CIVIL AVIATION AUTHORITY OF NEW ZEALAND
Te Mana Rererangi Tūmatanui o Aotearoa

Advisory Circular AC 00-3

Revision 2

9 November 2023

Internal Quality Assurance

General

Civil Aviation Authority (CAA) Advisory Circulars (ACs) contain information about standards, practices and procedures that the Director has found to be an acceptable means of compliance with the associated rule.

Consideration will be given to other methods of compliance that may be presented to the Director. When new standards, practices or procedures are found to be acceptable, they will be added to the appropriate AC.

Purpose

This AC describes an acceptable means of compliance with internal quality assurance (IQA) procedures, a key component of a Quality Management System (QMS). Since the skills developed through running IQA and QMS are relevant to running Safety Management Systems (SMS) procedures, it is hoped that organisations operating an SMS will also find useful tips and advice in this AC.

Related Rules

This AC relates to participants covered by one of three rule parts:

- Part 109, *Regulated Air Cargo Agent – Certification*, rule 109.69
- Part 140, *Aviation Security Service Organisations Certification*, rule 140.59 and
- Part 149, *Aviation Recreation Organisations Certification*, rule 149.63.

Organisations operating an SMS, as explained in AC100-1, Safety Management, may find useful guidance on the quality assurance processes that form part of their SMS, i.e. document control, internal audit, continuous improvement and management review.

Change Notice

This AC cancels AC00-3, Revision 1, dated 24 July 2007. Revision 2 of this AC is a complete rewrite and reordering of this AC. It also takes the opportunity to add Appendix 5, which provides a range of templates to help run an IQA process. Lastly, it adds a Version History.

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Version History

History Log

Revision No.	Effective Date	Summary of Changes
AC00-3, Rev 0	30 September 1996	Initial issue
AC00-3, Rev 1	24 July 2007	Replaced AC 120-01A by renumbering it to AC 00-3 as part of a project to standardise the numbering of all ACs
AC00-3, Rev 2	9 November 2023	Full review and update to enhance and incorporate current day approaches to QMS and IQA methodologies. Adds Appendix 5, which provides a range of templates to help run an IQA process. Adds a Version History.

Table of Contents

1. Introduction

This AC is intended for organisations using IQA processes as part of a QMS. It introduces a range of templates, suggestions and advice aimed to make QMS processes routine and more rigorous throughout an organisation and in doing so, strengthening quality systems within that organisation.

Organisations who have adopted SMS may also find this AC useful, as it explains the relationship between the systems, and outlines documents and procedures that are also applicable to SMS. The skills and procedures developed through a rigorous IQA and QMS complement an SMS, so understanding of them will help organisations build a strong and resilient SMS. It is recommended that participants who have adopted SMS read AC100-1*, Safety Management*, in conjunction with this AC.

2. Abbreviations and Definitions

Abbreviations	
CE	Chief Executive
IQA	Internal Quality Assurance
QA	Quality Assurance
QMS	Quality Management System
SMS	Safety Management System, also referred to as Safety Management.

Definitions	
Audit	A methodical, planned review used to determine how activities are being conducted. It compares results with how the activities should have been conducted according to established procedures.
Audit Process	The various elements that comprise an effective audit, including preparation, meetings, examination, investigation, interviewing key staff and audit report.
Audit Programme	A key element of the QMS, which ensures that the QMS is working as intended. The IQA procedure needs to define how audits will be carried out, by setting out associated procedures, frequency, reporting and ways of communicating findings.
Concern	A conclusion, supported by objective evidence, that does not demonstrate a finding, but rather a condition that may become a finding. A concern may generate further investigation or a preventive action.
Controls	Management and operational techniques, activities, and procedures that monitor the satisfactory performance of the IQA procedures, including the organisation's operating processes and procedures.

Corrective action	Something planned in the wake of a non-conformance or finding, to prevent it happening again. In contrast to a preventive action, which aims to prevent occurrence/s, corrective action is carried out after something has been found to go wrong or have been a near-miss.
Evidence	A documented statement of fact that is based on observations, measurements, or tests that can be verified.
Finding	A conclusion, supported by objective evidence, that demonstrates non-compliance with a specific standard. A finding will generate a corrective or preventive action.
Hazard	Something that could potentially cause harm, or damage to someone or something in an environment, for example a workplace.
Inspection	The act of observing, measuring, testing, or gauging one or more characteristics of a particular event or action. This is to ensure that correct procedures and requirements are followed during the accomplishment of that event, or action.
Member	Someone who is part of an incorporated society established to hold an aviation recreation organisations certificate under Part 149.
Non-conformance	Failure to conform to accepted standards, for example a deviation or failure of a process, service, or product. It can result in a non-conformance report, as part of quality control processes, addressing specification deviations or work that fails to meet quality standards, detailing the problem, how it occurred, and how to prevent it from happening again.
Preventive action	Something planned to prevent something going wrong before it happens. In contrast to a corrective action, which is carried out after a nonconformity or finding has occurred, preventive action is planned with the goal of preventing a nonconformity.
Risk	The effect of uncertainty on objectives.
Risk assessment	Analysis of a risk, including the expected outcome if it was to occur, the likelihood of this happening and the potential impact on the organisation.
Risk management	A programme of coordinated and managed activities to assess, evaluate and manage the risks to an organisation.
Root cause analysis	An assessment of an organisation's processes, procedure/s, methodology, structure or practices, or any combination of the above, to determine the underlying organisational cause, or causes, of any finding or concern.

3. Quality Management System (QMS)

Parts 109, 140 and 149 organisations seeking certification, must develop, document, implement, and maintain a QMS with appropriate IQA procedures, the planned activities that make up the QMS.

A certificated organisation should establish a QMS process that is:

(a) continual, incorporating inspections, audits, and reviews to assess the adequacy of controls in key programmes and systems

(b) ongoing, identifying deficiencies, developing corrective and preventive action plans to correct those deficiencies, and performing follow-up reviews, and

(c) independent, with straight-line reporting responsibility to top management.

