IECQ PUBLICATION

IEC Quality Assessment System for Electronic Components (IECQ Scheme)

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

withdrawn
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

withdrawn
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IEC Quality Assessment System for Electronic Components
(IECQ Scheme) –

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

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 third edition of QC 001002-5 replaces the second edition (2005-10). Main Changes to the second edition include:

- Reference to IECQ Operational Documents;
- Expansion on the association with ISO 9001:2000 system audits;
- Clarification on the handling of Non-Conformities;
- Introduction of standardized report forms, Compliance Report Form (CRF) and Site Assessment Report (SAR); and
- Expansion on the requirements for surveillance visits;
- Use of the term IECQ Certification Body (CB) which replaces SI (Supervising Inspectorate);
- Others.
1 Introduction

The IECQ Hazardous Substance Process Management (HSPM) requirements are designed to evaluate component and equipment manufacturers’ and related organizations’ processes for technical process management compliance with QC 080000 IECQ HSPM (IECQ HSPM) in addition to the compliance of the processes with their general ISO 9001:2000 Quality Management System (QMS) or equivalent. IECQ HSPM provides the requirements used to demonstrate that the organization has developed, documented, and implemented processes for managing the Hazardous Substance (HS) and/or Hazardous Substance Free (HSF) technical aspects of production, selection and use of electrical and electronic components and products in accordance with customer, local, national and international IECQ HSPM requirements. Organizations shall document, with justifications, all exceptions taken to elements of this standard according to the justifications allowed in the documents listed in clause 2.

2 Applicable documents

This list is not exhaustive:

- IECQ 01:2003, IECQ Basic Rules;
- IECQ OD 010: V1, Qualification Criteria for Assessors and Lead Assessors according to IECQ (third-party assessment);
- Directive 2002/95/EC on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment;
- Directive 2002/96/EC on Waste Electrical and Electronic Equipment;
- Directive 94/62/EC on packaging and packaging waste; and

and as they are amended from time to time.
3 Terms and definitions

3.1 Certificate of Approval

A Certificate of Approval is an IEC Quality Assessment System for Electronic Components (IECQ) certificate recognizing that an organization has the resources and facilities necessary to ensure the technical aspects of HSPM of products (including services) in accordance with the basic Rules of the IECQ detailed in the Operational Documents, QC 080000 and the requirements of this Rule of Procedure.

3.2 Designated Management Representative

A Designated Management Representative (DMR) is a person, acceptable to the IECQ Certification Body (CB), who is a member of the approved organization and who is responsible for liaison with the IECQ CB regarding the HSPM of that organization. That person is the focus of communication between the IECQ CB and the organization.

3.3 IECQ Certification Body (CB)

A IECQ CB is a body responsible for the surveillance of all procedures relating to the technical aspects of IECQ HSPM. This includes the evaluation, surveillance and approval of applicants and the supervision of the certification of conformity when applicable.

4 General requirements

4.1 Certification

4.1.1 An approved IECQ CB is the sole authority by which an IECQ HSPM Certificate of Approval may be issued.

4.1.2 An organization capable of demonstrating that it complies with the requirements shall be entitled to a Certificate of Approval in accordance with these IECQ Rules of Procedure and supporting IECQ Operational Documents.

4.1.3 Under the surveillance plan for maintenance of approval noted in 6.5, IECQ CBs issuing IECQ HSPM Certificates shall conduct site assessments on an annual basis. In addition, certificates shall be renewed at least once every three years, unless the termination rights provided for in the IECQ Basic Rules and Rules of Procedure are exercised. If an organization does not intend to renew its approval, it shall notify the IECQ CB in writing of its intentions not less than 60 days prior to its renewal date.

4.1.4 An organization’s right to use the Certificate of Approval is not transferable.

4.2 Requirements on the organization

An organization shall:

a) at all times comply with the requirements;

b) maintain and document a QMS in accordance with the requirements of IECQ QC 080000 which encompasses the requirements of QC 001002-3 and make available copies of that documented QMS should the IECQ CB require it for approval purposes;

c) not significantly vary the QMS or IECQ HSPM and its related processes under which any certificate is issued during the period of the approval 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 HSPM system and its related processes, the IECQ CB shall be notified;
d) give the representatives of the IECQ CB access, during normal working hours, to the premises and/or sites in which work being performed within the scope of their approval is being carried out for the purpose of examining systems, processes, methods of test, and records. These access rights shall include, where necessary, any agreed visits needed to verify that the procedures for the termination of approval described below have been carried out. The organization shall facilitate any arrangement allowing the IECQ CB to conduct assessment at the supplier upon aspects of operations having influence on the scope of approval;

e) nominate a DMR, in accordance with the IECQ Rules of Procedure, who shall be responsible for all matters in connection with the requirements of the Certificate of Approval; and

f) upon the termination or suspension of the Certificate of Approval, immediately discontinue the use of the IECQ logo on all materials and refrain from making or implying any statement of IECQ approval. No further release under IECQ can take place.

