

IECQ PUBLICATION

IEC Quality Assessment System for Electronic Components (IECQ System)

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



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IECQ OPERATIONAL DOCUMENT

IEC Quality Assessment System for Electronic Components (IECQ System)

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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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 IECQ.

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

This fifth edition of IECQ 03-5 replaces the fourth edition. Main changes to the fourth edition include:

- Amendment of Scope to include application
- Clarification of the IECQ HSPM internal auditor qualifications
- Amendment to Annex A table

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

Document	Report on MC Approval
IECQ WG05-030A-CD	MC/373/RM

Full information on the approval by MC 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) 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.

Further information concerning these procedures or any other aspect of the IECQ System, may be obtained by contacting the IECQ Secretariat as follows:

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

1 Scope

1.1 General

This publication contains the Rules of Procedure, hereinafter referred to as the "Rules", of the Scheme of the IECQ for the Hazardous Substance Process Management Requirements (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), Rules of Procedure (IECQ 03-1) and Operational Documents.

1.2 ISO 9001 application

Permissible exclusions relating to Clause 7 of ISO 9001, as provided in ISO 9001:2008, are not accepted within the IECQ Schemes and Programmes.

For the purposes of compliance with QC 080000 all requirements of ISO 9001:2015 shall apply.

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 (MC) shall decide the timetable for the introduction of revised editions of the publications.

IECQ 01, *Basic Rules*

IECQ 02, *Rules of Procedure – General requirements for the acceptance of IECQ Certification Bodies into the IECQ System*

IECQ 03-1, *Rules of Procedure – General requirements for all IECQ Schemes*

IECQ OD 010, *Qualification criteria for Assessors and Lead Assessors according to IECQ (third-party assessment) – General for all Schemes*

IECQ SAR QC 080000, *IECQ Standard Form IECQ-HSPM SAR – IECQ Site Assessment Report SAR QC 080000*

IECQ CRF QC 080000, *IECQ Standard Form IECQ-HSPM CRF – IECQ Compliance Report Form CRF QC 080000*

IECQ QC 080000, *Hazardous Substance Process Management (HSPM) System 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 17065, *Conformity assessment – Requirements for bodies certifying products, processes and services*

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 that enables the independent conformity assessment for compliance with IECQ QC 080000

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 Scheme 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 [publications/standardforms](#) area of the IECQ website 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 Scheme of the IECQ, by an IECQ CB, to the requirements of IECQ QC 080000. This CRF is primarily applicable to initial assessment and special assessments

NOTE The IECQ Compliance Report Form is available from the [publications/standardforms](#) area of the IECQ website 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 (CoC) 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 on-going 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 CoC 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 to all clauses 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 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.

- 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.
- The organization shall nominate a Designated Management Representative (DMR) with demonstrated technical competence as defined in IECQ QC 080000 Specification.
- The organization shall implement and maintain qualified internal auditors and maintain records of qualification and on-going requalification.
 - Internal auditor qualifications
 - shall have attended and successfully passed a QMS internal auditor course.
 - shall have attended and successfully passed an IECQ HSPM internal auditor training course or workshop.
 - performance of internal auditor.
- 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 CoC 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 Scheme 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.

6.2 IECQ Compliance Report Form (CRF) and IECQ Site Assessment Report (SAR)

6.2.1 Content

A CRF and 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.

An IECQ CB alternatively may use its own equivalent reporting system that incorporates as a minimum the SAR and CRF requirements.

6.2.2 Issue

Upon issuing CRFs and SARs, IECQ CBs shall ensure that the CRF and 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 and 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 Environmental Management system (EMS) audit and hence initial, surveillance and re-certification IECQ HSPM assessments shall not be substituted by ISO 9001 and/or ISO 14001 audits.

7.1.1 Integrated IECQ HSPM and ISO 9001 audit

In view of the fact that IECQ HSPM is designed based on ISO 9001, an integrated IECQ HSPM and ISO 9001 (or its full equivalent¹) audit may be considered, provided the following rules are observed.

- Integrated audit means the QMS and IECQ HSPM are being assessed concurrently² by the same audit team.
- The activity and geographical scopes of the QMS shall be identical or larger than the activities and geographical scopes of the HSPM.
- In an integrated audit, it is expected that there is only one closing meeting for presenting the audit findings and conclusions. However, should there be need to conduct two separate closing meetings, the audit conclusion of the QMS portion of the assessment shall be made earlier or coincide with the IECQ HSPM assessment. In other words, at the time of the IECQ HSPM audit conclusion, the IECQ HSPM audit team shall be confident that the QMS is in compliance with ISO 9001.

¹ "Full equivalent" means the standard in question covers all requirements of ISO 9001. Acceptable equivalent includes ISO TS 16949, AS 9100, International Railway Industry Standard (IRIS), and TL 9000.

² An integrated audit is when an organization has integrated the application of requirements of two or more management systems standards into a single management system and is being audited against more than one standard. See ISO/IEC 17021.

- All auditors participating in the integrated audit shall be qualified in both ISO 9001 (or its full equivalent) and IECQ HSPM, at a grade appropriate to the role of the concerned auditors in the integrated audit. The IECQ HSPM auditors shall be qualified in accordance with 7.3.
- Each audit team member in the audit team shall perform audits against both the QMS and IECQ HSPM standards.
- The IECQ HSPM assessment shall maintain a technical focus and evidence of compliance shall be recorded in strict accordance with 6, 7.4 and 7.5.
- Separate CRF and SAR reports for the IECQ HSPM assessment shall be compiled in accordance with 6 and 7.4.
- Maximum of 20 % of man-day reduction from the man-day stipulated in the initial assessment, surveillance, and re-certification columns of Annex A may be applied if the conditions stated in this paragraph are met. Reasons for the reduction shall be recorded.

