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Edition 4.0 2017-05

IECQ PUBLICATION

IEC Quality Assessment System for Electronic Components (IECQ System)

Hazardous Substance Process Management (HSPM) System Requirements

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE H

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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 4th edition of IECQ QC 080000 has been prepared in response to feedback from application of the 3rd edition. Changes included in this 4th 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 [1] regulation, the information communication within the supply chain, and notification to ECHA[2] about SVHC[3];
– enhancement of documented information requirements in response to the applicable statutory and regulatory obligations. For example, requirements in the re-casted RoHS[4] 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.

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[1] REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

[2] ECHA: European Chemicals Agency

[3] SVHC: Substances of Very High Concern

[4] 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:

Document	Report on MC Consultation
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*

3 Terms and definitions

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

HSPM
Hazardous Substance Process Management

HS
Hazardous Substance refers to any substances regulated by applicable legal or customer requirements as to prohibit, restrict, reduce its use or notify its existence, which will inherently do harm to human health or the safety of environment

HSF
Hazardous Substances Free refers to the reduction or elimination of any HS

hazardous characteristics of a product
one or more of the quality characteristic of products, which characterizes HS and their contents within the product

HSF aspect
element of an organization's activities or products or services that would possibly affect negatively the HSF characteristic of organization's final products

full equivalent QMS standard
the standard covers all requirements of ISO 9001. Acceptable equivalent includes IATF 16949, AS9100, International Railway Industry Standard (IRIS), and TL 9000

HSF management
coordinated activities to direct and control an organization in respect of HSF processes, including establishing HSF policies and objectives, and HSF processes to achieve these objectives through HSF planning, HSF implementation, and HSF improvement

HSF requirements
need or expectation that is explicitly stated or specified in applicable customer and regulatory requirements in respect of HS processes and their outputs

NOTE HSF requirements can include but not limited to HS limitation, labelling/marking, documented information, declaration of conformity, new material qualification, testing, information communication within supply chain, notification to competent body, report on changes, management system, audit, etc.

HSF process(es)
process(es) to achieve HSF

Refer to 3.4.1 of ISO 9000:2015 for definition of process(es)

HSF performance
measurable result, either quantitative or qualitative in respect of HSF processes

