Approval: M. D. Gardner _____ Date: 10/12/2004
Manager, National Spent Nuclear Fuel Program

I. PURPOSE AND SCOPE

This procedure establishes the process and responsibilities of the National Spent Nuclear Fuel Program (NSNFP) for identifying and reporting adverse quality trends through a periodic structured review of documented quality program deficiencies.

II. SUMMARY

This procedure describes the assignment of codes used for trending, assignment of personnel, scheduling for performing trending, trending process, report requirements, approval, and distribution.

III. PROCEDURE

A. Assignment of Codes

LA/Auditors 1. Assign subject codes and direct cause codes for conditions adverse to quality, and root cause codes when the condition adverse to quality is significant as directed by NSNFP Procedure 16.02, "Corrective Action." The codes are posted in the Corrective Action Trending Tracking System (CATTS) database to facilitate analysis for identifying adverse trends and are recorded on the Deficiency Report (DR)/Corrective Action Request (CAR) Part III form.

a. If a predominant cause code is not apparent, assign the appropriate code reflecting that the multiple causes are present or the cause is unknown.

b. The root cause code is assigned to correspond to the root cause identified by formal root cause analysis. When multiple contributing causes are listed without the root cause identified, assign the appropriate code reflecting multiple causes.

B. Trending Deficiencies

QASM 1. By mid-January, designate a LA to prepare the annual trend report and validate all subject, direct cause, and root cause codes used for trend analysis.

LA 2. Review the subject codes, direct cause codes, and root cause codes for quality program deficiencies listed in the CATTS database.

LA

3. Using the CATTS database, generate reports in relation to each of the following assessment areas:

   a. NSNFP

   b. Each NSNFP supplier.

4. Review the generated reports. If no subject or direct cause code has been assigned to a deficiency, either assign the code or have the responsible auditor do it. Root cause codes will not be assigned without formal root cause analysis.

5. Sort deficiencies by the associated cause codes (subject, direct, and root), and correlate the results with the NSNFP and NSNFP suppliers. Analysis of subject and cause codes will be limited to deficiencies tracked by the NSNFP.

   a. Generate bar charts for subject and cause codes from the CATTS database for each calendar year. Individual cause and subject codes are compared over time to identify increases in frequency of occurrence that may identify potential adverse trends.

   b. Generate a Pareto chart for subject and cause codes for the calendar year under evaluation. Subject codes and cause codes that have the highest frequency of occurrence are evaluated using the definition of an adverse quality trend.

6. Validate previously assigned subject and cause codes and evaluate the deficiencies.

   a. Compare DRs/CARs to establish that common issues are identified by the appropriate subject and cause codes.

   b. When validation of subject and cause codes (direct and root cause) results in a change to a code, document the change in the CATTS database on form DR/CAR Part III for the subject DR/CAR, and transmit to QA Records according to Section VII.

7. Review inputs received from NSNFP quality activity documents for indications of the emergence of adverse trends.

8. Evaluate corrective action management by comparing the average duration that corrective actions are open for discrete time periods. This comparison will consider overall performance for all NSNFP tracked DRs/CARS and may include individual organization performance when warranted. Increases in the duration for implementing corrective action are evaluated for an adverse trend.

9. Determine the presence of an adverse trend by using the following criteria separately or in combination.

LA

a. The identified deficiencies are repetitive in nature; the data indicate one of the following:

(1) Multiple occurrences of the same deficiency within one process or group of similar processes

(2) Occurrence of similar deficiencies by one or more individuals within one process.

b. An increased number of deficiencies cannot be attributed to increased work activities, new work activities, or increased assessment activities.

c. Previously implemented corrective actions have been ineffective in reducing the number of similar deficiencies.

d. Identified corrective actions have not been implemented in a timely manner.

e. Recurring deficiencies are related to the same subject or cause code.

10. Prepare a CAR in accordance with NSNFP Procedure 16.02 for any condition determined to be a significant condition adverse to quality.

