Revision History

Rev. No.	Effective Date	Page	Description of Change	Change Reason
00	09.09.2009	All	New Release	Nil
01	12.01.2013	All	Definition of AOC	Improvement

Approved by:
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Principal

1. OBJECTIVE

This procedure describes the process for initial, surveillance, recertification certification assessment of Management Systems and Integrated Management Systems (QMS, EMS, HSMS and IMS… respectively) including sector schemes.

2. PRE-ASSESSMENT (OPTIONAL)

Upon a request for a pre-assessment the EFRC shall establish the object of the pre-assessment with applicants prior to taking any action. The EFRC shall appoint the Lead Assessor to carry out the pre-assessment. The Lead Assessor may be supported for the pre-assessment depending on the scope and specialisation of the applicant. A written report shall be prepared by the Lead Assessor for EFRC and this will be made available to the client. Pre-assessment should not be confused with consultancy and it should not be used in lieu of any part of the certification assessment. A pre-assessment is defined as:

"Assessment of a client's management system prior to the performance of a certification audit to determine the client's ability to satisfy the requirements of the certification standard and where appropriate, supplementary requirements".

3. ASSESSMENT

The Assessment process comprises the following stages:

- Instructions to the Lead Assessor
- Audit Stage 1 - Preparatory review of the Client's Manual/Initial Visit
- Audit plan
- Audit Stage 2 - Certification Audit and Client Response, if required
- Audit Stage 3 - Audit Follow-up/Close-out activity, if required
- Preparation of Assessment Report

4.1 Contract Acknowledgement and Client Information

As per application review SOP

4.2 Instructions to Lead Assessor

The EFRC shall ensure that the Lead Assessor, any support assessor and technical specialist receive an schedules enclosing selected working documents and any special instructions. Additionally a copy of the application form denoting the intended scope of assessment will be included in the pack for the Lead Assessor.

4.3 Audit Stage 1

The Lead Assessor shall arrange and confirm any required initial visit with the client and advise the EFRC of the date. Initial visits should address the following:

(a) Confirmation that the intended Scope of Assessment and Standards are appropriate at the time of the assessment. The company can address any limitations within the agreed scope by completing FM921
(b) Review the system manual to ensure each requirement of the assessment standard(s) has been appropriately addressed.
(c) for ISO 9001:2008 audits include a review that the 8 quality principles are embodied in policy and objectives and are appropriately cascaded to procedures (see ISO 9000:2008); and that permissible exclusions; top management commitment; and customer satisfaction are addressed.
(d) mark up the client questionnaires as appropriate.
(e) notify the client in writing of any deficiencies and require them to be addressed for review and agreement at Initial Visit/Audit as appropriate.
(f) mark up the applicable sections of document FM921 including date arranged for any Stage 2 Visit, and send this to the EFRC.
(g) advise the EFRC of any proposed actions to significant deficiencies.
(h) Significant deviations outside the scope details on the Application Form or EFRC's instructions shall be reported to the EFRC / Hub Office for guidance **prior** to the Audit. An example of this is a significant difference in the number of staff at the client site from application form. It is the LA's responsibility to check that there is no difference between the technical review or make-up sheet and the actual audit conditions
(i) Confirmation that all the documentation required by the standards is in place and controlled, and reflects process complexity needs including claimed exclusions to the reference standard with no obvious omissions.
(j) Client process-walk to assist in preparation of an audit plan FM922
(k) Confirmation of the maturity and integrity of the client's management system i.e. the level of implementation and effectiveness of the internal audit and management review

(l) Initial Visits for Initial Certification of FM921
(g) The lead assessor shall report the outcome of Audit Stage 1 to the EFRC. Any deficiencies shall be recorded at the visit in a brief written statement requiring the client to respond with agreed remedial action.

4.4 Issue Plan

The lead assessor shall prepare a written plan FM922 and send it to the client with a copy to the EFRC. The latter shall receive this at least 2 weeks prior to the audit date. The deadline is the same in the case of an accreditation witnessed audit.

