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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE:
QUALITY ASSURANCE PROGRAM STATUS REPORTING

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Director, OCRWM	Date:	Director, OQA	Date:
[signature]	8/31/89	[signature]	9/12/89

1.0 PURPOSE

The purpose of this procedure is to establish methods and responsibilities for assessing and reporting PROGRAM quality status.

2.0 SCOPE

This procedure applies to those actions, data, and information necessary to comprehensively evaluate the status of PROGRAM quality. The information and data are provided by Office of Civilian Radioactive Waste Management (OCRWM) elements and PROGRAM participants to the Director of the Office of Quality Assurance (OQA) for analysis and reporting. The analyses cover the overall effect of reported deficiencies, timeliness and effectiveness of corrective action, and preventive measures applied to preclude deficiency or problem recurrence. The analyses will include identification of trends.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 "Quality Assurance Requirements for the Civlian Radioactive Waste Management Program," (QARD) DOE/RW-0214. (HQ0890109.0002)

3.1.2 "Quality Assurance Program Description," (QAPD) DOE/RW-0215. (HQ0890109.0003)

3.2 DEFINITIONS

3.2.1 The definitions of standard terms may be found in the Glossary contained in reference 3.1.1.

3.3 PROGRAM

3.2.1 The U.S. Department of Energy's Civilian Radioactive Waste Management Program.

102.7

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM, is responsible for:

4.1.1 Directing management and administration policy for PROGRAM quality evaluation and status reporting prescribed by this procedure;

4.1.2 Providing timely guidance and feedback to OCRWM Associate Directors, appropriate Project Managers, and the Director, OQA, with regard to the OCRWM Quality Assurance (QA) program status and overall PROGRAM quality status; and

4.1.3 Approving quarterly Quality Status Summaries (QSS).

4.2 ASSOCIATE DIRECTORS, OCRWM

The Associate Directors, OCRWM, are responsible for:

4.2.1 Participating in PROGRAM quality-effectiveness reviews; and

4.2.2 Taking timely and effective action to correct and prevent deficient conditions and quality-related problems.

4.3 DIRECTOR, OQA

The Director, OQA, is responsible for:

4.3.1 Preparing and maintaining this procedure;

4.3.2 Collecting quality-related data and information for analysis;

4.3.3 Defining trend-analysis methods and documenting the applications used to evaluate PROGRAM quality and to perform analyses of data trends;

4.3.4 Preparing and issuing status reports prescribed in Sections 6.4 through 6.7 of this procedure;

4.3.5 Implementing appropriate root-cause definition techniques to be applied to identified problem areas in the PROGRAM; and

4.3.6 Maintaining and controlling QA records generated as a result of compliance with this procedure.

5.0 GENERAL

5.1 Trend analysis of data compilations pertinent to activities affecting quality shall be used to assess the adequacy and effectiveness of the OCRWM QA program and PROGRAM quality. The techniques applied shall provide a basis for problem definition and identification of root causes, so that corrective actions are adequate and preventive actions are maintainable. Comparisons with data and analyses from previous, continuous periods shall be a basis for projections and shall be used to establish objectives for correcting or improving conditions affecting quality.

5.2 The Director, OQA, shall prepare monthly reports (lists) and quarterly Quality Status Summaries (QSS) that discuss the OCRWM QA program and PROGRAM quality (sections 6.4 and 6.5).

5.3 As a minimum, the Director, OCRWM; the Director, OQA; and Associate Directors will convene a PROGRAM quality effectiveness review of each QSS draft. An executive summary reflecting the management assessment of PROGRAM quality shall be incorporated in the QSS. The quarterly PROGRAM quality-effectiveness review may be held in conjunction with any other OCRWM meeting, or it may be convened separately.

5.4 The QSS shall be used by cognizant PROGRAM management, from the highest to the lowest affected management tier, to further assess quality effectiveness within PROGRAM organizations, to take actions necessary to correct identified problems and preclude recurrence, and to improve quality.

6.0 PROCEDURE

6.1 The Director, OQA, shall request that the PROGRAM participants periodically provide information concerning PROGRAM quality for which they are responsible. The information format should be defined in the request.

6.2 Analysis of OCRWM QA program data, such as Corrective Action Reports (CARs), Deficiency Reports (DRs), and Stop Work Order/Request (SWO/R), shall occur at a frequency sufficient to ensure that conditions adverse to quality are identified, and corrected or prevented as early as practicable. Similar analyzed data and information shall be obtained from PROGRAM participants for evaluation and reporting purposes. The trend-analysis approach shall be defined and documented by the Director, OQA. Guidance for trend analysis is provided in Attachment I.

