Advisory Circular
AC00-3

Internal Quality Assurance

09 August 2016

General

Civil Aviation Authority advisory circulars (AC) contain information about standards, practices and procedures that the Civil Aviation Authority has found to be acceptable for compliance with the associated rule.

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

In addressing a subject the use of the imperative, for example *shall* or *must*, is because it is associated with mandatory provisions of the Rule itself.

Purpose

The purpose of this Advisory Circular is to provide information and guidance relating to internal quality assurance procedures. Organisations seeking certification are required, under Civil Aviation Rules, to have such procedures in place. Any organisation requiring a certificate under Civil Aviation Rules can apply the procedures and practices outlines in this AC. They are equally applicable to flight, maintenance, or security operations, as appropriate.

Focus

This material is intended for Certificated Organisations operating in the Mongolian aviation environment. It describes the Quality Management System that you are expected to use.

Related Rules

This Advisory Circular relates specifically to CAR Part 119, Part 139, the 140-series Parts, and the 170-series Parts.

Change Notice

Subject to “Memorandum for Technical Cooperation” between the CAA of Mongolia and New Zealand on mutual cooperation in implementation of Assembly Resolution A29-3: Global Rule Harmonization, 29th ICAO Assembly, 1992, which urges States to promote global harmonization of national rules, dated 6th of May, 1999, Mongolian Civil Aviation Safety Regulation has been reconciled to the Civil Aviation Regulation of New Zealand.

Published by Civil Aviation Authority of Mongolia

Amendment 164 of Annex 1 to the Chicago Convention on International Civil Aviation urges flight crew members, ATC personnel and aircraft maintenance engineers to comply with the language proficiency requirements; and

Under Article 14 of the Civil Aviation Law of Mongolia 1999, “Use of foreign language in civil aviation” the AC has been released in English version only, in order to prevent any mistranslation and misuse of the aviation safety related documents.

This AC 00-3 was developed based on NZAC 00-3, dated on 24 July 2007.

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1. Background

A substantial change in regulatory requirements has taken place because of the recommendations of the Swedavia - McGregor Report of 1988. Previously, regulatory surveillance consisted mainly of inspection of end products of the aviation system. Little attention was given to the systems and procedures that produced them. The Civil Aviation Authority, in effect, provided an external quality control function for the aviation industry through a process of constant inspection and intervention.

Given the complexity of modern aircraft, aerodromes, and organisations engaged in aviation activities, this *hands on,* interventionist, approach from regulatory authorities is no longer appropriate. Inspections of end products provide a snap shot view of an organisation's activities and do not identify the underlying causal factors of the failures that occur.

The Swedavia - McGregor Report recommended that responsibility be placed on certificated organisations to have in place a Quality Management System with appropriate internal quality assurance procedures that constantly monitor, review and improve the organisation's performance.

The report concluded that it is more effective for the Civil Aviation Authority to examine the *system* that controls the activity, and ensure that there are appropriate procedures in place to address and achieve the required safety standard. Public safety is enhanced if deficiencies are identified and immediately corrected when they are discovered by the operator rather than waiting for discovery and reporting by a third party auditor.

1.1 Civil Aviation Rules safety standards

New Civil Aviation Rules (CAR) require organisations, seeking certification, to develop and maintain a safety policy and plan. The standards for the safety policy and plan are structured around elements of ISO 9000, Quality Management and Quality Assurance Standards.

The Civil Aviation Rules require the development, implementation, and maintenance of the elements of the ISO standard that will promote improved aviation safety, and, as a result, provide an environment in which aviation will operate with greater safely.

The Rules do not address all elements of the ISO standard, however, organisations certificated under the new rules will, if they so wish, have a sound basis on which to achieve ISO certification with its attendant benefits.

1.2 Quality Management System

To comply with a certificated-organisation Part, organisations seeking certification, must develop, document, implement, and maintain a Quality (Safety) Management System with appropriate internal quality assurance procedures. They are the planned activities that make up the Quality Management System.

The Quality Management System is the structure, responsibilities, processes, and procedures of an organisation that promotes and establishes an environment and culture of continuing improvement that will enhance the safety of the operations.