4.5 Audit Stage 2 – On Site Certification Audit

The Assessment team shall perform an audit of the client's implementation of its Management System and associated documentation to satisfy the requirements of the audit standard and to provide objective evidence for a report.
Audits may be witnessed by an Accreditation Body

(a) Assignment

The assessment team shall comprise the Lead Assessor (already assigned) and any Support Assessors, selected by the EFRC. The Lead Assessor is responsible for conducting the initial audit and controlling the activities of the other team members during the audit. This includes distributing all relevant documentation to all team members.

(b) Opening Meeting

At the commencement of the assessment, the assessment team will hold an opening meeting with the client's management.

(c) Audit Activity

The assessment team will perform the assessment in accordance with the assessment plan (e.g. client's process sequence) agreed at the opening meeting, using the questionnaire to identify applicable client procedures. Stage 2 Key objectives:

- Confirm client adheres to its policies and objectives and procedures
- Confirm Management Systems conform with audit standards in achieving policy objectives
- Confirm effective links between policy, environmental aspects and impacts, customer needs development, objectives/targets, programmes and resources, monitoring and measurement and feedback for management of improvement resources

For Integrated Audits e.g. Quality, Environmental and Safety Management Systems:

- Account shall be taken of the commonalties between the management system activities and their shared procedures. The aim shall be to achieve an efficient audit whilst ensuring that systems are compatible, interfaces are effective and that the individual requirements of each certification standard are addressed during the audit.

In QMS ISO 9001:2008 audits attention should be given to:

- confirm validity of permissible exclusions
- verify embodiment of the **8 Quality Principles:**

1. Customer needs and improvement focus
2. Organisational leadership for:
3. Involving people in achieving goals,
4. Process approach,
5. System approach to managing processes and improvement,
6. Continual improvement,
7. Fact/analysis based decision making,
8. Mutually beneficial supplier relationships

Key audit trails followed shall be identified and cross-referenced to any findings such that data may be revisited to ensure effective close out and to provide confidence in the depth of the audit. This may be conveniently noted on the client questionnaires or identified in the body of the audit report. Sector scheme checklists/questionnaires shall be completed as required under their scheme.

Factual findings will be recorded at the time of occurrence and agreed with the client. Findings shall be collated at the end of the audit and either non-conformities (CAR's) or opportunities for improvement (OFIs) prepared using a CAR form and form part of the final report.

Here is a reminder of the definitions of various audit findings:
We distinguish 5 types of audit finding:

1 - Major Non-Conformity (NCR)

- non-fulfilment of a requirement of the reference standard affecting the organization, application or formalisation of the Management System and resulting in a proved risk (i.e. based on objective elements) of non-compliance, recurrent or unique in the case of substantial risk, of a specified requirement. Depending on the reference standard, the risks to be taken into account concern different interested parties:

- ✓ for quality it will primarily concern the customers,
- ✓ for environment it will concern the community in the wide sense,
- ✓ for safety it will concern the personnel.

- non-fulfillment of a requirement calling into question the effectiveness or the improvement of the Management System.

2 - Minor Non-Conformity (NCR)

- non-fulfillment of a requirement of the reference standard affecting the organization, application or formalisation of the Management System and which does not result in a proved risk of non-compliance of a specified requirement.
- non-fulfilment of a requirement not calling into question the effectiveness or the improvement of the Management System.

For each finding relating to non-fulfilment of requirement (discrepancy), the auditor should:

- recall on the discrepancy form the requirement of the standard (or of the reference document) which is partially or entirely non-fulfilled,
- indicate clearly either the paragraph number or even the sub-paragraph number and not simply the chapter of the given reference standard, or the customer or self-specified requirement,
- indicate clearly the type(s) of the reference standard(s) in case of an audit covering several reference standards. Major and minor non-conformities are formalised in the document "Corrective Action Request FM923

3 – Area of Concern (AOC)

Area of concern is Potential NC. Point for which factual observations show that the organization may risk no longer fulfiling the requirements of the reference standard in the short or medium term. OFIs do not require proposition of corrective actions to the EFRC, nevertheless, this aspect will be audited in priority during the next audit.

