



OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title:

QUALIFICATION OF AUDIT PERSONNEL

Procedure No.:  
QAAP 18.1

Revision:  
2

Date:  
11/12/91

Page  
1 of 18

Concurrence

Date:

9/30/91

Approval

Date:

9/30/91

1.0 PURPOSE

This procedure establishes the responsibilities and methods for training and qualification of personnel who perform quality assurance (QA) program audits.

2.0 SCOPE

This procedure applies to all personnel who perform QA program audits for the Office of Civilian Radioactive Waste Management (OCRWM).

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 *Quality Assurance Requirements Document (QARD), DOE/RW-0214.*

3.1.2 *Quality Assurance Program Description Document (QAPD), DOE/RW-0215.*

3.2 DEFINITIONS

3.2.1 Auditor - An individual who is qualified to participate in any portion of a QA program audit.

3.2.2 Lead Auditor - An individual who is certified to organize, perform, and direct a QA audit; report observed conditions adverse to quality; and evaluate related corrective actions.

3.2.3 Technical Specialist - An individual assigned to support an audit team when the scope, complexity, and/or special nature of the activities to be audited warrant an individual with relevant technical expertise.

3.2.4 The definitions of other quality assurance related terms may be found in the Glossary contained in reference 3.1.1.



#### 4.0 RESPONSIBILITIES

##### 4.1 ASSOCIATE AND OFFICE DIRECTORS, OCRWM

Associate and Office Directors, OCRWM are responsible for:

- 4.1.1 Supporting the audit process;
- 4.1.2 Providing Technical Specialists to participate in audits; and
- 4.1.3 Nominating staff as Auditor candidates, as required.

##### 4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE, (OQA)

The Director, OQA is responsible for:

- 4.2.1 Preparing and maintaining this QAAP;
- 4.2.2 Implementing the requirements of this procedure;
- 4.2.3 Training prospective Auditors, Lead Auditors, and Technical Specialists;
- 4.2.4 Qualifying Auditors and examining and certifying Lead Auditors; and
- 4.2.5 Ensuring that QA records generated as a result of the implementation of this procedure are maintained.

##### 4.3 LEAD AUDITORS

Lead Auditors are responsible for maintaining their auditing proficiency.

#### 5.0 GENERAL

5.1 Personnel selected for QA program audit assignments shall have sufficient experience and training commensurate with the scope, complexity, or special nature of the activities to be audited.

5.2 Competence of personnel to perform required audit functions shall be established by the following:

- 5.2.1 Orientation that provides a working knowledge of the OCRWM QA program;



5.2.2 Formal training in general and specialized aspects of audit performance; and

5.2.3 In the case of Auditors, on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor.

5.3 As an alternative to audit participation required for the purposes of qualification and maintenance of proficiency, the Director, OQA may recognize participation on OCRWM surveillances, management assessments, vendor surveys, or similar verification activities.

## 6.0 PROCEDURE

### 6.1 AUDITOR QUALIFICATION

The Director, OQA based on the prospective Auditor's previous experience, possession of adequate audit skills, training, and supporting documentation, may qualify the individual as an Auditor. This qualification is documented on Attachment I, "Qualification/Certification Record."

### 6.2 LEAD AUDITOR QUALIFICATION

Individuals are qualified and certified as Lead Auditors using Paragraph 6.2.1 or 6.2.2 based upon the previous experience and certification of the individual.

#### 6.2.1 Previously Certified Lead Auditors

6.2.1.1 An individual who holds a current certification as a Lead Auditor in accordance with ASME NQA-1 or ANSI N45.2.23 may be certified by the Director, OQA based on documentation supporting previous certification and the satisfactory completion of training as required by the OCRWM QA program. Qualification shall be documented on Attachment I, "Qualification/Certification Record."

6.2.1.2 An individual who does not hold a current certification, however was previously certified as a Lead Auditor in accordance with ASME NQA-1 or ANSI N45.2.23 may be certified after:

- a) Demonstrating that proficiency has been maintained since the last Lead Auditor certification consistent with the requirements of Paragraph 6.3.1;
- b) Receiving training in the OCRWM QA Program;
- c) Providing documentation of previous certification; and



**d) Completing Attachment I.**

Note: If an individual cannot demonstrate proficiency maintenance in accordance with Paragraph 6.3.1, the individual shall be requalified in accordance with Paragraph 6.3.4.