6.3 Where there are trend indications that a deficiency or failure in PROGRAM quality or in the OCRWM QA program either exists or appears imminent, immediate corrective action shall be initiated as required by QAAP 16.1, "Corrective Action."

6.4 A monthly report on all DRs, CARs, and SWO/Rs shall be prepared by the Director, OQA. The monthly report shall list new areas requiring corrective action and overdue corrective-action responses. The report shall be distributed to responsible management. Where there are repetitive, significant slips in response dates or where overdue responses are numerous, the Director, OQA, will take further action to evaluate the causes and to correct the condition, as described in QAAP 16.1.

6.5 Quarterly, the Director, OQA, shall prepare a draft of the QSS that incorporates results of trend data obtained from PROGRAM participants and OQA. The data and any other information that may influence PROGRAM quality shall be evaluated, and the effect shall be summarized.

6.6 OCRWM management (Ref. section 5.3) and appropriate PROGRAM management shall review the draft QSS at the quarterly PROGRAM quality effectiveness review meeting within 6 weeks after the close of the report period. The Director, OQA, shall incorporate an executive summary in the QSS that discusses OCRWM management's assessment of the PROGRAM quality status. An assessment of the effect of significant adverse trends on overall PROGRAM activity shall be provided. The executive summary shall contain management-established objectives to be achieved in PROGRAM quality during the next quarter, along with target dates or milestones for each identified objective. These objectives shall be tracked in the same manner as described in Section 6.4. Attachment II provides guidance for QSS preparation.

6.7 The Director, OQA, shall finalize the quarterly QSS with the incorporation of the management assessment described in Section 6.6 and shall obtain the OCRWM Director's, approval. The QSS shall be distributed to OCRWM management and Project offices. A standard distribution shall be documented and maintained by OQA.

7.0 QUALITY ASSURANCE RECORDS

7.1 Documentation resulting from compliance with this procedure shall be collected and maintained in accordance with the requirements of QAAP 17.1, "QA Records Management." As a minimum, documentation for application of trend analyses to specific data compilations, and the QSSs are considered QA records.

8.0 ATTACHMENTS

8.1 Attachment I - Guidance for Trend Analysis

8.2 Attachment II - Guidance for Quarterly Quality Status Summary Content and Format

8.3 Attachment III - Flowchart

ATTACHMENT I

GUIDANCE FOR TREND ANALYSIS

A. This attachment contains guidelines to be used in trend analysis as prescribed in the foregoing procedure.

B. Definitions used in conjunction with these guidelines are as follows:

1. Trend - a measurable (negative or positive) change over a specific period, in a product or process value, away from a relatively constant average, which may be used to establish a benchmark for forecasts or projections.

2. Important trend - a measurable adverse change that, if not analyzed and investigated in a timely manner, may result in a significant deficiency.

3. Significant trend - a sudden negative change from the relatively constant average that indicates the presence of a significant condition adverse to quality requiring immediate attention by management.

4. Positive trend - an indication of improvement.

C. Trend analyses should be performed using specified statistical methods. Results should be presented graphically where practicable and summarized for purposes of analysis and reporting. The application of prescribed trend-analysis methods shall be documented and traceable to a specific analyzed data compilation.

The trend analysis process is comprised of the following basic steps:

Phase One: compilation and evaluation of source data, statistical manipulation of data, and identification of trends;

Phase Two: analysis of trends, problem definition, and root-cause determination; classification of trends, that is, significant, important, positive, or unchanged; and initial conclusions; and

Phase Three: confirmation of conclusions (modified as appropriate); definition of corrective and preventive actions where indicated; and implementation of corrective and preventive actions (modified as necessary).

D. ANALYTICAL PHASES

1. Phase One.

a) Defining and documenting the basic trend methods to be used and identifying affected data and information to be collected.

b) Routinely collecting specified data and information. This material includes pertinent trend results from OCRWM, Project Offices, and other participants;

c) Evaluating data and information;

d) Classifying deficiencies by criteria that parallel approved PROGRAM QA programs, and charting the information as shown in Figure 1, "Example of a Quarterly Trend-Analysis Chart of Deficiencies by Criteria."

e) Categorizing the deficiencies by type, such as CARs and DRs, and charting that information as shown in Figure 3, "Example of a Quarterly Trend-Analysis Chart by Deficiency Type."

f) Accomplishing necessary statistical manipulation to identify trends and documenting the trend methods used.