In cases where effectiveness or maturity is assessed, the AOC will be linked to the possibilities of moving up to a higher level and potential of violationg continual Improvement

4 - The Strong Point (Str P)

Point for which the organization has gone beyond the standard's requirements in such a way as this can be proved.It can also be an effective working means or method implemented by the organization . A strong point is either an element which goes beyond the standard's requirements, or an element which does not go beyond the standard's requirements but, on

which the organization can rely if it wants to keep its performance level or, if it wants to beyond the standard's requirements.

5 - Opportunity for Improvement [OFI]

Point for which factual observations recommended by the auditor. It shall be review in management review but action is not mandatory.

Note: these last three types of finding should be pointed out during audit conclusions and explained, like the discrepancies, at the closing meeting. Where multi-site audit reports are combined into a single report, the auditor providing the synthesis should ensure that the strong points, weak points, non-conformities, etc. are identified by the site they are related to.

(d) Closing Meeting

At the completion of the assessment, the assessment team will hold a closing meeting with the client's management.

(e) Preparation of Corrective Action Requests (CARs)

If not raised on the last day of the audit, CARs and OFIs shall be prepared on CAR form FM923 from the audit finding sheets as required by procedure MCP 33. Findings can be collated onto a single CAR for each area of the standard.
Within 1 week of the closing meeting the lead assessor shall send originals of each CAR to the client with a request to propose corrective actions/completion time-scales in the section provided on each CAR.

4.7 Audit Stage 2 - Client Response – CAR Proposals

After completing the response, the client shall return a copy of the CARs to the Lead Assessor and keep the original until final closeout.

If a response is not received within 1 month of the audit closing meeting then the Lead Assessor shall advise the EFRC/Hub Office in writing (except OFIs.). Corrective action is not required to obtain certificate for an OFI. The LA informs the client of this.
The Lead Assessor shall review the CAR corrective action responses and check they are appropriate and have the potential to address the non-conformities and their root causes within an appropriate time-scale.

If the responses do not have such potential or the proposed time-scale for completion of corrective action is greater than 3 months from the audit closing meeting then the Lead Assessor shall advise the Certification Manager in writing.

3.8 Audit Stage 3 - Follow-up/Close-out activity and decision-making

The Lead Assessor shall arrange a mutually acceptable date with the client to visit the client and verify the completion of the corrective action. Both parties will sign the appropriate section of the CAR, the original being kept by the assessor for the report and a copy left with the client.

All non-conformities major and minor found during Aerospace initial and reassessments shall be verified as closed out prior to issue of certificate. For H&S, E & Q audits, certification cannot be issued, maintained or renewed as long as there are any major non-conformances which have not been closed and/or as long as a minor non-conformance from a previous audit has not been closed, that calls into question the effectiveness or improvement of the MS. In this case the EFRC decides on what action to take.

For initial H&S, E & Q audits, if the proposed corrective action is essentially long term and both the proposal and action taken give confidence in obtaining compliance to the requirement at the time of the review of closure, then the final verification for definitive closing of the finding is done on-site during the next audit. However during the next audit, non-conformances not addressed are upgraded to a major non-conformance.

4.9 Preparation/Completion of Assessment Report

The audit report is composed of modules to document audit stages 1, 2 and 3. These modules are as follows:

- Preparatory Review
- Audit report for Initial and re-assessment
- Audit report for surveillance
- Appendix to audit report
- Appendices for 'specific' standards (sector specific)

	Documents used by the auditor	**Documents sent to the client (1)**	**Document sent to the EFRC for decision**
Audit preparation and audit plan (only for initial and	Stage 1 audit FM921	Stage 1 audit FM921	Stage 1 audit FM921

renewal)			
Initial or recertification audit	FM924	FM924	FM924
Surveillance audit	FM924	FM924	FM924

(1) The appendix can be provided, if it has been defined during the contracting with the client.

When the appendix doesn't need to be sent to the client, the auditor can use hand-written note form, as long as it remains readable and easily understood by the EFRC.

There are 2 key purposes of the audit report.

