IEC Quality Assessment System for Electronic Components (IECQ System)

Rules of Procedure –
Part 5: IECQ HSPM Scheme – Hazardous Substance Process Management Requirements

withdrawn
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

RULES OF PROCEDURE –
Part 5: IECQ HSPM Scheme – Hazardous Substance Process Management
Requirements

FOREWORD

This publication has been prepared by the Management Committee (MC) of the IEC Quality Assessment System for Electronic Components (IECQ).

Although developed for Hazardous Substance Process Management (HSPM), this publication may serve as a model for other areas with similar HSPM considerations.

This second edition of IECQ 03-5 replaces the first edition IECQ 03-5. Main changes to the second edition include:

- Move the requirements for organizations operating from more than one location (site) into IECQ 03-1 “General requirements for all Schemes”, IECQ 03-1 Clause 5,
- Move the requirements for organisations utilizing one management system on multi-sites into IECQ 03-1 “General requirements for all Schemes”, IECQ 03-1 Clause 5,
- Move Annex B Definition of “one management system” into IECQ 03-1 “General requirements for all Schemes”, Annex D,
- Update the “IECQ HSPM Certification procedure” requirements under “General” as per Decision CABC 2011/16, HSPM and ISO 9001 assessments conducted at the same time.
- Clarification of Annex A.

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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</thead>
<tbody>
<tr>
<td>IECQ MC/235/CA</td>
<td>MC/255A/R</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.
INTRODUCTION

Taking into account the object of the International Electrotechnical Commission (IEC) as given in Article 2 of the Statutes, the particular object of the IECQ System, operated in conformity with the Statutes and under the authority of the IEC, is to facilitate international trade in electronic components of assessed quality, by providing a global framework for independent assessment and certification.

The object is achieved by the implementation of quality assessment procedures in such a manner that organizations, processes, and components certified as conforming to the requirements of an applicable standard or specification, are acceptable to all participants.

The IECQ System provides manufacturers with a “Supply chain verification tool” for seeking assurance that electronic components, assemblies, processes and related materials conform to declared technical Standards and Specifications.

The IECQ Hazardous Substance Process Management Requirements are designed to evaluate equipment manufacturers’ and related organizations’ processes for compliance with IECQ QC 080000 IECQ HSPM (IECQ HSPM) in addition to the compliance of the processes with ISO 9001 QMS.

IECQ HSPM provides the requirements used to demonstrate that the organization has developed, documented, and implemented processes for managing the production, selection and use of electrical and electronic components and products in accordance with customer, local, national and international IECQ HSPM requirements.
RULES OF PROCEDURE –
Part 5: IECQ HSPM Scheme – Hazardous Substance Process Management
Requirements

1 Scope

This publication contains the Rules of Procedure of the Scheme of the IECQ, hereinafter
referred to as the "Rules", for the Hazardous Substance Process Management Requirements
System (IECQ HSPM Scheme).

This IECQ HSPM Scheme Rules of Procedure provides the requirements specific to this
scheme and is to be used in conjunction with applicable IECQ System management Basic
Rules (IECQ 01), General Rules of Procedures (IECQ 03-1) and Operating Documents.

2 Normative references

The following publications contain provisions, which, through reference in this text, constitute
provisions of these Rules. At the time of publication, the editions indicated were valid. The
IECQ Management Committee shall decide the timetable for the introduction of revised
editions of the publications.

IECQ 01, IEC Quality Assessment System for Electronic Components (IECQ System) – Basic
Rules

IECQ 02, General Requirements for the Acceptance of IECQ Certification Bodies into the
IECQ System

IECQ 03-1, General Requirements for all IECQ Schemes

IECQ OD 010, Qualification Criteria for Assessors and Lead Assessors according to IECQ
(third-party assessment)

QC 001002-2, IEC Quality Assessment System for Electronic Components (IECQ) – Rules of
Procedure – Part 2: Documentation

IECQ QC 080006, IECQ Hazardous Substance Process Management Requirements

ISO 9001, Quality management systems – Requirements

ISO/IEC 17000, Conformity assessment – Vocabulary and general principles

ISO/IEC 17021, Conformity assessment – Requirements for bodies providing audit and
certification of management systems

ISO/IEC 17025, General requirements for the competence of testing and calibration
laboratories

ISO/IEC Guide 65, General requirements for bodies operating product certification systems

In the event of conflict between the provisions of this document and any other directly or
indirectly referenced provisions, the provisions of this document shall take precedence.
3 Terms and Definitions

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

For the purpose of the IECQ HSPM Scheme the terms and definitions given in IECQ 01, IECQ 03-1 and the following apply.

