for managing this controlled document program.
- 5.5 Form – a printed or electronic document with spaces in which to write or fill-in information. All forms will have the series identifier, controlled document number, form number in sequential order, and revision number applied to the form.
- 5.6 Implementing Document – an implementing document is a specified series of actions or operations within an Administrative Procedure or Program Description, etc. which have to be executed in the same manner in order to always obtain the same result under the same circumstances.
- 5.7 Plan – a plan is used to achieve an objective, but does not have a series of actions which have to be executed in the same manner in order to receive the same result. It is a set of intended actions, through which one expects to achieve a goal.
- 5.8 Policy Statement – a written statement that communicates management's intent, objectives, requirements, responsibilities, and standards.
- 5.9 Program Description – a program description is used to develop, maintain and administer a formal, comprehensive document stating the aims and principles of a particular program.

6.0 RESPONSIBILITIES

- 6.1 Director, Office of Standards and Quality Assurance
 - 6.1.1 Responsible for the review and approval of controlled documents.
- 6.2 QA Lead, Office of Standards and Quality Assurance
 - 6.2.1 Responsible for identifying the need for a controlled document.
 - 6.2.2 Responsible for the writing and assembly of controlled documents.
- 6.3 EMCBC Office of Logistics Management
 - 6.3.1 Responsible for maintaining configuration control, change control, and coordination of periodic reviews of controlled documents.
 - 6.3.2 Responsible for the maintenance/use, storage, protection, retrieval and final disposition of controlled documents.

7.0 GENERAL INFORMATION

- 7.1 As used within the controlled documents, the words **shall/will/must** is used to denote a requirement. The word **should** denotes a recommendation and the word **may** is used to denote permission.
- 7.2 A controlled document must be developed, reviewed, revised, or cancelled when the following circumstances apply:
- DOE, federal, state, and local laws; regulatory requirements; or management's desire for a "Best Management Practice;" or and other requirements pertaining to the EM HLW and UNF Independent Oversight Program stipulate that a program be developed or changed; or
 - There is no existing document describing such actions.
- 7.3 Revisions of an existing controlled document must occur when the controlled document is:
- Not consistent with reference requirements;
 - Determined to be technically incorrect;
 - Affected by revision of another related controlled document which affects the accuracy of the document affected;
 - Outdated because new requirements have been accepted which require additional documentation;
 - Affected by accepted changes to existing requirements which require changes to existing controlled document; or
 - Affected by, or is outdated because of improvement to the controlled document or process.
- 7.4 Cancellation of an existing controlled document occurs:
- When the controlled document is superseded; or
 - When the need for the controlled document ceases.
- 7.5 All controlled documents are considered effective when approved by the Director, Office of Standards and Quality Assurance or designee.
- 7.6 To ensure the most recent version of a controlled document is being used, the user should access the electronic version of the controlled document, available from the EMCBC Office of Logistics Management webpage.

8.0 PROCEDURE

8.1 Determining the Need for a Controlled Document

8.1.1 The Policy Statements, Program Descriptions, Plans, Administrative Procedures, Forms, and Departmental Technical Instructions identified for use in this program will be developed and maintained as a controlled document, a document that is prepared, reviewed, and formally approved by the Director, Office of Standards and Quality Assurance or designee. The document may include methods, equipment, materials to be used, and the sequence of operations to complete the activity.

8.2 Document Formats

8.2.1 Controlled documents shall be prepared using the instructions and formats in Attachments A and B, and associated forms. Attachments A and B list the format for administrative procedures, plans, and program descriptions. Associated forms are fillable and used to document procedure revision.

8.3 Assembly of New/Revised Documents

8.3.1 Document Identifiers

- The QA Lead shall determine alpha identifiers (types i.e., Policy Statement, Administrative Procedure, Plan, Program Description, etc.).
- The QA Lead shall determine the identification series number and sequential identification numbers.

8.3.2 Document Preparation

- The QA Lead shall prepare the draft controlled document in accordance with format, document layout, and content requirements, as specified in Attachments A and B.
- The QA Lead will obtain electronic copies of all blank templates from associated forms for controlled documents.