NOTE The 20 % reduction is applied to the IECQ HSPM man-day only; total combined allowable man-day reduction shall not exceed the state 30 % of Annex A.

7.1.2 Combined IECQ HSPM and ISO 9001 audit

A combined audit³ as defined in ISO 17021:2011 is not considered an integrated audit described above. In a combined audit, the QMS and IECQ HSPM audits are scheduled to audit in parallel by two different teams. A combined audit is not eligible for the man-day reduction mentioned in 7.1.1.

7.1.3 Audit plan

The audit plan to be prepared by the audit team shall indicate clearly the time spent for each standard respectively in order to demonstrate the time allocated for each standard is sufficient.

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.

- Master list of HS
- HSPM documented requirements

7.3 Assessment team for IECQ HSPM assessments

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

Assessment team members	Function	Qualifications
IECQ CB assessors	Assessment of general IECQ HSPM elements; and management of audit process	IECQ HSPM Lead Assessor (to IECQ HSPM Standard Training IECQ 04-5) – Quality Systems and Electronic Components
IECQ CB assessors shall be electrical and electronic component expert	As necessary to form assessment team	IECQ HSPM Assessor or Lead Assessor (to IECQ HSPM Standard Training IECQ 04-5) – Quality Systems and Electronic Components

³ A combined audit is when an organization is being audited against the requirements of two or more management systems standards together. See ISO/IEC 17021.

Specialist	Provide specific knowledge and understanding	Relevant experience and knowledge of the organization's industry and product involvement
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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 – Stage 1

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

The IECQ CB assessment team shall conduct a Stage 1 examination of the documentation and processes to verify their compliance with the applicable requirements of IECQ QC 080000 and compile an IECQ Compliance Report Form (CRF) and IECQ Site Assessment Report (SAR), see 6.2.1. Evidence of compliance shall be recorded in the IECQ CRF.

7.5 Assessment of IECQ HSPM applicant's site(s) – Stage 2

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. The compiled IECQ Compliance Report Form (CRF) and IECQ Site Assessment Report (SAR) in accordance with 7.4 above shall be completed with sufficient evidence of compliance being recorded.

NOTE See 6.2.1 for report format and use.

The basis of all assessments is to seek evidence of compliance with requirements. The approach to assessment being that decisions shall be either "comply", "does not comply" or "not applicable". Selection/use of "not applicable" shall be justified in the report.

While there may be occasions where an observation may be deemed useful to the company such observations may be given verbally throughout the assessment but shall not be included as a result or commentary within the IECQ HSPM report or the assessor's assessment trail(s). Such verbally provided observations shall not be given or presented at the closing meeting.

7.6 Completion (Granting of Certification)

For the purpose of IECQ HSPM, the requirements for Completion (Granting of Certification) contained in Subclause 9.7 of IECQ 03-1 apply and the following.

Upon satisfactory completion of the work and a favourable reviewed by the IECQ CB for a certification decision, the IECQ CB shall:

- a) issue the finalized IECQ HSPM IECQ Compliance Report Form (CRF) and IECQ Site Assessment Report (SAR) (or the IECQ CB's IECQ approved equivalent document/system) worksheets
- b) issue the definitive IECQ HSPM Certificate of Conformity in accordance with clause 8.1 of IECQ 03-1 and clause 6.1 of this publication, 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 IECQ 01, these Rules and with respect to the IECQ Specification QC 080000.

- c) where requested by the applicant, issue a printed and signed copy of the definitive IECQ Certificate of Conformity in accordance with clause 8.1 of IECQ 03-1.

7.7 Surveillance

For the purpose of IECQ HSPM, the requirements for surveillance contained in Subclause 9.8 of IECQ 03-1 apply.

7.8 Renewal of the Certificate of Conformity (Re-certification)

Subclause 9.12 of IECQ 03-1 applies and the following.

All requirements of IECQ QC 080000 shall be covered in full, as required for compliance with the stated scope of activities.

All sites covered by the IECQ HSPM Certification shall be assessed by on-site audit.

The certification renewal once in a three-year period shall be completed prior to the anniversary of the certification cycle “certificate expiry date”.

7.9 Transfer of IECQ HSPM Certificate of Conformity

Subclause 9.18 of IECQ 03-1 applies.

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 that 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 Management Committee (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 Conformity Assessment Bodies Committee (CABC) and accepted by the IECQ MC.

8.3 Witness assessment of an IECQ CB

8.3.1 Initial

The application process for an applicant CB wishing to become an IECQ CB in the IECQ HSPM Scheme includes a witness assessment conducted by the IECQ. 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 Secretariat 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 (IECQ HSPM) 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.

8.3.2 On-going

The IECQ shall conduct a witness assessment at each 5-year re-assessment and at least one other occasion during a 5-year re-assessment cycle, ideally at 2,5 yearly intervals.

Witness assessments conducted by national accreditation bodies may be utilized where prior arrangements have been made according to IECQ OD 018.

Annex A (normative)

Initial, re-certification 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, re-certification and surveillance assessment based on the number of employees at each of organization's 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.

Certified entity number of employees	Initial assessments on-site days	Re-certification assessments on-site days	Initial assessment document review days. Re-certification document review as necessary	Annual surveillance days
1 – 75	2	2	0,5	1,5
76 – 150	3	2,5	0,5	2
151 – 600	4	3	1	3
601 – 1 000	5	4	1	3
1 001 – 2 000	5	4,5	1	4
2 001 – 3 000	6	5	1	4
3 001 – 4 000	7	6	1	5
4 001 – 8 000	8	6,5	1	5
8 001 – 15 000	8	7	1	6
15 001 – 20 000	9	8	1	6

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