Best Practice
Internal Quality Audit Program

SCOPE OF THIS PRACTICE. This document provides information that may be used by Production Approval Holders (PAH's), operating under Title 14 Code of Federal Regulations (14 CFR) part 21, Certification Procedures for Products and Parts (part 21), to design and implement an internal quality audit program. The procedures and practices outlined in this document can be applied to all aerospace industry manufacturers. This document also incorporates a section on corrective action that discusses the role of root cause corrective action in addressing quality system deficiencies.

Although there is no regulatory requirement for an internal quality audit program, the Federal Aviation Administration (FAA) encourages such a program, to increase the awareness of management and all employees of their responsibility to promote continuous compliance with all regulatory requirements and good operating practices. Establishing the type of program described in this document is voluntary.

BACKGROUND. Since the advent of the FAA Aircraft Certification Systems Evaluation Program (ACSEP), PAH's are finding some of their quality system deviations to be repetitive. This indicates that corrective actions identified and implemented by the PAH's do not always rectify the root cause of the deviations. Use of an effective internal quality audit program and a corrective action system will promote identification and resolution of such quality system deviations.

DEFINITIONS. The following definitions apply to the discussion in this document and may not be the same as similar terms used in other documents or applications:

a. Finding. A conclusion, supported by objective evidence, that there has been or is a process or product that is deficient in meeting the requirements of an established standard.

b. Observation. A noteworthy feature of a system or procedure. The feature noted may be positive or negative. All observations should be brought to the attention of management to ensure that the feature is corrected, preserved, or perhaps adopted in other places.

c. Internal Audit. A comprehensive, continual monitoring process that is initiated and managed by top quality assurance (QA) management. The personnel conducting the various audits in support of the internal quality audit program may be internal or external to the process. The objective of this process is to promote attitudes and procedures that focus on controlling processes, rather than depending on corrections of deficiencies, to meet quality goals.

INTERNAL QUALITY AUDIT PROGRAM. An internal quality audit program should be part of the overall quality system, be approved by top QA management, and have a detailed written description of the key elements of the program. Each PAH is unique with regard to size, facilities, personnel, resources, and methods of operation. Therefore, different types of programs

may be appropriate for individual organizations. The three basic audit programs commonly used are: (1) a dedicated internal quality audit department; (2) a dedicated individual manager with part-time auditors provided from throughout the organization; and (3) a combination of internal and external resources. The most critical elements of an audit program are: (1) an adequate level of independence; (2) a reporting process that ensures an accountable manager is aware of the audit results; and (3) an effective corrective action process to correct deficiencies and prevent recurrence of deficiencies. The program should have a structure and process designed to improve all system elements/processes that affect product quality. The key elements of an internal quality audit program are:

a. Audit Planning.

(1) Audit Schedules. Specific audit schedules should be developed to identify areas/activities subject to audit and assure they are audited in a predetermined frequency and defined timeframe. Audit schedules should be based on the criticality of the activity being audited, with consideration to factors such as audit result history, production volume, process performance, high-risk areas, and management concerns. As circumstances change, the schedule may require adjustment.

(2) Auditor Selection. The internal quality audit program should specify that evaluators receive training in auditing, audit principles, and systems analysis techniques. This training could be from any one, or a combination of, the following sources:

(a) Employer-provided training course or on-the-job training.
(b) College courses.
(c) Home study course materials.
(d) Industry seminars and workshops.

When full-time dedicated audit resources are not practical, developed procedures should show that persons performing audits or supervising audit teams do not have direct responsibility for the areas being audited.

When two or more auditors are assigned to an audit, management should designate a Lead Auditor or Team Leader to be responsible for coordination, planning, audit assignments, observation classifications, presentations, and reports.

(3) Audit Preparation. One of the most important audit activities, and often the least considered, is preparation for the audit. As a first step, an auditor needs to be cognizant of internal requirements, external requirements, and other factors that may impact the process. A few examples of these influences within the aviation environment include:

(a) Regulatory requirements.
(b) FAA guidance and policy.
(c) Contractual requirements.
(d) Corporate/Company requirements.

(e) Organization quality manual.
(f) Unusual processes.
(g) New technology.
(h) Critical parts and processes.
(i) Equipment and facilities.
(j) Safety.

An auditor should use current FAA programs and materials, available through the local MIDO and/or the AIR Home Page at http://www.faa.gov/certification/aircraft/, to ensure that the audit program addresses appropriate requirements.