3.1 IECQ HSPM Scheme

Scheme of the IECQ enables the independent conformity assessment for compliance with IECQ QC 080000, IECQ Hazardous Substance Process Management Requirements

3.2 IECQ Site Assessment Report (SAR)

A document that presents the results of an on-site assessment of an organization seeking certification under the IECQ HSPM (Hazardous Substance Process Management) Programme of the IECQ, by an IECQ CB, to the requirements of the IECQ HSPM Scheme.

NOTE The IECQ Site Assessment Report form is available from the member’s area of the IECQ website http://www.iecq.org.

3.3 IECQ Compliance Report Form (CRF)

A document that presents the results of an assessment of an organization seeking certification under the IECQ HSPM (Hazardous Substance Process Management) Scheme of the IECQ, by an IECQ CB, to the requirements of the IECQ QC 080000 Latest Edition, Principles of the IECQ HSPM Scheme. This CRF is primarily applicable to initial assessment and special assessments.

NOTE The IECQ Compliance Report Form is available from the member’s area of the IECQ website http://www.iecq.org.

4 Principles of the IECQ HSPM Scheme

IECQ HSPM Certificate of Conformity

Subclause 5 of IECQ 03-1 applies and the following:

4.1 The IECQ HSPM Scheme provides the means for organizations including manufacturers, suppliers and service providers to obtain an IECQ HSPM Certificate of Conformity that is intended to provide the international market with confidence that such organizations have implemented processes to identify and control the introduction of hazardous substances (HS) into its products in accordance with the technical and quality system requirements of the IECQ HSPM Scheme. This is ensured through independent conformity assessment and ongoing surveillance by an IECQ CB of an organization’s business and quality management systems and site assessments for compliance with the following:

- Designers, Manufacturers, suppliers, and service providers of products have developed processes to identify, control, quantify, and report the amounts of HS in the products they manufacture or supply
- The establishment and implementation of system procedures within the organization’s business and quality management systems
- Where HS are introduced into the products; the establishment and implementation of processes to test, analyse, or otherwise ascertain the HS content, and to make it available to the customer
4.2 IECQ QC 080000 and relevant requirements of ISO 9001 form the basis of the IECQ HSPM Scheme requirements.

4.3 The IECQ HSPM Certificate of Conformity may be issued for a specific area of operation of an organization, as clearly defined in the QMS scope of activity.

4.4 IECQ HSPM surveillance shall be conducted on all sites holding certification on an annual basis.

4.5 Where the IECQ HSPM Scope of Certification includes customer requirements the assessment shall include customer specific specification and these specifications may be listed in the Certificate of Conformance (COC). Use of such specification shall not remove or reduce any of the requirements of IECQ QC 080000.

Where such specifications are listed in the COC, annual surveillance shall include the manufacture control over the maintaining of updated requirements of these specifications.

5 Organizational structure

The Organization (Client)

An Organization shall have the responsibilities, specified in Subclause 7.2.3 of IECQ 03-1 and the following:

a) the organization shall maintain and document a QMS in accordance with the requirements of IECQ QC 080000 which encompasses the requirements of "IECQ Quality Management System requirements" IECQ 03-1 and make available copies of that documented QMS should the IECQ CB require it for certification purposes;

b) the organization shall nominate a DMR with demonstrated technical competence as defined in IECQ QC 080000 Specification;

c) the organization shall not significantly vary the QMS or IECQ HSPM and its related processes under which any IECQ HSPM Certificate of Conformity is issued during the period of the certification unless it has given the IECQ CB notice in writing of its intentions to do so, and has received confirmation in writing from the IECQ CB that such variations do not render the Certificate invalid. It is expected that changes may be made as a result of continuous improvement practices. However, when such changes result in significant changes to the IECQ HSPM system and its related processes, the IECQ CB shall be notified.

