APPROVAL OF A FIRM AND ITS QUALITY MANAGEMENT SYSTEM (AFQMS)

ISSUE I, DECEMBER 2011

DIRECTORATE GENERAL OF AERONAUTICAL QUALITY ASSURANCE

GOVERNMENT OF INDIA, MINISTRY OF DEFENCE
`H' BLOCK, NEW DELHI -110 011

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सचिव (रक्षा उत्पादन)
Secretary (Defence Production)

FOREWORD

Air Defence preparedness of a country depends on the quality and reliability of the aircraft. With constantly advancing technology, new concepts in Quality Management System have emerged through different international standards such as ISO 9000 series standard, AS 9100 Aerospace Standard, NATO Allied Quality Assurance Publications etc. It is imperative that Directorate General of Aeronautical Quality Assurance (DGAQA) keep pace with the changing environment.

I am glad that the "Approval of a Firm & its Quality Management System" document has incorporated latest versions of International Standards on the subject, while taking also into account the required local adaptations.

Use of this document by DGAQA for approving firms and carrying out QA activities in military aviation will improve the Quality Management System of aviation firms, leading to improved quality and reliability of aircraft. I am confident that it will provide extra confidence to the Indian Air Force. Increased quality and reliability of aviation systems and aggregates is the key to user satisfaction and therefore the release of this updated document of DGAQA is a step in the right direction.

I urge all involved in the design/development/production/repair/ overhaul of aviation systems in the defence sector to strictly adhere to this document.

(Shekhar Agarwal)
Secretary (DP)

New Delhi
29th Dec 2011

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PREFACE

The issue I of this DGAQA document dealing with "Approval of a Firm and its Quality Management System" has been necessitated due to rapid changes in the concepts of management in the field of quality assurance during design, development, production, overhaul & maintenance of military airborne stores. Areas like project management, configuration management, risk analysis, outsourcing, multiple suppliers, multiple vendors and increasing costs of military equipment, coupled with use of high end technologies have all impacted quality management.

Keeping in line with the technological developments, the defence ministry has emphasized on modernizing the way of working of the aeronautical industry in general and of DGAQA in particular.

This document will guide the stakeholders in military aviation towards the best practices in the world. Accordingly, earlier version of two DGAQA documents i.e. "Approval of a Firm's Inspection Organisation (AFIO) and Quality Control System Requirements (QCSR) for industry", have been updated and merged into this single document.

The document has incorporated the major features of present day standards such as AS 9100 (Revision C), ISO 9001-2008 etc. It also takes into account special requirements of DGAQA developed over the years as a result of interaction with the defence manufacturers. I hope this document will streamline quality assurance procedures and improve the air preparedness of the country.

(Manoj Saunik)

New Delhi
29 Dec 2011

LIST OF AMENDMENTS

Sl. No.	Amendment No.	Date of Amendment	Brief of Amendment	Authority

TABLE OF CONTENTS

LIST OF ACRONYMS

AQAP	-	Allied Quality Assurance Publication
AS	-	Aerospace Standard
ATE	-	Automated Test Equipment
ATF	-	Aviation Turbine Fuel
BARC	-	Bhabha Atomic Research Centre
CEMILAC	-	Centre for Military Airworthiness & Certification
CM	-	Configuration Management
CMP	-	Configuration Management Plan
CSI	-	Customer Satisfaction Index
DDPMAS	-	Design, Development & Production of Military Airborne Stores
DGAQA	-	Directorate General of Aeronautical Quality Assurance
DGCA	-	Directorate General of Civil Aviation
FOL	-	Fuel, Oil and Lubricants
GHE	-	Ground Handling Equipment
GSE	-	Ground Support Equipment
HAL	-	Hindustan Aeronautics Limited
IAF	-	Indian Air Force
IAQG	-	International Aerospace Quality Group
IIT	-	Indian Institute of Technology
ISO	-	International Standards Organization
ISRO	-	Indian Space Research Organization
IV & V	-	Independent Verification & Validation
NABL	-	National Accreditation Board for Testing & Calibration of Laboratory
NC	-	Non-Conformance
NDT	-	Non Destructive Testing
QA	-	Quality Assurance
QMS	-	Quality Management System
QAP	-	Quality Assurance Plan
RCMA	-	Regional Centre for Military Airworthiness
RDAQA	-	Regional Director, Aeronautical Quality Assurance
SOP	-	Standard of Preparation
UAV	-	Unmanned Aerial Vehicle

PART - I

APPROVAL OF A FIRM

SECTION – I

GENERAL CONDITIONS

1. Introduction
2. Grant of approval
3. Categories of Approval
4. Sub-contracts / Out sourcing
5. Special requirement for approval in the areas of Software Design and Development

SECTION –II

SALIENT FEATURES FOR APPROVAL OF FIRM AND ITS PERSONNEL

1. Introduction
2. Approval of Q.A. Staff
3. Approval of operators and their competence
4. Personnel involved in special process
5. Technology for execution of scope of activities
6. Accommodation and Equipment
7. Stores
8. Records
9. Testing
10. Release Notes
11. Inspection Stamps
12. Operator Stamps
13. Stamps for special processes
14. Production permits and concessions
15. Defect Investigation of premature failures of products released by Main Contractor
16. Application for grant of approval by DGAQA

SECTION –III

APPROVAL OF FIRM'S QUALITY ASSURANCE PERSONNEL

1. Requirements.
2. Procedure
3. Supervision

APPENDIX `A' : Format of application for grant of approval to a Firm by DGAQA.

SECTION - I

GENERAL CONDITIONS

1. INTRODUCTION

Directorate General of Aeronautical Quality Assurance (DGAQA) is the Quality Assurance Authority & Regulatory Body for Military Airborne Stores under the aegis of Ministry of Defence, Department of Defence Production, Government of India.

Firms dealing with design, development, production & installation/repair/modification/ overhaul of Military Airborne Stores like defence application aircrafts (including UAVs, missiles) aero-engines and associated accessories/systems/armaments including Ground Support Equipments for the same, are required to obtain firm's approval from DGAQA for carrying out such activities against Defence Supply Orders for which DG, AQA has been identified as the inspection authority.

2. GRANT OF APROVAL

2.1 A firm seeking approval of DGAQA should provide evidence that either it is in possession or likely to receive an order for development/supply/service of military airborne stores and associated Ground Handling/Ground Support Equipments. On receipt of such application, DGAQA or their authorised representatives shall organize audit of the firm for assessment of their resources including effectiveness of their Quality Management System. Part-II of this document deals with the detailed requirements of Quality Management System for such firms.

2.2 On being satisfied with the infrastructure, resources and existence of an effective Quality Management System, a letter/certificate of approval will be issued by DGAQA giving following details:

2.2.1 Name of the Firm

2.2.2 Approval Reference Number

2.2.3 Scope of Approval

2.2.4 Validity of Approval

2.2.5 Terms & Conditions of Approval

2.2.6 Names of release note signatories

2.3 DGAQA/ Resident in-charge shall be responsible for executive Q.A. function & effective supervision on continual basis for assuring that the products/services supplied by the main contractor meet the specified requirements.

2.3.1 Level of intervention of DGAQA will be mutually decided based on performance of airborne stores & effectiveness of the QMS at the firm.

2.3.2 Conduct of audits, spot checks or level & stages of re-verification by DGAQA shall be mutually decided based on criticality of stores, areas of concern, priorities and customer complaints.

2.3.3 For major projects, at the start of each project, level & stages of re-verification will be mutually determined between DGAQA & the Main Contractor based on risks involved. Periodic review of the same will be done by DGAQA in co-ordination with the main contractor.