The Quality Management System and internal quality assurance procedures establish and provide for the organisation's self regulation. This set-up allows for the change in relationship between the organisation (now self-regulating) and the Civil Aviation Authority (no longer inspecting, now monitoring).

Internal quality assurance procedures will identify, document and correct instances of non- conformance, or non-compliance. These procedures must be put in place for all areas of the organisation's activities that are covered by the rules. Internal quality assurance procedures, as well as providing confidence in the organisation meeting regulatory compliance, can improve the organisation's commercial performance and should be of benefit to both the organisation and its customers.

This Quality Management approach, where certificated organisations carry out their own internal quality assurance, is being followed by the regulatory authorities of Europe and America. The information in this advisory circular closely follows that presented by the FAA in their AC120–59 and the proposal by the JAA in their Joint Advisory Material AMJ OPS 1.035. It is essential that our processes, leading to certification, closely follow those of the major international agencies so that Mongolian organisations can be internationally recognised.

Definitions of key quality terms and a description of the basic elements (internal quality assurance procedures) of a Quality Management System are included in this AC. These definitions and programme elements are consistent with recognised quality principles and standards. Where appropriate, these terms have been tailored to conform to aviation standards and practices.

1.3 Internal Quality Assurance Procedures

The standards described in section 4 are intended to help organisations develop a Quality Management System and their own internal quality assurance procedures. Appendix 1, 2, and 3 provides sample outlines of key quality assurance procedures to give organisations further guidance.

All Civil Aviation Rules for the certification of organisations state that an organisation is entitled to a Certificate if it meets the requirements of the rule. The Director must be satisfied that an applicant can conduct its proposed activities safely. The Quality Management System and associated quality assurance procedures will facilitate approval of the organisation's safety policy and programmes.

1.4 CAA Monitoring and Intervention

The Civil Aviation Authority monitors the industry by carrying out surveillance and

analysis to verify that operators are upholding their responsibilities. Internal quality assurance procedures are intended to assist the Civil Aviation Authority's monitoring process by identifying and resolving safety related issues. The internal quality assurance documentation and records provide a convenient 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 is developed to cross-reference where the exposition addresses or meets the requirements of the relevant Rule.

The results of Civil Aviation Authority audits act as a barometer of the organisation's performance. It will be apparent from the level of findings and resolutions in the internal quality assurance documentation and records whether the Quality Management System and the safety policy are functioning satisfactorily. The performance of the organisation will dictate the level of Civil Aviation Authority intervention that is necessary.

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

2. Definitions

The following key terms and phrases are defined to ensure a standard interpretation and understanding of the Quality Management System and internal quality assurance procedures.

2.1 Evidence

Evidence is a documented statement of fact that is based on observations, measurements, or tests that can be verified. For an internal audit, evidence should generally be written documentation or reports that support the Internal Quality Assurance procedures. This data is necessary to provide findings or concerns, to provide proof that findings and concerns are addressed, and to enable management, staff, or auditors to determine the root causes of any reported findings. Objective evidence generally comes from the following four elements—

- Documents or manuals reviewed
- Equipment examined
- Activities observed
- Interview data, provided this data can be substantiated by one or more of the above elements

2.2 Controls

Controls are management and operational techniques, activities, and procedures that monitor the satisfactory performance of the internal quality assurance procedures, including the organisation's operating processes and procedures. Reviews, in process

tests, checklists, spot checks and audits are all examples of Controls.

As part of an internal quality audit or review, the controls of the area being evaluated should be verified and tested. Sometimes, personnel performing the internal quality audit or review may have to first determine the features of a control.

2.3 Finding

A finding is a conclusion, supported by objective evidence that demonstrates non-compliance with a specific standard. A finding will generate a Corrective or Preventive Action.

An internal audit or review may also produce a conclusion that is considered a finding by the operator, but is not a non-compliance with the rule.

2.4 Concern

A concern is 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 a Preventive Action.

2.5 Root cause

The root cause is the underlying organisational cause, or causes, of any finding or concern. A root cause is always identified with a process, a procedure, methodology, or an organisation's structure or practices.

In the analysis of safety, quality, or operational problems, the root cause, or causes, should be determined before any corrective action is 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 or complaint needs to be made to ensure the corrective action(s) address not only the immediate cause but any latent or organisational problems.