8.3.3 Document Review, Approval, and Comment Process

- The draft controlled document will be transmitted from the QA Lead to the other reviewers within the department for initial review and comment. The controlled document will then be returned to the QA Lead for resolution of comments.
- The QA Lead will determine the need and may transmit the controlled document to others who have cognizance association with the content

of said document. The draft controlled document will also be transmitted to the EMCBC who shall review documents for compliance with this procedure. The QA Lead shall resolve any comments prior to circulation/review by any other reviewers.

- The QA Lead shall select reviewers and include them on the Document Review and Comment (DRC) Sheet, Form 6.1-1. All reviewers shall ensure that the document represents applicable requirements accurately, the current organization responsibilities are up-to-date, the technical content is free of error, and the instructions are presented clearly to reduce and eliminate misunderstanding.
- The review period shall be limited to ten working days from the date the email is sent to all reviewers.

8.3.4 Resolution and Incorporation of Comments

- The QA Lead shall resolve reviewer comments and annotate the comments, reviewer names and whether the comments were either incorporated or not into the controlled document by creating a separate working document which will be attached to the Document Review Record Sheet.
- The QA Lead shall upload the controlled documents to the EMCBC Folder along with the separate working document.
- If comments cannot be resolved between the reviewer and the QA Lead, comment resolution will be handled by the Director, Office of Standards and Quality Assurance. In the unlikely situation where comments cannot be resolved by the Director, the final resolution will be made by the Deputy Assistant Secretary, Safety and Security Program.

8.3.5 Final Approval and Processing

- Once all comments have been incorporated, and all reviewer non-concurrences have been resolved, the controlled document shall be provided electronically to the EMCBC for final formatting, and assembly of a complete package for final review and approval.
- Upon approval by the Director, Office of Standards and Quality Assurance, the controlled document shall be submitted to the EMCBC for posting. The EMCBC shall maintain all original records, which include comments generated for final development.

8.3.6 Revision or Cancellation

- Revision of a controlled document shall be accomplished by issuing the form, Controlled Document Change Request, with the word “Revise Procedure” noted in the Proposed Revision Section. The dates, initiator, initiator’s phone number, title of the document, and the unique identifier shall also be completed. The body of the form shall contain the justification for revision of the controlled document. When revising a controlled document, the entire controlled document shall be reissued with each page identified with the new revision number.
- Individual page changes may be made before the 2 year review cycle is achieved. If a change has been made to the document, use track changes to the document. The use of track changes will place a change bar next to the paragraph where the change occurred. All page changes shall be incorporated into the controlled document during the next review cycle.
- Cancellation of a controlled document shall be accomplished by issuing the Controlled Document Change Request with the word “Delete Procedure” noted in the Proposed Revision Section. The dates, initiator, initiator’s phone number, title of the document and the unique identifier shall also be completed. The body of the form shall contain the justification for deletion of the controlled document. The Document Review Sheet must also accompany the Controlled Document Change Request. Concurrences by the QA Lead and approval by the Director, Office of Standards and Quality Assurance are required to cancel a controlled document.

8.3.7 Periodic Reviews

- Controlled documents shall be evaluated every 2 years to ensure the document is current and effective. The responsible author shall conduct and document this evaluation. The EMCBC shall coordinate with the responsible author to ensure timely review of controlled documents.
- Where both a policy and its corresponding administrative procedure exist, the author shall review both documents at the same time. This practice will enable the author to review, update, and coordinate needed changes at the same time.
- Periodic reviews of controlled documents may be conducted by the Office of Standards and Quality Assurance or the EMCBC Office of Logistics Management to evaluate compliance with the applicable requirements.

9.0 RECORDS MAINTENANCE

9.1 The forms and controlled documents generated through implementation of this procedure shall be prepared and submitted in accordance with AP-17.1Q, Quality Assurance Records.