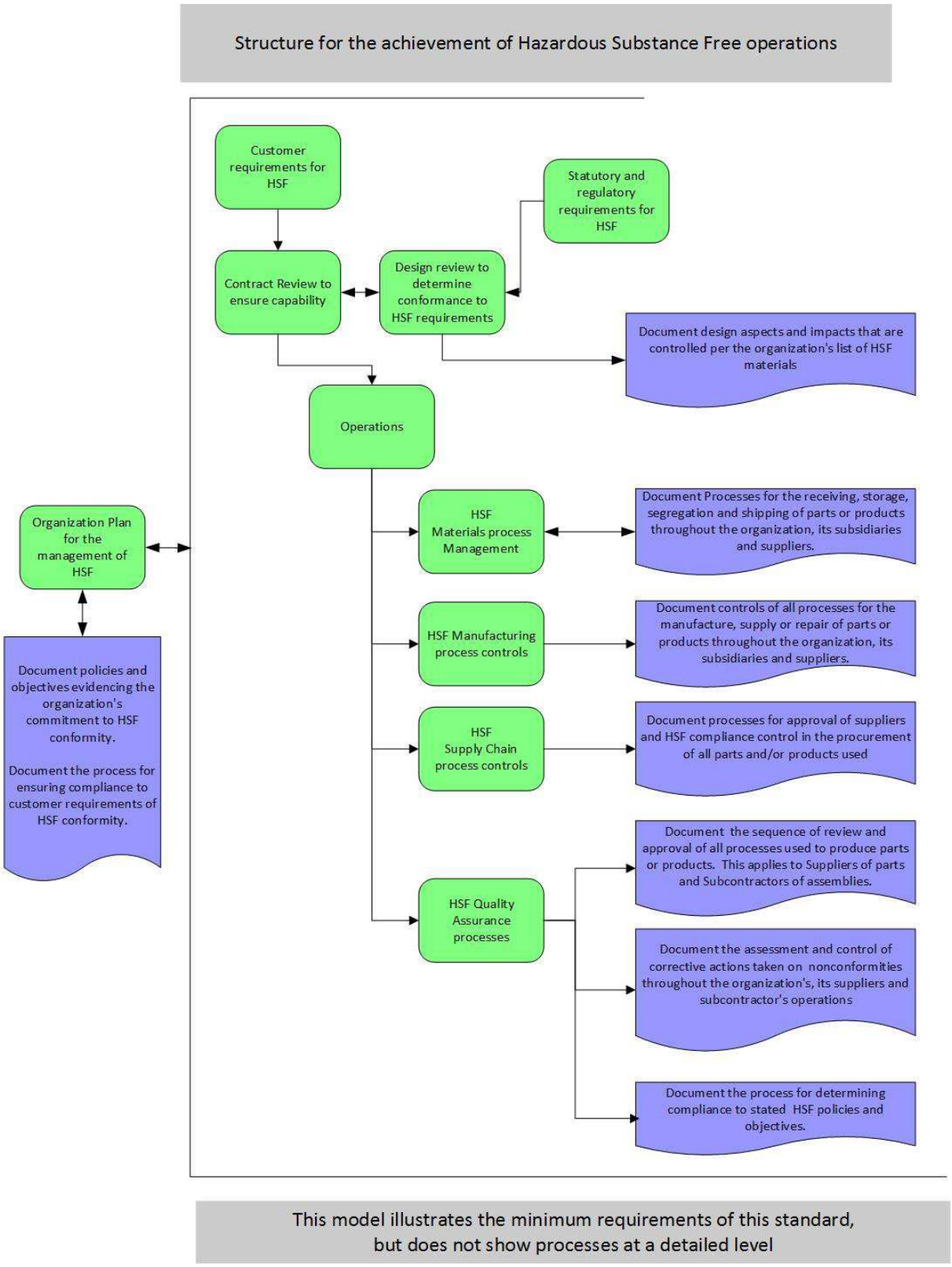
HSF conformity of products
fulfilment of the HSF requirements for products

HSF nonconformity
non-fulfilment of a HSF requirement

HSF nonconforming product
product that possess one or more HSF nonconformity

HS risks
risks related to HSPM

Refer to 3.7.9 of ISO 9000:2015 for definition of risk



4 Context of the organization

4.1 Understanding the organization and its context

The organization shall identify, monitor and review external and internal issues that have the ability to impact its HSPM system for achieving intended results of HSF goals. Those issues are relevant to its business purpose and strategic direction.

The organization shall monitor and review that information about these internal and external issues:

a) applicable legal and customer requirements regarding HSF content, use of marks on the products, and the preparation and retention of specific documented information to demonstrate product compliance to these requirements;

b) the organization's HSF goals;

c) the organization's ability to supply HSF products.

NOTE 1 Understanding the internal context could be facilitated by considering issues related to customer requirements, the type and scope of the products, the process and management of production.

NOTE 2 Understanding the external context could be facilitated by considering issues arising from environmental regulation, legal, market, whether international, national, regional or local.

4.2 Understanding the needs and expectations of interested parties

The organization shall determine, monitor and review the HS and relevant requirements of the interested parties on the on-going basis, their effect or potential effect on the organization's ability to provide products that meet customer HSF requirements and applicable statutory and regulatory requirements in a consistent manner.

The organization shall continuously monitor and review the environmental statutory and regulatory requirements, and the updated information about HS of the interested parties' requirements.

NOTE Examples of needs and expectation of interested parties are:

– environmental-friendly product design such as ease of dismantle;

– environmental-friendly packaging design;

– use of manufacturing methods that facilitate HSF production;

– use of materials that may have negative impacts to the environment but are not controlled by applicable legal and customer requirements.

4.3 Determining the scope of the HSPM system

In order to establish its scope, the organization shall determine the boundaries and applicability of the HSPM system and shall take into account its context, including the external and internal issues it faces, the relevant requirements of relevant interested parties, the products of the organization and its ability in provision of HSF products.

The scope shall be available and maintained as documented information and applying to the requirements of this International Specification.