CAA encourages organisations to extend their IQA procedures beyond regulatory compliance to determine the causes of other deficiencies in operations. Based on these determinations organisations can enhance operating practices before deficiencies occur and help embed an organisational culture which prioritises continuous improvement.

Because staff at all levels of an organisation can notice potential issues, the most effective QMSs are those where all staff, not only management and the Quality Assurance (QA) team, understand the QMS, why it is important and their role in maintaining it. All staff and managers have a part to play in ensuring that an organisation's policies and procedures provide for safety compliance, meet quality standards and allow individuals to perform work properly. This is achieved by continuously monitoring an organisation's performance and safety standards as part of normal work activities and ensuring that operations are safe and in compliance with the rules.

IQA procedures do not replace CAA's existing monitoring activities.

At its heart an effective QMS has elements in common with SMS, as discussed in more detail in Section 7. Organisations with an effective QMS typically show genuine management commitment, creating a working environment where staff are encouraged to engage in and contribute to the organisation's QMS processes. Identification of potential issues at an early stage, and making risk assessment, evaluation, and mitigations an integral part of day-to-day business, helps managers and staff understand that ongoing attention to standards and quality is the responsibility of all, not just the Quality Manager or QA team.

Organisations that develop this understanding benefit from developing a culture that encourages staff input, supported by regular feedback on what has been done in response to staff reports, and effective controls to manage identified risks.

3.1 Main components of a QMS

- ***Quality Control Planning***
    - Identifying quality goals and standards, the requirements necessary to meet them, and the procedures to be used to check that they are being met
- ***Quality Control***
    - Physically inspecting and testing what was laid out in the planning stage to make sure it can be done

- ***Internal Quality Assurance (IQA)***
    - Reviewing the delivery process of services or the quality management manufacturing of goods, and
- ***Quality Improvement***
    - Thoroughly reviewing the findings from the above three components, with the aim of improving methods in the future.

QMS is an ongoing process encompassing an organisation's structure, responsibilities, processes and procedures. An effective QMS promotes and establishes a culture of continuous improvement that will enhance safety, by combining:

- a process approach
- a continuous improvement focus
- IQA processes, and
- evidence-based decision making.

This is achieved through:

- engaging its own people in the process
- enabling leadership to promote a culture of continuous improvement, and
- relationship management and ongoing communication with customers, members, personnel, and/or stakeholders.

IQA procedures identify, document and correct instances of non-conformance, or non-compliance, which must be put in place for all areas of the organisation's activities that are covered by the rules. When done consistently, IQA procedures provide confidence in the organisation meeting regulatory compliance, can improve the organisation's commercial performance and benefit both the organisation and its customers, members, personnel and stakeholders.

QMS and IQA procedures establish and provide ways for the organisation to assess its own performance and provide assurance to staff, management, members of any governing bodies, customers and CAA that potential safety and quality issues are routinely noticed, analysed and rectified. This set-up allows for the change in relationship between the organisation, with a mature QMS and CAA, whose role shifts from a focus on inspections to monitoring.

4. Rule requirements

Rules 109.69, 140.59 and 149.63 establish that certificate holders are expected to establish an IQA system which includes:

- a safety policy and procedures relevant to the organisational goals and the expectations and needs of its members and/or personnel, which are understood, implemented, and maintained at all levels of the organisation

- procedures to ensure quality indicators, including feedback from the organisation's members, staff and/or customers, are monitored to identify existing problems, or potential causes of problems
- procedures for determining and issuing:
    - corrective action, to ensure existing problems identified in the system are improved or resolved, and
    - preventive action, to ensure potential causes of problems identified within the system are remedied which specify how:
        - existing or potential problems are prevented
        - action is followed up to ensure the end outcome was effective
        - procedures are amended as a result, and
        - management will review the effectiveness of any action taken, and
- an internal audit programme which:
    - specifies the frequency and location of audits
    - ensures audits are performed by trained auditing personnel independent of those having direct responsibility for the activity being audited
    - ensures the results of audits are reported to the personnel or members responsible for the activity being audited and the manager responsible for internal audits
    - requires preventive or corrective action/s to be taken if problems are identified by the audit, and
    - ensures follow up audits to review the effectiveness of any preventive or corrective action taken, and
- management review procedures to ensure the continuing suitability and effectiveness of the IQA system which:
    - specify the frequency of management reviews taking into account the need for the continuing effectiveness of the system
    - identify the responsible manager to review the system
    - ensure the results of the review are evaluated and recorded, and
    - ensure the senior person with responsibility for IQA has direct access to the Chief Executive (CE) on matters affecting safety, including security which is a subset of safety.
- a records system that clearly documents what has taken place, allowing information analysis to monitor trends, determine the effectiveness of the QMS and help the organisation to:
    - raise preventive actions to avoid potential problems

- raise corrective actions to prevent the recurrence of issues, and
- determine the best organisational goals and safety policy and plan for the future, and

- a document control procedure to manage, develop, document, change, and distribute the organisation's quality and operational procedures.

***Note**: For more detailed advice on how a document control procedure could work, refer to Appendix 1 of this AC.*

The standards for the safety policy and plan are structured around elements of ISO 9001 which is covered in more detail in the section What is ISO:9001?

The rules do not address all elements of the ISO standard. However, organisations certificated under the rules will, if they so wish, have a sound basis to further their work towards attaining ISO accreditation. Organisations also have the option to adopt measures beyond those elements listed above, depending on what suits the scale of their organisation and provides the most rigorous assurance.

5. Key processes

5.1 Identifying a Quality Assurance (QA) team or Management Representative

An organisation should identify a person or a group of people, within the organisation, with the responsibility and authority to:

(a) develop, implement and maintain the QMS

(b) manage the organisation's internal audit programme

(c) identify and record any findings or concerns, and the evidence necessary to confirm findings or concerns

(d) initiate, recommend, or provide solutions to findings or concerns through consultation with the management owning the non-conforming process or activity

(e) communicate and co-ordinate activities with external auditors

(f) analyse the root causes of concerns and findings for presentation to management for a review of trends and potential areas of concern[1], and

(g) conduct and record regular management reviews to ensure corrective and preventive actions are addressed and closed out within a specific time.

