Transport Canada Transports Canada

Advisory Circular

Subject: **Quality Assurance Programs**

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1.0 INTRODUCTION

(1) This Advisory Circular (AC) is provided for information and guidance purposes. This AC on its own does not change, create, amend or permit deviations from regulatory requirements, nor does it establish minimum standards.

1.1 Purpose

(1) This document provides guidance on the establishment and maintenance of a Quality Assurance Program (QAP) that complies with the Canadian Aviation Regulations.

1.2 Applicability

(1) This document applies to enterprises that hold a Canadian Aviation Document (CAD) and are required to establish and maintain a Quality Assurance Program.

1.3 Description of Changes

(1) Not applicable.

2.0 REFERENCES AND REQUIREMENTS

2.1 Reference Documents

(1) It is intended that the following reference materials be used in conjunction with this document:

(a) Canadian Aviation Regulations (CARs);

(b) Advisory Circular (AC) SUR-002 – *Root Cause Analysis and Corrective Action for TCCA Findings*;

(c) Advisory Circular (AC) SUR-004 – *Canadian Aviation Surveillance Programs*.

2.2 Cancelled Documents

(1) Not applicable.

(2) By default, it is understood that the publication of a new issue of a document automatically renders any earlier issues of the same document null and void.

2.3 Definitions and Abbreviations

(1) The following **definitions** are used in this document:

(a) **Compliance:** The state of meeting approved policy, procedure or regulatory requirements.

(b) **Corrective Action Plan (CAP):** A plan submitted in response to findings. The CAP outlines how the enterprise proposes to address findings and ensure on-going compliance.

(c) **Enterprise:** The holder of one or more TCCA-issued Canadian Aviation Document(s) under a single Accountable Executive. For example, a company holds an Approved Maintenance Organization Certificate, an Air Operator Certificate, and an Approved Training Organization Certificate. The term Enterprise identifies the whole business entity not an individual Canadian Aviation Document**.**

(d) **Finding:** A factual record, supported by evidence, of how an enterprise is not in compliance with its own policies and procedures.

(e) **Functional area:** The areas of an enterprise's operations that are subject to regulatory requirements.

(f) **Internal Audit:** An evaluation for compliance with policies and procedures conducted by an enterprise on itself.

(g) **Lot:** A population of units (persons, records, process outputs, etc.) from which a sample can taken as determined by a sampling process.

(h) **Non-compliance:** The failure to meet policy or procedures.

(i) **Process:** A group of inter-related or interacting activities that convert inputs into outputs.

(j) **Quality:** The state of meeting established criteria with the goal of achieving regulatory compliance.

(k) **Quality Assurance (QA):** A planned and systemic set of activities implemented to evaluate and verify compliance to established and defined processes.

(l) **Quality Assurance Program (QAP):** The QA policies and procedures established and maintained by the enterprise to comply with CARs.

(m) **Record**: The specific details of events that have occurred during the performance of activities authorized by a Canadian Aviation Document. Records include, but are not limited to:

- QAP check lists, findings, corrective actions, verifications.;
- Journey log books and other aircraft technical records;
- Maintenance releases;
- Completed checklists;
- Incident reports;
- Equipment-servicing records;
- Training records; and
- Submissions made under internal safety reporting systems under SMS.

(n) **Regulatory Requirements:** The Canadian Aviation Regulations (CARs) and standards as well as any documentation required by reference.

(o) **Root Cause Analysis (RCA):** An analysis conducted to identify the cause(s) of a finding.

(p) **Sampling:** A process through which a portion of a larger population (lot) is reviewed to determine the degree of compliance of said population.

(q) **Surveillance:** All activities directly related to TCCA evaluating an enterprise's compliance with applicable regulatory requirements including, but not limited to, assessments, program validation inspections and process inspections.

(r) **System:** A group of inter-dependent processes and people working together to achieve a defined result. A system comprises policies, processes and procedures. It is through systems that enterprises should achieve compliance to their regulatory requirements on an ongoing basis.