Justification of any requirements of this International Specification shall not exist to jeopardize the conformity of HSF products meeting customer requirements and regulatory and statutory requirements for enhancement of customer satisfaction. The scope shall state the justification if it exists.

The activities and geographical scopes of the organization's QMS shall be identical or larger than the activities and geographical scopes of the HSPM system.

One or more of the normative requirements contained in the Annexes or other National/ International HS or Waste Electrical or Electronic related statutory and regulatory requirements shall be included in the scope of HSPM.

4.4 HSPM system and its processes

4.4.1 General

The organization shall establish, implement, maintain and continually improve a process-based HSPM system, including the processes needed for the provision of HSF products and their interactions, in accordance with the requirements of this International Specification.

The organization shall determine the processes relevant to the realization of its HSF objectives and their application throughout the organization, including processes with the involvement of HS and those without the involvement of HS but affecting the realization or provision of HSF products.

Consideration shall be made particularly on addressing risks and opportunities determined, and on changes needed for those processes to achieve their intended results.

As necessary, the organization shall maintain documented information to support its process operations and retain documented information as evidence that the process operations are being carried out as planned for HSF.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to HSPM as follows:

a) including HSF in management reviews (see 9.3.2);
b) establishing the HSF policy and ensuring that HSF objectives are established;
c) providing resources needed to ensure progress toward HSF products and production processes;
d) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements on HS management.

5.1.2 Customer focus

Top management shall ensure that customer HSF requirements are determined and met with the aim of customer satisfaction.

5.2 HSF policy

5.2.1 Establishing the HSF policy

Top management shall in establishing the HSF policy:

a) include a commitment to satisfy applicable HSF requirements;
b) include a commitment to continual improvement of the HSF performance of the organization.

5.2.2 Communicating the HSF policy

The HSF documented policy shall be made available, communicated, understood within the organization and where appropriate be available to relevant interested parties.

5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that HSF related responsibilities and authorities are defined and communicated within the organization.

Top management shall appoint a Designated Management Representative (DMR). The DMR shall be responsible for the processes of the entire HS management system, including multi-sites as stipulated in IECQ 03-1 Annex A.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 Planning for HSPM system

When determining risks and opportunities for the HSPM system, the organization shall take into account processes, products, services, and materials from the external providers, and internal processes affecting or influencing the achievement of HSF conformity of products and services, considering a life cycle perspective.

The organization shall maintain and retain the documented information about results of risks and opportunities determining processes, including all identified HS contained in, introduced or potentially introduced into its products or processes directly or indirectly.

6.1.2 Organization

The organization shall plan the actions required to address these risks and opportunities, their integration within the HSPM system, evaluation of their effectiveness, including how to prevent or reduce HS risks to ensure HSF conformity of products and services.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the HSF conformity of products and services.

NOTE Risks may include but not limited to:

- use of tools, jigs and fixtures, and auxiliary materials such as lubricants that may contaminate the products;
- incompetence of personnel, including employees, contractors, and suppliers, performing works that may affect HSF conformity of products and services;
- use of materials, packaging and components whose HS conformity are not clearly known.

6.2 HSF objectives and planning to achieve them

6.2.1 HSF objectives

a) The organization shall ensure that HSF objectives are established at relevant functions, levels and processes necessary for the HSPM system. The HSF objectives shall be measureable, consistent with the HSF policy, relevant to HSF conformity of products and services

b) The HSF objectives shall include a timeline, as appropriate, for the reduction or elimination of HS identified and used in processes or products, including externally provided processes, products, services or materials in accordance with applicable legal and customer requirements. When setting the HSF objectives timeline the organization shall consider any requirements that are specified in legislation but will enter into force in the future

c) The HSF objectives shall be communicated, monitored and remain appropriately updated as necessary

The organization shall maintain and retain documented information on the HSF objectives.

6.2.2 Planning for HSF objectives

The organization shall determine and plan what needs to be done to achieve its HSF objectives, ensuring it has appropriate resources, responsibilities are clearly defined, timelines are set and how the results will be evaluated.

6.3 Planning of changes

When determining and planning any necessary changes to the HSPM system the organization shall consider the purpose and any potential risks that may impact HSF conformity of products and services with the applicable legal and customer requirements.