2.6 Inspection

An inspection is 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. The primary purpose of an inspection is to verify—

(a) that established standards are followed during an observed event or action; and
(b) that the end result conforms with the specified requirements of the event or action.

2.7 Audit

An audit is a methodical, planned, review used to determine how activities are being

conducted, and compares results with how the activities should have been conducted according to established procedures. Audits are conducted for different purposes and have distinct identities that are defined for the purposes of this AC as:

First party audits are those conducted internally by the organisation, using its own trained staff, to evaluate the organisation's, 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.

The auditor must be independent of the function, operation or group being audited. For small operators it may be necessary to engage an outside agency. To contain costs, provided they can provide a substantive report and produce creditable findings and concerns, the outside agency could be—

- *a relative*
- *another small operator*
- *a sub-contractor*
- *a business associate.*

Second party audits are carried out by an organisation on its suppliers or subcontractors. These audits are intended to satisfy the contracting organisation that the subcontractor meets the agreed quality requirements.

Third party audits are those carried out by independent bodies such as regulatory authorities or commercial auditing companies. In the aviation industry one such body is the Civil Aviation Authority. They are intended to give the Authority an assurance that the organisation is in control and that the organisation's Quality Management System and internal quality assurance procedures are working effectively. Third party audits will confirm that non-compliances are being identified and corrected by first, or second, party audit.

2.8 Audit Construction

The various elements that comprise an effective audit are as follows:

(a) Audit preparation by the auditor(s)
(b) The opening or entry meeting:
  (i) introduce the audit team and confirm the scope of the audit;
  (ii) outline the audit process to be used and the schedule;
  (iii) confirm the resources, people and facilities needed for the audit are aware and available for the audit.
(c) The examination:
  (i) interview personnel, review documents, observe and inspect operations and select samples;

(ii) document evidence;
(iii) document findings and concerns.

(d) The closing or exit meeting:
(i) present findings and concerns;
(ii) establish a programme to close-out findings.

(e) A written audit report containing:
(i) descriptions of all the findings and observations with the supporting evidence;
(ii) the agreed corrective and preventive actions;
(iii) the schedule for follow up and the closure of the corrective and preventive actions.

3. Basis of the Quality Management System

The Quality Management System supports the requirement of the rules that operators are primarily responsible for continuously monitoring and ensuring that their operations are safe and in compliance with the rules.

A certificated organisation is required to establish a Quality Management System that embraces the following principles:

(a) A continual process that incorporates the techniques of inspections, audits, and reviews to assess the adequacy of managerial controls in key programmes and systems
(b) An ongoing process that identifies deficiencies, develops corrective action plans to correct these deficiencies, and performs follow-up reviews
(c) An independent process that, organisationally, has straight-line reporting responsibility to top management

The Civil Aviation Authority encourages organisations to extend their internal quality assurance procedures beyond regulatory compliance to determine the causes of other deficiencies in company operations. From these determinations the necessary enhancements to company operating practices can be made before deficiencies occur.

The quality policy must stress the self-audit responsibilities of individual employees as well as the organisation's management. Each employee has an equal responsibility to ensure that company policies and procedures provide for safety compliance and allows individuals to perform work properly.

The internal quality assurance procedures should not be misunderstood as a process that will replace the existing third party audit requirements that are carried out by the Civil Aviation Authority.

4. Internal Quality Assurance Procedure Guidelines

The Quality Management System of certificate holders must include the internal quality assurance procedures in their exposition.