(2) The following **abbreviations** are used in this document:

(a) **AC:** Advisory Circular

(b) **AE:** Accountable Executive

(c) **CA:** Corrective Action

(d) **CADs:** Canadian Aviation Documents

(e) **CAR:** Canadian Aviation Regulations

(f) **QAP:** Quality Assurance Program

(g) **RCA:** Root Cause Analysis

(h) **SMS:** Safety Management Systems

(i) **TCCA:** Transport Canada Civil Aviation

3.0 BACKGROUND

(1) Enterprises holding CADs (i.e. airports, flight training units, air operators, private operators, manufacturers of aeronautical products, approved maintenance organizations, approved training organizations and air navigation services) must adopt a QAP for all parts of their operations. These requirements are detailed in the relevant CARs.

(2) Enterprise policies and procedures drafted to comply with applicable regulations are contained within their TCCA approved manuals (except Part 604). The purpose of the QAP is to verify compliance with regulatory requirements and the approved manuals.

(3) The CAR specific to QAP provide non-prescriptive, top level requirements to allow enterprises to design their own QAP procedures in line with the size and complexity of the organization.

(4) Industry outreach has identified its need for guidance on how to establish and maintain QAPs to provide a better understanding of the elements that contribute to an effective QAP.

***Note**: Some approval holders such as those under CAR 505 and 521 are not required to have a QAP under existing regulations. These organizations are strongly encouraged to adopt a QAP as a best practice.*

4.0 TRANSPORT CANADA CIVIL AVIATION QUALITY ASSURANCE PROGRAM

4.1 What is Quality Assurance Program?

(1) Quality involves the complete adherence to an established standard. A QAP is a systematic program an enterprise designs, adopts and maintains to verify that all their policies and procedures are effective, being adhered to and where they are not, to analyze and correct any non-compliance. Under the CAR's, QAP consists primarily of an internal audit. The internal audit process must be defined within the TCCA approved enterprise manuals.

(2) The QAP also uses the audit program to verify the enterprise complies with regulatory requirements through adherence to internal company requirements specified in TCCA approved company manuals.

(3) A QAP does not replace TCCA surveillance. As the enterprise establishes their QAP, they should be aware of TCCA surveillance procedures explained in *AC SUR-004* and specifically the *Expectations of a compliant Quality Assurance Program in section 5.1 of Appendix B.* One of the main objectives of TCCA surveillance is to ensure that the enterprise QAP is effective in identifying and correcting any non-compliance of their own policies, procedures and the regulations.

(4) Failure to maintain an effective QAP will result in TCCA taking action as described in *AC SUR-004*. Depending on the severity of the TCCA finding, action can range from a request for a corrective action plan up to the suspension of an enterprises certificate.

4.2 What is the difference between QA and Quality Control (QC)?

(1) The difference is that QA is process oriented and QC is product oriented. Testing, therefore is product oriented and thus is in the QC domain. Testing for quality isn't assuring quality, it's controlling it. On the other hand, Quality Assurance makes sure you are doing the right things, the right way.

(2) Assuring quality is about confidence. It's about the processes by which we go about doing what we do. Part of that is knowing that we're doing the right things at the right time, and part of it is that we are doing them the right way. Processes must be established and understood before we start working, not afterwards.

(3) QA aims to prevent defects with a focus on the process used to make our product or provide our service (It is a proactive quality process). QC aims to identify and correct defects in the finished product or after the service is provided. Quality control, therefore, is a reactive process.

4.3 What is the difference between QAP and SMS?

(1) SMS applies only to those enterprises identified in CARs107.

(2) A SMS is a documented system for managing risks that integrates operations and technical processes/activities with the management of financial and human resources to ensure aviation safety and the safety of the public. A QAP is one of six components of an SMS.

(3) A QAP is the internal validation function of the SMS. The QAP allows an enterprise to verify and validate whether or not the controls (e.g., policies, processes, procedures) it has put in place to manage its risk are effective in achieving on-going compliance with regulatory requirements. This makes all the components of an enterprise's SMS subject to QAP audits.

(4) Do not confuse a QAP with the SMS management review function. The management review evaluates the performance of the SMS as a whole with the aim of improving it. QAP outputs become one of the many inputs to the management review to:

- Inform management of the level of compliance within the organization; and
- Identify where corrective action is required.

5.0 ASPECTS OF A QUALITY ASSURANCE PROGRAM

(1) The following sub-sections form a QAP that are acceptable to TCCA:

(a) Management control;

(b) QAP documentation;

(c) Auditor selection and training;

(d) Audit program;

(e) Finding/corrective action process; and

(f) Record keeping.