C. Reporting and Correcting Adverse Trends

LA

1. Prepare the Annual NSNFP QA Program Trending Report using the format shown in Attachment A.

2. Submit the Annual NSNFP QA Program Trending Report and DR/CARs, as appropriate, to the NSNFP QASM for review and approval.

QASM

3. Review the Annual NSNFP QA Program Trending Report to determine if adverse quality trends have been adequately identified and supported by the process described in Subsection 4.a.

4. Issue CARs according to NSNFP Procedure 16.02, as appropriate, to the management of the organization responsible for the corrective action.

5. Ensure the Annual NSNFP QA Program Trending Report is issued to the management of affected organizations by March 1 of each year.

IV. REFERENCES

None.

V. DEFINITIONS

Terms appearing in italics followed by the notation "see glossary" are defined in the NSNFP Documents Manual Introduction and Glossary.

VI. ATTACHMENTS

Attachment A, Annual NSNFP QA Program Trending Report Format and Content Guidelines

Attachment B, Direct Cause and Root Cause Codes

VII. QUALITY RECORDS

The following quality records generated as a result of this procedure require retention in accordance with the identified classification and NSNFP Procedure 17.01.

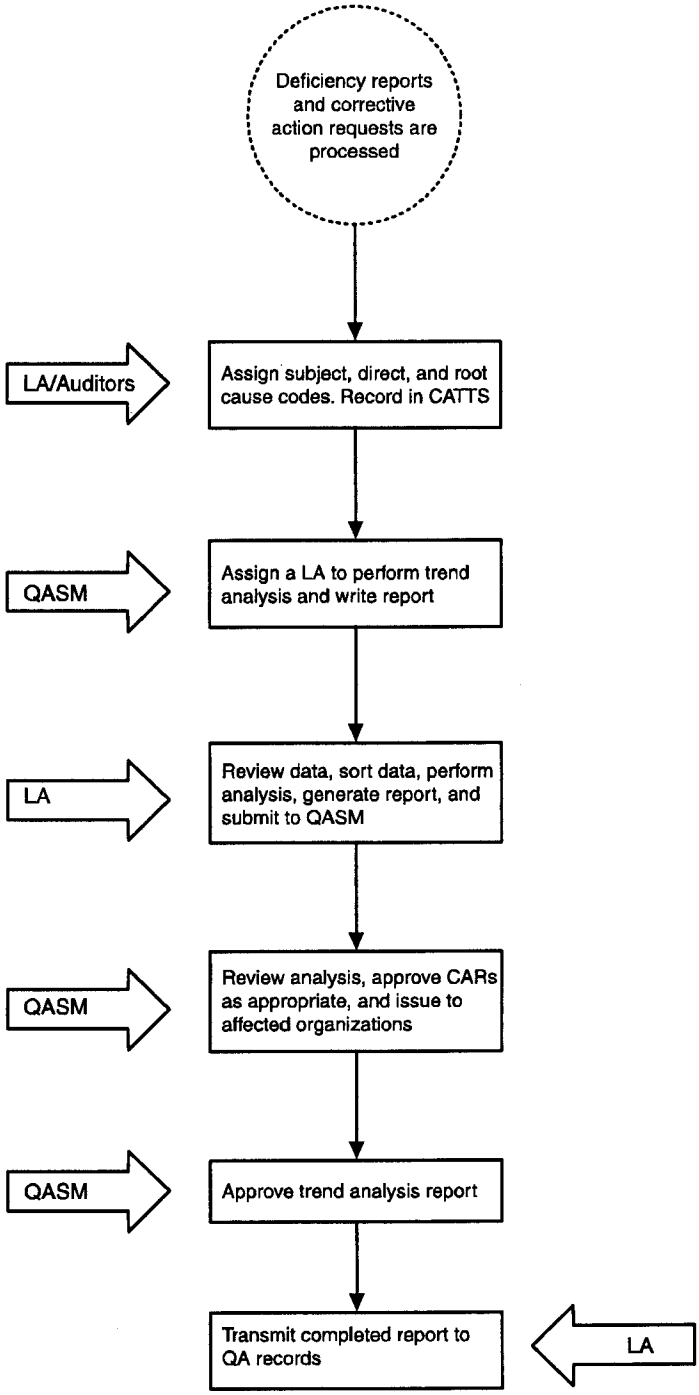
Lifetime

Process the DR/CAR Part III form documenting changes to subject, direct, and root cause codes, and process the record in accordance with NSNFP Procedure 16.02 to ensure file codes are the same as the original DR/CAR quality record.