The Management Representative or the QA Team must have:

- the delegated authority and responsibilities to implement and maintain the procedures, and

[1] Outlined in more detail in Section 5.3 below.

- a direct reporting line to the highest level of management necessary to sustain management commitment to the policy and plan.

For some organisations, operating size may justify the costs of having a separate QA team. However, when full-time, dedicated, resources and personnel are not practical, the organisation should develop procedures that preclude persons directly responsible for the areas being evaluated from participating in the selection of the audit team.

For very small organisations, an appropriate IQA procedure should consist of developing checklists and a schedule for:

- evaluating the checklist items
- signing off checklists, and
- scheduling independent reviews of the checklists and the checklist items.

5.2 Establishing a Safety Policy

The organisation should establish a clear policy that safety is part of its business. It should develop procedures that reflect a commitment to safety and will promote and demonstrate a clear corporate safety culture. The policy should define a set of beliefs, norms, attitudes, roles, and social and technical practices concerned with minimising exposure of employees, managers, customers, and members of the general public to conditions considered dangerous or hazardous.

The characteristics that define a safety culture include:

(a) senior management emphasising safety as part of the strategy of controlling risks

(b) a realistic view of short- and long-term hazards and risks involved in the organisation's activities

(c) senior managers fostering a culture in which there is a positive attitude and just culture towards feedback, both constructive and positive, from all levels of the organisation and its stakeholders

(d) an awareness of the importance of communicating relevant safety information at all levels of the organisation – both within it and with outside entities and stakeholders

(e) promotion of appropriate, practical, and workable rules relating to hazards, to safety, and to potential sources of damage, with such rules being supported and endorsed throughout the organisation, and

(f) staff and/or members being well trained and educated and able to fully understand the consequences of unsafe acts and how to prevent them, and escalate situations where safety risks could occur.

Resources that might help an organisation frame their safety goals and objectives include the State Safety Programme (SSP):

- https://www.aviation.govt.nz/safety/state-safety-programme/

And section 2.4.2*, Element 7: Monitoring and Measuring Safety Performance, in AC100-1, Safety Management*.

5.3 Root cause analysis

The root cause is the underlying cause/s of any finding or observation. It often stems from an organisation's process/es, procedure/s, methodology, or combinations of these elements, or an underlying weakness in an organisation's structure or practices.

In analysing safety, quality, or operational concerns, root cause analysis should be done to determine the underlying cause, or causes, before any preventive or corrective actions are planned.

Often the root cause is not obvious. Consequently, a careful and considered analysis of all processes, activities, records, reports, and other evidence associated with a failure, concern or complaint is needed to ensure the corrective and/ or preventive action(s) address not only the immediate cause but any latent organisational problems.

5.4 Corrective and Preventive Actions

Corrective Actions

IQA procedures should ensure that corrective actions are developed in response to findings or concerns, including:

(a) recording the corrective action

(b) assigning and accepting ownership

(c) monitoring each corrective action to verify timely and effective implementation and completion, and

(d) reviewing that the corrective action is effective and has a lasting impact, so the issue does not recur.

Preventive Actions

The preventive action procedure is similar to the corrective action procedure, except that preventive action anticipates and corrects potential failures. Often a corrective action will generate one or more associated preventive actions to ensure a complete and long-term fix.

***Note**: For more detailed advice refer to Appendix 2 of this AC.*

5.5 Management Review

Management must, at regular intervals, review:

(a) the IQA procedures, the quality indicators, and inspection and audit results to verify the QMS is working

(b) that corrective and preventive actions have been recorded, implemented, and suitably closed

(c) that QA programmes are regularly reviewed and improved.

The organisation must regularly review all their policies, processes, and procedures, carried out by dedicated staff. It will encompass all the activities, policies, procedures, and processes

of the organisation. The programme should be a comprehensive and continual process that considers:

(a) the overall effectiveness of the organisation in achieving its goals

(b) the ability of IQA policies and procedures to respond and adapt to new technologies, market strategies, legislative or regulatory changes, and social or environmental conditions, and

(c) whether-current policies, processes and procedures are up-to-date, effective, and relevant.

Note: *For the purposes of this, the term* ***management*** *means the team or person who has the authority to resolve issues and take action.*

The management reviews with supporting documents should be recorded. The organisation needs to determine and document the frequency, format, and structure for informing management of IQA plans, trends, results, and follow-up actions. These procedures will define the responsibilities of personnel who perform or supervise the management reviews.

5.6 Audits, Records and Documentation

There are different types of audits which are conducted for different purposes:

First party audits are conducted internally by the organisation, using its own trained staff, to evaluate the organisation, or parts of the organisation's performance. The results are used by management to confirm compliance with the documented standards and procedures to initiate corrective action when the standard is not met or preventive actions where there is potential for non-conformance or non-compliance**.**

Second party audits are carried out by an organisation on its suppliers or sub-contractors. These audits are intended to satisfy the contracting organisation that the sub-contractor meets the agreed quality and performance requirements**.**

Third party audits are carried out by independent bodies such as regulatory authorities or commercial auditing companies. CAA carries out audits for the aviation industry. The audits are intended to give CAA assurance that the organisation is compliant with rules and regulations, is managing risks, and that the organisation’s QMS and IQA procedures are working effectively. Third party audits will confirm that non-compliances are being identified and corrected by first, or second, party audit.

5.6.1 Audit Process

The various elements that comprise an effective audit are:

(a) audit preparation by the auditor(s) including work to:

(i) inform and advise the area/organisation being audited, including when, where, who is required to attend, requesting any materials to review before the audit, and informing which areas the audit will cover and the scope of the audit

(ii) request and review documentation (where practical), and

(iii) identify areas which may require further enquiry via interview or testing during audit

(b) an opening or entry meeting to:

(i) introduce the audit team and confirm the scope of the audit

(ii) outline the audit process to be used and the schedule, and

(iii) confirm the resources, people and facilities needed for the audit are aware and available for the audit

(c) an initial examination to:

(i) interview personnel, review documents, observe and inspect operations and select samples for testing

(ii) document evidence, and

(iii) document findings and concerns

(d) closing or exit meeting to:

(i) present findings and observations, and

(ii) establish a programme to close-out findings

(e) a written audit report containing:

(i) descriptions of all the findings and observations with supporting evidence

(ii) the corrective and preventive actions, and

(iii) the schedule for resolving actions and closing corrective and preventive actions when appropriate.