(2) We describe each aspect below in terms of what they are; what their purpose/intent is; and what they are supposed to look like in the end. The explanations focus on a general case to illustrate that each aspect can be implemented by any enterprise, regardless of type of operations, size, complexity, SMS status, or any other factor.

5.1 Management Control

(1) Management control is critical to an effective QAP. Senior management has the resources and authority to ensure regulatory compliance and are an integral part of any quality program. For a QAP to be established and maintained effectively, it must be under the control of someone with the resources to ensure its desired outcome is regulatory compliance. Under the CARs, the certificate holder appoints a person who has this authority and that person is identified in the approved documentation. This person may assign the management function of the QAP to another person under certain regulatory conditions.

(2) The individual with the management function of the QAP, shall have the knowledge and resources to effectively manage the QAP. They shall:

(a) Understand the regulatory requirements that apply to the enterprise to the extent that they know what the QAP must cover.

(b) Understand the policies and procedures used by the enterprise to conduct their operation while complying with the CARs;

(c) Understand the basics of quality assurance, specifically quality auditing so they know how to set up and conduct effective audits as well as manage the associated finding/corrective action process;

(d) Be or have direct access to senior decision makers so they can mobilize adequate resources (human, financial or otherwise) to effectively deal with any non-compliance detected as part of QAP activities.

(3) The person assigned management control of the QAP will be dependent on the size of the enterprise. TCCA is keenly aware that in a:

(a) **Larger enterprise**, this person may be a manager within the enterprise with a dedicated staff whose full-time jobs have to do with the QAP;

Note: *The person assigned management control of the QAP may assign functions associated with the QAP to other personnel provided they meet all regulatory requirements. However, this does not free them from their responsibility for the performance of the QAP as a whole.*

(b) **Medium sized enterprise**, this person may be a dedicated manager within the enterprise whose focus is QAP activities; and

(c) **Small enterprise**, this person would probably be an individual whose responsibilities include many other things besides the QAP.

5.2 QAP Documentation

(1) Since maintaining a QAP is a regulatory requirement, it must be documented so the enterprise can follow it consistently and TCCA can review it during certification and surveillance activities. Enterprise QAP documentation shall cover all of the aspects of the QAP. Specifically, QAP documentation shall:

(a) Identify the person responsible for the management control of the QAP and specify their place within the structure of the organization;

(b) Provide procedures for tasks done to comply with the CARs;

(c) Provide detailed audit procedures to be used in the conduct of all QAP audits in terms of scope, criteria, frequency and methods;

(d) Provide a process to be used in writing findings resulting from QAP audits, as well as the development, management and follow-up of corrective action plans;

(e) Provide procedures and requirements for generation and retention of QAP records; and

(f) Identify other enterprise positions directly involved within the QAP (e.g., auditors) as well as their training and competency requirements.

(2) The QAP regulatory requirements of the CARs are documented in the TCCA approved manuals as policy and procedure. Examples of approved manuals include:

(a) Airport Operations Manual – CAR 302;

(b) Manufacturing Control Manual – CAR 561;

(c) Maintenance Policy Manual - CAR 573; and

(d) Maintenance Control Manual - CAR 406 & 706.

(3) The approved manual sets out how the enterprise meets the regulatory requirements and must provide sufficient detail to allow the reader to understand the QAP and how it is designed to function. Uncomplicated bullet-form steps laid out in a logical sequence are acceptable as long as the QAP is readily understandable. While all enterprise manuals approved by TCCA must address their specific regulatory requirements as policy, the associated procedures and methods will be tailored to the size and complexity of the enterprise. Note: No procedure can contradict policy or regulation.

(4) All QAP documentation must be kept current, especially in response to:

(a) Any changes to the enterprises operations; and

(b) Feedback obtained through findings of non-compliance both internally via audits and externally via TCCA surveillance.

5.3 Auditors

(1) QAP audits must be conducted by auditors that:

(a) Meet enterprise established selection criteria with respect to experience and training;

(b) Are trained and shown to be competent to perform the audits in question; and

(c) Are independent of the work being audited.

(2) With respect to training and competency, auditors should understand the basics of the:

(a) Regulatory requirements upon which the criteria are based;

(b) Communication protocols during and after the audit;

(c) QAP checklist methodology, system, format, etc. being used by the enterprise;

(d) Audit techniques, including sampling/review methods, interviewing and documenting of compliance and non-compliance;

(e) Drafting a finding quoting offended rule and detailing specific examples of the non-compliance; and

(f) Record keeping requirements.