2. Phase Two.

a) Reviewing trend data and analyzing the effect on PROGRAM quality;

b) Charting performance by comparative analysis with previously analyzed and charted data.

c) Summarizing conclusions based on information, as shown in Figure 2, "Example of a Quarterly Deficiency Trend-Analysis Chart for Comparison by Criteria," and Figure 4, "Example of a Quarterly Trend-Analysis Chart for Comparison by Deficiency Type."

d) Establishing priorities for problem areas to expedite problem definition, root-cause determination, correction, and prevention, as well as improvement.

3. Phase Three.

a) Monitoring for adverse trends and initiating investigations appropriate to the circumstances to determine validity of the initial conclusions;

b) Re-reviewing data and analytical methods used and considering application of alternate trend-analysis techniques to further define trend conditions;

c) Reporting, quarterly, results of trend analyses and identifying whether trend conditions are significant, important, positive, or unchanged;

d) Identifying or initiating, when appropriate, applicable corrective, preventive, and improvement processes based on the conclusions reached in D.2d), D.3a), and D.3c).

e) List of Figures

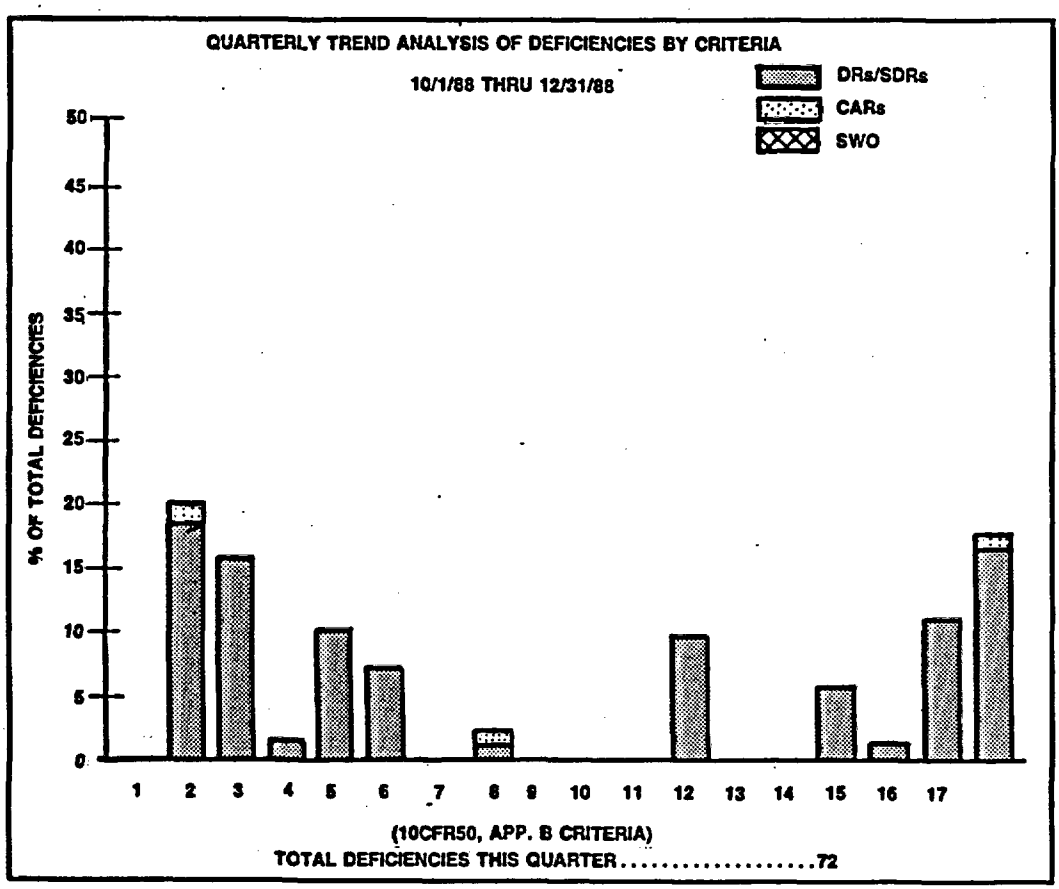
1) Figure 1 - Example of a Quarterly Trend-Analysis Chart of Deficiencies by Criteria

