

This is a preview - click here to buy the full publication



**QC 080000**

Edition 4.0 2017-05

# IECQ PUBLICATION

**IEC Quality Assessment System for Electronic Components (IECQ System)**

---

**Hazardous Substance Process Management (HSPM) System Requirements**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

PRICE CODE

**H**

---

## CONTENTS

FOREWORD.....	4
1 Scope.....	6
1.1 General.....	6
1.2 Application.....	6
2 Normative references .....	6
3 Terms and definitions .....	7
4 Context of the organization.....	9
4.1 Understanding the organization and its context.....	9
4.2 Understanding the needs and expectations of interested parties .....	10
4.3 Determining the scope of the HSPM system.....	10
4.4 HSPM system and its processes .....	11
4.4.1 General .....	11
5 Leadership .....	11
5.1 Leadership and commitment .....	11
5.1.1 General .....	11
5.1.2 Customer focus .....	11
5.2 HSF policy .....	11
5.2.1 Establishing the HSF policy .....	11
5.2.2 Communicating the HSF policy.....	11
5.3 Organizational roles, responsibilities and authorities.....	12
6 Planning.....	12
6.1 Actions to address risks and opportunities .....	12
6.1.1 Planning for HSPM system .....	12
6.1.2 Organization.....	12
6.2 HSF objectives and planning to achieve them .....	12
6.2.1 HSF objectives .....	12
6.2.2 Planning for HSF objectives.....	13
6.3 Planning of changes .....	13
7 Support .....	13
7.1 Resources .....	13
7.1.1 General .....	13
7.1.2 People.....	13
7.1.3 Infrastructure.....	13
7.1.4 Environment for the operation of processes .....	13
7.1.5 Monitoring and measuring resources .....	13
7.1.6 Organizational knowledge.....	14
7.2 Competence .....	14
7.3 Awareness.....	14
7.4 Communication.....	15
7.5 Documented information .....	15
7.5.1 General .....	15
7.5.2 Creating and updating .....	15
7.5.3 Control of documented information .....	16

8	Operation .....	16
8.1	Operational planning and control .....	16
8.2	HSF requirements for products and services .....	16
8.2.1	Customer communication .....	16
8.2.2	Determining HSF requirements for products and services .....	17
8.2.3	Review of requirements for products and services .....	17
8.2.4	Changes to requirements for products and services .....	17
8.3	Design and development of products and services .....	17
8.3.1	General .....	17
8.3.2	Design and development planning .....	18
8.3.3	Design and development inputs .....	18
8.3.4	Design and development controls .....	18
8.3.5	Design and development outputs .....	18
8.3.6	Design and development changes .....	19
8.4	Control of externally provided processes, products and services .....	19
8.4.1	General .....	19
8.4.2	Type and extent of control .....	19
8.4.3	Information for external providers .....	20
8.5	Production and service provision .....	20
8.5.1	Control of production and service provision .....	20
8.5.2	Identification and traceability .....	20
8.5.3	Property belonging to customers or external providers .....	21
8.5.4	Preservation .....	21
8.5.5	Post-delivery activities .....	21
8.5.6	Control of changes .....	22
8.6	Release of products and services .....	22
8.7	Control of nonconforming outputs .....	22
9	Performance evaluation .....	22
9.1	Monitoring, measurement, analysis and evaluation .....	22
9.1.1	General .....	22
9.1.2	Customer satisfaction .....	23
9.1.3	Analysis and evaluation .....	23
9.2	Internal audit .....	23
9.3	Management review .....	24
9.3.1	General .....	24
9.3.2	Management review inputs .....	24
9.3.3	Management review outputs .....	24
10	Improvement .....	24
10.1	General .....	24
10.2	Nonconformity and corrective action .....	24
10.3	Continual improvement .....	24
	Annex A (normative) EU RoHS requirements .....	26
	Annex B (normative) China RoHS 2 requirements .....	28
	Bibliography .....	31

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

---

# Hazardous Substance Process Management (HSPM) System Requirements

## FOREWORD

This publication has been prepared by the Management Committee (MC) of the IECQ.

This publication is directly related to Publication IECQ 03-5 containing the Rules of Procedure for the IECQ HSPM Scheme.