(4) Checklist Development. An essential part of planning an audit involves development of an appropriate checklist. A thorough audit program will be designed to determine and evaluate how an organization's quality manual, operating procedures, process controls, methods, and practices account for and incorporate all internal and external requirements. The auditor must study these criteria and translate them into a well defined checklist. On the simplest level, a checklist denotes points to be checked and helps the auditor determine the correct order in which to proceed with an audit. A checklist supplements an auditor's memory and provides the basis for reconstructing an audit trail. In essence, a checklist question is the transposition of a standard, regulation, or procedural requirement into a question.

b. Conducting the Audit. An auditor needs objective evidence to answer audit questions. The audit checklist should be used by the auditor to gather this evidence to determine compliance or noncompliance to the quality system and/or standard being evaluated against. Evidence is gathered via review of parts, documents, observation of activities, record checks, and interviews with key individuals in the area(s) under review. Evidence gathered during the audit should be documented as the audit is conducted, and preliminary results should be shared with the auditee as each step of the audit is completed. Upon completion of an audit, results are presented to cognizant management to assure full understanding of the findings/observations before a written report is prepared.

c. Reporting the Results. A report should be prepared documenting the results of the audit. Procedures should be in place that allow straightline reporting of the audit team to top QA management. The audit report should include, at a minimum:

(1) Date the audit was conducted.
(2) Auditor performing the audit.
(3) Standard/procedure the audit was conducted against (i.e., part 21, internal procedure, etc.).
(4) Summary of findings, including brief descriptions of the findings and supporting references to related procedures, records, etc.
(5) Evaluation and relative importance of a finding. A single occurrence of a deficiency that posed no risk to a deliverable product might be considered a "minor" finding. Conversely, multiple occurrences of a deficiency indicating a trend or a deficiency posing risk to a deliverable product, might be considered a "major" or "critical" finding.

(6) Summary of observations, both positive and negative.

d. Corrective Action Plan Development and Implementation. It is the responsibility of the process owner to analyze the audit report, determine root causes of deficiencies, develop a corrective action plan to address the root cause of the deficiency, correct existing deficiencies, and prevent recurrence of the deficiencies in the future. Top QA management is responsible for corrective action validation, verification, and follow-up reviews associated with the internal quality audit process.

(1) Determination of Root Cause. The key to determining root cause is to identify underlying causes (a fundamental breakdown or failure of the process), not effects. Some questions to ask in determining root cause can include:

(a) Is the company policy/procedure clear?
(b) Does the procedure address who does what and when?
(c) Does the procedure/training correctly address how to perform the process?
(d) Does the process consistently produce the desired outcome?
(e) Have the employees been trained to perform the process?
(f) Have the employees been trained on revisions to the process?
(g) Has the process been tested for human factors issues (fatigue, ergonomics)?
(h) Has the equipment (tooling, gauges, machinery) been maintained and calibrated?
(i) Is the equipment adequate/correct for the process?
(j) Is the material appropriate for the application/process?
(k) Is there a material deficiency?
(l) Is the training program adequate?

Once arriving at the suspected root cause, begin asking "why?" CONTINUE to ask "why" until you reach an answer that is fundamental to the organization (company policies/procedures, systems, training, etc.) or is fundamental to the environment (weather, gravity, momentum, etc.).

(2) Development of the Corrective Action Plan. Based on determination of the root cause, prepare a written plan (including actions, implementation dates, and responsible personnel) to be implemented to correct the deficiency and remove the root cause to prevent recurrence.

(3) Approve the Corrective Action Plan. Prior to implementation, the process owner and QA management should review the corrective action plan for concurrence and approval.

(4) Implement the Corrective Action. The process owner implements the process changes as defined in the corrective action plan.

(5) Validate the Corrective Action. Upon completion of corrective action implementation, QA management should verify that the process changes were effective in correcting the existing deficiency and preventing recurrence. If the validation process indicates that the corrective action was not effective, the process owner will initiate additional corrective

action and notify QA management of the new corrective action implementation plan. Revalidation of new corrective action should be built into the implementation plan to ensure long-term consistency.

e. Close the Audit Findings. After indication of completion from the process owner, QA management will verify that the process changes were effective in correcting the existing deficiency and preventing recurrence. If the verification process indicates that the corrective action was not effective, QA management will request additional corrective action and revalidation from the process owner.

f. File Report. Audit reports, including corrective action and closure data, should be maintained on file for a minimum or two years, and be accessible for reference by future auditors.

g. Process Flow Map. A process flow map for the audit process described above can be found in Appendix 1.