(3) The extent of the training required to develop the desired level of competence in the areas listed above will vary based on the enterprise. In a larger, more complex enterprise, a more formalized training program may be required as the QAP may cover a wide array of operational areas and regulatory requirements. In a smaller, less complex enterprise, the training may be limited to reviewing the QAP procedures in the approved manuals and any other documents that may be incorporated by reference in the approved manual to become familiar with their responsibilities during the audit.

(4) In those cases where QAP auditing services are contracted out to a third party, the enterprise is still responsible for ensuring the auditors meet their established selection/training criteria. This may take the form of:

(a) Training third party staff on enterprise manuals specifically, audit procedures;

(b) Requesting training records; or

(c) Performing reference checks.

(5) Persons trained to be QAP auditors can be employees of the enterprise provided they do not audit their own work. Enterprises should ensure refresher training is available for those cases where auditors infrequently perform audits.

(6) Once auditors are trained and shown to be competent to perform audits, they must also be independent of the work they are auditing. This means auditors must not audit their own work. In a larger enterprise, this may be easily done as they may have dedicated auditors or sufficient staff to exchange amongst groups within the organization to perform audits. In a smaller enterprise, this may prove more challenging, which is why certain QAP regulations (CAR 302, 604, 805) allow auditors to audit their own work as long as:

(a) The size, nature and complexity of the enterprise justify the conduct of audits by the person responsible for carrying out the tasks or activities being audited;

(b) The enterprise demonstrates to the Minister, by means of a risk analysis, that auditors auditing their own work will not result in an unacceptable risk to aviation safety; and

(c) The enterprise provides the Minister, in writing, with the information required under paragraphs (a) and (b).

Note: *The work and documentation needed to meet the conditions specified in sub-paragraphs (b) and (c) should be done using the enterprise's SMS risk assessment process.*

(7) The enterprise must retain experience, training and competency records in support of each auditor used. Competency is normally confirmed via an examination or attestation by the responsible person following an interview.

5.4 Audit Program

(1) As stated in Section 4.0, it is through internal audits that TCCA expects enterprises to use their QAP to verify and ensure their own compliance. Therefore, an audit program needs to be defined in terms of:

(a) Criteria, i.e. to what regulatory requirements and related documents it will audit each functional area;

(b) Scope, i.e. what area(s) of enterprise operation each audit will cover;

(c) Frequency, i.e. how often it will conduct audits; and

(d) Methods, i.e. how it will conduct audits.

(e) Each of these items is described in further detail below.

5.4.1 Criteria

(1) Criteria are those standards by which something may be judged or decided. Audit criteria are those standards auditors must review to ensure regulatory compliance. In more practical terms, audit criteria are developed into audit checklist questions the auditor uses to determine if the enterprises policies and procedures are compliant or not. Good checklist questions must reflect all activities within the approved manuals and applicable CARs to assist auditors in their

determination of compliance or non-compliance. The level of detail of the checklist shall reflect the detail of any process and prompt the auditor to sample where appropriate.

(2) With respect to developing checklists, a simple technique is to take the, enterprise policy or procedure which reflect regulatory requirements and re-phrase them as a question to be asked by the auditor. For example, one requirement for record keeping within some QAP requirements of the CARs is:

The records required ... shall be retained for the greater of:

Two audit cycles; and

Two years.

(3) This can be easily turned into checklist question by simply turning it into the following question:

Where all QAP audit records kept for the greater of two audit and two years?

(4) This can be simplified even more depending on the design of the QAP. For example, if an enterprise has an audit cycle of six months, the greater of two audit cycles and two years would be two years. Therefore, the audit checklist question could be as short as:

Were all QAP audit records kept for two (2) years?

(5) The audit could also break down the preceding example to include the types of records to be kept:

Were all QAP audit records kept for two (2) years? This includes:

(a) Completed audit checklists;

(b) Findings;

(c) Corrective actions; and

(d) *Follow-up*.

(6) Checklists are a living document that must continue to reflect all activities described in the approved manual one year to the next. The person responsible for the QAP must take into account all changes to the enterprise during the past audit cycle and confirm before each audit that the checklists continue to meet this requirement.

5.4.2 Scope

(1) The scope of an audit specifies the focus, extent, and boundary of a particular audit and is considered during audit planning. Many small to medium size enterprises will carry out their entire internal audit covering all areas at one point in time. This approach may reduce the elements of “scope” to be considered. Where the enterprise has a progressive audit over the audit cycle, planning for scope is required.