4.3 Requirements on the IECQ CB

The IECQ CB shall:

a) after granting approval to an organization, initiate a surveillance assessment plan in accordance with IECQ Rules and IECQ Operational Documents, except as modified in 6.5;

b) not disclose any information concerning the organization which is of a confidential nature, other than information which is in the public domain, or which may be required by law; and

c) notify the organization of customer complaints relating to the compliance of its product, process or service with the specified requirements.

5 Maintaining compliance

5.1 Temporary inability to comply

If an organization is temporarily unable to comply with the requirements, the IECQ CB may require that certification of the organization be suspended and the manufacturer to discontinue use of the IECQ logo or any claim to IECQ approval under this Rule of Procedure. This will be effective until the IECQ CB is satisfied that the conditions of approval are again achieved or pending the result of an appeal as described under 6.7.

NOTE The IECQ logo is only for use on printed matter. It is not a Mark of Conformity.

5.2 Failure to comply

If the organization fails to comply with the present requirements the IECQ CB may, subject to the provisions in 6.5, as appropriate:

a) revoke or suspend the certificate of approval; and

b) refuse to issue or renew the certificate of approval.

5.3 Changes made by IECQ

In the event that the IECQ makes changes to the present requirements or the IECQ Rules which affect the approval of the organizations, the Conformity Assessment Bodies Committee (CABC) shall determine the effective global implementation date and the IECQ CB shall formally:

a) inform approved organizations of the effective date of the change allowing them sufficient time to amend their IECQ HSPM processes; and

b) notify all the approved organizations affected by the new requirements of the scope of the changes.

Failure of an approved organization to take required action by the effective date may lead to withdrawal or suspension of the approval.
6 Implementation procedures

6.1 General

6.1.1 An organization seeking IECQ HSPM approval shall comply with the requirements for organization approval as described in the IECQ Rules of Procedure QC 001002-3 clause 2. In accordance with these rules, relevant provisions of ISO 9001:2000 quality management system standard or equivalent QMS shall be met. Compliance with the requirements for IECQ organization approval (QC 001002-3) can be assessed in conjunction with the IECQ HSPM assessment or during an independent IECQ assessment.

6.1.2 Organizations that have already obtained, from a suitably accredited registrar, ISO 9001:2000 registration or a registration to an equivalent QMS standard, as applicable, may not be required to be re-assessed to those QC 001002-3 requirements for their IECQ HSPM assessment where evidence exists that such requirements are duly met. Such organizations shall submit the most recent report and a copy of the registration certificate detailing the scope of registration, covering a complete cycle of assessments (all elements of the standard assessed) to the IECQ CB for review. The IECQ CB shall determine what, if any, elements of the standard need to be assessed in addition to the IECQ requirements for organization approval. QMS registrations awarded by unaccredited bodies shall not be taken into account for the purposes of IECQ HSPM certification.

6.1.3 Organizations not registered to ISO 9001:2000 or equivalent QMS requirements need not obtain a registered quality system but shall comply with the requirements of the applicable standard as well as the additional IECQ requirements of QC 001002-3. As a result, these organizations shall be required to undergo an assessment to the requirements of QC 001002-3, which includes ISO 9001:2000, prior to an initial IECQ HSPM assessment, as well as subsequent surveillance assessments to these requirements in addition to those noted below in 6.5.

6.1.4 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>
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<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 organisation’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.

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

6.1.5 IECQ HSPM assessments for compliance with QC 080000 involve a technical and detailed focus beyond that normally required for an ISO 9001:2000 QMS and/or EMS audit and hence initial and surveillance IECQ HSPM assessments shall not be conducted as an integral assessment of an ISO 9001:2000 and/or ISO 14001:2005 audit.
6.2 Documentation review

The organization seeking approval shall submit or make available the following documentation (non exhaustive) for review by the assessment team:

a) Quality Manual;
b) Master List of HS;
c) Management Review Procedure;
d) Internal Assessment Procedure;
e) Corrective/Preventive Action Procedure;
f) HSPM documented requirements; and
g) Registration report(s) covering all clauses of ISO 9001:2000 or equivalent QMS.

The assessment team shall review the documents for compliance with the applicable requirements and compile an IECQ Compliance Report Form (CRF), available for download from the IECQ members’ area of the internet site www.iecq.org, or equivalent. Alternatively the IECQ CB may use its own equivalent reporting system. The IECQ CB shall notify the organization if there are any issues that need to be resolved. Upon satisfactory review of the documentation a site assessment plan shall be developed and the site assessment shall be scheduled.

6.3 Assessment

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

6.3.2 At the completion of the assessment, and generally prior to leaving the site, the assessment team shall provide the DMR with a Site Assessment Report (SAR), including the team’s findings and any action requests generated during the evaluation which itemize non-conformities uncovered during the assessment. It is permissible for the team to provide a brief or hand written report prior to leaving the site, however the formal SAR shall be issued not later than 1 month after the site visit. SAR blanks are available for download to IECQ CBs from the IECQ Internet website www.iecq.org. Alternatively the IECQ CB may use its own equivalent reporting system.

