IECQ OPERATIONAL DOCUMENT

IEC Quality Assessment System, IECQ

Principles for the Development, Implementation, and Assessment of Aerospace, Defence, and High Performance (ADHP) Component Plans
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IECQ Operational Document 3401 –

Principles for the Development, Implementation, and Assessment of Aerospace, Defence, and High Performance (ADHP) Component Plans

INTRODUCTION

This Operational Document (OD) describes the processes for development, implementation and assessment of Aerospace, Defence, and High Performance (ADHP) Component Plans developed for compliance to the following requirements documents:

- Electronic Components Management (Table 1, 1 & 2)
- Lead-free Electronics (Table 1, 3 & 4)
- Counterfeit Parts (Table 1, 5 & 6)
- Obsolescence (Table 1, 7 & 8)
- COTS Assembly Management (Table 1, 8 & 10)

The processes described in this document are applicable to the organization that develops and implements the Plan (hereinafter called the Plan owner), and the organization(s) that performs conformity assessments, implementation assessments, and surveillance of the Plan. The processes described in this document ARE NOT applicable to the manufacturers of piece parts. The organizations that perform assessments and surveillance are third party (an IECQ certification body (CB)).

This OD describes the roles of the Plan owner and assessment/surveillance teams and shall be used together with IECQ 03-4 which describes the differences between Conformity and Implementation audits.

Each assessment and/or surveillance is independent.

An integral part of all the activities described in this OD is familiarity with the acceptable evidence of compliance, as described in IECQ OD 3402.

Based on technical, business, and other considerations, the Plan owner may decide to pursue Conformity Assessment, and/or Implementation Assessment to demonstrate compliance to any or all of the referenced industry standards Table 1, 1-10.

Edition 2.1 is an administrative update to the IECQ logo and title.

The text of this publication is based on the following documents:

<table>
<thead>
<tr>
<th>Document</th>
<th>Report on MC Consultation</th>
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<tr>
<td>IECQ-WG04-053B-CD</td>
<td>MC/376/CA</td>
</tr>
</tbody>
</table>

Full information on the report of MC approval of this publication can be found in the report indicated in the above table.

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1 The term “Plan” is used throughout this document to indicate any Plan prepared to comply with the requirements of the referenced industry standards Table 1, 1-8.
IECQ Operational Document 3401 –

Principles for the Development, Implementation, and Assessment of Aerospace, Defence, and High Performance (ADHP) Component Plans

1 Scope and application

This Operational Document (OD) describes the processes for development, implementation and assessment of Aerospace, Defence, and High Performance (ADHP) Component Plans.

2 Normative references

For dated References, only the revision cited applies. For undated References, the latest revision applies.


SAE EIA-STD-4899, Requirements for and Electronic Components Management Plan.

IECTS 62647-1, Process management for avionics – Aerospace and defence electronic systems containing lead-free solder – Part 1: Preparation for a lead-free control plan.


SAE AS5553, Fraudulent/Counterfeit Electronic Parts; Avoidance, Detection, Mitigation, and Disposition.

SAE STD-0016, Standard for Preparing a DMSMS Management Plan.

IEC 62402, Obsolescence management – Application guide

SAE EIA-933, Requirements for a COTS Assembly Management Plan.


IECQ 03-4, IEC Quality Assessment System for Electronic Components (IECQ System) - Rules of Procedure - Part 4: IECQ AVIONICS Scheme Avionics Parts and Assembly Management

IECQ OD 3402, IECQ Process for Building Check Lists for Assessment, Evidence of Compliance Summaries, and Assessment Reporting Forms for Aerospace, Defence, and High Performance (ADHP) Component Plans.

IECQ OD 3403, Assessment Procedures for acceptance of Candidate Technical Experts (TE) in the IECQ Aerospace, Defence, and High Performance (ADHP) Scheme.


IECQ OD3405, Procedures for the Issuing of IECQ Certificates of Conformity for Aerospace, Defense, and High Performance Electronics Control Plans.

IECQ OD3406, Procedures for the Issuing of IECQ Certificates of Implementation for Aerospace, Defense, and High Performance Electronics Control Plans.
3 Terms and definitions

The basic definitions concerning conformity assessment contained in ISO/IEC 17000 apply.

For the purposes of this document, the following terms and definitions apply.

3.1 ADHP Plan

A document prepared by an ADHP Plan owner, that documents the processes used to satisfy the requirements of any or all of the referenced industry standards. The ADHP Plan may be taken to mean control Plans for any or all of the following: Parts Management, Lead-free Electronics, Counterfeit Parts, Obsolescence, and COTS Assemblies.