(2) Elements of scope for consideration within the audit procedures include:

(a) What areas or range of activities are we going to audit?

(b) How far back in time is the auditor looking? What periods of records are subject to the audit?

(3) Larger enterprises, the person responsible for the QAP often establishes, documents and accepts the audit plan detailing the scope of each audit before it is carried out. An audit plan can form the basis of an audit schedule.

5.4.3 Frequency

(1) While the enterprise must set audit frequencies, these frequencies cannot exceed those imposed by regulatory requirements for that enterprise.

(2) Where there is no regulatory or other requirement to leverage, the enterprise must determine an interval that works for them. Factors to consider include:

(a) Resources, i.e. how many people you dedicate to audits over a given time period;

(b) Frequency of operations, i.e. something that is done often should undergo audit more often and vice-versa; and

(c) Performance of operations, i.e. areas of operation that have historically resulted in a greater number of non-compliances (whether found through internal audits or TCCA surveillance) should be audited more frequently.

(3) Please note that for new enterprises, regulations require a complete audit cycle within a certain timeframe following initial certification. Therefore, newly certified enterprises should take this into account when developing their initial audit schedule.

(4) It is important for an enterprise to settle on audit frequencies that work for them and comply with their particular CAR. Once an enterprise sets the audit frequency, they must ensure to audit all functional areas within the set audit cycle.

(5) Once it selects audit frequencies an enterprise should create an audit schedule for their full audit cycle which shows which audits are to be completed when within the cycle. A documented audit schedule will serve as a reminder and will assist in work planning.

(6) Should changes to the audit schedule be made for any reason (e.g., operational pressures, resource constraints, seasonal operations), the person responsible for the management of the QAP should make the decision as to how to best revise the audit schedule. The enterprise should keep a record of the change.

Note: *It should be noted that while the schedule can be revised, it cannot violate its audit frequencies.*

(7) The enterprise may still conduct audits for cause (e.g., following some type of safety event). However, they must conduct them at a minimum, at their specified frequency within the full audit cycle.

5.4.4 Methods

(1) An enterprise should consider how they conduct their audits. Audit sampling methodology should be defined, detailed and documented throughout the audit process. TCCA expects the enterprise's audit program to describe how it conducts audits in terms of:

(a) How auditors are selected for audits;

(b) How the auditor will conduct the audit;

(c) How it documents, communicates and corrects (if applicable) audit findings within the enterprise; and

(d) How it records results of the above.

(2) The enterprise must define what experience and training their auditor requires to achieve an effective audit for their type of operation. It must also set criteria of an acceptable auditor within the audit procedures. Competence of the auditor is confirmed by management before the audit begins either through an exam or interview. Using an auditor who is not familiar with auditing practices or the type of operation being audited may result in undetected non-compliance.

(3) Audit methods as defined in the QAP procedures, will:

(a) Provide guidance for the auditors as they conducts the audit;

(b) Define the correct use of tools used by the auditor such as the audit checklist and finding forms; and

(c) Establish how the auditor communicates with the auditee and the enterprise QA manager.

(4) Audit methods will define how and where it is appropriate for the auditor to use a sampling process when reviewing records. Where the checklist requires only a small population of items to audit, an enterprise should review the entire population. Where the population is a greater number, the enterprise may wish to use a sampling process. Should this be the case, auditors should document what was sampled during the audit so items are not audited multiple times.

(5) The enterprise shall be prepared to justify any sampling process it uses and to demonstrate how the sample selected is representative of the entire population.

Note: *The sampling rate TCCA uses when conducting oversight of aviation enterprises assumes that the organization has already conducted internal oversight on their system. TCCA recommends that organizations use a more stringent rate, because the enterprise is still responsible to ensure complete compliance.*

(6) If an enterprise uses a sampling methodology, they should specify:

(a) Which groups of items can be subject to a sampling process;

(b) How to determine the quantity of items to be audited versus the entire population; and

(c) How the items to be audited are selected from the population.

Refer to *AC SUR-004 Civil Aviation Surveillance Program* for further information related to TCCA's sampling process. An internet search is a useful tool to locate sample generators.