2.4 Pre-requisites for grant of Approval:

2.4.1 Approval may be granted subject to satisfactory assessment of the firm by DGAQA after ensuring the availability of the following:

(i) Requisite infrastructure, buildings, workspace and associated utilities, process equipment and supporting devices such as transport, communication etc.
(ii) Availability of experienced and trained manpower having requisite competency and skill for carrying out specified activities on the aircraft and associated systems/accessories. This shall include organisation for ensuring quality of products/services.
(iii) Machineries & associated Ground Support Equipments/Systems specified in the technology of proposed activity.
(iv) Work environment such as Temperature, Humidity, Lighting, Cleanliness etc, as applicable, to achieve conformity to product/service requirements.
(v) Implementation & Maintenance of Quality Management System and continuous improvement of its effectiveness.
(vi) The firm shall also have the clearances from local authority/body for registration of the firm to carry out the business and meeting all safety requirements meant for the type of industry.

2.4.2 Primary responsibility for quality of products/services rests with the main contractor.

2.4.3 Procedure for non-conformance control of products/services is to be strictly followed (Root cause analysis, Corrective/Preventive Action) as per defined documentation.

2.4.4 Non-conformances with respect to Ground Support Equipments or testing requirements vis a vis specifications are to be controlled as per documented procedure.

2.4.5 Only acceptable products/services will be offered by the concerned approved inspection personnel of the main contractor to DGAQA representative(s) for re-verification as per agreed programme identified in the

approved QA plan. Main contractor top management should take serious note of the non-conformances reported by DGAQA representatives during their check stages inclusive of observations during spot/surveillance checks as these will be indicative of discrepancies in the Quality Management System of the firm.

2.4.6 The approval is subject to satisfactory Periodical Audits by DGAQA. Non-Conformances of minor nature during such audits will need to be corrected at the earliest possible. In case of Major Non-Conformances or not adhering to given time frame for resolution of other non-conformances, issue may need to be taken up with top management for resolution.

2.4.7 Any changes in the scope of approval of products/personnel should be mandatorily brought to the notice of DGAQA for appropriate action/amendment in the approval letter by DGAQA who will take appropriate action within next one month of receipt of information from the main contractor.

2.4.8 For renewal of approval, the firm shall apply at least 3 months in advance through respective Regional Director/Resident Officer-In-Charge, DGAQA with an advance copy to HQ, DGAQA. The case for renewal of approval at HQ will be processed within 30 days of receipt of recommendation from respective Regional Director/Resident Officer-In-Charge, DGAQA.

NOTE : Redressal in case of disputes on the understanding and implementation of this document between the Resident Office of DGAQA and the Main Contractor shall be addressed by HQ, DGAQA and Corporate Office of the Main Contractor.

3. CATEGORIES OF APPROVAL

3.1 DGAQA Approval may be granted for the following categories:-

3.1.1 Design/Development/Manufacture/Repair/Overhaul/ of Aircraft, Aero-engines, Air Armaments, Missiles, UAVs, Electrical and Electronic Equipment, Instrument etc, and their components / accessories or supply of Raw Materials including critical aircraft consumables such as Fuel, Oils & Lubricants produced indigenously.

3.1.2 Process workshops (Protective Treatment, Heat Treatment, Plating, Surface Treatment, Painting etc.).

3.1.3 Stockists of the above, for Certification that they are re-consigning parts or materials received from approved sources including foreign origin in the condition in which received & storage in specified environment conditions.

3.1.4 Test Houses or Laboratories for testing to specific requirements/specifications.

NOTE : *Any other category of approval not mentioned above may also be considered on as required basis.*

3.2 Change of scope of approval:-

3.2.1 Firm shall inform HQ, DGAQA through resident RDAQA/Officer In-charge for any change in scope of approval required.

3.2.2 HQ, DGAQA through their authorized representatives shall have further assessment of firm's facilities and capabilities for the changes sought and decide accordingly.

3.3.3 Validity of the DGAQA approval shall be for a period of 3 years. This would be subject to satisfactory periodic assessment by resident office of DGAQA/HQ, DGAQA.

4. SUB-CONTRACTS/OUTSOURCING :

A firm may be a Main Contractor for some contracts and Sub-Contractor for others. All the sub-contract / outsourcing activities will be governed as per the DGAQA Guidelines for QA during outsourcing. But whether a firm is acting as a Main Contractor or Sub Contractor, does not affect its status as an Approved Firm, provided it fulfils the necessary conditions.

5. SPECIAL REQUIREMENTS FOR APPROVAL IN THE AREAS OF SOFTWARE DESIGN AND DEVELOPMENT :

5.1 Indigenous manufacturers involved in Design and Development in embedded system software for Airborne Applications, Ground System Software, Rig System Software and ATE Software should have sufficient In-house expertise in software development, testing and flight evaluation. The manufacturer should comply with the certification requirement as specified by Airworthiness authorities in respect of Air borne embedded system software and certification requirement for Ground System/Rigs/ATEs as specified by DGAQA. Some of the major requirements to be complied by the manufacturer in respect of the Airborne software and Ground system software are mentioned below.

a) Criticality Classification,
b) Software Development life cycle,
c) Software Configuration Management,
d) Software Quality Assurance,
e) Software Verification and Validation,
f) Validation of Software tools,
g) Standards for software products,
h) Formal Reviews.

5.2 Software Certification Process for indigenous Airborne and Ground system shall comply with the procedure as defined by airworthiness

authorities and DGAQA. The major phases of software certification process are as follows -

a) Software Certification Phases
b) Planning for Software Certification
c) System Requirement Reviews and Analysis Phases
d) Software Design Reviews and Analysis Phases
e) Source code Reviews and Analysis Phases
f) Module level testing Reviews and Analysis Phases
g) Hardware Software Integration and testing Reviews and Analysis Phases
h) Software Independent Verification and Validation
i) System Integration testing Reviews and Analysis Phases
j) Platform Integration Testing and Reviews and Analysis Phases
k) Functional and Physical Configuration Audit and Clearance

5.3 Independent Verification and Validation (IV & V) team : In addition to in-house verification and validation software team, an independent verification and validation team shall be constituted by the main contractor comprising of members from CEMILAC, DGAQA, HAL, IAF/ Army/ Navy and experts from Private firms, universities, IIT etc. The IV & V should be capable of verifying and validating the software during the various phases of software development.

5.4 Software Standards: Applicable national/international standards are to be used. Some of the relevant standards on the subject are given below for reference.

a) IEEE/EIA-12207.0-1996 (ISO/IEC 12207) standard for information technology.
b) RTCA-DO-178B "Software Considerations in Airborne Systems and Equipment Certification".
c) DOD-STD-2167A: Defence System Software Development.

5.5 Certification of Ground/Test equipment software and Test Rig software :

This software will be certified by DGAQA/RCMA. The firm should follow the procedure given at Para 5.2 above for certification / clearance of ground system software also. However, the requirement of IV & V and detailed documentation shall be based on the criticality of the software and guidelines issued by DGAQA on the subject from time to time.

NOTE : Guidelines given in DDPMAS Volume-II on software development and certification will take precedence for procedures to be followed.