Nonpermanent

Annual NSNFP QA Program Trending Report.

VIII. PROCEDURE FLOW DIAGRAM



Attachment A

Annual NSNFP QA Program Trending Report Format and Content Guidelines

The Trending Report should address, as a minimum:

1. Executive Summary

2. Introduction

   - Purpose

   - Summary of documents reviewed for the report.

3. Results

   - Description of trending process and methodology

   - Identification of deficiencies used for trending

     If no data are available for an area (i.e., NSNFP supplier), indicate that status and the reason.

   - Summary of ineffective or overdue corrective actions including overdue corrective action closures

   - Conclusions reached on potential trends in the NSNFP

   - Adverse quality trends

   - CARs issued as a result of the identified trends.

4. Figures, as appropriate, displaying analysis discussed in the report.

Attachment B

Direct Cause and Root Cause Codes

To facilitate identifying the cause of the deficiency, there are three levels of cause demonstrated by the deficiency code tables. A direct cause code and root cause code may be assigned from any of the three levels listed. The three levels are:

- General
- Basic
- Root.

Deficiency Codes		
Description	Code	Category
PROCEDURES/IMPLEMENTING DOCUMENTS	1	General
Procedure Not Used	1 A	Basic
No/incomplete documents/procedure	1 A a	Root
Lost/missing documents/procedure	1 A b	
Procedure difficult to use	1 A c	
Procedure not available or inconvenient to use	1 A d	
Procedure use not required but should be	1 A e	
Inadequate/Wrong Procedure	1 B	Basic
Typographical error	1 B a	Root
Sequence wrong	1 B b	
Technical facts/data wrong	1 B c	
Requirements:	1 B d	
Updates not incorporated	1 B d (1)	
Not covered/addressed	1 B d (2)	
Wrong documents/procedure used	1 B e	
Wrong revision used	1 B f	
Implementing documents/process:	1 B g	
Not adequate/cannot be followed	1 B g (1)	
Incomplete	1 B g (2)	
Does not exist	1 B g (3)	
Does not describe how the requirement will be implemented	1 B g (4)	

Attachment B

Deficiency Codes		
Description	Code	Category
Conflicting instructions	1 B h	
Error in Following the Procedure	1 C	Basic
Format confusing	1 C a	Root
More than one action per step	1 C b	
Multiple references	1 C c	
No sign-off space	1 C d	
Checklist misused	1 C e	
Information/Data/Computation wrong or incomplete	1 C f	
Ambiguous instructions	1 C g	
Inadequate limits/parameters	1 C h	
Self -imposed Requirement—Not Needed for QARD Compliance	1 D	Basic
PERSONNEL—HUMAN PERFORMANCE	2	General
Lack of Attention to a Task	2 A	Basic
Carelessness	2 A a	Root
Oversight	2 A b	
Work overload	2 A c	
Procedure not used or used improperly	2 A d	
Wrong revision used	2 A e	
Lack of direction	2 A f	
Lack of Qualification	2 B	Basic
MANAGEMENT SYSTEM	3	General
Standards, Policies, Administrative Controls (SPAC)	3 A	Basic
No SPAC	3 A a	Root
SPAC not used	3 A b	
Inadequate communication of SPAC	3 A c	
SPAC recently changed	3 A d	
Inadequate drawings/prints	3 A e	
Inadequate accountability	3 A f	