This IECQ International Specification (here after known as International Specification) and its requirements are based on the belief that the achievement of Hazardous Substance Free (HSF) products and production processes cannot be realized without an effective integration of management disciplines. This International Specification is a supplement to and exists in concert with the ISO 9001 Quality Management System (QMS) framework for the comprehensive, systematic, and transparent management and control of processes pursuant to HSF goals. This 4<sup>th</sup> edition of IECQ QC 080000 has been prepared in response to feedback from application of the 3<sup>rd</sup> edition. Changes included in this 4<sup>th</sup> edition include:

- alignment with ISO 9001:2015;
- adoption of ISO Annex SL High Level Structure;
- adapt to global increasing hazardous substances legislation. For example, additional controlled substances, change control, product recall, as specified by the REACH<sup>1</sup> regulation, the information communication within the supply chain, and notification to ECHA<sup>2</sup> about SVHC<sup>3</sup>;
- enhancement of documented information requirements in response to the applicable statutory and regulatory obligations. For example, requirements in the re-casted RoHS<sup>4</sup> such as compliance assessment, preparation of technical file, preparation of self-declaration, use of markings, etc. can now be managed through IECQ QC 080000.

IECQ QC 080000 specifies how organizations establish and implement key processes to manage their hazardous substances other than focusing on the removal and avoiding restricted substances in products.

The processes used to identify, control, quantify, and report the HS content in electrotechnical products, or their components thereof, must be defined and understood in sufficient detail to assure all relevant interested parties of the HSF status of a product. The processes must be appropriately documented and conducted in a controlled and consistent manner to:

- facilitate verification of compliance to applicable customer requirements and regulations;
- allow efficient and effective compliance checks;
- facilitate the consistent deployment across organizations and their supply chain
- allow harmonization of compliance and enforcement methods.

As a result the technical barriers to trade of products around the world is minimized.

---

<sup>1</sup> REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

<sup>2</sup> ECHA: European Chemicals Agency

<sup>3</sup> SVHC: Substances of Very High Concern

<sup>4</sup> RoHS: Restriction of Hazardous Substances

This fourth edition of IECQ QC 080000 replaces the third edition upon publication. The transition arrangements for IECQ HSPM Certification according to this edition are detailed in IECQ MC/345A/CD. Refer to IECQ MC Decision 2016/22.

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

<b>Document</b>	<b>Report on MC Consultation</b>
IECQ MC/344D/CA	Feb+Mar 2017

# Hazardous Substance Process Management (HSPM) System Requirements

## 1 Scope

### 1.1 General

This International Specification is intended for use by:

- manufacturers, suppliers, repairers, maintainers and service providers (and their supply chain) of electrotechnical component products to develop processes to identify, control, quantify, and report the amounts of HS in the products they manufacture, supply or service;
- customers and users of the products to know the HSF status of a product, and to understand the processes by which it is determined.

This International Specification defines the requirements for establishing, implementing, monitoring and continually improving processes to:

- identify HS of the products and processes;
- determine (test, analyse, or otherwise ascertain) the HSF status of products;
- control the introduction of HS into products;
- make available the degree of HS compliance of delivered products to the customer, where the HS content exceeds the applicable customer and regulatory requirements.

It is important that HS process management is part of, and integrated with, the organization's overall business and quality management systems.

### 1.2 Application

This International Specification is applicable only to organizations that have implemented ISO 9001:2015 or its full equivalent QMS standard.

The requirements of this International Specification are in addition to those contained within ISO 9001.

While in ISO 9001:2015 an organization may claim a clause as non-applicable, within the IECQ HSPM Scheme all requirements within this International Specification are applicable.

Organizations wishing to pursue certification under the IECQ HSPM Scheme shall comply with ISO 9001:2015 and this International Specification, including one or more Annex(es). The applicability of the Annex(es) shall be consistent with the IECQ HSPM Scope of Certification.

Organizations in sectors other than those specified in 1.1 may also adopt this International Specification for the management of HS; however, certification under the IEC Conformity Assessment Systems is not available.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IECQ 03-1, *Rules of Procedure – Part 1: General Requirements for all IECQ Schemes*

IECQ 03-5, *Rules of Procedure – Part 5: IECQ HSPM Scheme – Hazardous Substance Process Management Requirements*

ISO 9000: 2015, *Quality management systems – Fundamentals and vocabulary*

ISO 9001:2015, *Quality management systems – Requirements*

RoHS, *Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment*

China RoHS 2, 2016-01-21, *Management Methods for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products*