SECTION – II

SALIENT FEATURES FOR APPROVAL OF FIRM AND IT'S PERSONNEL

1. INTRODUCTION

While the Quality Management System of the firm should meet the requirements given in part-II of this document, other features specific to the firm and its QA organisation are as given below:

2. APPROVAL OF Q.A. STAFF

2.1 The head of QA Department of the firm will be the one approved by DGAQA by name. He shall have an adequate number of QA personnel working under him to ensure execution of inspection/QA activities in all the technical work centers of the organisation. He shall also co-ordinate approval of the QA personnel from resident DGAQA office/DGAQA HQ for respective scope of work. He shall be responsible to ensure that only competent & approved QA personnel certify the activity in respective work centers.

2.2 Head of the Quality Assurance Department will be placed under the functional and administrative control of top management. He shall be given adequate authority & freedom by the Top Management of the firm to ensure effective functioning of the QA Department & Quality Management System and resolve matters pertaining to quality. All personnel in the quality department shall be under functional as well as administrative control of the Head of Quality Assurance Department.

3. APPROVAL OF OPERATORS AND THEIR COMPETENCE:

3.1 Firm's management is responsible for establishment of a system to approve the operators for carrying out a specified job. Selection process will take into account qualification, training, experience and competence level of the personnel. A suitable representative from the firm's Q.A. department should also be a member in the selection process of the operators. Periodic review of such personnel will be part of this system. DGAQA will oversee that such a system is in place, effective and also that adequate records are maintained.

3.2 There will be provision for self inspection by operators who are found to be competent by QC department of the main contractor and also meeting the inspection approval requirement of the DGAQA. However suitable guidelines on the procedure to be followed in such cases would need to be prepared by the Main Contractor in co-ordination with DGAQA.

4. PERSONNEL INVOLVED IN SPECIAL PROCESSES :-

4.1 Personnel carrying out special processes such as WELDING, NDT etc shall be approved by DGAQA after assessing their education, training, experience, competence and special tests if any. Only personnel approved by

DGAQA or other Govt. Approved agency shall be authorised to carry out and certify such activities. There will be provision for periodical review of these approvals.

4.2 As regards process of SOLDERING, the firm will have in-house guidelines for assessment and approval of personnel involved in such type of processes. There will be provision for periodical review by DGAQA of all the special processes including that of soldering.

5. TECHNOLOGY FOR EXECUTION OF SCOPE OF ACTIVITIES :- The firm will have in place duly approved technology from authorised agency for carrying out scope of activities including requirement of special processes, if any.

6. ACCOMMODATION AND EQUIPMENT

The Quality Assurance Department shall have requisite accommodation and equipment for adequate process – control and / or efficient inspection and functional tests. Equipment may include precision tools, instruments, test apparatus etc., and facilities to check their accuracy and calibration periodically against standards having traceability to national/ international standards so as to ensure continued serviceability and reliability. The firm will also be required to provide at the works adequate furnished accommodation and essential communication facilities to the DGAQA to enable working of DGAQA in line with the firm's working system.

7. STORES

The firm should have suitable stores, inward goods inspection and satisfactory system of stores documentation to effectively control the receipt, storage and issue of aeronautical equipment, item & material. Materials awaiting disposition or having evidence of incomplete inspection are to be quarantined in a separate store maintained for the purpose, and will be called "Quarantine Store". All items, parts, and sub-assemblies or materials which have passed Inspection with valid shelf life are to be properly stored in "Bonded Stores" and these alone are to be used for aeronautical purposes. The stores will have requisite environmental control viz temperature, humidity, cleanliness, lighting etc as per the specified requirements of respective type of products.

8. RECORDS

A system of process [job / route] cards or other records are to be maintained for each item, so that:

8.1 Quality Assurance documentation is maintained through all stages of manufacture / overhaul / repair and / or storage.

8.2 The personnel responsible for each stage can be identified. These records are to be preserved by the firm for a minimum period of Ten Years or next overhaul, whichever is later. However, in the case of FOL, the same may

be kept as per the retention period mentioned in the Quality Assurance System of the firm.

8.3 The system of recording will also ensure the identity of raw materials / or the component / manufacturer / Lot No. etc., so that full details can be traced at any stage of manufacture / overhaul / repair.

8.4 In case of FOL, samples of batches produced/supplied should be retained for a period equal to one year more than the authorised shelf life of respective consumable as per type record/specification except ATF which should be retained for a minimum period of one month.

9. TESTING

Physical or Analytical testing for which the firm is not equipped, is to be carried out by a Laboratory approved for the purpose by the DGAQA or NABL. For special testing requiring advanced technology/equipment, firms/labs of national/international repute can be considered with prior approval from DGAQA. Test reports are to be relevantly recorded to enable the sample tested and result obtained to be co-related and shall conform to applicable standards. In case of non-conformance, full lot shall be quarantined and will be put-up to authorized committee / board for further disposition as per existing provisions of DDPMAS.

10. RELEASE NOTES

All deliveries and releases of Aeronautical Equipment and stores are to be accompanied by Release Note. These are to be issued serially and should contain a certificate, the form and wording of which should be approved by the DGAQA. The Release Note should contain all such particulars as will enable the goods to which it refers to be easily identified. These will be signed by Release Note Signatories duly authorized and approved by DGAQA.

11. INSPECTION STAMPS

The products of an approved firm must, before their induction in an aircraft/aero engine/electronic and electrical equipment etc. or issue to another firm, bear an Inspection Stamp as evidence of having been produced to the required standards. The inspection stamp may be affixed on the product or/and appropriate inspection documentation depending upon the type of product. In case of FOL items, released products should be accompanied with a certificate of conformity bearing the stamp & signature of the approved Test Report Signatory. The design of these stamps shall be submitted to DGAQA for approval and agreed to before the Approval of the firm and its Quality Management System (QMS) is granted. Metal and rubber stamps in suitable sizes shall be provided and in case of metal stamps, it is important that the border should be of a design in which sharp corners are avoided. Further precautions to be observed on the subject of inspection stamps are as follows:

11.1 Metal stamps should be used only for metallic parts which are not liable to damage thereby.

11.2 Rubber stamps are to be used for metallic parts which might be damaged by the impression of a metal stamp such as parts constructed of tubing or strip. For the same reason, rubber stamps should be used on non-metallic materials.

11.3 When the parts are too small for individual marking, the parts are to be bundled and the Inspection Stamp impressed on the tape or label appropriately attached to the bundle.

11.4 As these Stamps are individual specific & not generic, therefore the same will remain non-transferable at all times.

12. <u>OPERATOR IDENTIFICATION</u>: Firm's management will devise a methodology for identification & traceability of operators carrying out work on airborne stores. This may be in the form of stamp/PB Number/Unique Identity number etc.

13. <u>STAMPS FOR SPECIAL PROCESSES</u>: After satisfactory execution of the special processes i.e. welding, soldering, NDT etc, the item/material/documentation will be affixed with the appropriate stamp at an identified location. While the design of stamp shall take into consideration easy identification of the process/area of activity, use of rubber or metallic stamps shall be decided accordingly.

Affixation of stamp on the item/material, when required, shall be in addition to the certification in appropriate column of inspection documents.

14. <u>PRODUCTION PERMITS AND CONCESSIONS</u>

14.1. A PRODUCTION PERMIT is permission granted by the Regional Director/Resident Officer-In-Charge, DGAQA to manufacturer, in advance of manufacture, to use materials or to make components or stores which differ from the approved drawings or specification. This permission is operative for a limited quantity and/or period.

14.2. A CONCESSION is permission granted by the Regional Director/Resident Officer-In-Charge, DGAQA to a manufacturer to use or release a limited quantity of material, components or stores already manufactured but not complying strictly with the approved drawings or specification or SOP.