2) Figure 2 - Example of a Quarterly Deficiency Trend-Analysis Chart for Comparison by Criteria

3) Figure 3 - Example of a Quarterly Trend-Analysis Chart by Deficiency Type

4) Figure 4 - Example of a Quarterly Trend-Analysis Chart for Comparison by Deficiency Type

ATTACHMENT I, FIGURE 1: Example of a Quarterly Trend-Analysis Chart of Deficiencies by Criteria

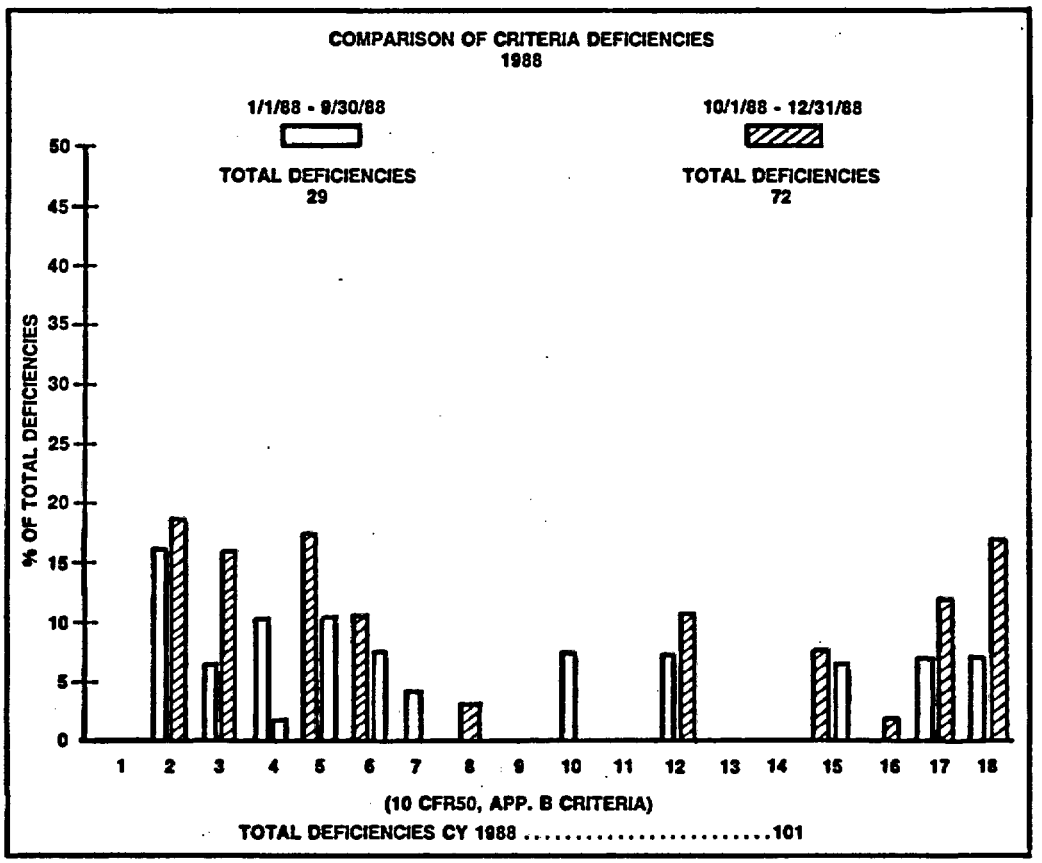


CRITERIA	TOTAL
1. ORGANIZATION	0
2. QA PROGRAM	13
3. SCIENTIFIC INVESTIGATION AND DESIGN CONTROL	11
4. PROCUREMENT DOCUMENT CONTROL	1
5. INSTRUCTION, PROCEDURES, AND DRAWINGS	7
6. DOCUMENT CONTROL	5
7. CONTROL OF PURCHASED ITEMS/SERVICES	0
8. IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA	2
9. CONTROL OF PROCESSES	0

CRITERIA	TOTAL
10. INSPECTION	0
11. TEST CONTROL	0
12. CONTROL OF MEASURING AND TEST EQUIPMENT	7
13. STORAGE AND SHIPPING HANDLING	0
14. INSPECTION, TEST, AND OPERATING STATUS	0
15. CONTROL OF NONCONFORMING ITEMS	4
16. CORRECTIVE ACTION	2
17. QA RECORDS	8
18. AUDITS	12