**6.2.2 Prospective Lead Auditor Not Previously Certified**

In addition to the requirements of Subsection 6.1, a prospective Lead Auditor shall also meet the requirements of Subparagraphs 6.2.2.1 through 6.2.2.5 before being certified as a Lead Auditor. Successful completion is documented on Attachment I.

**6.2.2.1** The prospective Lead Auditor shall demonstrate skills for effective communication, both oral and written. These skills are evaluated and documented by the Director, OQA.

**6.2.2.2** The prospective Lead Auditor shall have training sufficient to assure competence in auditing skills. This training may include, but is not limited to, on-the-job training. The following areas are considered in determining training needs:

- a) Knowledge and understanding of the OCRWM QA program, ASME NQA-1 and other related codes, standards, regulations, and regulatory guides, as applicable;
- b) Knowledge and understanding of the general structure of quality assurance programs as a whole;
- c) Knowledge and understanding of auditing techniques, planning, examining, questioning, evaluating, reporting, follow-up, and close-out;
- d) Knowledge and understanding of audit planning in the quality-affecting functions for activities such as design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, safety aspects of the work, and records management; and
- e) Knowledge and understanding of quality assurance administrative procedures applicable to audits.



6.2.2.3 The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within the three (3) years prior to qualification. Audits performed prior to qualification by OCRWM may be used to meet this requirement. At least one of the audits shall have been a nuclear QA audit within one year prior to qualification.

6.2.2.4 The prospective Lead Auditor shall successfully complete an examination which evaluates comprehension of, and ability to apply, the body of knowledge identified in Subparagraph 6.2.2.2. This examination may be oral, written, practical, or any combination of the three types.

6.2.2.5 The prospective Lead Auditor shall provide verifiable evidence that a minimum of ten (10) credits have been accumulated as delineated in Attachment II.

6.2.2.6 When the prospective Lead Auditor meets the requirements of Subsection 6.1 and Subparagraphs 6.2.2.1 through 6.2.2.5, the Director, OQA may certify on Attachment I that the individual is qualified as a Lead Auditor.

### **6.3 MAINTENANCE OF PROFICIENCY**

6.3.1 Lead Auditors shall maintain their proficiency through one or more of the following activities:

- a) Participation in at least one QA audit per year (See Paragraph 5.3); or
- b) Review and study of the codes, standards, procedures instructions, books, and other documents related to quality assurance program and program auditing; or
- c) Documented participation in training programs.

6.3.2 The activities performed by Lead Auditors to maintain their proficiency shall be listed on Attachment III, "Qualification Maintenance Record," by each Lead Auditor. The Director, OQA shall review the "Qualification Maintenance Record" during the annual evaluation described in Paragraph 6.3.3.

6.3.3 Based on annual evaluations of the Lead Auditor, the Director, OQA may extend the qualification, require retraining, or require requalification. Attachment III identifies the activities performed, the date the activity was performed, and the type of proficiency maintenance activity (i.e., audits performed per Paragraph 5.3, reviews/studies conducted, or participation in



training programs) performed. The Director, OQA signs and dates on Attachment III when the results of the evaluation are satisfactory. The certification for Lead Auditor is then extended for a period of one year from the date of the evaluation.

6.3.4 Lead Auditors who fail to maintain their proficiency for a period of two (2) years or more shall require requalification. Requalification includes retraining and reexamination in accordance with the requirements of Subparagraphs 6.2.2.2 and 6.2.2.4 and participation as an Auditor in at least one (1) nuclear quality assurance audit (See Paragraph 5.3). The recertification of Lead Auditor is documented by the Director, OQA on Attachment I.

#### 6.4 TECHNICAL SPECIALISTS

Technical Specialists may be Auditors qualified in accordance with Subsection 6.1 who participate in the preparation and conduct of the QA audit. Technical Specialists who are not qualified as Auditors shall receive training identified in QAAP 2.1, *Indoctrination and Training* and shall read and sign Attachment IV, "Audit Guide For Technical Specialists" prior to the QA audit. This guide addresses the basics of the QA audit process, the conduct of personnel during the QA audit, and identifies applicable QA auditing documents.

#### 6.5 RECORD OF AUDIT PARTICIPATION

6.5.1 A listing of each QA audit in which a Lead Auditor participates is documented on Attachment III by the individual Lead Auditor.

6.5.2 A file for each Lead Auditor and Auditor is established and maintained by the Director, OQA that contains the "Qualification/Certification Record" and other documentation relating to or supporting the qualification.