3.2 Common ADHP Plan

An ADHP plan that is common across multiple sites (locations) of an applicant organization.

3.3 ADHP Plan Owner

An organization that manufactures electronic equipment and/or systems for the ADHP industries (also may be known as a OEM).

3.4 ADHP Conformity Assessment

An activity to determine if an ADHP Plan conforms to the requirements of the relevant referenced industry standard(s), and has been implemented effectively in the Plan Owner’s organization.

3.5 ADHP Implementation Assessment

A document issued by an IECQ CB that certifies that an ADHP Plan conforms to the requirements of the relevant referenced industry standard(s), and has been implemented effectively in the Plan Owner’s organization.

3.6 Surveillance

The continue process of reviewing the Plan owner’s implementation of the Plan after the initial assessment to determine if it remains in compliance to the Plan.

3.7 Assessment team

The personnel that perform conformity assessments, implementation assessment, and/or surveillance of a Plan.

3.8 Second party

The Plan owner’s customer.

3.9 Third party

An independent compliance assessment organization, taken to mean IECQ in this document.

3.10 Lead assessor

The person who leads the assessment team.
3.11 Technical Expert (TE) [Formally known as Subject Matter Expert (SME)]

A person who provides specific knowledge of or expertise on the subject material of the relevant referenced industry standard, and whose qualifications are in accordance with ADHP Technical Experts Requirements, IECQ OD 3403 and IECQ OD 3404.

3.12 Relevant industry standards

Any or all of the referenced industry standards Table 1, 1-8, for which compliance is being assessed.

3.13 Abbreviations, Acronyms, and Initials

- ADHP – aerospace, defence, and high performance;
- CB – IECQ certification body;
- LA – lead assessor;
- OD – operational document published and maintained by IECQ;
- OEM – original equipment manufacturer;

4 Plan Development

The Plan owner, who is typically an Original Equipment Manufacturer (OEM) for an aerospace, defence, or high performance (ADHP) electronics system, develops the Plan in response to a customer requirement to have such a Plan in compliance to the referenced industry standards Table 1, 1-10.

4.1 Understanding the Requirements

The Plan owner begins the Plan development process by becoming familiar with all the contents of the relevant requirements document(s) and IECQ 03-4 which describes the 2 different types of assessments available: Conformity and Implementation audits.

The Plan owner then assembles a team that includes representation from all the disciplines that can contribute to the Plan development. Typically, this includes component engineering, quality assurance, electrical design engineering, mechanical design engineering, reliability, manufacturing, material management, configuration management, and others as needed.

4.2 Gap Analysis

The Plan owner reviews the Plan owner’s existing processes and documentation that are relevant to the requirements of the relevant requirements document(s); and prepares a gap analysis that includes:

a) Existing processes and documentation that satisfy at least one of the requirements, and identifies which of the requirements are satisfied;
b) Existing processes that, with improvement, can be used to satisfy at least one of the requirements;
c) Existing processes that, with improved documentation, can be used to satisfy at least one of the requirements;
d) Processes that do not exist, and need to be developed and documented to satisfy all the remaining requirements; and

e) A gap analysis report that serves as a basis for satisfying all the requirements.

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2 If possible, it is recommended that the Plan owner and the Plan owner’s customer agree about which requirements document will be used: which may be any combination of the referenced industry standards Table 1, 1-10.
4.3 Process Development and Documentation

Based on the gap analysis report, the Plan owner develops and documents, in the Plan owner’s controlled document system, all the processes required to satisfy the requirements of the relevant requirements document(s).

4.4 Plan Preparation

After all the required processes are developed and documented, the Plan owner prepares the Plan. The Plan includes references to all the processes, and their document numbers, that are being used to satisfy the requirements of the relevant requirements document(s). The Plan also includes a brief description of each documented process, stating clearly, concisely, and unambiguously, how it satisfies a given requirement.

5 Plan Conformity Assessment

Content assessment is conducted to determine whether or not the Plan content conforms to the requirements of the relevant industry standards (any or all of the referenced industry standards Table 1, 1-10), and to determine whether or not the Plan is effectively implemented by the Plan owner.

5.1 Conformity Assessment

IECQ 03-4 and OD3405 define the IECQ rules for conformity assessments.

5.2 Self-Assessment

Prior to the assessment, it is recommended that the Plan owner conduct a self-assessment, using the processes and formats that will be used in the assessment.

A key part of the self-assessment is to assure the proper use of “requirements language,” i.e., the use of “shall,” “should,” “may,” “will,” “needs to,” “is required,” “must,” etc. As a minimum, the assessors expect to see at least one “shall” for each requirement.