10.0 FORMS USED

Form 5.1-1, Record of Revision

Form 5.1-2, Controlled Document Change Request

Form 6.1-1, Document Review and Comment (DRC) Sheet

11.0 ATTACHMENTS

Attachment A – Administrative Procedure (IP) Format

Attachment B – Plan (PL) and/or Program Description (PD) Format

12.0 FLOWCHART

N/A

Attachment A
Administrative Procedure (AP) Format

1.0 PURPOSE

Develop a “PURPOSE” statement to describe the intent of the procedure. A procedure is a specified series of actions or operations which have to be executed in the same manner in order to always obtain the same result under the same circumstances to be followed to meet stated objectives, DOE Orders and Directives, or government regulations.

NOTE: Administrative Procedures should function in relationship with Policy Statements.

2.0 SCOPE

Include a statement of purpose establishing the limitations or parameters of the procedure, what it applies to and to what it applies (i.e., that is, receipt of incoming material, excess capital equipment, vendor drawings, etc.)

3.0 APPLICABILITY

Determine who shall comply with said procedures.

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

Identify and list requirements (drivers) such as DOE, federal, state, and local codes, rules, regulations, and laws, that apply to the implementation of the procedure. Include document number and title. Avoid inclusion of revision number or date of document whenever possible.

4.2 References

Identify and list reference documents that have been mentioned in the procedure. Include document number and title.

5.0 DEFINITIONS and ACRONYMS (Optional)

Identify those terms and statements contained in the procedure that require definition for uniform interpretation and clarity. Include any acronyms or abbreviations that are specific in the procedure. If this section is not required, then state "Not Applicable."

6.0 RESPONSIBILITIES

Identify the managerial position or function (not the name of the individual) responsible for taking action and as appropriate, the groups associated with the responsibility to execute the appropriate procedural requirements contained therein.

7.0 GENERAL INFORMATION (Optional)

Include supplementary background information associated with the orderly implementation of this policy or procedure. This section will NOT always be required; however, as appropriate, this section shall be a normal extension of the Policy or Purpose statement and may include general responsibilities, for example, any that are not specific to a position or group of employees. If this section is not required, then state "Not Applicable" in this section.

8.0 PROCEDURE

This section is an orderly, step-by-step, and logical description of instructions detailing the actions and requirements needed to complete the procedure.

NOTE: It is appropriate to include a flow chart, providing the user with a clear picture of the process steps necessary to complete the required activities effectively and accurately. See Section 12 of this attachment.

9.0 RECORDS MAINTENANCE

The following is an example of a Records Maintenance section. This information shall appear in each Records Maintenance section. Additional information may be included to further clarify the Records Maintenance section.

EXAMPLE:

9.1 Records generated as a result of implementing this document are identified as follows, and are maintained by the Office of the Director, in accordance with that office Organizational File Plan:

9.1.1 “Document Number,” and “Document Title,” if applicable.

OR

9.0 RECORDS MAINTENANCE

No records are generated as a result of implementing this document.

10.0 FORMS USED

This section shall list all forms used (*both Internal and External*) in the procedure. The correct and complete form title and assigned form series number assigned by the EMCBC Controlled Document Coordinator shall be included. The words “latest revision” shall either be included after the form reference OR a general statement, “all forms are the latest revision unless otherwise specified” shall be included in the section. Forms that are used as an example in the procedure shall have the word (example) placed after the form series number. Forms that exist in another procedure, but have been referenced shall be labeled with the following statement:

SEE _____

FOR LATEST REVISION

11.0 ATTACHMENTS

All attachments shall be listed in this section and shall contain the unique designator numbers and titles. Each attachment shall be alphabetically labeled starting with A, B, C, etc., in consecutive order.

Attachment B
Plan (PL) and/or Program Description (PD) Format

1.0 PURPOSE

Develop a “PLAN” statement which is a comprehensive description of direction to be followed to achieve a goal, stated objectives, DOE Orders and Directives, or government regulations. Develop a “PROGRAM DESCRIPTION” statement which describes what the program is intended for and the purpose or use of the program.

2.0 SCOPE (Optional)

Include a statement of purpose establishing the limitations or parameters of the Plan and/or Program Description, what it applies to and to what it applies (i.e., that is, receipt of incoming material, excess capital equipment, vendor drawings, etc.).