6 IECQ HSPM Certification

6.1 IECQ HSPM Certificate of Conformity for an Organization (Client)

Subclause 8.1 of IECQ 03-1 applies except as follows:

6.1.1 Issue

An IECQ CB, on the basis of a satisfactory IECQ Compliance Report Form (CRF) and IECQ Site Assessment Report (SAR), issues an IECQ HSPM Certificate of Conformity certifying that the organization has developed and implemented IECQ HSPM procedures and processes which conform with the applicable requirements for IECQ HSPM organization certification which is in accordance with the Basic Rules IECQ 01, these Rules of Procedure and with respect to the IECQ Specification QC 080000.
6.2 IECQ Compliance Report Form (CRF) and IECQ Site Assessment Report (SAR)

6.2.1 Content

A CRF & SAR is prepared and issued by an IECQ CB recording the assessment of an applicant organization’s implemented management system and procedures for compliance with the IECQ HSPM Scheme requirements. The assessment includes assessing conformity of the organization’s documented management system with the requirements of the IECQ HSPM Scheme in addition to assessing the implementation of the technical processes used.

6.2.2 Issue

Upon issuing CRFs & SARs, IECQ CBs shall ensure that the CRF & SAR refers to all of the location(s) of the organization’s activities and includes a copy of the assessor(s) assessment trail.

6.2.3 Restrictions

The CRFs & SARs are documents used in the preparation of IECQ organization’s Certificate of conformity and basis for on-going surveillance of the organization; they shall not be used in any form of advertising or sales promotion in a way that the information may be misrepresented.

7 IECQ HSPM Certification procedure

Subclause 9 of IECQ 03-1 applies except as follows:

7.1 General

IECQ HSPM assessments for compliance with IECQ QC 080000 involve a technical and detailed focus beyond that normally required for an ISO 9001 QMS and/or EMS audit and hence initial and surveillance IECQ HSPM assessments shall not be substituted by ISO 9001 and/or ISO 14001 audit.

7.2 Application

The applicant may be a designer, manufacturer, supplier, repairer, or maintainer of product(s).

The organization seeking approval shall submit or make available the following documentation (non exhaustive) for review by the assessment team in addition to that specified in IECQ 03-1:

a) Master List of HS; and
b) HSPM documented requirements.

7.3 Assessment Team for IECQ HSPM Assessments

The assessment team for IECQ HSPM assessments shall be comprised as follows:

<table>
<thead>
<tr>
<th>Assessment team members</th>
<th>Function</th>
<th>Qualifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>IECQ CB assessors</td>
<td>Assessment of general IECQ HSPM elements; and management of audit process</td>
<td>IECQ HSPM Lead Assessor – Quality Systems and Electronic Components</td>
</tr>
<tr>
<td>IECQ CB assessors shall be electrical and electronic component expert</td>
<td>As necessary to form assessment team</td>
<td>IECQ HSPM Assessor or Lead Assessor – Quality Systems and Electronic Components</td>
</tr>
<tr>
<td>Specialist</td>
<td>Provide specific knowledge and understanding</td>
<td>Relevant experience and knowledge of the organization’s industry and product involvement</td>
</tr>
</tbody>
</table>
The number of assessors and assessment days is dependent on the size of the enterprise and the complexity of the assessment. Guidelines are detailed in Annex A. Deviation from these guidelines shall be compliant with ISO/IEC 17021 and requires the IECQ CB to formally record the justification for doing so within their files, on each occasion.

An IECQ HSPM qualified IECQ CB lead assessor shall lead the assessment with responsibility for assuring all elements of the assessment plan are covered including IECQ requirements, applicable IECQ HSPM processes.

NOTE  The term “IECQ Lead Assessor” is detailed in IECQ OD 010.

7.4 Examination

Subclause 9.5 of IECQ 03-1 applies and the following.

The IECQ CB assessment team shall conduct an examination of the documentation to verify its compliance with the applicable requirements of IECQ QC 080000 and compile an IECQ Compliance Report Form CRF), available for download from the IECQ members’ area of the internet site http://www.iecq.org, or equivalent. Alternatively the IECQ CB may use its own equivalent reporting system.

7.5 Assessment of IECQ HSPM Applicant’s Site(s)

Subclause 9.6 of IECQ 03-1 applies and the following.

The assessment shall be conducted in accordance with the assessment plan and the requirements of IECQ QC 080000 and these Rules of Procedures.