5.6.2 Audit Programme

A mandatory element of the QMS is the organisation's audit programme. This needs to:

(a) define the audit types and associated procedures

(b) maintain and manage a cyclic schedule of audits

(c) manage the review, reporting, and close-out of findings and concerns, and

(d) identify the personnel to conduct the audit.

Rule 149.63 (f) (2) specifies that audits have to be performed by trained and independent personnel but does not specify the type of training. While there are many courses in audit training, auditing an organisation's QMS is about more than the financial side: it is about analysing an organisation's operations at all levels. Auditors will need to develop a thorough understanding of how the organisation operates, what it is trying to achieve, and obstacles to this.

Planned Audits are audits that will be performed during a set calendar period.

To facilitate and ensure the audit is thorough, divide the organisation into audit components based on the organisation's operational or functional structure. Depending on the size of the organisation, and the level of risk each area represents the audit cycle might

be greater than one year, with the frequency of audits supported by robust rationale and evidence for why an organisation has opted for the set frequency. Schedule the audit within each component to allow enough flexibility for resources to be committed.

Special Audits or Spot Checks are based on concerns or priorities identified by the organisation, external audits, customer complaints, or following a review of the organisation, or industry trends.

External Audits are initiated and conducted by agencies with a regulatory interest in the operation of the organisation, for example, CAA, WorkSafe, and Inland Revenue (IR). The content and focus of an organisation's internal and special audits will be largely determined by the need to anticipate or respond to the requirements and findings of external audits.

5.6.3 Quality Indicators

Each organisation needs to develop, measure and monitor their **own** quality indicators. Some examples of typical quality indicators are:

(a) reports derived from the analysis and investigation of operational logs and records kept of incidents, occurrences, accidents, and other safety indicators

(b) root cause analysis from corrective and preventive action records

(c) performance measurements of both the QMS and the organisation's operation

(d) customer complaints, and/ or

(e) customer surveys, external and internal.

5.6.4 Records

The organisation needs to keep and manage records documenting the performance and results of carrying out IQA procedures, since these records are the principal form of evidence. Documented evidence is essential in analysing and determining the root cause of findings or concerns so that potential areas of non-compliance or non-conformance can be identified by the organisation. Records must be accurate, complete, reliable, and accessible.

AC00-6, *Electronic Signatures, Electronic Record keeping and Electronic Manuals,* provides detailed guidance, including an appendix with the various applicable rules.

It is recommended that following quality records be maintained:

(a) audit reports

(b) management reviews and associated minutes, reports and programmes

(c) corrective and preventive action with supporting documentation

(d) analysis of root causes and the ensuing trends and management reports

(e) customer feedback, including:

- customer complaints
- customer surveys
- industry news sheets

- observations through day-to-day contact, and
- comment during audit

(f) training plans and records, and

(g) a copy of all policy and procedures.

5.6.5 Documenting IQA Procedures

Controlled documented IQA and operational procedures are a key element and requirement of a QMS.

Each organisation should review the size and complexity of their operation to determine the scale of policies, processes and procedures that will maximise the benefits of their QMS and their operations and improve their safety level and organisational results.

Each organisation will require several, possibly many, processes to sustain their operation. Each process may consist of one or more procedures.

Each IQA procedure should:

(a) be concise and complete enough to be a useful guide for a user with the appropriate skills to perform the task(s) within the procedure

(b) state specifically *how* the organisation will address and meet the requirements of rules, relevant legislation and regulations, ACs, or other reference standards or documents initiating the procedure. For example, a procedure needs to say more than: *Organisation ABC will comply with Rule XYZ* to pass approval or audit.

(c) be current and met the requirements of referenced document(s).

(d) be accessible to all users of the process

(e) comply with a defined (by the organisation) standard format, for example:

(i) **Title** *

(ii) **Purpose** * (outline the objective of the procedure)

(iii) **Scope** (what the procedure applies to)

(iv) **Responsibility** (who is responsible for what?)

(v) **References** (what other documents (Rules, Acts, standards, other procedures) affect or are related to this procedure?)

(vi) **Definitions** (definitions of terminology introduced by this procedure, or statements that may lead to misinterpretation)

(vii) **Procedure** * (what is actually done to ensure compliance?)

(viii) **Flowchart**(s) (to support or clarify the procedure)

(ix) **Records** (what records? For example but not limited to, checklists, reports, reviews, measurements.)

Note: *This is not the only way set out a procedure: what is important that a standard format is followed, which is clear and easy for users to understand, and clearly shows what the procedure consists of and why the steps are important. This list is not definitive, but the headings marked with an asterisk are highly recommended to make procedures as clear and distinctive as possible to follow and later assess.*

6. CAA Monitoring and Intervention

CAA monitors the industry by carrying out monitoring and analysis to verify that operators are upholding their responsibilities. IQA procedures are intended to assist CAA's monitoring process by identifying and resolving safety-related issues. IQA documentation and records provide a practical point of entry to the organisation for auditing purposes.

To assist internal and external auditors, and the organisation's personnel, it is recommended that a matrix be developed to cross-reference where the exposition addresses or meets the requirements of the relevant rule.

CAA audits assess the organisation's safety performance. It will be apparent from the level of findings in IQA documentation and records whether the QMS and safety policy are working effectively. The performance of the organisation will indicate the level and type of regulatory intervention that is necessary by CAA.

If the organisation performs well CAA will have less need to monitor its compliance. As confidence is built up the level, and frequency, of audits can be reduced.