3.0 APPLICABILITY

Determine who shall comply with said plan/program description statement.

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

Identify and list requirements (drivers) such as DOE, federal, state, and local codes, rules, regulations, and laws, etc., that apply to the implementation of the plan/program description. Include document number and title. Avoid inclusion of revision number or date of document whenever possible.

4.2 References

Identify and list reference documents that have been mentioned in the plan/program description. Include document number and title.

5.0 DEFINITIONS and ACRONYMS (Optional)

Identify those terms and statements contained in the controlled document that require definition for uniform interpretation and clarity. Include any acronyms or abbreviations that are specific in the document. If this section is not required, then state “Not Applicable.”

6.0 RESPONSIBILITIES

Identify the managerial position or function (not the name of the individual) responsible for taking action and as appropriate, groups associated with the responsibility to execute the appropriate implementation requirements contained therein.

7.0 GENERAL INFORMATION or IMPLEMENTATION REQUIREMENTS (Optional)

7.1 General Information – Include supplementary background information associated with the orderly implementation of this plan/program description. This section will NOT always be required; however, when appropriate, this section shall be a normal extension of the plan/program description and may include general responsibilities, for example, that are not specific to a position or group of employees.

7.2 Implementation Requirements – This section may be used when the document identifies specific criteria that must be included in the department’s plan/program descriptions to implement correctly the requirements of the plan/program.

8.0 RECORDS MAINTENANCE

The following is an example of a Records Maintenance section. This information shall appear in each Records Maintenance section. Additional information may be included to further clarify the Records Maintenance section.

EXAMPLE:

8.1 Records generated as a result of implementing this document are identified as follows, and are maintained by the Office of the Director, in accordance with that office Organizational File Plan:

8.1.1 “Document Number,” and “Document Title,” if applicable.

OR

8.0 RECORDS MAINTENANCE

No records are generated as a result of implementing this document.

9.0 FORMS USED

This section shall list all forms used (*both Internal and External*) in the procedure. The correct and complete form title and assigned form series number assigned by the EMCBC Controlled Document Coordinator shall be included. The words “latest revision” shall either be included after the form reference OR a general statement, “all forms are the latest revision unless otherwise specified” shall be included in the section. Forms that are used as an example in the procedure shall have the word (example) placed after the form series number.

Forms that exist in another procedure, but have been referenced shall be labeled with the following statement:

SEE _____

FOR LATEST REVISION

10.0 ATTACHMENTS

All attachments shall be listed in this section and shall contain the unique designator numbers and titles. Each attachment shall be alphabetically labeled starting with A, B, C, etc., in consecutive order.

Form 5.1-1 – Record of Revision

RECORD OF REVISION

DOCUMENT:

If there are changes to the controlled document, the revision number increases by one. Indicate changes by one of the following:

- I Placing a vertical black line in the margin adjacent to sentence or paragraph that was revised.
- I Placing the words GENERAL REVISION at the beginning of the text.

<u>Rev. No.</u>	<u>Description of Changes</u>	<u>Revision on Pages</u>	<u>Date</u>
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Form 5.1-2 – Controlled Document Change Request

CONTROLLED DOCUMENT CHANGE REQUEST

DATE: _____

INITIATOR: _____

INITIATOR PHONE NUMBER: _____

DOCUMENT AFFECTED: _____

SECTION: _____ PARAGRAPH #: _____

CONTROLLED DOCUMENT NUMBER: _____ PARAGRAPH #: _____

NEW CONTROLLED DOCUMENT: _____

PROPOSED REVISION: _____

JUSTIFICATION: _____

Requested by:

_____ DATE: _____

Approval:

_____ DATE: _____

Assigned to:

_____ DUE DATE: _____

RECORD OF REVISION

DOCUMENT: AP-5.1Q, Preparing Implementing Documents

If there are changes to the controlled document, the revision number increases by one. Indicate changes by one of the following:

- I Placing a vertical black line in the margin adjacent to sentence or paragraph that was revised.
- I Placing the words GENERAL REVISION at the beginning of the text.

Rev. No.	Description of Changes	Revision on Pages	Date
0	Original	All	04/27/2011