The organization shall ensure the integrity of the HSPM system, that it has adequate resources and has allocation or reallocation of responsibilities to achieve the necessary changes.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources (including those from external providers) needed to implement and maintain HSF processes and provide HSF products, to continually improve its effectiveness, and to enhance customer satisfaction by meeting customer and legal requirements.

7.1.2 People

The organization shall determine and provide the persons needed to implement and maintain HSF processes and provide HSF products, to continually improve its effectiveness, and to enhance customer satisfaction by meeting customer and legal requirements.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to HSF process and product requirements. Infrastructure includes, as applicable,

a) buildings, workspace and associated utilities;
b) process equipment and testing equipment, and supporting services (such as testing, computing, communication or information systems).

In the case that HS and HSF products and services are provided concurrently or alternatively on the premises, the organization shall ensure that sufficient infrastructure is provided in order to prevent contamination of products from occurring.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the operational environment needed to achieve HSF products.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and make available the monitoring and measuring resources needed to provide evidence of conformity of product to determined HSF requirements.

The organization shall ensure the fitness for purpose of the monitoring and measurement resources is demonstrated by documented evidence.

Measuring equipment for HSF characteristics shall be managed to ensure valid results.

7.1.5.2 Measurement traceability

Measurement traceability for HSF characteristics is required, and measurement equipment shall be calibrated or verified against international or national measurement standards.

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary to achieve conformity of HSF products and services through the operation of its processes.

This knowledge shall be maintained and be made available to the extent necessary.

Organizational knowledge with regards to HSPM system shall include:

a) applicable legal and customer requirements and their implication for the organization;
b) material risks and their controls;
c) process risks and their controls;
d) measurement methods and their constraints;
e) understanding of HS measurement results and their implication.

7.2 Competence

The organization shall ensure that the competences include ability to:

a) identify, understand and apply applicable legal and customer requirements;
b) conduct HSF product design and development;
c) qualify and manage external provider;
d) qualify new material;
e) conduct risk analysis on both internally and externally provided processes, products, services or materials and the abilities of external providers on HS control;
f) conduct HS measurement where appropriate;
g) Communication with customers and relevant authorities regarding HSF conformity of the products and services;
h) prepare HSF documented information according to applicable legal and customer requirements. (for example the technical documentation according to IEC 62321 and EN 50581 where necessary).

The organization shall maintain and retain documented information on these competences.

NOTE The competence could be collectively possessed by persons of the organization.

7.3 Awareness

The organization shall ensure that:

a) top management are aware of the implication of violation of HSF legal and customer requirements;
b) persons doing work under the organization’s control are aware of the risks of introducing HS into process outputs or products and how they contribute to the achievement of the HSF objectives.

7.4 Communication

The organization shall determine the internal and external communications relevant to the HSPM system. Information to be communicated shall include as a minimum:

– applicable legal or customer requirements on HS control and their updates;
– HSF policy and HSF objectives and updates;
– HSF requirements on process operation and their changes;
– HSF performance or any problems with process operation;
– information on HSF conformity of outputs and relevant evidences, including processes;
– feedback from customers or legal authorities concerning HSF conformity of products and services or HSF management;
– communication of HS information throughout the supply chain in specified format and through specified channels;
– notification to customers or legal authorities as applicable;
– communication with distributors for possible withdrawal or recall of nonconforming products.

The organization shall retain documented information as evidence of its communications, as appropriate.

7.5 Documented information

7.5.1 General

The HSPM management system documentation shall include:

a) HSF policy and objectives with inclusion of a timeline for elimination of use of identified HS, as appropriate;
b) a list of all HS contained in or will potentially be introduced into products;
c) documented information required by applicable legal and customer requirements with regard to HSF control.

NOTE Documented information required by applicable legal and customer requirements can include, e.g.:

– supplier declaration or contractual agreement in regard to HSF conformity;
– technical documentation/dossiers;
– declaration of conformity;
– Safety Data Sheet/Material Safety Data Sheet;
– material declaration for products of and for the electrotechnical industry IEC 62474 DB (http://std.iec.ch/iec62474);
– declaration of chemical composition;
– test reports;
– international authority databases or platform (e.g. BOMcheck, JAMP (Joint Article Management Promotion-consortium), IPC-1752A, etc.).