The Quality Management System should include the following essential elements in the internal quality assurance procedures—

(a) definition of the organisation's management commitment and responsibilities to the quality plan and procedures. It is required that the organisation nominate a Senior Person, known in this AC as the **Management Representative,** to establish an independent and focused Quality Management System (see appendix 4); and

(b) a documented, approved, **safety policy** and plan to identify, implement, and maintain safety policy procedures that—
   (i) meet the requirements of the rules;
   (ii) are relevant to the applicant's organisational and business goals, and;
   (iii) meets the expectations and needs of its customers; and

(c) a procedure for—
   (i) **corrective action** to ensure existing problems that have been identified within the system are corrected, and;
   (ii) for **preventive action** to ensure that potential causes of problems that have been identified within the system are remedied; and

(d) establish a procedure to ensure the Quality Management System and the internal quality assurance procedures are subjected to continual, regular and structured **review**; and

(e) an **internal audit programme** to audit the applicant's organisation for conformity with the procedures in its exposition and achievement of the goals set in its safety policy; and

(f) a procedure to ensure **quality indicators**, including defect and incident reports, and personnel and customer feedback, are monitored to identify existing problems or potential causes of problems within the system; and

(g) a **records system** that clearly documents what has taken place, allowing statistical analysis to monitor the continuing suitability and effectiveness of the Quality Management System and the organisation's operation. The records will be used to indicate trends to allow the organisation to—
   (i) raise preventive actions to avoid potential problems, and;
   (ii) determine the best goals to set for the future; and

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

These elements are further described in the following sections 4.1 through 4.8.

4.1 The Quality Assurance team or Management Representative

An organisation's internal quality assurance procedures should identify a person or a group of persons, within the organisation, that has the responsibility and authority to:

(a) develop, implement and maintain the Quality Management System;

(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;

(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 Quality Assurance Team must have the delegated authority and responsibilities to allow them to work within the organisation to implement and maintain the internal quality assurance procedures. The Management Representative or the Quality Assurance Team will have a direct reporting line to the highest level of management necessary to sustain the management commitment to the organisation's Safety policy and plan.

For some organisations, operating size may justify the costs associated with the necessity of having full-time, dedicated, resources and personnel in a separate Quality Assurance Department or group. However, when full-time, dedicated, resources and personnel are not practical, the organisation should develop procedures that preclude persons directly responsible for the areas to be evaluated from participating in the selection of the audit team.

For very small organisations, an appropriate internal quality assurance procedure should consist of developing check-lists and a schedule for accomplishing the check-list items.

Each checklist must be signed. The operator must schedule an occasional independent review of the check-lists and the checklist items.

4.2 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 and that decision-makers should observe when modelling the corporate safety culture include:

(a) senior management places strong emphasis on safety as part of the strategy of controlling risks;

(b) decision-makers and operational personnel hold a realistic view of short- and long-term hazards involved in the organisation's activities;

(c) those in top positions do not use their influence to force their views or to avoid criticism;

(d) those in top positions foster a climate in which there is a positive attitude towards criticisms, comments, and feedback from lower levels of the organisation;

(e) there is an awareness of the importance of communicating relevant safety information at all levels of the organisation – both within it and with outside entities;

(f) there is promotion of appropriate, realistic, 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

(g) personnel are well trained and well educated and fully understand the consequences of unsafe acts.

4.3 Corrective and Preventive Actions

4.3.1 Corrective Actions

Internal quality assurance procedures should include a procedure to ensure that corrective actions are developed in response to findings or concerns.

The procedure should include:

(a) recording the corrective action;

(b) the allocation and acceptance of ownership;

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

(d) test that the corrective action is long-term and ensures the issue does not recur;

(e) regular reviews of root causes of all corrective actions.

4.3.2 Preventive Actions

The preventive action procedure is identical to the corrective action procedure. The only difference is 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.

4.4 Management Review

Management must, at regular intervals, review—

(a) the internal quality assurance procedures, the quality indicators, and inspection and test results to verify the Quality Management System is working;

(b) that the corrective and preventive actions have been recorded, implemented, and closed out;

(c) that the operation and quality assurance programmes are under constant review and improvement.

The organisation must prepare and conduct a programme to regularly review all company policies, processes, and procedures. The review should be carried out by dedicated staff. It will encompass all the activities, procedures, and processes of the organisation. The programme should be a comprehensive and continual process that considers the following:

(a) The overall effectiveness of the organisation in achieving its stated objectives.

(b) The ability of the internal quality assurance and the operational procedures to respond to new technologies, to market strategies, to legislative or regulatory changes, and to social or environmental conditions.

(c) Are the current processes and procedures up-to-date, effective, and relevant?