#### 6.6 ADMINISTRATIVE REQUIREMENTS

6.6.1 When required to qualify an individual, the Director, OQA develops and administers the examination for a Lead Auditor.

6.6.2 An independent organization may be delegated this responsibility, however the Director, OQA retains overall responsibility to see that the examination and its administration conform to this procedure.

6.6.3 Responsibility for the integrity of the examination is maintained by the Director, OQA or other responsible organization through appropriate confidentiality of files and, where applicable, proctoring of the examination.



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6.6.4 When the examination is administered by the Director, OQA a record of the objective evidence of the examination contents is retained.

6.6.5 The Director, OQA maintains a current list of personnel certified as Lead Auditors.

**7.0 RECORDS**

7.1 Qualification/Certification Records, Qualification Maintenance Records, objective evidence of examination contents, the cover sheet of the Audit Guide for Technical Specialists and supporting documentation generated as a result of this procedure are considered QA Records. The Director, OQA shall ensure that all documentation is collected and maintained in accordance with QAAP 17.1, *QA Records Management* or QMP-17-01, *Records Management: Record Source Implementation*.

7.2 Auditor certification files are controlled as privileged DOE System 80 records in the OCRWM records management system. Access to these records is limited to authorized personnel and those provided access under a routine use as described in DOE System 80.

**8.0 ATTACHMENTS**

- 8.1 Attachment I - Qualification/Certification Record
- 8.2 Attachment II - Education and Experience of Lead Auditors
- 8.3 Attachment III - Qualification Maintenance Record
- 8.4 Attachment IV - Audit Guide for Technical Specialists
- 8.5 Attachment V - QAAP Flowchart



**ATTACHMENT I (Example)**

SHEET 1 OF 2  
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**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

**QUALIFICATION CERTIFICATION RECORD**

**CHECK ONE:**     AUDITOR     CERTIFICATION LEAD AUDITOR     RECERTIFICATION LEAD AUDITOR

**NAME** \_\_\_\_\_ **DATE** \_\_\_\_\_

**EMPLOYER** \_\_\_\_\_

**BASIS OF QUALIFICATION FOR LEAD AUDITOR** **CREDITS**

**EDUCATION - University/Degree/Date**  
 • Undergraduate Level  
 • Graduate Level  
**4 Credits Max.**

**EXPERIENCE - Company/Dates**  
 • Technical (0-5 credits) and  
 • Nuclear Industry (0-1 credits) or  
 • Quality Assurance (0-2 credits) or  
 • Auditing (0-4 credits)  
**9 Credits Max.**

**PROFESSIONAL ACCOMPLISHMENTS - Certificate/Date**  
 • Professional Engineer  
 • Society  
**2 Credits Max.**

**RIGHTS OF MANAGEMENT**

**Justifications:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Evaluated by:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
Signature and Title  
**2 Credits Max.**

**TOTAL CREDITS AWARDED**

**AUDIT COMMUNICATION SKILLS**

**Evaluated by:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
Signature and Title

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ATTACHMENT I (cont'd)

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QA

OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

QUALIFICATION/CERTIFICATION RECORD

NAME:

AUDITING RELATED TRAINING COURSES  
(Course Title or Topic)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

ON-THE-JOB TRAINING AND/OR ORIENTATION  
(Description)

\_\_\_\_\_  
Signature of Evaluator      Date

\_\_\_\_\_  
Signature of Evaluator      Date

\_\_\_\_\_  
Signature of Evaluator      Date

AUDIT PARTICIPATION  
Organization

Location

Audit No.

Date

- 1.)
- 2.)
- 3.)
- 4.)
- 5.)

EXAMINATION:     Written    Oral    Practical    PASSED:    Yes    No    DATE: \_\_\_\_\_

ADMINISTERED BY \_\_\_\_\_ DATE: \_\_\_\_\_  
Signature and Title

AUDITOR QUALIFICATION

\_\_\_\_\_  
Signature Director, OQA      DATE: \_\_\_\_\_

CERTIFICATION OF LEAD AUDITOR QUALIFICATION

\_\_\_\_\_  
Signature Director, OQA      DATE: \_\_\_\_\_

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**ATTACHMENT II**

**EDUCATION AND EXPERIENCE OF LEAD AUDITORS**

The prospective Lead Auditor shall provide verifiable evidence that a minimum of ten (10) credits have been accumulated under the following score system:

a) Education (4 credits maximum)