7. Relationship between Safety Management Systems (SMS), QMS and IQA

Although SMS is becoming the default for civil aviation organisations, this does not mean QMS has no place, as the two systems can be seen as complementary. As noted in AC100-1:

> "SMS and QMS share a number of common purposes and processes:
>
> - both depend upon measuring and monitoring
> - both strive for continuous improvement
> - both use some of the same tools, such as auditing and review.
>
> However, a QMS does not include all the elements, features and activities of an SMS, as it focuses mainly on compliance, conformance and monitoring. SMS goes further and requires the organisation to identify and manage risk to achieve an acceptable level of safety performance.
>
> It is not so much a case of replacing QMS by SMS, but instead, realising that they are complementary and inextricably linked - one cannot build an effective SMS without applying QMS principles."[2]

[2] AC100-1, *Safety Management*, section 1.6.1.

An effective SMS incorporates QMS concepts that can result in more structured management practices and continuous improvement of operational processes. For more information refer to AC100-1, *Safety Management*, Section 2.2.1.

8. Hazard identification and Risk Management

Risk management involves the framework, process and culture of managing risk to achieve an appropriate balance between realising opportunities while minimising threats.

Not all risks can be eliminated, nor are all conceivable risk management measures economically feasible. The expectation is that risks will be managed as far as is reasonably practicable, to keep the risk level as reasonably practicable.

That is, how actively a risk will be managed or mitigated will be agreed after assessing:

- the extent of the risk
- available ways to eliminate or minimise the risk, and
- the cost associated with available ways of eliminating or minimising the risk, including whether the cost is grossly disproportionate to the risk.

For more information refer to Section 10, *Other resources*, in this AC.

Section 2.3, *Component 2: Safety Risk Management,* in AC100-1 contains advice on hazard identification and effective risk management processes and how to set them up and maintain them in a way that best manages risk in their organisation.

9. ISO-9001

ISO-9001 is a generic quality management system and a way of organising workflow to encourage continuous improvement and improve customer satisfaction. While not mandatory, some participants may find the concepts useful in developing their own systems.

The basic concepts of ISO-9001 include:

1. ***Process approach –*** a way of thinking about the whole business in terms of individual processes. This is achieved by breaking down the process into smaller pieces, helping organisations to prioritise. There are five essential checkpoints:
    - **Sources of inputs –** anything providing resources
    - **Inputs –** physical materials, information
    - **Activities –** the actions performed during the processes
    - **Outputs –** results of the processes, information, services, policies
    - **Receivers of outputs –** where the outputs go, for example to customers.

    Note: *Each of the processes should have a process owner to keep track of its success*.

2. ***Risk-based thinking*** – While risks cannot be eliminated, when an organisation is dedicated to assessing, evaluating and managing risks, this can help keep risks to a manageable and acceptable level. Section 8 of this AC provides further detail on this concept.

3. ***Plan/Do/Check/Act Cycle (PDCA)*** This can be seen as a "map" of ISO-9001. The cycle shows how the entire quality management system works towards continuous improvement.

Plan

- **Determine the context of the organisation** by examining its influences – people, policies, facilities, interested parties. These form the context of the organisation.
- **Leadership** Top management needs to take ownership by setting objectives and delegating responsibilities. They should also review the system regularly and provide the organisation the resources it needs to achieve quality.
- **Applying risk-based thinking** This means examining all the risks identified and coming up with objectives to address them, by creating goals the organisation can actually benchmark.
- **Support and Resources,** particularly Communication and Awareness. Everyone needs to be aware of policies and changes in the organisation.

Do

This next phase enacts the plans made in the planning phase. There are two main parts:

- ***Operations*** **-** everything that goes into creating the products and services
- ***Control*** **-** the steps taken to direct the processes towards the desired results. By controlling specific risks, the organisation can avoid costly errors.

Check

The third phase is ***performance evaluation***. Operators should consider***:***

- *How the results stack up against the goals set, and*
- *The outputs of the processes. Are there any non-conformities? An internal audit enables the organisation to conduct a test run to find issues and correct them before certification.*

Act

- ***Corrective actions*** are targeted at the root cause of the problem to avoid it happening again. They need leadership, which is at the centre of the Plan/Do/Check/Act cycle.

10. Other resources

There is a wealth of information and resources on the CAA website and other websites about QMA, IQA and SMS. These resources are recommended:

Quality management:

- https://www.iso.org/iso-9001-quality-management.html
- The Four Main Components of a Quality Management System (docxellent.com)
- https://kanbanize.com/lean-management/improvement/what-is-pdca-cycle
- https://asq.org/quality-resources/pdca-cycle
- AC00-6, Electronic Signatures, Electronic Record keeping and Electronic Manuals
- What Is ISO 9001? - YouTube
- (6) What is ISO 9001:2015 Context of the Organization in a Nutshell (And How Exactly to Audit It) - YouTube
- Revision control of documents in QMS - YouTube

Risk management:

- 839WKS-5-HSWA-identifying-assessing-managing-work-risks%20(1).pdf
- https://www.iso.org/iso-31000-risk-management.html
- Reasonably practicable (worksafe.govt.nz)
- What is 'reasonably practicable' — business.govt.nz
- https://www.hse.gov.uk/enforce/expert/alarpglance.htm#:~:text=%22ALARP%22%20is%20short%20for%20%22,money%20needed%20to%20control%20it.

Safety management:

- AC100-1, Safety Management
- https://www.aviation.govt.nz/assets/publications/sms-resources/sms-booklet-2.pdf
- https://www.aviation.govt.nz/safety/sms-safety-management-systems/
- State safety programme | aviation.govt.nz
- AC12-2, Occurrence Investigation

Root cause analysis and the 5 WHYs technique:

- Vector – Autumn 2020 Root cause analysis
- https://kanbanize.com/lean-management/improvement/5-whys-analysis-tool
- https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/fivewhys.pdf

- https://www.isixsigma.com/cause-effect/determine-root-cause-5-whys/
- https://en.wikipedia.org/wiki/Five_whys

APPENDIX 1: Document control

Purpose:

Document control procedures will establish processes that:

(a) define manual standards

(b) identify documents to be controlled

(c) control the amendments and distribution of amendments and documents

(d) remove obsolete documents from use, and

(e) periodically review and revise procedures.