6.3.3 The basis of all assessments is to seek evidence of compliance with IECQ QC 080000 requirements with the approach to assessment being that decisions shall be either “comply” or “does not Comply”. 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.

6.4 Granting of approval

6.4.1 Following the assessment, the relevant assessment information shall be reviewed by the IECQ CB for a certification decision, in accordance with IECQ Operational Documents. The certification decision shall be notified to the organization.

6.4.2 Approval is granted only if the organization evaluated meets all the applicable IECQ HSPM requirements for which the organization has requested approval. The organization shall respond directly to the IECQ CB regarding any non-conformities determined during the assessment. If the non-conformities are not satisfactorily resolved, the IECQ CB shall provide an explanation of the reasons for rejection. If necessary, arrangements shall be made for a follow-up assessment.
6.4.3 Upon successful completion of assessment requirements, a Certificate of Approval is issued by the IECQ CB indicating that the organization meets all applicable IECQ HSPM requirements for the activities, products, and/or services covered in the scope of the approval.

6.4.4 The approved organization shall be listed in the IECQ web based certification database.

6.5 Surveillance plan for maintenance of approval

In accordance with IECQ Rules, surveillance assessments are conducted to ensure continued compliance with the requirements. The following principles are included as part of the surveillance plan:

- on-site assessments shall be conducted annually for each organization’s specific IECQ HSPM requirements;
- there shall be no unannounced on-site assessments;
- the DMR shall notify the applicable IECQ CB if significant changes are made in the application of the IECQ HSPM requirements or the processes controlled by the IECQ HSPM requirements;
- a special surveillance visit may be conducted by the IECQ CB in situations where:
  - an organisation has relocated;
  - an organisation has been taken over or acquired by another organisation which may have resulted in changes to personnel, management and or management system procedures; and
  - the IECQ CB has just cause for concern regarding an organisation’s continued compliance with QC 080000 requirements.

6.6 Renewal of the certificate of Approval

Refer to clause 4.1.3 of this Rule of Procedure.

6.7 Suspension or withdrawal of approval

Suspension and withdrawal of approvals are conducted in accordance with IECQ Rules of Procedure QC 001002-3 sub-clause 2.7.

6.8 Appeals

Appeals are handled in accordance with IECQ 01, Basic Rules.
Annex A  
(normative)

Guidance for Initial 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; and
- Stability of the IECQ HSPM System.

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 organisations 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 organisation. Ideally, organisations 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 organisation involved may conduct the document review in a similar manner to that arranged for smaller organisations.

<table>
<thead>
<tr>
<th>Certified Entity Number of Employees</th>
<th>Initial Assessment On-site Days</th>
<th>Initial Assessment Document Review Days</th>
<th>Annual Surveillance Days</th>
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<tbody>
<tr>
<td>1 – 75</td>
<td>1.5</td>
<td>.5</td>
<td>1</td>
</tr>
<tr>
<td>76 – 150</td>
<td>2.5</td>
<td>.5</td>
<td>2</td>
</tr>
<tr>
<td>151 – 600</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>601 – 1000</td>
<td>5</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>1001 – 2000</td>
<td>5</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2001 – 3000</td>
<td>6</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3001 – 4000</td>
<td>7</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>4001 – 8000</td>
<td>8</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>8001 – 15000</td>
<td>8</td>
<td>3</td>
<td>6</td>
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<tr>
<td>15000 – 20000</td>
<td>9</td>
<td>3</td>
<td>6</td>
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</tbody>
</table>
Annex B
(normative)

Definition of “one management system”

One management system on multi-sites comprises:

- One set of management system procedures throughout all locations;
- One ultimately responsible DMR;
- Central control of internal audit program, investigation of root causes, and deployment of corrective/preventive actions; and
- Central management review.

NOTE 1 Each location could have its own local management representative for local operation, but there should be an ultimate DMR responsible for the compliance of the entire system.

NOTE 2 Similarly for internal audit and management reviews. Due to geographical separation or travelling restrictions (e.g. visa issue), internal audits or management review could be performed locally but the ultimate DMR should be well aware of the results and the corrective/preventive actions are deployed throughout the entire system.

One management system with multi-site requirements includes:

- All locations involved are subject to the same set of HS requirements;
- The sites together form one complete production stream if the sites are located in different countries/areas; and
- These sites together form one application/registration.

NOTE One complete production stream means that although each location individually may be responsible for one or more processes (e.g. sales, R&D, moulding, painting, PCB assembly, etc), all locations must be put together to complete the final product.

Treatment of multi-sites:

- All locations will be assessed to all clauses annually, no sampling allowed;
- Each location must have its own Certificate of Approval;
- The activity scope is to be covered on a company Certificate of Approval and identical to the sum of all site Certificates of Approval; and
- The IECQ scope is identical on all Certificates of Approval.
Withdrawn
Withdrawn