Associate degree from an accredited institution, score one (1) credit, or if the degree is in engineering, physical sciences, mathematics or quality assurance, score two (2) credits; or

A Bachelor degree from an accredited institution score two (2) credits, or if the degree is in engineering, physical sciences, mathematics or quality assurance, score three (3) credits. In addition, score one (1) credit for a Master's degree or higher in engineering, physical sciences, business management, or quality assurance from an accredited institution.

b) Experience (9 credits maximum)

Technical experience in engineering, manufacturing, construction, operation, or maintenance, score one (1) credit for each full year with a maximum of five (5) credits for this aspect of experience.

If two (2) years of this experience have been in the nuclear industry, score one (1) additional credit; or

If two (2) years of this experience have been in quality assurance, score two (2) additional credits; or

If two (2) years of this experience have been in auditing score three (3) additional credits; or

If two (2) years of this experience have been in nuclear quality assurance, score three (3) additional credits; or

If two (2) years of this experience have been in nuclear quality assurance auditing, score four (4) additional credits.

c) Other Credentials of Professional Competence (2 credits maximum)

For certification of competency in engineering, science, or quality assurance specialties issued and approved by a state agency or national professional or technical society, score two (2) credits.

d) Rights of Management (2 credits maximum)

The Director, OQA may grant up to two (2) credits for other performance factors applicable to auditing which may not be explicitly called out in this instruction. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses.



ATTACHMENT III (Example)

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QA

OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

QUALIFICATION MAINTENANCE RECORD

NAME

PERIOD COVERED BY THIS RECORD

EMPLOYER

FROM TO

TRAINING: Other Than Documented Training Identified in Accordance With QAAP 2.1 (i.e. self study, program documents read, etc.)

SUBJECT COVERED

DATE


AUDIT PARTICIPATION

ORGANIZATION

LOCATION

AUDIT NO.

DATES


LEAD AUDITOR ANNUAL EVALUATION:

Qualification Extended: \_\_\_ Yes \_\_\_ No (If Yes, certification is valid for a period of one year from date below)

CERTIFICATION \_\_\_\_\_ DATE \_\_\_\_\_  
Director, OQA

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**ATTACHMENT IV (Example)**

**AUDIT GUIDE FOR TECHNICAL SPECIALISTS**

Read and understood by:

\_\_\_\_\_  
Technical Specialist

\_\_\_\_\_  
Date



**AUDIT GUIDE FOR TECHNICAL SPECIALISTS (cont'd)**

**I. INTRODUCTION**

This document is written on the basis of the current requirements of the OCRWM QARD and QAPD that relate to QA audits, and QAAP 18.2, *Audit Program*. These requirements apply to the preparation, performance, reporting, and follow-up of QA audits.

The purpose of this document is to provide sufficient information to Technical Specialists so that they can effectively advise audit team members and make optimum contributions to the QA audit. The established methods and requirements for QA audits are delineated in QAAP 18.2.

QA audits are unique opportunities to gain further understanding of activities which are normally related to the Technical Specialist's work or area of expertise. The management systems, procedures, work controls, and other mechanisms which are included in the audit scope are frequently unfamiliar because of the pressures of day-to-day problems in one's own discipline. The QA audit experience provides an opportunity to participate in an orderly analysis of such systems. Therefore, time spent in preparation for and participation in a QA audit can be worthwhile and can significantly improve the overall value of the QA audit.

You are urged to take sufficient time prior to the first meeting of the audit team to become as familiar as possible with the information provided herein. If you have questions about the audit process, talk to the Audit Team Leader before the QA audit.

**II. THE AUDIT PROCESS**

As an advisor to the audit team, you will be primarily concerned with the preparation and performance of the audit. You may also participate in writing the report as directed by the Audit Team Leader. The audit follow-up is the responsibility of the Audit Team Leader.

The first audit function in which you may participate is the development of the audit plan. This plan will identify the audit scope, which activities are to be audited, the applicable documents to be audited against, the audit schedule, and the written checklists to be utilized by the Auditors.

One of the major activities in planning the audit will be a review of deficiencies or problems reported during previous audits and surveillances or past experience with the audited organization. The past audit records and other related reports provide information pertaining to both past problems for which corrective action has been implemented and for open items which have not yet been closed out.