Attachment B

Deficiency Codes		
Description	Code	Category
Immediate Supervision	3 B	Basic
Inadequate job/task analysis	3 B a	Root
No preparation/planning	3 B b	
Inadequate selection of performer(s)	3 B c	
Individual not qualified	3 B c (1)	
Team selection not balanced/adequate	3 B c (2)	
Performers not trained	3 B d	
No supervision during work	3 B e	
Infrequent task	3 B f	
Communications	3 C	Basic
No/late communication	3 D	Root
Misunderstood verbal communication	3 E	
Audits/Evaluations	3 F	Basic
No Audits/Evaluations	3 F a	Root
Audit checklist misused	3 F b	
TRAINING	4	General
No Training	4 A	Basic
Decided not to train	4 A a	Root
No learning objective	4 A b	
Lack of Understanding	4 B	Basic
Learning objectives need improvement	4 B a	Root
Lesson plan need improvement	4 B b	
Training instructions need improvement	4 B c	
Testing need improvement	4 B d	
Continued/Refresher training need improvement	4 B e	
Inadequate Training Methods	4 C	Basic
Incomplete training	4 C a	Root
Inadequate facilities	4 C b	
Continuous training inadequate	4 C c	

Attachment B

Deficiency Codes		
Description	Code	Category
Inadequate testing or measure of aptitude	4 C d	
DESIGN/SCIENTIFIC INVESTIGATION	5	General
Design Documents/Scientific Investigation	5 A	Basic
Documents do not exist	5 A a	Root
Data/computation wrong, incomplete, or less than adequate	5 A b	
Requirements:	5 A c	
Not identified	5 A c (1)	
Incorrectly identified	5 A c (2)	
Scientific investigation not performed per study plan	5 A d	
Problems not anticipated in design or investigation	5 A e	
Equipment environment not considered	5 A f	
Technical Review	5 B	Basic
Review not performed	5 B a	Root
Review inadequate	5 B b	
Reviewer lack of independence	5 B c	
FABRICATION/INSTALLATION	6	General
Fabrication/Installation	6 A	Basic
Fabrication/installation error	6 A a	Root
Fabrication/installation not per design	6 A b	
Wrong sequence fabrication/installation	6 A c	
Wrong material	6 A d	
Defective material	6 A e	
Lack of proper tools used for fabrication/installation	6 A f	
Quality Control	6 B	Basic
No inspection	6 B a	Root
Wrong inspection instructions	6 B b	
Wrong inspection technique	6 B c	

Attachment B

Deficiency Codes		
Description	Code	Category
RELIABILITY SYSTEM	7	General
Inadequate Preventative Maintenance	7 A	Basic
No preventative maintenance for equipment	7 A a	Root
Inadequate preventative maintenance for equipment	7 A b	
Unreliable Equipment	7 B	Basic
Equipment past design lifetime	7 B a	Root
Equipment repeated failure, previous corrective action inadequate	7 B b	
SOFTWARE	8	General
Computer Software Controls	8 A	Basic
Inadequate software design	8 A a	Root
Inadequate validation, verification, or testing	8 A b	
Defects:	8 A c	
Inadequate defect report	8 A c (1)	
Inadequate defect resolution	8 A c (2)	
Inadequate software maintenance	8 A d	
Inadequate software identification	8 A e	
Inadequate User Information Manuals	8 B	Basic
Inadequate Control of Usage	8 C	
Inadequate Data Update	8 D	
PROCUREMENT	9	General
Vendor Not in the Approved Supplier List	9 A	Basic
Vendor Not Qualified	9 B	
Receiving Inspection	9 C	
No receiving inspection	9 C a	Root
Inadequate receiving inspection	9 C b	

Attachment B

Deficiency Codes		
Description	Code	Category
MISCELLANEOUS OR MULTIPLE AREAS	10	General
Multiple Causes Present	10 A	Basic
Material/Equipment Inadequate	10 B	
Unknown	10 C	
Natural Causes	10 D	
Planned Failure	10 E	