Manual Standards:

Manual standards should include:

(a) title page

(b) contents page(s)

(c) authority for issuing and amending the manual, and

(d) record of amendments.

The following standards are recommended:

(a) list of effective pages

(b) every page to be identified as belonging to the organisation by including the title of the organisation in the document header or footer

(c) every policy, procedure or work instruction to be written as a *standalone* document, and uniquely identified by a subject code in the document header or footer

(d) every page within a policy, or procedure or work instruction to be identified in the document header or footer as *Page x of y*

(e) following an amendment, a policy, procedure or work instruction should be issued.

Procedures:

1. Identification and Authorisation of Controlled Documents

Documents to be controlled will be identified by reviewing the content of the document against the following criteria:

(a) any document that provides instruction or guidance to the organisation's personnel to support them in achieving the planned quality and business objectives

(b) any document containing legislative requirements that the organisation is responsible for administrating or required to conform with, and

(c) any document containing standards, recommended practices, or guidance material that has been adopted, and used when undertaking the functions and activities of the organisation.

If one or more of the above criteria apply, the document must be controlled.

2. Amendment of Controlled Documents

Document a procedure that defines an amendment process that:

(a) allows any member or staff of the organisation to suggest a manual amendment

(b) ensures amendments to a document are shown on the actual document

(c) details the documentation to be raised when requesting an amendment

(d) advises who is to check and approve amendment requests

(e) describes what records are to be retained for future reference.

3. Document Distribution

Controlled documents are to be physically identified as controlled documents, with consideration given to numbering each controlled document.

Obsolete pages are to be promptly removed from all points of issue or use. In most cases these documents will be destroyed to ensure they are not used in the workplace. However, a hard copy of an obsolete document may be archived, provided each page is identified as obsolete.

4. Document Review

All documents originating within the organisation need to be reviewed at least annually to ensure they are current and continue to meet the organisation's needs. The organisation must establish and maintain a programme to complete these reviews.

The number of amendments should be defined, and a process put in place to decide when the document should be rewritten and reissued to conform with current standards and practices.

5. External Document Review

Documents that are written, amended and distributed by external agencies that the organisation uses, should be reviewed twice yearly to ensure they are current.

External documents used for day-to-day activities must be current. Any person using them for this purpose must check and maintain their currency.

APPENDIX 2: Corrective and Preventive Actions

Purpose:

To document a procedure that defines the corrective and preventive action processes that ensure existing issues and potential problems are identified, recorded, corrected and followed up to ensure they do not re-occur.

Definitions:

Corrective and preventive actions are raised as a result of:

(a) in-process verification by individuals, or a team, performing their tasks

(b) any review process performed by management

(c) customer feedback

(d) statistical and survey methodologies and

(e) internal and external audit findings.

Procedures:

Reporting

The following details must be recorded for every corrective and preventive action raised:

(a) name of person who raised the action

(b) reason action raised

(c) a recommended solution(s)

(d) root cause of issue or problem

(e) approved action to be taken

(f) name of person assigned to take action

(g) date action to be taken by

(h) outcome of action taken, and

(i) measurement applied to ensure action taken was effective and permanent.

Review

All corrective and preventive actions should be reviewed by the management representative responsible for quality.

The root causes of all actions raised over a set period will be reviewed to determine any significant trends. This process is designed to identify potential issues and problems.
A preventive action should be raised for any action to be taken as a result of the review.
The results of reviews are to be recorded and retained for future reference.

APPENDIX 3: Management Reviews

Purpose:

To define the procedure establishing a management review process, that tests and confirms the suitability and effectiveness of the quality system.

Procedure:

A review meeting will be held regularly (for example once a month), with minutes, action plans and documents kept to support the observations, conclusions and recommendations reached. These will be retained for future reference and analysis.

The manager and management representative will nominate the attendees.

The agenda should include a review of the following items:

(a) corrective and preventive actions

(b) internal and external audit program and results

(c) training and development

(d) document control

(e) operational and managerial performance measurements

(f) customer surveys, and

(g) customer complaints.

APPENDIX 4: Management Representative

Purpose:

To define the role and responsibilities of the management representative.

Definition:

The management representative is delegated by management to facilitate and maintain the organisation's quality system.

Responsibilities of the Management Representative:

(a) Initiate and record monthly management review meetings for the manager. Chair the review meeting in the manager's absence.

(b) Manage the corrective and preventive action process:

  (i) maintain the corrective and preventive action registers

  (ii) follow up the corrective and preventive actions

  (iii) review progress with the owners

  (iv) review close-off.

(c) Co-ordinate new quality system procedures or changes to current procedures.

(d) Initiate in-house reviews of processes and procedures.

(e) Review external documents for currency.

(f) Represent group or unit for internal or external audits.

(g) Review root causes of all corrective and preventive actions and provide management and group with a report on trends with recommended actions.

(h) Prepare and distribute statistical information and survey results that measure and test the current processes and the organisation's performance to the manager and the team.

APPENDIX 5: Templates, tip sheets and guides

In this appendix we have included some of the templates, tip sheets and process guides that CAA and other parties have developed for participants to use to enhance their IQA processes.

While this material is focused around Regulated Air Cargo Agents (RACAs), elements can be adapted by organisations which operate in different areas of aviation.

Guidelines for meeting the requirements of rule 109.69

The following is an example drawn from material CAA has developed for RACAs. Not all of these elements will be applicable to other sectors, but most of the processes and procedures can be adapted across a wide range of sectors.

Introduction

- It is clear from the personnel requirements that the CE and other senior people cannot fulfil their responsibilities unless they have a thorough understanding of both the requirements of Part 109 and what is going on in the business.
- One of the ways to ensure your RACA is meeting the requirements is through an IQA process.

The Requirements of a RACA QA System

CAA provides advice on the requirements of a QA system in AC00-3 on the CAA website.