**AUDIT GUIDE FOR TECHNICAL SPECIALISTS (cont'd)**

The Audit Team Leader will conduct a preaudit team meeting to discuss details of the audit plan and establish individual responsibilities. A preaudit meeting will be conducted with the audit team and representatives of the audited organization to outline the audit scope, the audit plan, and other details of the audit. The preaudit meeting will also introduce the Auditors and other participants to personnel of the audited organization with whom the Auditors will work. The proposed sequence of events for the audit will be reviewed, and tentative plans for the postaudit meeting will be made.

During the conduct of the audit, it may be advantageous to split the audit team into several groups. The Technical Specialist of the audit team will be in a group which includes the Audit Team Leader or another Auditor. This will assist the Technical Specialist in concentrating on his/her specialized areas.

The principal audit goal or objective is to verify compliance with the Quality Assurance Program and other stated requirements. Objective evidence may take the form of records such as, drawings, specifications, logs, data sheets, test results, or other documents which will assist the Auditor in drawing meaningful conclusions in regard to effective implementation of applicable requirements. The Audit Team Leader should be kept fully aware of any needs for special information and should be advised if it is necessary to talk to people or examine records outside the scope of the audit as originally planned. Whenever deficiencies are identified during an audit, they should be pointed out to the responsible members of the organization being audited.

The purpose of the postaudit meeting is to review the audit findings with responsible management of the audited organization. This is essential so that if there are any misunderstandings based on insufficient or incorrect information, they can be clarified. In addition, the exit interview gives the audited organization a good understanding of the overall findings so that appropriate corrective action can be initiated as expeditiously as possible, often even before the audit report is returned to the audited organization for formal acknowledgement.

After the QA audit has been completed, the audit team usually meets one or more times to develop the audit report. This report will be prepared in accordance with QAAP 18.2 and be signed by the Audit Team Leader. It will include a summary of the findings and a statement of effectiveness of the QA Program audited. Corrective Action Requests which identify deficiencies noted during the audit, will be issued prior to the audit report in accordance with QAAP 16.1. The audit report is to be issued by the audit team within 30 days of completion of the audit.



**AUDIT GUIDE FOR TECHNICAL SPECIALISTS (cont'd)**

**III. PERSONAL CONDUCT**

One subject of prime importance is the matter of personal conduct of the audit team members. Audits will have various degrees of personal involvement on the part of the audit team and members of the organization being audited.

Conflicts of opinion are frequently unavoidable; however, conflicts of personalities can almost always be avoided by a skillful team member. The point to remember is that an audit evaluates the performance of others. To varying degrees, differences of opinion are almost always factors in the auditor-auditee relationship. Consequently, it is imperative that an Auditor be fully aware of the sensitivity of his/her position. The following guidelines are provided to minimize the impact of personal involvements in the audit process.

1. The audit plan and checklist should be used as a guide; however it should not restrict the audit investigation. Departure from the audit checklist should be discussed with the Audit Team Leader.
2. Be objective and listen carefully to responses. Remember that the audited organization will normally understand its system better than you.
3. Avoid personal accusations in audit related conversations with the audited organization.
4. Arguments with individuals from the audited organization should be avoided. If you feel you are correct, accurately document the finding. Next, summarize the audited organization's opinion and acquire concurrence on their position.
5. Tentatively classify each finding at the time it is found. The reason(s) which prompted the classification should be carefully noted for future reference.
6. Record names, titles, places, etc. of individuals you contact during the audit. Material which will be required to support findings should be reproduced, if possible, or its' identity carefully recorded.
7. A finding which is deemed severe enough to warrant immediate action should be brought to the attention of the Audit Team Leader.



AUDIT GUIDE FOR TECHNICAL SPECIALISTS (cont'd)

IV. REFERENCES \*

These references provide more detailed information relative to QA audits and should be consulted for answers to specific questions. The Audit Team Leader can direct you to the reference which addresses your question.