- To satisfy the client who has been audited that their system is effective, compliant and highlight any areas that need further consideration.
- To satisfy the EFRC that an effective audit has taken place to enable a certification decision to be made.

The Lead Assessor shall prepare the Assessment Report FM924 using the headings given. The report should be balanced and present the client's:

- Strong points
- Opportunities for improvement (sensitive points)
- Way of improvement

Attention should be given, for example, to report on the level of conformity in customer focused and key process/environmental impact areas and where the client has introduced improvements or performed well, as well as reporting areas of non-conformity.

The report should also indicate the level of implementation and effectiveness of the client's internal audit and management review system including the reliance that can be placed on the internal audits and for ISO 9001:2008 certification audits confirm that the system embodies the 8 Quality Principles.

The reports should include a statement verifying the client's own evaluation of their performance against legal and regulatory requirements. For QMS, the requirements must be checked and are mandatory when:

- They apply to the product and the conditions in which it is produced and used (if the use is known).

- apply as compulsory measures for the product (laws and their associated regulatory texts, such as decrees and statutes),
- concern the safety of use of the product or of provision of a service (passenger transport for example),
- have an impact on the quality of the supplied product because they set the requirements concerning design, manufacture, service provision or marketing.

The EMS and HSMS reports should include a statement about the key performances of the system and should be followed and reported during all the certification cycle. See Appendix 3 for the elements for which factual data are required in the audit report.

The Lead Assessor shall complete the Audit report and include a statement that close out has occurred and the Lead Assessor is satisfied with the outcome i.e. recommend the issue of a certificate. The Lead Assessor shall forward the completed Audit report to the EFRC.

The EFRC requires a minimum of content from the audit reports in order to make a decision.

5. COMPLAINTS AGAINST A CLIENT – REVIEW OF DATA BY THE EFRC AND ACCREDITATION BODIES

Customer complaint and product non-conformity data shall be made available to the EFRC and to authorised representatives of the Accreditation Bodies upon request through EFRC.

7. DOCUMENTS

The relevant documents are:-

FM921 Stage 1 Audit Report
FM922 Audit Plan
FM923 CAR
FM924 Audit Report

Sector schemes AS9100 (Aerospace), TickIT, ISO13485, QS-9000 & TE Supplements
AS 9101 - Aerospace Sector Scheme Questionnaire (less financial section)

APPENDIX 1 - PREPARATION OF AN AUDIT PLAN

1.0 General

The audit plan is done after preparation where the LA (preparatory review form) states the audit feasibility.

1.1 The audit duration in mandays shall be as defined on the Job Sheet. If there appears to be a need for a significant (>½ manday) reduction or increase in the time spent on a particular part of the audit the reasons shall be recorded by the Lead Assessor and referred to the EFRC / Hub Office.

1.2 The audit plan shall be drawn up to reflect the client's process sequence and so that all sections of the Assessment Standard are addressed. This means all sections of each assessment standard for an integrated audit.

1.3 The audit plan should be flexible to ensure effective use of resources in meeting the audit objectives.

1.4 The audit plan shall be provided to the client in writing 2 weeks prior to the audit with a copy to the EFRC / Hub Office.

1.5 Any change of dates shall be notified immediately to the client and the EFRC / Hub Office.

2.0 Plan

2.1 The Lead Assessor and the client shall agree the audit dates and the areas to be covered each day.

2.2 The formulation of a detailed audit plan is the ultimate responsibility of the Lead Assessor. However, the following points should be considered:-

i. The client's process sequence so that the interfaces and interaction of various procedures and resources can be audited, and for ISO 9001:2008, where the 8 quality principles operate and may be audited, e.g. customer needs focus/continual improvement.

ii. Physical location of different functions within a large site and/or location of functions or facilities at locations in other parts of the country. Note that sampling of Sites for AS 9100 and QS9000 audits is not permitted.

iii. Possible different start and finish times for works and office staff.

iv. The level of work being undertaken on products within the proposed scope noting any technologies or processes requiring specific assessor knowledge.

v. Provision of organisation chart with names of the current post holders.

vi. Provision of a current contract list to facilitate an audit trail

vii. The need to split an audit team in order to enhance audit efficiency.

viii. Review of outstanding CARs from a previous (not current) Certification or Registration Body

ix. Team debriefing sessions.

x. Proposing a time for the closing meeting, to allow department heads to plan their diaries.