(7) The enterprise needs to define how it will communicate findings of non-compliance in a timely manner to the appropriate parties, and how it will take corrective actions to prevent recurrence. More details concerning the finding/corrective action process is provided in Section 5.5.

During the audit, the auditor must also record findings of compliance. In other words the auditor records which samples he or she reviewed in order to establish the process in question was compliant. This record establishes audit credibility and may be used for trending purposes year to year.

5.5 Finding/Corrective Action Process

5.5.1 Findings

(1) The auditor first records any non-compliance on the checklist as a working record. A finding form or similar mechanism is generally used to document the specific area of non-compliance and record the details of the non-compliant example(s).

Note: *It is important that the auditor clearly identifies the exact clause of policy or procedure found to be non-compliant. Normally the offended section of policy or procedure is quoted on the finding form. Together with a description of non-compliant examples, this information provides a strong foundation to develop an effective corrective action from. But if the auditor does not complete this section clearly the enterprise can misdirect its efforts to develop sustaining corrective action.*

(2) The auditor must communicate all findings of non-compliance to the person assigned management control of the QAP, or the Accountable Executive as specified in the specific regulations. The following information should be supplied:

(a) The name of the auditor and the date of the audit;

(b) Section of checklist found non-compliant and its associated regulatory requirement; and

(c) Details of non-compliant example(s) and extent of the non-compliance.

(3) Should the auditor be concerned that a finding has identified a safety risk, immediate notification to the person responsible for the QAP is required.

5.5.2 Corrective Action (CA)

(1) Once the auditor generates and shares findings, the enterprise must take action. The person assigned management control of the QAP is responsible for:

(a) Determining the full extent of the non-compliance in the balance of any sampled population; and

(b) Assessing any safety risks created by the identified non-compliances.

For example: If the auditor found training records to be non-compliant from those employees that were sampled, immediate corrective action requires the enterprise to review the whole population to find any other examples of non-compliant training records. The enterprise must apply short term corrective actions to all examples before it develops effective preventative (long term) corrective actions. This might include suspending duties or authorities until appropriate training is confirmed.

(c) Ensuring that a corrective action plan (CAP) is developed, approved and implemented in a timely period.

(2) With respect to correcting the examples of non-compliance, the person responsible for the management of the QAP must make certain the enterprise takes immediate or short term corrective actions to ensure compliance is re-established. The term *immediate* is appropriate when a safety concern is identified that must be addressed immediately **on the same day**. Short term corrective action might apply to more administrative finding and may include interim measures to bring awareness to the finding before a full analysis and preventative corrective action is developed.

(3) In smaller enterprises, the person assigned management control of the QAP may develop and implement the Corrective Action (CA) themselves or with a small team. However, in larger enterprises the person assigned management control of the QAP may assign the task of determining and implementing corrective actions to appropriate management personnel (e.g., supervisors, department heads).

(4) The manner through which an enterprise can prevent a non-compliance from recurring is by determining and correcting its cause(s), i.e. develop preventative corrective actions based on root cause analysis.

(5) Root Cause Analysis is an accepted QA best practice used to develop preventative corrective action. The enterprise should identify in their QAP a root cause analysis procedures to be used as a minimum standard. Root Cause analysis records should be retained in support of preventative corrective action.

Note: *Transport Canada has developed an Advisory Circular AC SUR-002- Root Cause Analysis and Corrective Action for TCCA Findings that can help the enterprise develop its QAP root cause analysis and preventative corrective action process.*

(6) In smaller enterprises, the *finding form* is often used as a means to document the various activities including immediate/short term corrective actions, root cause analysis, preventative corrective action and approval, implementation, follow-up inspections and closure with appropriate sign-offs throughout the process. In larger enterprises other means including electronic management may be more appropriate. The method chosen must be clearly detailed in the QAP.

5.5.3 Follow-up

(1) Follow-up inspections occur outside of the scheduled audit and are intended to confirm if corrective action has been effective in preventing a recurrence of the finding. A follow-up inspection is normally scheduled to take place within a timeframe after the CAP is in place which allows the previously non-compliant activity enough time to repeat. For example: Some activities such as log book entries might repeat daily, while others such as new employee training may not occur for some months.

(2) The person conducting the follow-up inspection should meet the similar criteria as that set for an auditor and follow the same process to ensure that they are reviewing a representative sample of records that have been created since implementation of the CAP took effect.