There is also general advice in AC109-1 on the CAA website. If you read the section on QA you will see that CAA makes it clear that:

- you should not be concerned with an over-complicated system, and
- whatever QA system you design should be part of your standard business practices.

The Matrix (or CAA Form 24109-02) which needs to be competed and accompany a security exposition sets out exactly what needs to be in the QA system and how to set it out in your security exposition.

109.69 Internal Quality Assurance		
109.69(b)(1) *Security policy and procedures*		
109.69(b)(2) *Quality indicators*		
109.69(b)(3) *Corrective action*		
109.69(b)(4) *Preventive action*		
109.69(b)(5) *Audit programme*		
109.69(b)(6) *Management review*		
109.69(c) *Access to CEO*		

Security Policy and Procedures

This is pretty straightforward – it's simply stating that a QA system is a combination of a policy and procedures.

You might wish to look at the aim of Part 109 and the personnel requirements to help form your organisation's policy.

An example might be:

> *Audit Policy*
>
> *At Lucky Panda all staff take personal responsibility for making security a vital part of our business. Aviation security matters for three reasons:*
>
> 1. *the safety and well-being of our team, our customers and our colleagues in the aviation industry;*
> 2. *the reputation of New Zealand on the international stage; and*
> 3. *sustaining the long-term future of Lucky Panda.*
>
> *The purpose of the IQA system is to provide assurance to the Chief Executive that Lucky Panda is in compliance with its exposition and Civil Aviation Authority Rules. Lucky Panda encourages a 'no blame' policy in order to encourage full compliance.*

Here Lucky Panda has decided that the key things for the organisation were that they wanted people to:

- take responsibility, and
- realise how important aviation security is to its business.

It is important to have a policy that is appropriate. It doesn't have to be too detailed, and if all you want to say is that your organisation is committed to complying with Part 109 requirements and continually improving the effectiveness of the QA system that would probably be enough as long as it is true.

There is no need to include detail of the procedures in this section – they come later on.

Quality Indicators

Quality indicators (QIs) are "things" or markers that tell you how your business is going along. Part 109 states what the minimum requirement is, and there are only three things that need looking at:

- any security type incidents
- customer feedback, and
- staff feedback.

These should be monitored to identify existing problems or potential causes of problems within the system.

For example, if you have:

- staff feedback telling you that material from known customers often has to be treated as unknown because it is presented without a statement of content, and

- telephone calls from customers saying that they don't really understand what is required of them

then you have just identified a problem with your Known Customer process.

One of the easiest ways of monitoring QIs is to review any incidents or feedback before each audit, if you do this ensure that you make a formal note of the review.

Alternatively you might wish to look at QIs during the management review phase.

It does not really matter when QIs are reviewed, but it is important that:

- a review takes place and
- it is noted.

Here is an example from the Lucky Panda Cargo Company:

> *Quality Indicators*
>
> *Lucky Panda's procedure for monitoring quality indicators is to review them before audits to see if they identify any problems or potential causes of problems with our aviation security processes. Our quality indicators are:*
>
> - *Any incidents or potential incidents related to the processing, storage or dispatch of air cargo.*
> - *What our customers tell us about the way we do things.*
> - *Any ideas that our staff have on what works well and what could be done better.*

Corrective Action

This is again pretty straightforward. If something is not right, it needs to be fixed. As a minimum, a named person should be made responsible for putting the corrective action in place within a set time and then checking again later to ensure that the action is effective.

Preventive Action

The procedure for dealing with these will be similar to that used for corrective actions. The big difference is that in order to have an effective preventive action, you need to get to the root cause of the problem.

There are many different approaches to causal analysis. A very simple method that comes from car manufacturing is called '5 Whys'. The idea is that if something goes wrong you ask 'why' up to five times (you won't necessarily need that many) to get to the root cause. It's probably easier to give an example.

Causal Analysis –5 Whys Example

A QA manager audits the Lucky Panda known cargo receipt procedures in May and finds that some cargo has been treated as unknown despite it coming from a known customer.

In order to get to the root cause of the problem, the QA manager asked '5 Whys':

Question	Answer
Why?	The person in the warehouse thought that they knew all the known customers off the top of their head.
Why?	Most known cargo comes from a limited number of customers and the person in the warehouse has got out of the habit of checking the known customer list.
Why?	The known customer list was removed from the warehouse a month before the audit.
Why?	The Sales Team wanted to update the list but didn't replace it.
Why?	It took longer than the Sales Team anticipated to update the list and they forgot to return a hard copy to the warehouse.

So, the root cause of the cargo being treated as unknown instead of known – and costing Lucky Panda time and resource – was the reliance on a hard copy of the known customer list.

Lucky Panda's corrective action was to give the warehouse team a copy of the known customer list – but its preventive action was to find an old computer and screen and put those in the warehouse by the checking in desk. That way, the team in the warehouse can check the known customer list which is always current.

Lucky Panda thinks that causal analysis is really useful, and it has created a form for it which combines the corrective and preventive actions and the causal analysis together – it's called Procedure for Dealing with Findings from Audits.

An example is given in the Lucky Panda Security Exposition:

> *Corrective and Preventive Actions*
>
> *Lucky Panda's procedure for dealing with findings from IQA is to carry out an analysis to determine what caused the finding and then put in place a corrective action to sort the problem out straight away and if required, a preventive action to stop the incident happening again.*
>
> *Findings, what went wrong, and the corrective and preventive action(s) will be written down in the IQA report.*
>
> *Responsibility for putting things right will be allocated to a named person.*
>
> *He or she will make sure that the problem has been solved – and check again after a month to ensure that the solution is a long-term solution and not just a quick fix.*

Procedure for Dealing with Findings from Audits

Cause

Think: People – Procedures – Environment – Tools/Equipment

Why?	
Why?	
Why?	
Why?	
Why?	

Corrective Action(s):

Person responsible:

To be completed by:

Preventive Action(s) – Who is responsible for carrying this out?

Person responsible:

To be completed by:

The Audit Programme

The key elements are that there must be a programme of audits – a plan if you like - and a method of carrying them out. The AC talks about nominating personnel to carry out audits and providing training for them but remembering that you should not be concerned with an over-complicated system. Formal training is not necessary if the person carrying out the audits has a good understanding of the requirements of Part 109.