2.3 The Audit Plan shall include:-

i. The type of audit: Initial, Surveillance, Renewal, Extension scope, Follow up.

ii. The date of the audit and the details of the areas to be visited each day including the expected time and duration of each major audit activity.

iii. The Management System Standard to be used for the assessment, together with any supplementary sector scheme i.e. Aerospace, TickIT, ISO 13485, etc.

iv. The names of the people forming the assessment team.

v. The audit report distribution.

vi. The language of the audit, where deemed appropriate.

vii. For Integrated Audits (e.g. ISO 9001 and ISO 14001) the plan shall show plan items where either or both standards apply and the assigned auditor.

The Audit Plan shall also carry the appropriate logo of the EFRC.

APPENDIX 2 - Assessment Opening and Closing Meetings

Opening Meeting

(i) The Lead Auditor introduces the EFRC in operation.

(ii) Assessment team members introduce themselves.

(iii) Confirm the objective and scope of the audit and audit standard.(Discuss any changes)
Significant deviations outside the scope details on the Application Form or EFRC's instructions shall be reported at once to the EFRC / Hub Office for guidance.

(iv) Confirm the assessment plan – changes should be addressed due to changed circumstances e.g. availability of personnel.

(v) Confirm availability of relevant documentation, audit guides and office accommodation and that the audit team will comply with any rules or restrictions operating within the audited areas.

(vi) Advise the client that the method of assessment will be by sampling and that where no deficiencies are found this does not imply they do not exist.

Closing Meeting

(i) Signatures on the attendance register.

(ii) Thank the client for their co-operation during the audit.

(iii) Reconfirm scope of the assessment and the assessment standard. The details on document (scope wording) shall be reviewed and confirmed with the client.

(iv) Present the non-conformities, opportunities for improvement, strong points and ways of improvement arising from the assessment to ensure that they are fully understood and acknowledged. Also present the audit summary sheet. (Any finding sheets will be collated by the lead assessor and summarised and cross referenced onto Corrective Action
Requests (CARs) for each Audit Standard clause heading.

The lead assessor shall send these CARs to the client within 1 week). Non conformities presented to the client during the closing meeting may be reformulated

during the meeting , in order to be understood by all parties. Subsequent to this meeting, their wording and the classification in major or minor non-conformity is final (even if they are still hand-written). They must also be understood by third parties. Any unexplained abbreviations, "in-house" jargon, etc. making understanding difficult must therefore be avoided. If the client does not agree to one or more findings, he shall record it on an attendance register and explain his disagreement.

(vii) Present an overall summary and conclusion of the assessment Team's findings.

(viii) Invite the client to discuss any specific points.

(ix) Required to the non-conformities. The effectiveness of the corrective action taken will be evaluated by the Lead Assessor at a close-out visit to be arranged.

(x) Explain that the assessment is only a sample of the management system and the onus for maintenance of the system rests with the client.

(xi) Briefly explain the certification process that follows close-out, i.e. review of final report by the Certification Manager for a certification decision and subsequent issue of certificate.

APPENDIX 3 - ENVIRONMENTAL OR HEALTH & SAFETY PERFORMANCE

The following data has been identified in the last audit; any evolution should be indicated in the report.

- General presentation:

- ✓ Surface area
- ✓ Number of employees (not forgetting interim and casual labour)
- ✓ Administrative situation
- ✓ The nature and volume of the activity / activities
- ✓ Additional facilities

- Environmental description
  - ✓ A description of the environment:
    - Natural environment (discharge environment, protected species, etc.)
    - Urbanisation
    - External relations (existence, frequency, quality,...) with:
      - Administrative departments
      - Neighbourhood
      - Associations
      - Others