(3) If a follow-up inspection identifies continued non-compliance, the inspector must draft another finding referencing the first finding. The enterprise must re-examine their process for root cause analysis and develop a corrective action until the non-compliance is corrected. Provided the QA records show that the enterprise followed its QAP processes, a CAP failure is not seen as a failure of QAP.

5.6 Record Keeping

(1) Records of audits, including auditor selection & training records, completed check sheets, findings and corrective actions become evidence of the QAP functioning and of compliance to QAP regulatory requirements. The enterprise must ensure all QAP records are:

(a) Legible;

(b) Protected from harm and/or degradation;

(c) Retained for the required time; and

(d) Accessible.

(2) Timeframes for how long an enterprise must keep records are often given within the regulation. The timeframe is usually the greater of two audit cycles or two years. The enterprise must follow any specified timeframe. If there is no timeframe specified, the enterprise must select one. As a general rule, where no record retention timeframe is specified, the enterprise should keep records of two complete audit cycles.

(3) An enterprise must keep all QAP records in a way that protects them from damage or degradation and are easily accessible throughout the retention period. An enterprise may wish to store their QAP records electronically. This is acceptable as long as the enterprise complies with the requirements of CAR 103.04 – Record Keeping.

(4) It is a good idea to keep original hard copies in a simple filing cabinet (preferably fire proof). Whether stored electronically or physically, it is advisable to classify the records so they are easy to find and use.

(5) An enterprise should apply this basic record keeping process to confirm and demonstrate its compliance to regulatory requirements. TCCA inspectors will also review records as part of TCCA surveillance activities.

6.0 INFORMATION MANAGEMENT

(1) Not applicable.

7.0 DOCUMENT HISTORY

(1) Not applicable.

8.0 CONTACT OFFICE

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Original signed by Robert Sincennes

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APPENDIX A — REQUIREMENTS FOR A COMPLIANT QAP

(1) *AC SUR-004 – Civil Aviation Surveillance Program, Appendix B* contains Expectations of a compliant Quality Assurance program. The purpose of the Expectations is to define the intent of regulatory requirements in plain language. There can be various ways for the enterprise to meet these expectations in an effective manner dependent on the size and complexity of the organization. Each expectation must be addressed during the development of an enterprise QAP. The enterprise QAP will include policies and procedures in the approved manuals. Failure to address each QA expectation may result in the rejection by TCCA of the enterprise manual submission.

(2) TCCA expects the enterprise's documentation to describe how the QAP works and explain how persons involved with the QAP perform their duties. Key questions for consideration when establishing QAP procedures should include:

(a) Who has overall authority for the QAP?

(b) What is the audit frequency? Who is responsible for audit planning? How is the audit plan made? How is it documented? When is the audit required? On what dates will the audit take place? How is the audit plan approved?

(c) Who develops and maintains the audit checklist(s) to confirm they still cover all activities of the approved manuals? When is this done? How is it recorded?

(d) What are the experience requirements for an auditor? How are auditors selected and training provided before a determining competence? How is this recorded? Who does this?

(e) How and when is sampling used during the audit?

(f) How does the auditor use the checklist to record samples audited and identify both compliant and non-compliant examples audited?

(g) How do the auditors confirm a potential non-compliance with the auditee?

(h) What action is required in case of a safety related finding?

(i) How is a finding drafted and by whom?

(j) How does management stay informed during the audit? Is the auditor required to provide a briefing or report?

(k) How does the person responsible for the QAP ensure that the AE is notified of any systemic deficiency and of the corrective action taken?

(l) How are audit and finding status reported to/by the responsible manager?

(m) How are findings managed throughout the stages of corrective action through to closure?

(n) What is the corrective action process including immediate action taken to correct non compliance examples already identified? What short term corrective action is required to assess and correct other potential non-compliances in the sampled population? What timeline is appropriate for safety related non-compliance versus administrative non-compliance?

(o) Which root cause analysis tools are used to develop long term CA to prevent the recurrence? How are they used? Who approves CA?

(p) How and when are follow-up inspections conducted to verify that long term corrective action was effective? What happens when a corrective action fails?

(q) How and which QAP Records are retained and for how long?

(r) Have persons required to carry-out QAP duties, been properly trained and their competence assessed? Consideration should be given to not only auditors but those tasked with RCA and CA development.

(s) When is the audit considered to be closed and who does this?

NOTE: The complexity of this section will be driven by the size and needs of the enterprise.