The Audit Plan

When constructing a programme or plan bear in mind that the overarching reason for having a QA system is so that the CE can be assured that the RACA is in compliance with its exposition and Civil Aviation Authority Rules. Therefore the programme needs to cover every aspect of Part 109 and the exposition – including the exposition itself.

When constructing a plan, you will find it more practical and useful to do a small audit frequently rather than attempt to audit your whole operation in one go once a year.

Consider auditing those things which are most likely to throw up problems most frequently, like receipting and screening.

Other parts of the requirements can be looked at just once a year, for example authorisations, the exposition and training.

Here is an example of an audit plan from the Lucky Panda Security Exposition:

January	*Management review – set QIs and audit plan*	*July*	*Management review – review QIs and audit plan*
February	*Receipt and screening*	*August*	*Receipt and screening*
March	*Facility, Storage and dispatch*	*September*	*Facility, Storage and dispatch*
April	*Authorisations including security clearances, training and competences*	*October*	*Records, Known Customers, Security Exposition*
May	*Receipt and screening*	*November*	*Receipt and screening*
June	*None*	*December*	*None*

Audit Methods

The method to be used for auditing depends on the subject to be audited.

A good approach to take is to build QA into everyday business practices.

This example from the Lucky Panda Cargo Company shows how a booking in sheet contains within it a number of steps that staff need to work through when accepting cargo. These have the effect of quality assuring the acceptance process as it happens:

The Lucky Panda Air Cargo Company Ltd

Booking In Sheet

HAWB No:_____ Completed by:_____

Date	***Time***	***Received From***	***UIN***
Weight		***Dimensions***	
Known		***Unknown***	

Known Customer? *(Check register)*	*Yes/No*	*Some shipments may be exempt from screening. These are listed in the Security Sensitive Air Cargo Security Guidance Material. If this shipment falls into one of those categories, it must still be stored and transported in the same way as known cargo and a security declaration must still be issued even if no screening is required.*	
Other RACA? *(Check security declaration)*	*Yes/No*	*Suitable for search by hand?* *(Check against the contents list.)*	*Yes/No/To be passed on to CTO as unknown.*
Is there a Statement of Content? *SoC must be present before cargo may be accepted as known.* *Check it is from the known customer and does not list any weapon/explosive/dangerous device.*	*Yes/No/Not yet*	*If yes.* *Date* *Time* *Name of person searching*	
Is there any evidence that the freight has been tampered with? *If yes – make unknown and report to your supervisor*	*Yes/No*	*Confirmation that a security declaration may be issued.*	*Yes/No/Not yet – see comments*
<u>Comments</u>			

Another approach is to use check sheets. There is an example below for auditing the signing of security declarations.

<u>Security Declarations</u>

Any Quality Indicators to be considered?

Security Declarations	*Comments*

Check at least ten shipments retrospectively. *Try to witness at least two live shipments.*	
Are staff checking to ensure that the cargo or mail is known and a security declaration may be issued?	
Are staff completing the security declarations correctly? No pre-signed declarations.	
Does the person signing the security declaration have an authorisation allowing them to do so?	

In some instances it might be better to have a simple list of points to help the person carrying out the audit structure their approach. Here is an example for auditing authorisations:

Lucky Panda Audit Aide Memoire – Authorisations

Any Quality Indicators to be considered?

1. *Obtain a current staff list from personnel.*
2. *Work through the list making a note of what security functions staff carry out.*
3. *Check that those staff have an authorisation.*
4. *Check that the authorisation is supported by evidence of in date security clearance, training and an assessment of competence. Note any training requirements for the next 12 months.*
5. *Check all other staff who do not carry out a security function to ensure that they have an authorisation to enter an access-controlled area if they need to do so.*
6. *Re-draft authorisations as necessary. Apply for security clearances if required. Plan training events for coming year.*

But for some things like auditing the Security Exposition, a blank piece of paper is just as useful. In this instance, it is just a case of reading the thing through – or even better getting someone else to read it through – and noting those things which need updating or removing.

Management Review

The purpose of a management review is - as the name suggests – to get management to review the QA system to verify that it works, that it is effective and that it is still relevant.

As part of that you would expect the management review to ensure that all the corrective and preventive actions have been carried out and closed off – you would also expect the management review to pick up on any trends that are not apparent when you look at the results of audits independently. These trends can be in findings or in QIs.

In the example given under the Audit Programme you can see that Lucky Panda has decided to carry out a management review twice a year in January and July – but you can have them more or less frequently. Bear in mind that, unless the review covers a number of audits, you won't get much value out of it because there won't be enough information to work with to identify trends.

The other thing is that the management review needs to be documented and any recommendations fed back to the staff.

The example paragraph from the Lucky Panda Security Exposition is:

> *Management Review*
>
> *Twice a year the management team will review:*
>
> *1. The IQA procedures, quality indicators and any training and test results to verify that any problems are being identified and fixed, and that the aviation security processes are working well and in accordance with CAR109 and the Lucky Panda exposition.*
>
> *2. That any corrective and preventive actions have been dealt with in line with the procedures.*
>
> *3. Whether anything could be done better.*

Access to CEO

The person responsible for internal QA has to have direct access to the CE. If you decide that the CE will carry out the audits – as is sometimes the case in smaller companies – that is fine. However you need to note this in your security exposition.

Key Points

- The outcome sought by this rule is for the internal QA system to provide assurance to the CE that:
  - the RACA is in compliance with its exposition and its security objectives, and
  - the exposition demonstrates compliance with all the applicable rule requirements.
- You should not be concerned with an over-complicated system.
- Whatever QA system you do design should be part of your standard business practices.
- Use the minimum requirements in Part 109 as a guide to designing your system.
- A small, focussed audit carried out regularly is better than one large audit once a year.
- Your QA system must cover <u>all</u> the elements of Part 109.
- Management review can be a really useful management tool.
- Keep good records of all aspects of your QA programme.