7.5.2 Creating and updating

When creating and updating documented information, the organization shall take into consideration, the legal or customer requirements regarding the procedures, contents and format.

NOTE For example, the technical documentation required by EU RoHS should follow EN 50581, the labels required by China RoHS 2 shall follow SJ/T 11364-2014.

7.5.3 Control of documented information

Documented information shall be maintained or retained according to legal or customer requirements, e.g. on the constant availability and the retention duration.

8 Operation

8.1 Operational planning and control

In planning HSF product realization, the organization shall determine the following, as appropriate:

a) determining the HSF requirements for the products and processes within its HSF management as well as management requirements for HS control on all relevant processes;

b) establishing criteria for:

   1) the processes to ensure the provision of HSF outputs and HSF products;

   2) the acceptance of HSF outputs and HSF products in line with legal and customer requirements;

c) determining the resources needed to achieve conformity to HSF requirements of the product and service;

d) determining, maintaining and retaining documented information to the extent necessary:

   1) to have confidence that the processes have been carried out as planned, including documented information for processes that will potentially have adverse impact on the HSF characteristic of products;

   2) to demonstrate the conformity of products to their HSF requirements;

   3) to fulfil legal and customer requirements on documented information with regard to HS management.

The organization shall control planned changes, identify and verify the consequences of unintended changes, to ensure HSF conformity. Changes that have adverse impact on HSF characteristic of products shall not be implemented without approval of customers, where necessary.

The organization shall ensure that outsourced processes are controlled to ensure the HSF conformity of outputs or products and services from those processes. (see 8.4).

NOTE “Adverse impact” may include but not limited to contamination by or mixing with HS, etc.

8.2 HSF requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

a) obtaining legal and customer requirements on HSF products and HS control;

b) providing information relating to HSF characteristics of products and processes requested by customers and/or legal authorities, including HS data, HSF documented information, evidences of HSF conformity where necessary;

c) handling enquiries, contracts or orders in respect of HSF management including changes;

d) obtaining customer feedback relating to HSF conformity of products and processes, including customer complaints;

e) handling or controlling customer property with regard to HSF conformity;

f) establishing specific requirements for contingency actions (e.g. when HS nonconforming products are identified).

8.2.2 Determining HSF requirements for products and services

When determining the HSF requirements for the products to be offered to customers, and management requirements of customers for HS control, the organization shall ensure that the requirements for the products and services are defined, including:

a) legal HSF requirements applicable to the products and processes;

b) HSF requirements specified by the customer;

c) HSF requirements as specified by the organization.

The organization shall meet the claims for the HSF products and services it offers.

The organization shall determine the responsibility and channel for the collection, delivery and summarization of these requirements, and determine how these requirements apply to its products.

NOTE HSF requirements can include but not limited to HS limitation, labelling/marking, documented information, declaration of conformity, new material qualification, HS testing, information communication within supply chain, notification to legal authorities, report on changes, management system, audit.

8.2.3 Review of requirements for products and services

The organization shall ensure that it has the ability to meet the HSF requirements for products and the management requirements on HS control, including claims for the HSF products it offers.

The organization shall ensure the competences of reviewers and the sound evidences on which the review results are based.

The organization shall retain documented information, as applicable, on the review results and any new HSF requirements for the products and services.

8.2.4 Changes to requirements for products and services

Changes shall be determined, reviewed and communicated to ensure the organization’s continuing ability to meet the HSF requirement.

NOTE Examples of changes are but not limited to:

– applicable legal and customer requirements;

– organization requirements.

8.3 Design and development of products and services

8.3.1 General

The design and development process shall include the design and development of the organization’s products and services as well as the development of all production processes, tools, jigs and fixtures, and auxiliary materials that may be included in the provision of the products and services, as applicable.

The organization is responsible for the HSF compliance of the outputs of design and development process.

NOTE Production processes include all activities after the final design validation, e.g. manufacturing, packaging, labelling, delivery, documentation.