  - ✓ Environmental aspects and impact, in the normal situation, with respect to specific themes (see note 1) and the conclusion concerning how adequately these aspects and impacts have been identified in relation to:
    - Activities
    - Products
    - Services
    - Environmental aspects and impacts, in the accidental situation, with respect to specific themes(see note 1) and the conclusion concerning how adequately these aspects and impacts have been identified in relation to:
      - Activities
      - Products
      - services

Note 1: Environmental points (Water, Waste, Soil and subsoil, Power sources, Air, Noise, Other environmental aspects or impacts)

- Safety description
  - ✓ A presentation of safety:

    - Description of organization / responsibilities,
    - Organization of delegation of power,
    - Auditee's perception of prevention measures taken,
    - Frequency rate (over the current year and preceding year),
    - Severity level,
    - Level of contribution (over 2 years),
    - Number of days stoppage, average duration of stoppage, total number of hours worked,

- Total number of hours training

✓ Description of the environment:
- Risk of aggravating accidents due to a potentially harmful environment
- Presence of dangerous activities in the vicinity (domino effect)
- Urbanization

✓ Significant hazards and risks associated with the activities in the normal situation and description of the risk control methods.

✓ Significant hazards and risks associated with the activities in the accidental situation.

✓ External relations (existence, frequency, quality, etc.) with:
- Inspection / advisory body,
- Work inspectors,
- Insurance,
- Others (specialized associations, etc.).

✓ Internal relations (existence, frequency, quality, etc.) with:
- Workers representative: work's council,
- Occupational medicine,
- Others

Appendix 4 – Minimum content required in the audit report for making a decision

The report is standardized, and the content should also be standardized in terms of providing information.

The following information should appear in the audit report.

Description of the Company

- Information about the company: size, income data, structure….

- Description of all the activities, including non certified, with description of the incoterms i.e. the responsibilities in the realization process (design, realization, sales -within a Group, to the costumer…-, transport, and delivery… To understand a Management System, we should know what the MS must control.

- Organization:
  - ✓ People and the organization: staff, continuous working patterns (3x8, 2x8, seasonal working, works during the week end…)
  - ✓ Type of task (simple, complex…)

Elements for audit trail

- Number and category (executives, employees…) of people interviewed by process.

- The auditor describes the audit realization and the observations. It should be very close to the audit plan and describes the processes observed, and gives special focus to interfaces with other processes (input/output) and control of the management system.

- Positioning / evaluation by the auditor on the efficiency of the processes and organization, the ability to reach the conformity and to improve.

Elements for standard requirements

For each chapter, or at least the main ones, we should find information structure on PDCA (Plan, Do, Check, Act) continuous improvement cycle:

- The elements are planned
- The elements are implemented
- The elements are realized
- The elements are measured
- The element are improved / corrected

For each one, when applicable, evidence observed (tools, proofs, results, objectives…). The appendix to the audit report is written for initial and renewal audits. For surveillance audits, the auditor only indicates the modifications since the previous audit, so that the reader can easily identify any changes. When the appendix doesn't need to be sent to the client, the auditor can use handwritten note form, as long as it remains readable and easily understood by the EFRC.

REMINDER: For an OFI, corrective action is not a requirement for certification decision, excepting some specific standards (AS 9100).

Elements for the CAR forms

The non-conformity description must provide:

- The standard requirement concerned and/or the MS requirement
- Description of the element observed:
  - ✓ The practice observed
  - ✓ Factual evidence (references of products, …) of non-compliance
  - ✓ If not clear, why it doesn't comply with the requirement
- Risk: what is the impact of the non-compliance (product conformity, client satisfaction, improvement process…)
- A statement about the capacity of the system to remain conform

The client provides analysis of the causes and then proposes corrective actions, and the auditor chooses whether to close out the discrepancy or not. He will indicate if the corrective action gives him confidence for correction and if a verification on site is necessary or not.

During the next audit, he checks and closes definitively (or not) the non-conformity.

The paragraphs to be examined over the three years audit programmed is elaborated during the initial and renewal assessment. The audit team should demonstrate that the entire system is reviewed during the three years cycle. Some processes and requirements should be reviewed systematically and specifically (e.g. production processes, major risk of failure on conformity …) and others via the audit of the production processes, not specifically.