The IECQ CB may use its own reporting system which incorporates as a minimum the IECQ SAR requirements.

While there may be occasions where an observation may be deemed useful to the company such Observations may be given verbally but shall not be included as a result or commentary within the IECQ HSPM report or the assessor’s assessment trail(s).

8 Acceptance of IECQ Certification Bodies (IECQ CB)

8.1 General

New IECQ CBs or existing IECQ CBs seeking to participate in the IECQ HSPM Scheme shall comply with the general requirements of IECQ 02 plus the following additional requirements.

8.2 Specific requirements for IECQ HSPM

CBs shall be assessed for their competence to comply with these Rules which shall be demonstrated by an IECQ assessment. The general competence, efficiency, experience, familiarity with IECQ QC 080000 IECQ HSPM, IECQ System rules, IECQ HSPM Scheme requirements and competence to carry out quality management system assessments as well as compliance with ISO/IEC 17021 shall be assessed. Acceptance in another IECQ Scheme or accreditation by a recognized national accreditation body shall be taken into account. In those cases, the IECQ MC shall decide upon the extent of the assessment that is necessary. A satisfactory assessment as documented in an IECQ Assessor Report (IECQ OD 013) shall be approved by the IECQ CABC and accepted by the IECQ Management Committee (IECQ MC).
8.3 Witness Assessment of an IECQ CB

The application process for an applicant CB wishing to become an IECQ CB in the IECQ HSPM Scheme includes a Witness Assessment. The Witness Assessment shall be conducted within 12 months of the applicant being accepted as an IECQ CB. The witness assessment shall be conducted on the first IECQ HSPM client application conducted by the applicant IECQ CB.

The New IECQ CB shall inform the IECQ secretariat upon receipt of their first IECQ HSPM application and the willingness of their applicant to participate in the IECQ Witness Assessment of the New IECQ CB.

IECQ Secretary, in consultation with the CABC Chairman, shall appoint an IECQ Assessor(s) to conduct the Witness Assessment.

During the visit to an applicant IECQ HSPM organization, the IECQ Secretariat Assigned Assessment Team shall have access to the documentation referred to in ISO 9001 QMS and required in IECQ QC 080000 and which is relevant to the component production under review. The earlier provision of this documentation shall be at the organization’s discretion. This documentation may be in any language, the candidate being responsible for providing oral translation into one of the official languages of the IEC at the time of the visit.
Annex A
(normative)

Initial, Recertification and Surveillance Assessment Days

The following factors (non-exhaustive) may increase or decrease the times shown below:

- Type of business
- Complexity
- Logistics
- Multiple or Single process
- Language
- Variety of activities undertaken by employees
- Degree of regulation
- Stability of the IECQ HSPM System

The IECQ CB shall determine the total man days required for the initial, recertification and surveillance assessment based on the number of employees at each of organizations facility/location(s) and shall not combine the total number of employees for all sites.

The increase or reduction in the times shown below may be altered due to the factors above or combinations of, but not by more than 30%. Any change to the times shown below shall be justified in the report.

For organizations with 150 staff or less, the ½ man-day document review may be conducted on-site immediately prior to commencement of the initial assessment where upon the scope and timetable for the initial assessment shall be agreed between the IECQ CB and the organization. Ideally, organizations with more than 150 staff will have their document review conducted on or off-site sometime prior to the planning of the initial assessment. However, those IECQ CBs with confidence of their knowledge of the organization involved may conduct the document review in a similar manner to that arranged for smaller organizations.

<table>
<thead>
<tr>
<th>Certified Entity Number of Employees</th>
<th>Initial &amp; Recertification Assessments On-site Days</th>
<th>Initial Assessment Document Review Days. Recertification Doc Review as necessary</th>
<th>Annual Surveillance Days</th>
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<tbody>
<tr>
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<td>0,5</td>
<td>1</td>
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<td>76 – 150</td>
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<td>0,5</td>
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<tr>
<td>151 – 600</td>
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<td>3</td>
</tr>
<tr>
<td>601 – 1 000</td>
<td>5</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>1 001 – 2 000</td>
<td>5</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2 001 – 3 000</td>
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<td>3 001 – 4 000</td>
<td>7</td>
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<td>9 001 – 15 000</td>
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<td>15 001 – 20 000</td>
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