14.3 Each request for a Production Permit or Concession is to be submitted in writing by the Firm's Head of Quality System/authorised representative to the Regional Director/Resident Officer-In-Charge, DGAQA as per the format given in DDPMAS. It will be dealt with, in accordance with the instructions on the subject given in DDPMAS. When the need for a Production Permit or Concession arises at a Sub-Contractor's Works, the agreement of the Main Contractor to the acceptance of the products must also be obtained in co-ordination with Regional Director/Resident Officer-In-Charge, DGAQA.

14.4 There will be provision for Periodical Review of production permits/concessions granted by DGAQA vis a vis the performance of such products/services during exploitation.

14.5 In case of organisations not having resident office of 'DGAQA', the procedure remains same except that in all such instances, Headquarters DGAQA, New Delhi will be the nodal centre to be approached for appropriate disposition.

15. DEFECT INVESTIGATION OF PREMATURE FAILURE OF PRODUCTS RELEASED BY MAIN CONTRACTOR

All premature withdrawals as well as customer complaints of products/services released by the main contractor including the ones involving incidents/accidents are required to be investigated for finding root cause so as to take corrective/preventive measures both at factory as well as user end, if applicable.

Periodic review of recommendations of such investigations will form part and parcel of the quality assurance system.

16. APPLICATION FOR GRANT OF APPROVAL BY DGAQA.

16.1 A firm requiring approval should apply to DGAQA Ministry of Defence, New Delhi on form of application given at Appendix `A'. Arrangements will then be made by the DGAQA to detail a Team to assess the firm and report on the capacity of the firm with respect to infrastructure, human resources, workshop facilities and existence of Quality Management System (Requirements given in Part II of this document). The duty of the assessment team will be to satisfy that the firm has the capacity and resources which will facilitate it to execute the specified class and nature of work satisfactory as per the requirements.

16.2 Subject to the firm and its Quality Management System being found satisfactory, the firm will be required to submit a draft copy of the release note and a facsimile of the QA personnel stamp, which is proposed to be used for approval and record purpose. DG, AQA after due consideration will inform the firm of his decision regarding approval.

NOTE: It should be understood that the grant of 'Approval' only indicates that at the time of granting, the Firm's Organization fulfilled all the requirements for such approval. The Supervising Representatives from the DGAQA will carry out periodical assessment of the approved firms. The continuation of the approval will be subject to the periodical verifications showing that the required standards are being maintained.

SECTION III

APPROVAL OF FIRM'S QUALITY ASSURANCE PERSONNEL

1. REQUIREMENTS

A Candidate will be eligible for consideration of approval only if he meets the following criteria:-

1.1 GENERAL

1.1.1 Has completed 19 years of age.

1.1.2 Has passed Diploma in Engg./B.Sc Degree (PCM) or its equivalent. This may, however, be relaxed in the case of candidates with extensive experience.

1.1.3 Is a permanent employee of the organization.

1.2 TECHNICAL

1.2.1 Technical experience for a minimum period of one Year in the relevant field which may include apprenticeship with an approved firm or Government Organisation and / or Government Training Scheme etc. (A degree in Science (B.Sc) or Diploma in Engineering will be considered equivalent). In case of existing inspection personnel who are already approved by DGAQA in other areas of work, a minimum of six months inspection experience is required in the area of scope for which approval is sought.

1.2.2 Ability to read drawings and interpret them.

1.2.3 Adequate knowledge of measuring instruments, gauges and test equipments.

1.2.4 Conversant with the relevant inspection procedures, instructions and specifications issued by the concerned authorities.

1.2.5 Not less than one year inspection experience including training period if any, in the field of quality, for provisional approval, depending upon the approval sought, in their respective field of inspection. Should also have undergone training and have knowledge on inspection/quality standards being followed currently.

1.2.6 In areas of sophisticated technology, the personnel of higher qualification, more experience and specialized training may be needed for verification activities.

2. PROCEDURE

2.1 The Head of Quality System of the Firm should be a professional of repute in the respective discipline having preferably post graduate/doctoral qualification. After his approval by DG, AQA, he will forward to the Regional Director/Resident Officer-In-Charge, DGAQA ,application for approval of his Quality Assurance Personnel giving the following details :-

2.1.1 NAME :

2.1.2 DATE OF BIRTH :

2.1.3 ACADEMIC QUALIFICATIONS:
2.1.4 TECHNICAL QUALIFICATIONS:
2.1.5 EMPLOYEMENT WITH THE PRESENT EMPLOYER INCLUDING TRAINING
2.1.6 EXPERIENCE (A) TOTAL
(B) SPECIALIZATION IF ANY
(C) INSPECTION

2.1.7 SCOPE OF APPROVAL REQUESTED INCLUDING EXISTING APPROVAL (IF ANY)

2.1.8 **REMARKS** :

2.2 Eligible candidates will be required to appear for an interview before an approving board constituted by Regional Director/Resident Officer-In-Charge, DGAQA. The board shall include a member of the Firm's Quality Assurance Organisation.

2.3 A candidate who has failed to satisfy the Board will be permitted to re-appear for re-examination after a minimum period of six months from the date of declaration of results. However, exceptional cases may be considered by respective RDAQA after 3 months in case of recommendation of the same by the Quality Head of the organisation.

2.4 Approval may be granted to a QA person to cover more than one field of inspection at a time subject to his fulfilling the necessary conditions for each of such areas. Such cases will be considered more as exception and not as a rule. Personnel approved by the board with specified scope of approval will be issued approval stamps uniquely identified by head of quality, under intimation to resident DGAQA office.

2.5 Validity of approval will be for a period of three years subject to the conditions laid in the approval letter by respective DGAQA office. However, inspection personnel already approved and waiting for revalidation after expiry of three years, may continue to be having approval status for the scope in which they are approved till such time the revalidation is declared.

3. SUPERVISION

3.1 The Firm's Head of Quality System will in the first instance submit a complete list of their QA personnel to the Regional Director/Resident officer In-Charge, DGAQA. Any additions, changes in assignment or termination of personnel approved by DGAQA ought to be informed to DGAQA on quarterly basis.

3.2 The Head of Quality System of the Firm will apprise DGAQA of any faulty inspection on the part of his QA personnel. Approval of an inspector is liable to be withdrawn by DGAQA with suitable annotation in approval records if repeated failures are noted against him/her.

3.3 Approval Cards in duplicate to cover each approved person will have to be raised by the firm and completed cards forwarded to the Resident officer In Charge / HQ DGAQA for scrutiny and issue. The original card will be returned to the Head of Quality Assurance System of the firm concerned and the duplicate retained by the Resident officer in Charge / HQ DGAQA. In the event of any change in assignment, posting to outside station or superannuation of service, the approval card will be sent to RDAQA/Resident officer In-charge / HQ, DGAQA for appropriate annotation. In such cases Approval Stamp is to be returned to Quality Engineering department of the Main Contractor for safe custody under intimation to DGAQA.

APPENDIX `A'

FORMAT OF APPLICATION FOR GRANT OF APPROVAL BY DGAQA TO A FIRM & ITS QUALITY MANAGEMENT SYSTEM

1. Para 16 of Section II "Requirements for Approval of a Firm and its Quality Management System" refers.

i) Name of Firm with complete address

ii) Approximate number of employees with detailed organisation chart

iii) List of manufacturing facilities relevant to the contract/order available.

iv) List of Inspection equipment available

v) Name, Qualifications & experience of Head of Quality System

vi) Number of QA personnel with adequate experience in the requisite field.

vii) Approval of the firm in the following categories (delete categories not applicable) :

a) Manufacture / overhaul / repair agencies of Aircraft, Engines, Missiles, Electrical and Electronic Equipment, Instruments etc., and their components / accessories or Aircraft materials.

b) Process workshops, (Protective Treatment, Heat Treatment, Plating, Surface Treatment etc.)

c) Stockist of the above, for Certification that they are re-consigning parts or materials received from approved sources in the condition in which received.

d) Test houses or Laboratories for testing to specific requirements / specifications.