The easier it is for the assessor to discern that each requirement is met, the easier and more efficient the assessment will be, and the more likely it will yield a positive result.

5.3 Preparation for Conformity Assessment

The Plan owner contacts the assessing organization to request an assessment, and notifies the assessing organization of the requirements document(s) against which the Plan (any or all of the referenced industry standards Table 1, 1-10) is to be assessed, see OD3405.

It is recommended that the Plan and key documentation to support the assessment be provided to the assessor, with sufficient time prior to the assessment, to allow the assessor to become familiar with the contents, and to resolve obvious issues prior to the assessment.

Confidentiality issues, including all necessary non-disclosure agreements, are resolved prior to the assessment. In some cases, it may be necessary to remove all information related to some programs, and not allow it to be used in any way in the assessment.

The Plan owner’s team leader assures that all necessary information, including process documentation, training records, labelling requirements, etc., and key personnel are available at the assessment. Relevant information typically includes ISO 9000 or AS 9100 certificates.

Estimated times to complete various aspects of the assessment are agreed to prior to the assessment.

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3 The current revisions of the referenced industry standards Table 1 and IECQ OD 3402 contain Compliance Matrices that may be used as examples to illustrate at least one method of documenting compliance to the referenced industry standards Table 1, 1-10.
5.4 Conformity Assessment Team

The assessing organization assembles the assessment team, which typically includes a Technical Expert (TE), a Lead Assessor (LA), and any other required participants.

The TE has the necessary credentials, training, and experience to assess initial compliance to the technical requirements of the relevant industry standards (any or all of References 1-10). The CB conducting the assessment will require the TE to be certified according to the requirements of IECQ OD 3403 and IECQ OD 3404. Typically, the TE has the following, or equivalent, credentials:

- Possibly AS/EN/JISQ 9100 Lead assessor
- A relevant degree in engineering or science, e.g., electrical engineering, mechanical engineering, physics, etc.
- A minimum of 10 years’ experience in a related field in and ADHP industry, such as parts engineering, system design, electronics manufacturing, quality assurance, etc.
- Recent experience in performing ECMP assessments, i.e., a minimum of two in the previous 24 months.

Detailed information on TE qualifications is contained in IECQ OD 3403 and IECQ OD 3404.

The TE is responsible to provide sufficient information about the TE’s background and experience to allow the Plan owner to evaluate potential conflicts of interest.

The CB performing the assessment maintains a list of TEs that are qualified and available, and agrees with the Plan owner on the appointment of the TE for a specific assessment.

The LA has the necessary credentials, training, and experience to assess initial compliance to non-technical requirements of the referenced industry standards Table 1, 1-10 and may also be a TE. The CB will require the LA to be certified according to the requirements of IECQ OD 3403 and IECQ OD 3404.

It is important for all members of the assessment team to act, at all times in a professional, confidential and impartial manner. This includes timely identification and resolution of all perceived conflicts of interest.

In cases where confidentiality has been breached, it is the responsibility of both the SME and LA to notify the CB immediately, and not proceed further until the issue has been resolved.

5.5 Conformity Assessment Findings

When, during the course of the assessment, one of the following is observed, a finding is issued:

- The Plan does not include a documented process for a specific requirement of the relevant requirements document(s);
- The documented process does not satisfy a specific requirement of the relevant requirements document(s); or
- The process satisfies the requirement of the standard, but the documentation does not.
- The Plan owner has not implemented the processes documented in the Plan effectively

The assessment team compiles a list of findings, and recommended corrective actions for each finding.

The findings report is limited to the minimum information needed by the Plan owner to understand the findings, and to implement corrective action.

5.6 Conformity Assessment Report

After the completion of the assessment, the assessment team prepares a report, including the following information, and presents it to the Plan owner:
6 Plan Implementation Assessment

Implementation assessment is conducted to determine whether or not the Plan owner has effectively implemented the requirements of the Plan (that has been prepared according the relevant industry standards (any or all of the referenced industry standards Table 1, 1-10)). Its purpose is not to determine whether or not the Plan conforms to the requirements of the relevant industry standards. As indicated in Clause 2, in certain instances, Plan implementation assessment may be considered a subset of Plan conformity assessment.

6.1 Implementation Assessment

IECQ 03-4 and OD3406 contain the IECQ rules which apply.

6.2 Self Assessment

Prior to the surveillance, it is recommended that the Plan owner conduct a self-assessment, using the processes and formats that will be used in the assessment.