TOTAL DRs/SDRs - 72
TOTAL CARs - 3
TOTAL SWOs - 0

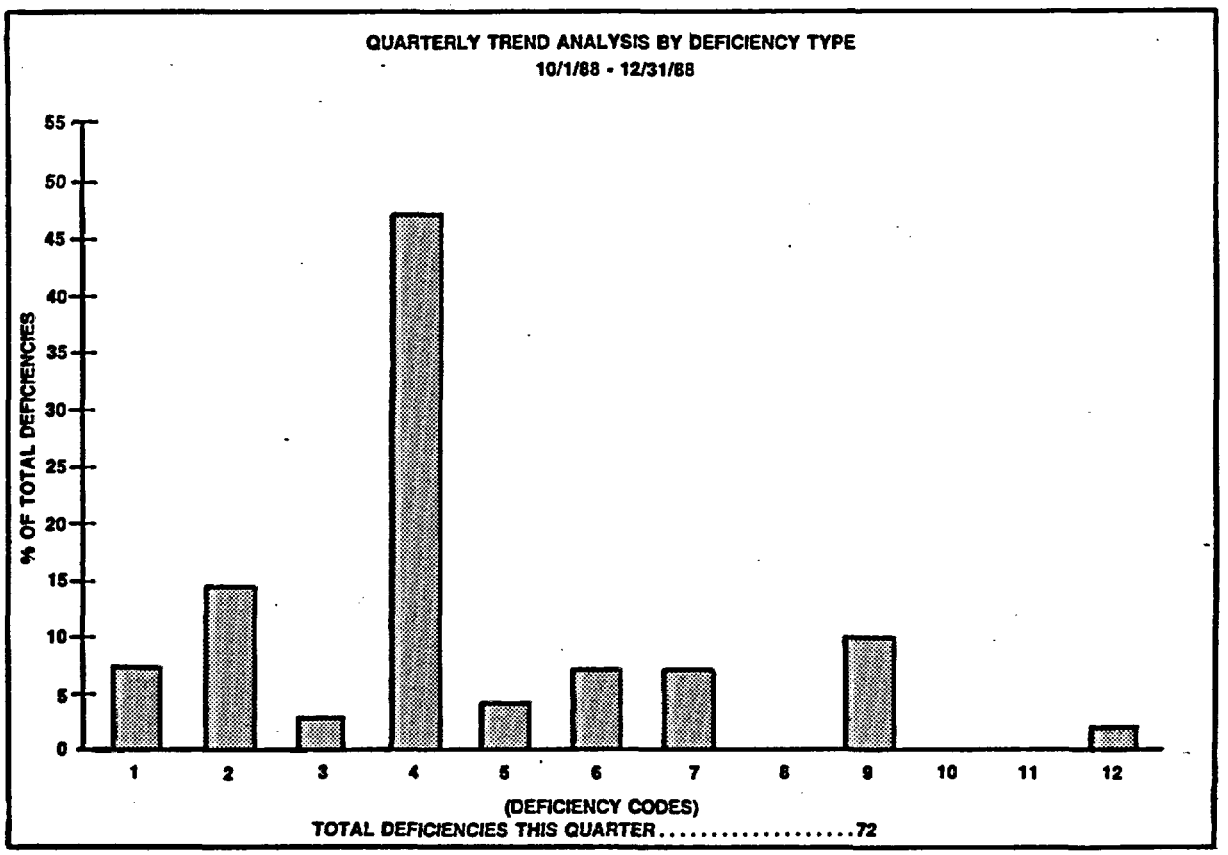
ATTACHMENT I, FIGURE 2: Example of a Quarterly Deficiency Trend-Analysis Chart for Comparison by Criteria