(viii) List of special processes involved, availability of technology & trained manpower.

(ix) Details of previous supply orders executed.

2. Certificate from the Head of the Firm (Organisation) that it meets all the requirements given in the DGAQA document "Approval of Firm & its Quality Management System".

3. Please provide details of other approvals held.

a) Third Party Approvals against national/international standards e.g. AS 9100, ISO 9000 series, ISO 14000 etc.

b) Approvals from external agencies/organizations such as Boeing, British Aerospace, Rolls Royce etc along with their scope of approval.

c) Approval from national agencies/organizations such as DGCA, ISRO, BARC, ADA, DRDO etc.

4. Completed application giving the above details is to be forwarded to:

DIRECTOR GENERAL
DIRECTORATE GENERAL OF AERONAUTICAL
QUALITY ASSURANCE,
GOVT. OF INDIA, MINISTRY OF DEFENCE
“H” BLOCK, NIRMAN BHAWAN PO
NEW DELHI – 110 011.

PART - II

QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR APPROVAL OF A FIRM

FIRM'S QUALITY MANAGEMENT SYSTEM – REQUIREMENTS

TABLE OF CONTENTS

6.3 Infrastructure
6.4 Work Environment

7. PRODUCT REALIZATION

7.1 Planning of Product Realization
7.2 Customer-Related Processes
7.2.1 Determination of Requirements Related to the Product
7.2.2 Review of Requirements Related to the Product
7.2.3 Customer Communication
7.3 Design and Development
7.3.1 Design and Development Planning
7.3.2 Design and Development Inputs
7.3.3 Design and Development Outputs
7.3.4 Design and Development Review
7.3.5 Design and Development Verification
7.3.6 Design and Development Validation
7.3.6.1 Documentation of Design and/or Development Verification and Validation.
7.3.6.2 Design and/or Development Verification and Validation Testing
7.3.7 Control of Design and Development Changes
7.4 Purchasing
7.4.1 Purchasing Process
7.4.2 Purchasing Information
7.4.3 Verification of Purchased Product
7.5 Production and Service Provision
7.5.1.1 Production Documentation
7.5.1.2 Control of Production Process Changes
7.5.1.3 Control of Production Equipment, Tools and Numerical Control (NC) Machine Programs
7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities
7.5.1.5 Control of Service Operations
7.5.2 Validation of Processes for Production and Service Provision
7.5.3 Identification and Traceability
7.5.4 Customer Property
7.5.5 Preservation of Product
7.6 Control of Monitoring and Measuring Devices

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General
8.2 Monitoring and Measurement
8.2.1 Customer Satisfaction
8.2.2 Internal Audit
8.2.3 Monitoring and Measurement of Processes
8.2.4 Monitoring and Measurement of Product
8.2.4.1 Inspection Documentation
8.2.4.2 First Article Inspection
8.3 Control of Nonconforming Product

8.4 Analysis of Data
8.5 Improvement
8.5.1 Continual Improvement
8.5.2 Corrective Action
8.5.3 Preventive Action

1. INTRODUCTION

1.1 General: The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by:-

a) it's organizational environment, changes in that environment, and the risks associated with that environment,

b) it's varying needs,

c) it's particular objectives,

d) the products it provides,

e) the processes it employs,

f) its size and organizational structure.

The quality management system requirements specified in this document are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

1.2 Process Approach: This document promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,
b) the need to consider processes in terms of added value,
c) obtaining results of process performance and effectiveness, and
d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this Document, but does not show processes in detail.

NOTE: In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

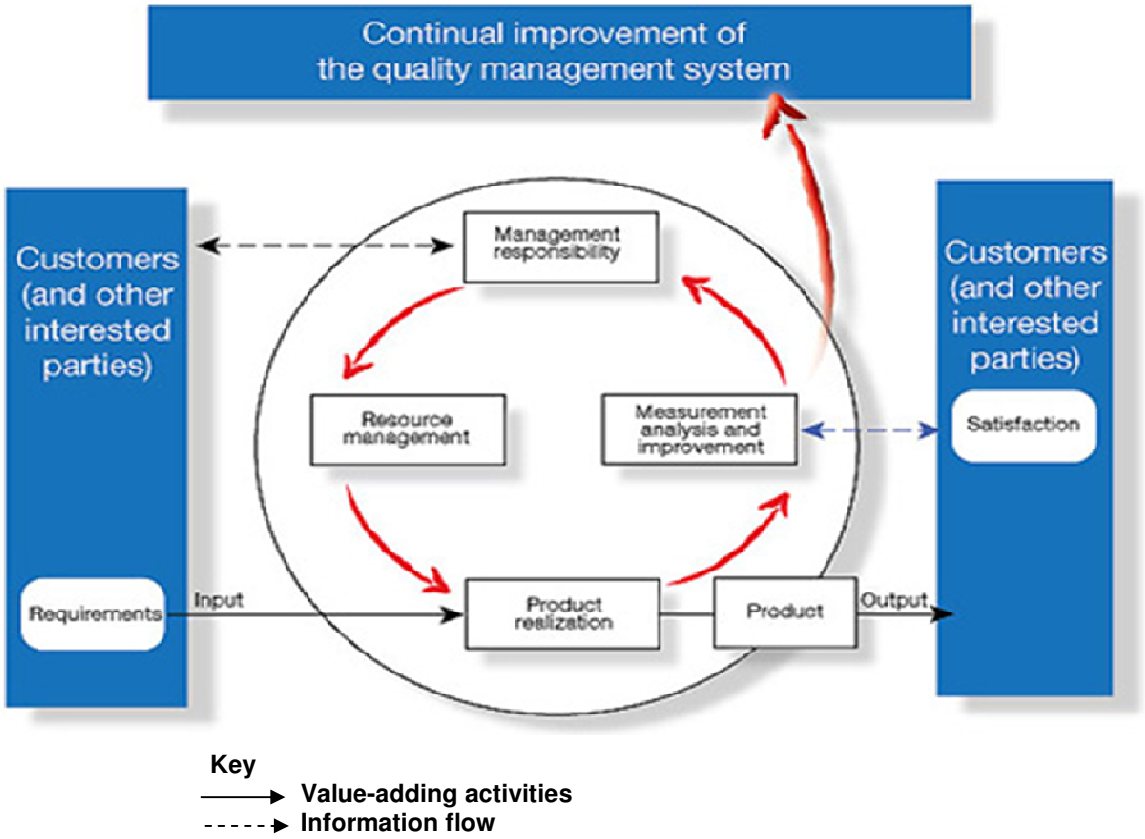

FIGURE 1 – Model of a Process-Based Quality Management System

2. SCOPE

2.1 General: This document includes ISO 9001:2008 quality management system requirements and specifies additional aviation, space and defence industry requirements, definitions and notes as shown in bold text. *Further additional requirements of DGAQA are shown in italics.*

This document specifies requirements for a quality management system where an organization:

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1: In this document, the term "product" only applies to:

a) product intended for, or required by, a customer,

b) any intended output resulting from the product realization processes.

NOTE 2: Statutory and regulatory requirements can be expressed as legal requirements.