The easier it is for the assessment team discern that each document referenced in the Plan requirement is properly implemented, the easier and more efficient the assessment will be, and the more likely it will yield a positive result.

6.3 Preparation for Implementation Assessment

The Plan owner contacts the assessment organization to request implementation assessment, and provides a copy of the Plan for which implementation assessment will be conducted.

It is recommended that key documentation to support the assessment be provided to the assessment organization, with sufficient time to allow the assessment organization to become familiar with the contents, and to resolve obvious issues prior to the surveillance.

Confidentiality issues, including all necessary non-disclosure agreements, are resolved prior to the assessment. In some cases, it may be necessary to remove all information related to some programs, and not allow it to be used in any way in the assessment.

The Plan owner’s team leader assures that all necessary information, including process documentation, training records, labelling requirements, etc., and key personnel are available at the assessment. Relevant information typically includes ISO 9000 or AS 9100 certificates.

Estimated times to complete various aspects of the assessment are agreed to prior to the surveillance.

6.4 Implementation Assessment Team

The assess organization assembles the assessment team, which typically includes a Lead Assessor (LA), a Technical Expert (TE), and any other required participants.

The TE has the necessary credentials, training, and experience to assess initial compliance to the technical requirements of the relevant industry standards (any or all of References 1-10). The CB conducting the assessment will require the TE to be certified according to the requirements of IECQ OD 3403 and IECQ OD 3404. Typically, the TE has the following, or equivalent, credentials:

– Possibly AS/EN/JISQ 9100 Lead assessor
– A relevant degree in engineering or science, e.g., electrical engineering, mechanical engineering, physics, etc.
– A minimum of 10 years’ experience in a related field in and ADHP industry, such as parts engineering, system design, electronics manufacturing, quality assurance, etc.
– Recent experience in performing ECMP assessments, i.e., a minimum of two in the previous 24 months.

Detailed information on TE qualifications is contained in IECQ OD 3403 and IECQ OD 3404.

The TE is responsible to provide sufficient information about the TE’s background and experience to allow the Plan owner to evaluate potential conflicts of interest.

The CB performing the assessment maintains a list of TEs that are qualified and available, and agrees with the Plan owner on the appointment of the TE for a specific assessment.

The LA has the necessary credentials, training, and experience to conduct the assessment. In the case of a third party assessment, the CB will require the LA to be certified according to the requirements of IECQ OD 3404.

It is important for all members of the assessment team to act, at all times in a professional, confidential and impartial manner. This includes timely identification and resolution of all perceived conflicts of interest.

In cases where confidentiality has been breached, it is the responsibility of the LA to notify the CB immediately, and not proceed further until the issue has been resolved.

6.5 Implementation Assessment Findings
When, during the assessment, one of the following is observed, a finding is issued:
– There is no existing documented process to satisfy at least one of the Plan requirements;
– The documented process does not satisfy a specific requirement of the Plan; or
– The process satisfies the requirement of the standard, but the documentation does not.

The assessment team compiles a list of findings, and recommended corrective actions for each finding.

The findings report is limited to the minimum information needed by the Plan owner to understand the findings, and to implement corrective action.

6.6 Implementation Assessment Report
After the completion of the assessment, the assessment team prepares a report, including the following information, and presents it to the Plan owner:
– The Date
– The Location
– The Plan document number;
– Members of the assessment team;
– A list of findings, with recommended corrective action for each.

After completion, the Plan owner completes the “IECQ ECMP Witness Assessment Form” of IECQ OD 3404, and presents it to the CB.

7 Surveillance
The steps of the surveillance process are identical those of the Plan implementation assessment process, as described in Clause 3. The only difference is that surveillance is performed at prescribe intervals of time after the initial conformity assessment or implementation assessment, to determine that the Plan owner is continuing to implement the processes documented in the Plan.
## Annex A Document Reference Tables

### Table 1 - Referenced industry standards

<table>
<thead>
<tr>
<th>Number</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>SAE EIA-STD-4899 Requirements for and Electronic Components Management Plan</td>
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</tr>
<tr>
<td>4</td>
<td>SAE GEIA-STD-0005-1 Performance Standard for Aerospace and High Performance Electronic Systems Containing Lead-free Solder</td>
</tr>
<tr>
<td>5</td>
<td>IEC TS 62668-1 Process management for avionics – Counterfeit Prevention – Part 1: Avoiding the use of counterfeit, fraudulent, and recycled electronic components</td>
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<tr>
<td>6</td>
<td>SAE AS5553 Fraudulent/Counterfeit Electronic Parts; Avoidance, Detection, Mitigation, and Disposition</td>
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