CRITERIA	TOTAL BY QUARTER								CY	
	DR	CAR	DR	CAR	DR	CAR	DR	CAR	DR	CAR
1. ORGANIZATION	0		0		0		0		0	
2. QA PROGRAM	2		3		3		13	1	21	1
3. SCIENTIFIC INVESTIGATION AND DESIGN CONTROL	1		4		0		11		16	
4. PROCUREMENT AND DOCUMENT CONTROL	—		1		1		1		3	
5. INSTRUCTION, PROCEDURES, AND DRAWINGS	1		2		2		7		12	
6. DOCUMENT CONTROL	2		1		1		5		9	
7. CONTROL OF PURCHASED ITEMS/SERVICES	0		0		0		0		—	
8. IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA	1		1		0		2	1	4	1
9. CONTROL OF PROCESSES	—		—		—		—			
10. INSPECTION	—		—		—		—		—	
11. TEST CONTROL	1				1		—		2	
12. CONTROL OF MEASURING AND TEST EQUIPMENT	1						7		8	
13. STORAGE AND SHIPPING HANDLING	0		0		0		0		0	
14. INSPECTION, TEST, AND OPERATING STATUS	0		0		0		0		—	
15. CONTROL OF NONCONFORMING ITEMS	0		0		0		4		4	
16. CORRECTIVE ACTION	—		—		—		2		2	
17. QA RECORDS	—		—		—		8		8	
18. AUDITS	0		0		0		12	1	12	1
TOTAL	9		12		8		72	3	101	3

— NO ACTIVITY

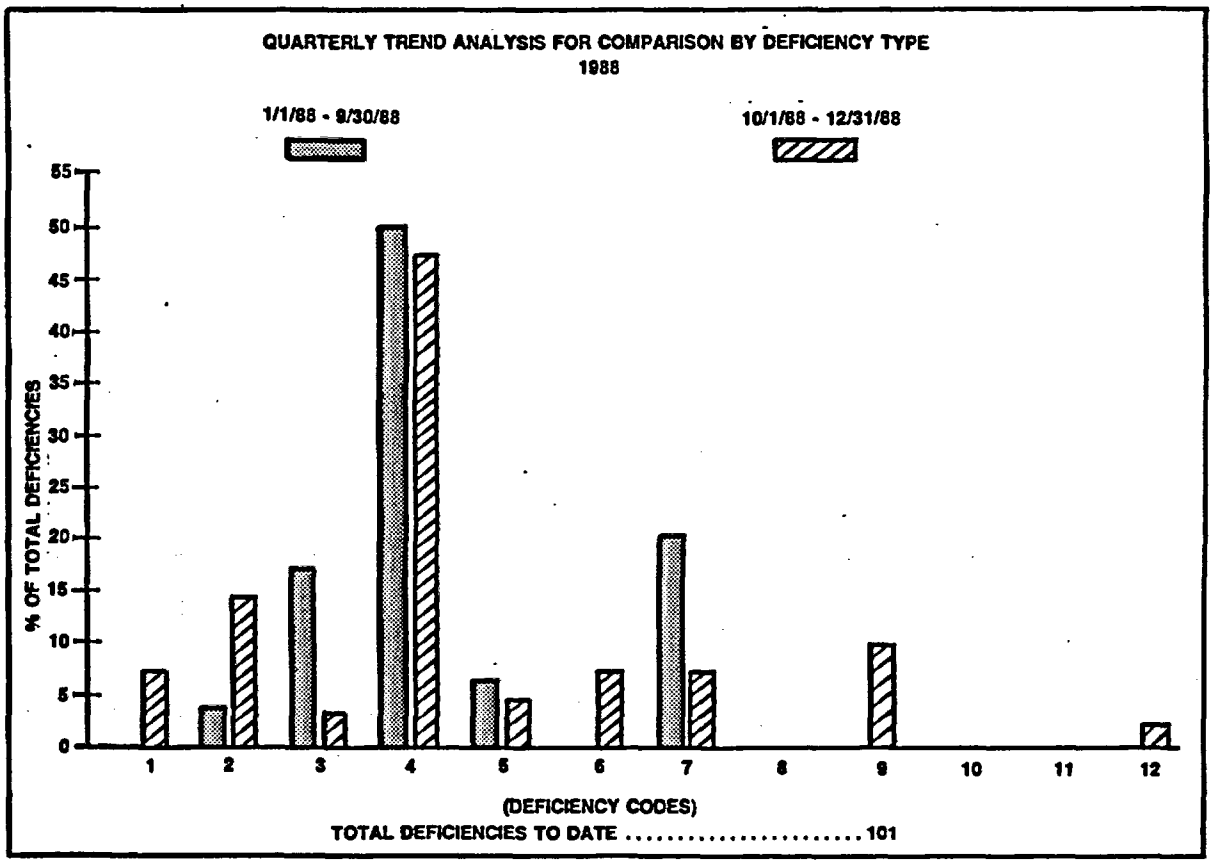
ATTACHMENT I, FIGURE 3: Example of a Quarterly Trend-Analysis Chart by Deficiency Type



DEFICIENCY CODE KEY:

1.	DOCUMENTATION	5
2.	INADEQUATE REVIEW/APPROVAL	10
3.	TRAINING/INDOCTRINATION	2
4.	PROCEDURAL/IMPLEMENTATION	33
5.	TRACEABILITY	3
6.	TIMELINESS	5
7.	INADEQUATE PROCEDURE	5
8.	MANAGEMENT ASSESSMENT	0
9.	INADEQUATE PROGRAM	7
10.	PROCUREMENT REQUIREMENTS	0
11.	QUALIFICATION/CERTIFICATION	0
12.	INADEQUATE CORRECTIVE/ PREVENTIVE ACTION	2
	TOTAL	72

ATTACHMENT I, FIGURE 4: Example of a Quarterly Trend-Analysis Chart For Comparison By Deficiency Type



DEFICIENCY CODE KEY:

1. DOCUMENTATION
2. INADEQUATE REVIEW/APPROVAL
3. TRAINING/INDOCTRINATION
4. PROCEDURAL/IMPLEMENTATION
5. TRACEABILITY
6. TIMELINESS
7. INADEQUATE PROCEDURE/INSTRUCTION
8. MANAGEMENT ASSESSMENT/REPORTING
9. INADEQUATE PROGRAM
10. PROCUREMENT REQUIREMENTS
11. QUALIFICATION/CERTIFICATION
12. INADEQUATE CORRECTIVE/PREVENTIVE ACTION

ATTACHMENT II
QUARTERLY QUALITY STATUS SUMMARY
CONTENT AND FORMAT
OUTLINE

A. REPORT PERIOD BEGINNING STATUS

Part I of the Quality Status Summary (QSS) should state the begin-and-end dates for the period. It should restate the PROGRAM quality status reported in the previous QSS. Significant areas of concern from the previous report period may be emphasized at this time, as appropriate, as well as major quality objectives and the associated target dates or milestones.

B. REPORT PERIOD CURRENT STATUS

Part II of the QSS should summarize the efforts to improve, correct, and prevent problems as follows:

1. Major Problems and Significant Trends - Explanations of major problems affecting PROGRAM quality and/or significant trends encountered, together with the status of corrective actions. Impacts on major PROGRAM areas should be assessed.

2. Important Trends and Impact Assessment - An explanation of indicated important trends and potential impacts on the overall PROGRAM.

3. Areas of Improvement - As indicated by positive trends, a discussion of major improvements in quality, together with a brief descriptions of the improvements, corrective and preventive actions taken, and benefits derived therefrom.

4. Quality Objectives Status Report - A quantitative report on management-established quality objectives that are new, closed, and open. Remarks concerning impacts on the QA program and PROGRAM quality may be included, as appropriate.

5. Stop-Work Directive Status Report - A quantitative report on any SWDs that are new, closed, and open. Remarks on individual status may be made, as appropriate.

6. Corrective Action Reports Status - A line-item report on new, closed, and open CARs.

7. Total Number of Open Deficiencies - Preferably graph or table.

8. Indoctrination and Training Status - The status that addresses the indoctrination and training program development and implementation, including performance dates, topics covered, schedule slips, and projected dates for the next quarter.

9. Status of QA Audits - A summary of the audits scheduled and performed during the report period, and any impact on projected activities for the next report period (number planned as internal, external, and follow-up) should be provided. Slippages or accelerated schedules should be addressed as well as staffing requirements and staff availability.

10. Status of Surveillances - A summary of surveillances scheduled and performed and major areas surveyed. Projected surveillances for the next report period (number planned and areas to be covered) should be provided. Staffing needs should also be addressed.

11. Licensing and Regulatory Status - A discussion of any changes in licensing positions and regulatory changes that affect the PROGRAM quality-assurance efforts. The status of NRC findings and investigations should be addressed as well.

12. Other Information and Data - Information concerning other sources outside the PROGRAM that may affect quality should be assessed for impact.

13. QA Program Document Status - A brief description of major revisions to the QA Program Description, QA Administrative Procedures, and Implementing Line Procedures and the reasons for the revisions.