2.2 Application: All requirements of this document are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this document cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

This document is intended for use by organizations that design, develop and/or produce aviation, space and defence products; and by organizations providing post-delivery support, including the provision of maintenance, spare parts or materials for their own products.

Organizations whose primary business is providing maintenance, repair and overhaul services for aviation commercial and military products; and original equipment manufacturers with maintenance, repair and overhaul operations that operate autonomously, or that are substantially different from their manufacturing/production operations; should use the IAQG-developed 9110 standard (see Bibliography) *in place of the clauses of AS 9100 which have been adopted in this document.*

Organizations that procure parts, materials and assemblies and resell these products to a customer in the aviation, space and defence industries, including organizations that procure products and split them into smaller quantities for resale, should use the IAQG-developed 9120

standard (see Bibliography) *in place of the clauses of AS 9100 which have been adopted in this document.*

3. TERMS AND DEFINITIONS

For the purpose of this document, the terms and definitions given in ISO 9000 apply. Throughout the text of this document, wherever the term "product" occurs, it can also mean "service".

3.1 Risk:

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.2 Special requirements:

Those requirements identified by the customer, or determined by the organisation, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

3.3 Critical items:

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc. In case of licensed projects, critical items are as identified by the OEM.

3.4 Key Characteristic:

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

NOTE: Special requirements and critical items are new terms and, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 7.2.1 & 7.2.2). Special requirements can require the identification of critical items. Design output (see 7.3.3) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

4. QUALITY MANAGEMENT SYSTEM

4.1 General Requirements:

The organization shall establish, document, implement and maintain a quality management system that **shall address customer and applicable statutory and regulatory quality management system requirements** and continually improve its effectiveness in accordance with the requirements of this document.
The organization shall

a) determine the processes needed for the quality management system and their application throughout the organization ,

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes including human resources.

e) monitor, measure where applicable**,** and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this *document to satisfy the objective evidence, which may include documentation from first, second and/or third party assessment/certification processes that the QMS is compliant with these requirements and is effective.*

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes.

The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2: An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not

absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

(a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements.
(b) the degree to which the control for the process is shared.
(c) the capability of achieving the necessary control through the application of 7.4.

4.2 Documentation Requirements:

4.2.1 General: The quality management system documentation shall include:

a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures required by this document and,
d) documents including records, determined by the organization to be necessary to ensure the effective planning, operation and assurance of its processes,
e) records required by this document**,** and

The organization shall ensure that personnel have access to and are aware of relevant quality management system documentation and changes.

NOTE 1: Where the term "documented procedure" appears within this document, this means that the procedure is established, documented, implemented and maintained. **A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.**

NOTE 2: The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,
b) the complexity of processes and their interactions, and
c) the competence of personnel.

NOTE 3: The documentation can be in any form or type of medium.

4.2.2 Quality Manual: The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system,
b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

d) Quality Manual, in addition, may have incorporated the following chapters:

(i) Assessment & approval of firms

(ii) Vendor rating and monitoring

(iii) Outsourcing procedures and Quality Control at sub-contractor's works.

4.2.3 Control of Documents: Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified and their point of embodiment defined.
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and to prevent the unintended use of obsolete documents, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

NOTE : *A procedure shall be established in co-ordination with DGAQA and specified in the QMS of the organisation for issue of Duplicate Certificate/Log Card in respect of lifed items arising out of loss or damage to (OEM supplied) such documents.*

4.2.4 Control of Records: Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

Records shall remain legible, readily identifiable and retrievable.

The supplier shall provide the DGAQA with the necessary access to quality related records in a mutually agreed format.

5. MANAGEMENT RESPONSIBILITY :

5.1 Management Commitment: Top management shall provide evidence of its commitment to the development and Implementation of the quality management system and continually improving its effectiveness by:

a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
b) establishing the quality policy,
c) ensuring that quality objectives are established and linked to the performance parameters of respective sections.
d) conducting management reviews, and
e) ensuring the availability of resources.

5.2 Customer Focus:

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved.

5.3 Quality Policy:

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

5.4 Planning:

The Organisation shall prepare a Quality Plan (QP) which addresses the contractual requirements prior to the start of activities. The QP shall be a clearly identified discrete document or part of another document that is prepared under the contract.

The QP shall play three complimentary roles:

1. Describe and document the QMS requirements 'contract specific' necessary to satisfy the contract requirements (making reference, where applicable to the 'company wide' QMS).

2. Describe and document the planning of the product realization in terms of quality requirements for the product, needed resources, required control activities (verification, validation, monitoring, inspection, testing & reliability demonstration) and Acceptance Criteria.

3. The DGAQA will then specify in the Quality Plan their own check stages depending upon the criticality of the stage which will be considered as hold points. The DGAQA will examine the relevant documents for compliance by the manufacturer and also for ensuring that the work pertaining to those stages meets the laid down quality requirements. The DGAQA representative will then carry out the re-verification at the designated stage and ensure that the results of re-verification checks meet the stipulated requirements.

NOTE : *The Supplier and Sub-supplier shall ensure that risks are considered during planning, including but not limited to Risk Identification, Risk Analysis, Risk Control and Risk Mitigation. The planning shall start with risk identification during contract review and updated thereafter in a timely manner. The DGAQA & main contractor will mutually finalise QPs, Risk Plans & Revisions.*

5.4.1 Quality Objectives: Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measureable and consistent with the quality policy.

5.4.2 Quality Management System Planning: Top management shall ensure that

a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication:

5.5.1 Responsibility and Authority: Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management Representative: Top management shall appoint a member of the organization's management who, shall have responsibility and authority that includes:

a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
b) Reporting to top management on the performance of the quality management system and any need for improvement,
c) Ensuring the promotion of awareness of customer requirements throughout the organization**,**

d) The organizational freedom and unrestricted access to top management to resolve quality management issues.

e) Reporting directly to top management on quality related issues.

NOTE: The responsibility of a management representative can include liaison with parties on matters relating to the quality management system.

5.5.3 Internal Communication: Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. *The organisation shall establish lines of communication with the DGAQA on all aspects affecting quality.*

5.6 Management Review:

5.6.1 General: Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

5.6.2 Review Input: The input to management review shall include information on

a) results of audits,
b) customer feedback,
c process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

5.6.3 Review Output: The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

NOTE: *Records from management reviews shall be maintained and made available to the DGAQA when asked for, that shall include Reviews of Input & Output.*

6. <u>RESOURCE MANAGEMENT</u>:

6.1 Provision of Resources: The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources:

6.2.1 General: Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 Competence, training and awareness: The organization shall

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,

b) where applicable, provide training or take other actions to achieve the necessary competence.

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience.

Contents of Para 3 Section-II Part - I are also relevant in this regard.

6.3 Infrastructure:

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport/communication/information systems).

6.4 Work Environment:

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE: Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, strong magnetic field, noise, vibration etc.

7. PRODUCT REALIZATION:

7.1 Planning of Product Realization:

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (refer 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

NOTE: Quality objectives and requirements for the product include consideration of aspects such as –

- **product and personal safety.**
- **reliability, availability and maintainability,**
- **producibility and inspectability,**
- **suitability of parts and materials used in the product,**
- **selection and development of embedded software, and**
- **recycling or final disposal of the product at the end of its life.**

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (refer 4.2.4)***;***

e) configuration management appropriate to the product;

f) resources to support the use and maintenance of the product.

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2: The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.1 Project Management:

As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product

a) assignment of responsibilities for risk management

b) definition of risk criteria (e.g. likelihood, consequences, risk acceptance)

c) identification, assessment and communication of risks throughout product realization.

d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and

e) acceptance of risks remaining after implementation of mitigating actions.