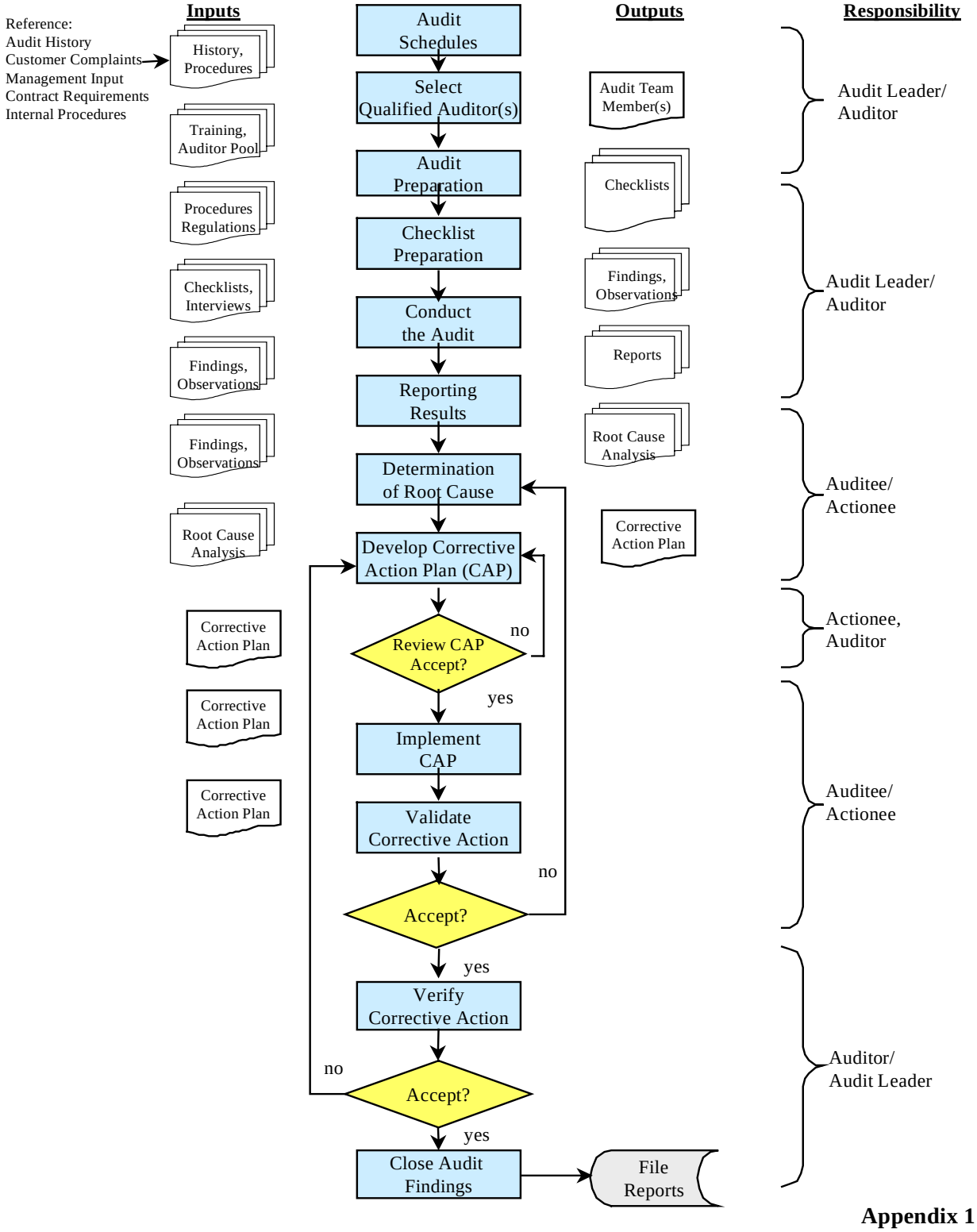
CONCLUSION. Development of internal quality audit programs, as discussed in this document, should help to ensure that company policies and procedures are responsive to growth, change, and continual compliance with requirements. Furthermore, the FAA strongly encourages PAH's to make internal quality audit programs an integral part of their management process and take full advantage of the FAA Voluntary Disclosure Program. Information and guidance on this program may be found in FAA Advisory Circular (AC) 00-58, Voluntary Disclosure Reporting Program. This program allows, in most cases, the FAA to consider foregoing civil penalty when a part 21 approval holder has promptly disclosed to the FAA an apparent violation and has taken prompt action to correct the violation and prevent its recurrence. A copy of this AC may be obtained by mail. Send written request to:

U.S. Department of Transportation
Subsequent Distribution Office, SVC-121.23
Ardmore East Business Center
3341Q 75th Avenue
Landover, MD 20785

Aviation safety is best served by programs that allow PAH's to identify and correct system deficiencies, rather than expend significant resources correcting system breakdowns, recalling, replacing/repairing products, and facing FAA compliance and enforcement actions.

Nothing Follows

Internal Quality Audit Process Map



Appendix 1