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

The management reviews with supporting documents will be recorded. The organisation will determine and document, as a quality assurance procedure, the frequency, format, and structure for informing management of internal quality assurance plans, trends, results, and follow-up actions. The procedure will define the responsibilities and the independence of personnel who perform or supervise the management reviews.

4.5 The Audit Programme

A mandatory element of the Quality Management System is the organisation's audit programme. The Audit internal quality assurance procedure will:

(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;

(d) identify the personnel to conduct the audit;

(e) provide training for the audit personnel

4.5.1 Planned Audits

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. Dependant on the size of the organisation the audit cycle might be greater than one year, however, eighteen months is the maximum.

Schedule the audit within each component to allow enough flexibility for resources to be committed.

4.5.2 Special Audits or Spot Checks

Conduct special audits, or spot checks, based on concerns or priorities identified by the organisation, external audits, or customer complaints.

Schedule special audits, or spot checks, based on a review of the organisation's, or industry, trends.

4.5.3 External Audits

External audits are initiated and conducted by agencies with a regulatory interest in the operation of the organisation. For example but not limited to, the Civil Aviation Authority, Occupational Safety and Health, and the Inland Revenue Department. 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 the external audits.

4.6 Quality Indicators

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

(a) Reports derived from the analysis 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 Quality Management System and the organisation's operation;

(d) Customer complaints;

(e) Customer surveys, external and internal.

4.7 Records

Records documenting the performance and results of carrying out the internal quality assurance procedures will be maintained by the organisation. 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. The record must be accurate, complete, reliable, and accessible.

It is recommended that following quality records should 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, being–
- customer complaints
- customer surveys
- industry news sheets
- observations through day-to-day contact
- comment during audit

(f) training plans and records; and

(g) the master copy of all policy and procedures.

4.8 Documenting Quality Assurance Procedures

Controlled documented internal quality assurance and operational procedures are a mandatory element and requirement of a Quality Management System and for all aviation certificated organisations.

Each organisation shall review the size and complexity of their operation to determine the scale of processes and procedures that will maximise the benefits of their Quality Management System and their operations. Consequently they will improve their safety level and the business results.

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

The Quality Management System is a process. The internal quality assurance procedures that are mandatory for an effective Quality Management System are defined in section 4 of this AC.

Each internal quality assurance 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, Acts, ACs, CASOs or an other reference standard or document initiating the procedure. For example, it is not sufficient, to pass approval or audit, for a procedure to simply state:
Organisation ABC will comply with Rule XYZ.

(c) be current and met the requirements of referenced document(s). For example. the rule;

(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.)

Each heading must be considered, but this list is not definitive, however, the headings denoted by an asterisk are mandatory.

5. Conclusion

The development, implementation, and conscientious application and maintenance of a Quality Management System and the associated internal quality assurance procedures, as discussed in this AC, will ensure that a certificated organisation is responsive to growth and change, and the organisation continually complies with appropriate safety and regulatory requirements.

Furthermore, it is strongly recommended that organisations make the Quality Management System an integral part of their everyday management process. Aviation safety is best served by procedures that allow organisations to identify and correct their own instances of non-compliance and invest more resources in efforts to preclude their recurrence.

APPENDIX 1

Title: 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.

Consideration should be given to including the following standards:

(a) List of effective pages;

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

(c) Every policy, procedure or work instruction to be written as a *stand alone* document, and will be 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;* and

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

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) allow any member of the company to initiate 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 cannot be 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 company 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.

Define the number of amendments a document may have before it will be reviewed against current documentation and editorial standards and if necessary re-write and re-issue the document to conform with current standards and practices.

5. External Document Review

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

External documents used for day-to-day activities must be current. Any person using these documents for day-to-day activities must check and maintain the currency of the documents each time the document is used.

APPENDIX 2

Title: 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 of time 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

Title: Management Reviews

Purpose:

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

Procedure:

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

The Manager and Management Representative will nominate the attendees. The agenda should include a the 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

Title: Management Representative

Purpose:

To define the role and responsibilities of the Management Representative.

Definition:

Management representative— The Management Representative is delegated by the Senior 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 absence of the Manager

(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 the implementation 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) The preparation and distribution to the Manager and the team, statistical information and survey results that measure and test: the current processes and the organisation’s performance.