C. REVIEW OF OVERALL QUALITY PROGRAM EFFECTIVENESS

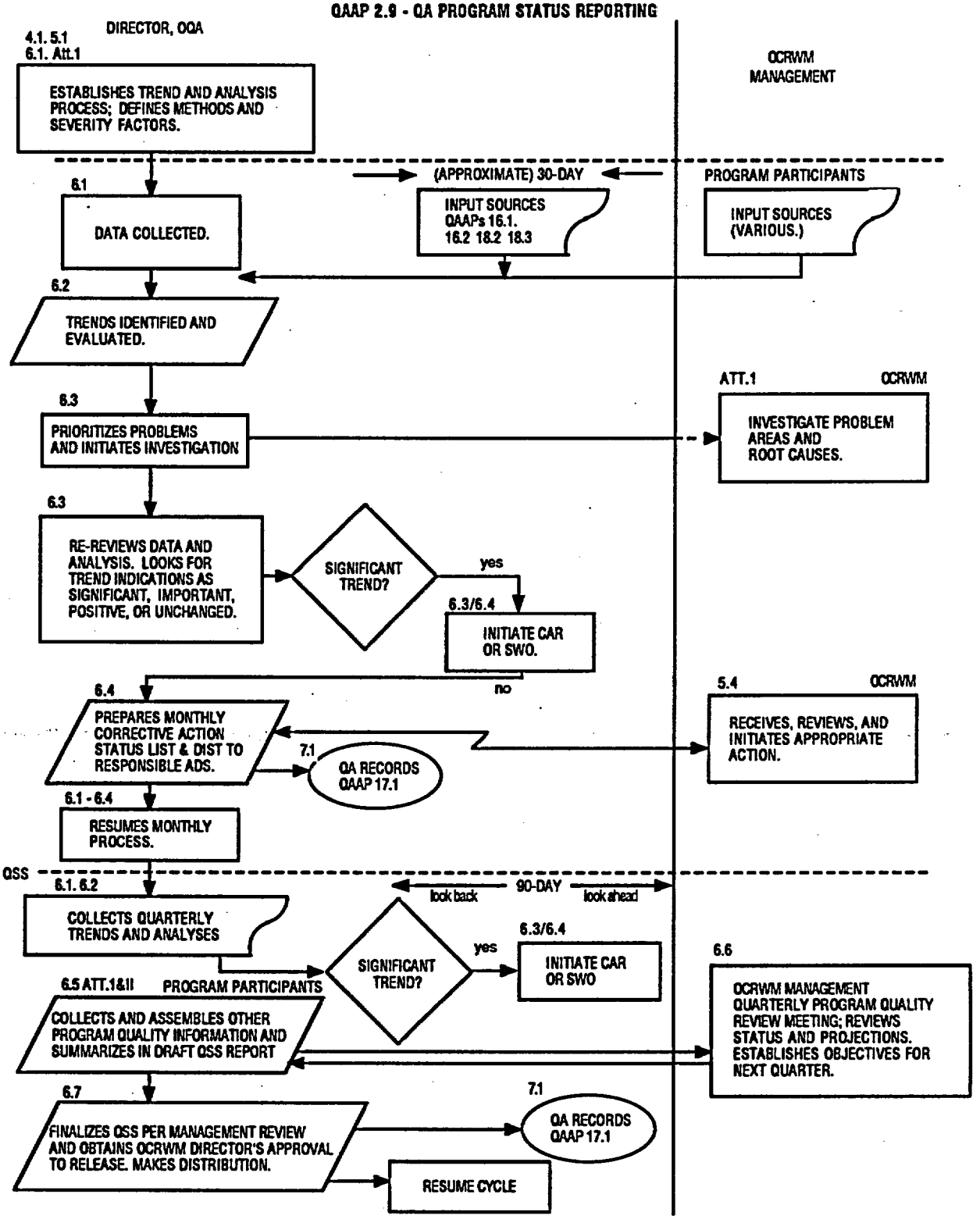
Part III of the QSS should provide an executive summary by PROGRAM management of conclusions on the status of the overall effectiveness of the QA Program. The summary may also include recommendations for further action to improve or correct conditions, such as elevating an objective to a CAR, or recommending a special investigation to further define root cause, revising QA program documents, etc.

D. MANAGEMENT OBJECTIVES SUMMARY

Part IV of the QSS should be used to identify the quality objectives established by management for the next report period, as well as long-range objectives and established target dates or milestones. The objectives may be any range of items that PROGRAM Management deems appropriate for achievement of an effective QA program.

E. SUPPORTING MATERIALS - Part V of the QSS should contain any supporting materials to amplify the summary contents.

QAAP 2.9 - QA PROGRAM STATUS REPORTING



QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES

2.9

The following number is for OCRWM records management purposes only and should not be used when ordering this publication.

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