7.1.3 Configuration Management:

The organization shall establish, implement and maintain a configuration management process that includes, appropriate to the product.

a) configuration management planning,

b) configuration identification,

c) change control,

d) configuration status accounting, and

e) configuration audit.

NOTE: See ISO 10007 for guidance.

7.1.4 Control of work transfers:

The organization shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work (e.g. from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements.

7.2 Customer-Related Processes:

7.2.1 Determination of Requirements Related to the Product: The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements applicable to the product, and

d) any additional requirements considered necessary by the organization.

NOTE 1: Requirements related to the product can include special requirements.

NOTE 2: Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.2.2 Review of Requirements Related to the Product: The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved,

c) the organization has the ability to meet the defined requirements*,* and

d) special requirements of the product are determined, and

e) risks (e.g. new technology, short delivery time frame) have been identified. (see 7.1.2)

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements *within a given reasonable time frame as per factory document procedure*.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer Communication: The organization shall determine and implement effective arrangements for communicating with customers *and DGAQA* in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.3 Design and Development:

7.3.1 Design and Development Planning: The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

Where appropriate, the organization shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.

The different design and development tasks to be carried out shall be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.

Design and development planning shall consider the ability to produce, inspect, test and maintain the product.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs: Inputs relating to product requirements shall be determined and records maintained (refer 4.2.4). These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and Development Outputs: The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria,

d) specify the characteristics of the product that are essential for its safe and proper use*,* and

e) specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items.

The organization shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained; including for example

- **the drawings, part lists, and specifications necessary to define the configuration and the design features of the product; and**
- **the material, process manufacturing and assembly data needed to ensure conformity of the product.**

NOTE: Information for production and service provision can include details for the preservation of product.

7.3.4 Design and Development Review: At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (refer 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements,

b) to identify any problems and propose necessary actions*,* **and**

c) to authorize progression to the next stage.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (refer 4.2.4).

7.3.5 Design and Development Verification: Verification shall be performed in accordance with planned arrangements (refer para 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (refer para 4.2.4).

7.3.6 Design and Development Validation: Design and development validation shall be performed in accordance with planned arrangements (refer para 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (refer para 4.2.4).

7.3.6.1 Design and Development Verification and Validation Testing: Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:

a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;

b) test procedures describe the method of operation, the performance of the test, and the recording of the results;

c) the correct configuration standard of the product is submitted for the test;

d) the requirements of the test plan and the test procedures are observed; and

e) the acceptance criteria are met.

7.3.6.2 Design and development verification and validation documentation : At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

7.3.7 Control of Design and Development Changes: The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Design and development changes shall be controlled in accordance with the configuration management process (see 7.1.3)

Records of the results of the review of changes and any necessary actions shall be maintained (refer 4.2.4).

7.4 Purchasing:

7.4.1 Purchasing Process: The organization shall ensure that purchased airborne product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The main contractor shall provide a list of items purchased/outsourced to DGAQA for their effective supervision.

The organization shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (refer para 4.2.4).

NOTE: One factor that can be used during supplier selection and evaluation is supplier quality data from objective and reliable external sources, as evaluated by the organization (e.g. information from accredited quality management system or process certification bodies, organization approvals from government authorities). Use of such data would be only one component of an organization's supplier control process and the organization remains responsible for verifying that purchased product meets specified purchase requirements.

The organization shall:

- **a) maintain a register of approved suppliers that includes approval status (e.g. approved, conditional, disapproved) and the scope of the approval (e.g. product type, process family);**
- **b) periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of assurances to be implemented;**
- **c) define the necessary actions to take when dealing with suppliers that do not meet requirements;**
- **d) ensure where required that both the organization and all suppliers use customer- approved special process sources;**
- **e) Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on their approval status, and**
- **f) determine and manage the risk when selecting and using suppliers (see 7.1.2).**

7.4.2 Purchasing Information: Purchasing information shall describe the product to be purchased, including where appropriate:

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel,

c) quality management system requirements**,**

d) the identification and revision status of specification, drawings, process requirements, inspection/verification instructions and other relevant technical data,

e) requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics.

f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,

g) requirements regarding the need for the supplier to

- **notify the organization of non-conforming product,**
- **obtain organization approval for non-conforming product disposition,**
- **notify the organization of changes in product and/or process, changes of suppliers, change of manufacturing facility location and, where required, obtain organization approval, and**
- **flow down to the supply chain the applicable requirements including customer requirements,**

h) records retention requirements,

i) right of access by the organization, their customer, and regulatory authorities to the applicable areas of all facilities at any level of the supply chain, involved in the order and to all applicable records, and

j) requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product: The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

NOTE 1: Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective control of quality and does not absolve the organization of its responsibility to provide acceptable product and comply with all requirements.

NOTE 2 : Verification activities can include

- **obtaining objective evidence of the conformity of the product from the suppliers (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records),**
- **inspection and audit at the supplier's premises,**
- **review of the required documentation,**
- **inspection of products upon receipt, and**
- **delegation of verification to the supplier, or supplier certification.**

Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and Service Provision:

7.5.1 Control of Production and Service Provision:

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

NOTE: This information can include drawings, parts lists, materials and process specifications.

b) the availability of work instructions, as necessary,

NOTE: Work instructions can include process flow charts, production documents (e.g. manufacturing plans, travelers, routers, work orders,

process cards) and inspection documents.

c) the use of suitable equipment,

NOTE: Suitable equipment can include product specific tools (e.g. jigs, fixtures, moulds) and software programs.

d) the availability and use of monitoring and measuring equipment,

e) the implementation of monitoring and measurement,

f) the implementation of product release, delivery and post-delivery activities**,**

g) accountability for all product during production (e.g., parts quantities, split orders, non-conforming product),

h) evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,

i) provision for the prevention, detection, and removal of foreign objects,

j) monitoring and assurance of utilities and supplies (e.g. water, compressed air, electricity and chemical products) to the extent they affect conformity to product requirements, and

k) criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

Planning shall consider, as applicable,

- **establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified.**
- **designing, manufacturing and using tooling to measure variable data.**
- **identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and**
- **Special processes (see 7.5.2).**

7.5.1.1 Production process verification: The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing part and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g. engineering changes, manufacturing process changes, tooling changes). This activity is often referred to as First Article Inspection Report (FAIR).

7.5.1.2 Control of Production Process Changes: Persons authorized to approve changes to production processes shall be identified.

The organization shall control and document changes affecting processes, production equipment, tools or software programs.

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

7.5.1.3 Control of Production Equipment, Tools and software Programs:

Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.

Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage.

7.5.1.4 Post-delivery support: Post-delivery support shall provide as applicable for the

- **a) collection and analysis of in-service data,**
- **b) action to be taken, including investigation and reporting, when problems are detected after delivery,**
- **c) control and updating of technical documentation,**
- **d) approval, control and use of repair scheme, and**
- **e) controls required for off-site work (e.g. organization's work undertaken at the customer's facilities.**

NOTE: *In case of serious observations related to flight safety, the same may be brought to the notice of DGAQA at the earliest possible opportunity. All warranty activities related to the quality of product by the firm and undertaken at customer's facilities by the firm's reps shall be informed to DGAQA on quarterly basis.*

7.5.2 Validation of Processes for Production and Service Provision: The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

NOTE: These processes are often referred to as special processes.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including,

as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (refer para 4.2.4), and

e) revalidation.