1. 10 CFR 50 - Appendix B - *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*
2. 10 CFR 60 - Subpart G - *Quality Assurance*
3. 10 CFR 71 - Subpart H - *Quality Assurance*
4. 10 CFR 72 - Subpart G - *Quality Assurance*
5. ASME NQA-1 - *Quality Assurance Program Requirements for Nuclear Facilities*
6. DOE 5700.6 - *Quality Assurance*
7. DOE/RW-0005 - *Mission Plan*
8. DOE/RW-0215 - *Quality Assurance Program Description Document*
9. DOE/RW-0214 - *Quality Assurance Requirements Document*
10. QAAP 18.1, *Qualification of Audit Personnel*
11. QAAP 16.1, *Corrective Action Requests*
12. QAAP 18.2, *Audit Program*

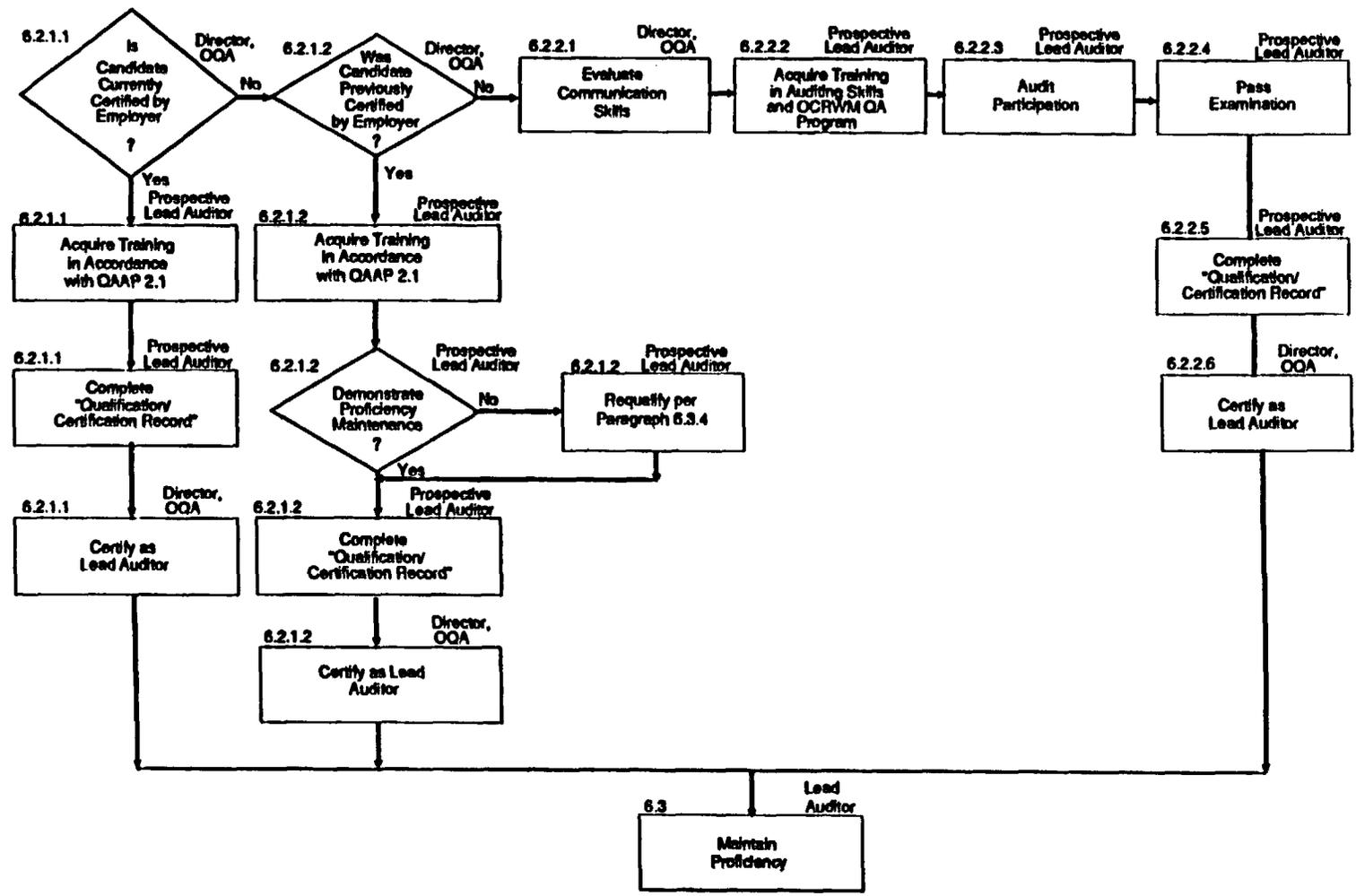
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\*Latest applicable revision



ATTACHMENT V

LEAD AUDITOR





ATTACHMENT V (cont'd)

LEAD AUDITOR PROFICIENCY MAINTENANCE