7.5.3 Identification and Traceability: Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate control for the media.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (refer 4.2.4).

NOTE: Traceability requirements may include

- **identification to be maintained throughout the product life,**
- **the ability to trace all products manufactured from the same batch of raw material or from the same manufacturing batch to the destination (delivery, scrap),**
- **for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and**
- **for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.**

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained ***(***see 7.1.3***)***.

7.5.4 Customer Property: The organization shall exercise care with customer property while it is under the organization's assurance or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer/*DGAQA* and maintain records (see 4.2.4).

7.5.5 Preservation of Product: The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Preservation of product shall also include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for:

a) cleaning;

b) prevention, detection and removal of foreign objects,

c) special handling for sensitive products,

d) marking and labeling including safety warnings,

e) shelf life control and stock rotation, and

f) special handling for hazardous materials.

7.6 Control of Monitoring and Measuring equipment:

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall maintain a register of these monitoring and measuring equipment, and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

NOTE: Monitoring and measuring equipment includes, but is not limited to, test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

The organization shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and testing being carried out.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist,

the basis used for calibration or verification shall be recorded (see 4.2.4),

b) be adjusted or re-adjusted as necessary;

c) have identification in order to determine its calibration status,

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage***;***

f) The organization shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (refer 4.2.4).

When an item or measuring equipment is found to fail re-calibration or is not in calibration and when there are affected products, the concerned DGAQA office is to be informed & presented with detail of affected products, including products already delivered.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT:

8.1 General:

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity to product requirements,
b) to ensure conformity of the quality management system, and
c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support

- **design verification (e.g., reliability, maintainability, safety),**
- **process control,**
  - **selection and inspection of key characteristics,**
  - **process capability measurements,**
  - **statistical process control,**
  - **design of experiment,**
- **inspection, and**
- **failure mode, effect and criticality analysis.**

8.2 Monitoring and Measurement:

8.2.1 Customer Satisfaction: As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. Organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results. *For efficient monitoring of these efforts, use of Customer Satisfaction Index (CSI) may be considered by the main contractor.*

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

NOTE: *Any complaints or deficiencies relevant to the contract reported by DGAQA, will be recorded as customer complaints.*

8.2.2 Internal Audit : The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this document and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

NOTE: Planned arrangements include customer contractual requirements.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and

methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4)

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

The supplier shall make available internal audit reports to DGAQA when asked for.

NOTE: See ISO 19011 for guidance.

8.2.3 Monitoring and Measurement of Processes: The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE: When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

In the event of process non-conformity, the organization shall:

a) take appropriate action to correct the non-conforming process,

b) evaluate whether the process nonconformity has resulted in product non-conformity,

c) determine if the process non-conformity is limited to a specific case or whether it could have affected other processes or products, and

d) identity and control any non-conforming product (see 8.3).

8.2.4 Monitoring and Measurement of Product: The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned

arrangements (refer 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Measurement requirements for product acceptance shall be documented and shall include

a) criteria for acceptance and/or rejection,

b) where in the sequence, measurement and testing operations are performed,

c) required records of the measurement results (at a minimum, indication of acceptance or rejection), and

d) any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified, the organization shall ensure they are controlled and monitored in accordance with the established processes.

When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e. matching the sampling plan to the criticality of the product and to the process capability).

Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

Where required to demonstrate product qualification, the organization shall ensure that records provide evidence that the product meets the defined requirements.

The release of product and delivery of service to the customer shall not proceed until all the planned arrangements (refer 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The organization shall ensure that all documents required to accompany the product are present at delivery.

8.2.4.1 <u>Inspection Documentation</u>: Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production/technology documentation and shall include Quality Management System:

a) Criteria for acceptance and/or rejection,

b) where in the sequence measurement and testing operations are performed,

c) a record of the measurement results, and

d) type of measurement instruments required and any specific instructions associated with their use.

Test records shall show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.

8.2.4.2 <u>First Article Inspection</u> : The organisation's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result. *Records of same to be maintained and attached with clearance request to DGAQA for first article clearance.*

NOTE: See (AS) (EN) (SJAC) 9102 for guidance. The above two paras have been retained from revision B of Aerospace Standard 9100 for more clarity on First Article Inspection and relevant documentation.

8.3 Control of Non-conforming Product:

The organization shall ensure that product which does not conform to specified requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Applicable clauses on control of Non Conformances in DDPMAS-2002 shall be followed accordingly. This is applicable for outsourced products also.

Procedures for disposition of Non-conforming product shall be detailed in the QMS of the organisation.

The methodology for disposition of non-conforming products shall consist of a root cause analysis conducted by the organization and preventive and corrective measures identified.

The supplier shall notify DGAQA on non-conforming product received from a sub-contractor that has been subject to DGAQA Clearance.

NOTE: The term "non-conforming product" includes non-conforming product returned by a customer.

The organization's documented procedure shall define the

responsibility and authority for the review and disposition of non-conforming product and the process for approving personnel making these decisions.

Where applicable, the organization shall deal with non-conforming product by one or more of the following ways:

a) by taking action to eliminate the detected non-conformity;
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) by taking action to preclude its original intended use or application;
d) by taking action appropriate to the effects, or potential effects, of the non-conformity when non-conforming product is detected after delivery or use has started;

- **The organization's non-conforming product control process shall provide for timely reporting of delivered nonconforming product.**

e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.

NOTE-1: Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities.

Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design.

NOTE-2: Authorized representative includes personnel having delegated authority from the design organization.

The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the non-conformity results in a departure from the contract requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

When non-conforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained, shall be maintained (refer 4.2.4).

8.4 Analysis of Data:

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management

system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),

b) conformity to product requirements (see 8.2.4),

c) characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and

d) suppliers (see 7.4).

8.5 Improvement:

8.5.1 Continual Improvement: The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

NOTE: Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of the best practices.

8.5.2 Corrective Action: The organization shall take action to eliminate the cause of non-conformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the non-conformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing non-conformities (including customer complaints),
b) determining the causes of non-conformities,

c) evaluating the need for action to ensure that non-conformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken (refer 4.2.4),

f) reviewing the effectiveness of the corrective action taken**,**

g) flowing down corrective action requirement to a supplier, when it is determined that the supplier is responsible for the non-conformity,

h) specific actions where timely and/or effective corrective actions are not achieved, and

i) determining if additional non-conforming product exists based on the causes of the non-conformities and taking further action when required.

8.5.3 Preventive Action: The organization shall determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.
A documented procedure shall be established to define requirements for

a) determining potential non-conformities and their causes,

b) evaluating the need for action to prevent occurrence of non-conformities,

c) determining and implementing action needed,

d) records of results of action taken (refer 4.2.4), and

e) reviewing preventive action taken.

NOTE: Examples of preventive action opportunities include risk management, error proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources.

BIBLIOGRAPHY :

(i) Aerospace Standard 9100

(ii) AQAP Series Publications

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(iv) Approval of Firm's Inspection Organisation (AFIO) - DGAQA document.

(v) AS/EN 9110 – Quality management System – Requirements for Aviation Maintenance Organisations

(vi) AS/EN 9120 – Quality Management System – Requirements for Aviation, Space and Defence Distributors

(vii) ISO 9000 – Quality Management System – Fundamentals and vocabulary

(viii) ISO 9001 – Quality Management System – Requirements

(ix) ISO 9004^2 – Managing for the sustained success of an organization – A quality management approach

(x) ISO 10007 – Quality Management Systems – Guidelines for configuration management

(xi) ISO 19011 – Guidelines for quality and/or environmental management systems auditing