8.3.2 Design and development planning

The organization shall plan and control the design and development of HSF product, which includes:

a) the suitable stages and methods determined for the review, verification and validation of the HSF characteristic of product during design and development;

b) responsibilities and authorities relating to HSF compliance;

c) the internal and external resource needs, including the need for cooperation or support of external providers and the involvement of customers as applicable;

d) the requirements for subsequent provision of HSF products and services;

e) the documented information needed to demonstrate that HSF requirements have been met.

In planning the design, the use of any HS shall be identified in the documented information and a plan for control and eventual replacement or elimination of the HS shall be created.

8.3.3 Design and development inputs

HSF requirements shall be taken into account when determining the design and development inputs. The organization shall consider:

a) information derived from previous design and development activities of similar products, including HS information of materials or parts used;

b) HSF requirements for the products and processes for HS control and the acceptance criteria of HSF outputs and products determined during operational planning.

The organization shall retain documented information on design and development inputs related to HSF requirements.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved in respect of HSF conformity are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet HSF requirements, including validity of evidences employed to conduct review;

c) verification are conducted to ensure that the design and development outputs meet the input requirements in respect of HSF conformity. Methods used for verification shall be determined and validated;

d) validation of HSF conformity of products are conducted where necessary, considering the involvement of customer where necessary.

Controls to the design and development process shall be applied to the products and services as well as processes, tools, jigs and fixtures, and auxiliary materials under design and development.

The organization shall retain documented information on activities of design and development controls, including determination of HSF requirements, review, verification and validation.

NOTE Although design and development validation activities usually are not applicable in determining the HSF conformity, the potential effect due to HS control on the specified application or intended use should be considered.

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

a) meet the HSF input requirements;

b) are adequate for the subsequent processes for the provision of products, such as internal and external communication, external provision of processes, products, or services, production, product marking, information releasing, notification, tracing, preservation, etc.;

c) include or reference HSF requirements for monitoring and measuring requirements for HSF conformity, as appropriate, and acceptance criteria;

d) specify the hazardous characteristics of the products and services;

e) include validated and qualified processes, products or services to be provided by external providers and their potential HS risk level in terms of specific HS;

f) include HSF documented information according to legal or customer HSF requirements.

The organization shall retain documented information on design and development outputs.

8.3.6 Design and development changes

The organization shall identify and control design and development changes which may lead to the change of HSF characteristic of product.

The changes shall be reviewed, verified and validated as necessary, and authorized or even approved by customer where requested before implementation.

Documented information of these changes shall be retained.

NOTE Examples of changes are but not limited to:

– criteria for products, services or processes change;

– product and material change;

– process change.

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to HSF requirements.

The organization shall determine the controls to be applied to both external provider and externally provided processes, products and services that will adversely affect HSF conformity of products.

The criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers shall consider their ability to provide processes or products and services in accordance with HSF requirements.

The organization shall retain documented information of qualified HSF external providers with validated HSF processes, products and services they provided.

NOTE The organization could consider the use of certified IECQ HSPM organizations as external providers for better compliance and risk management.

8.4.2 Type and extent of control

When planning the type and extent of control, the organization shall:

a) take into consideration:

1) the potential risk level of the externally provided processes, products and services on the organization’s ability to consistently meet legal and customer requirements on HS control;

2) the ability of the external provider in HS management and the effectiveness of the controls applied by the external provider to ensure HSF conformity;

b) purchase only validated HSF processes, products and services from qualified external providers for HSF production, otherwise documented information of approval mandated;

c) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet HSF requirements;

d) ensure any HSF purchased product is free from possible contamination or mixture;

e) identify timely changes in supply chain and revalidate relevant processes, products and services that may adversely affect HSF conformity of products.

NOTE Where practicable, to determine and qualify the procurement route and the whole supply chain for HSF conformity is good practice in HS management.

8.4.3 Information for external providers

The organization shall communicate to external providers its HSF requirements for:

a) the processes, products and services to be provided;

b) the approval of:

1) products and services;

2) the changes to be implemented by external provider;

c) the external providers' interactions with the organization, including contingency actions (e.g. when HSF nonconforming purchased products are identified);

d) verification and audit activities that the organization, or its customer, intends to perform at the external providers' premises for HSF conformity;

e) identification of HSF products to ensure traceability;

f) documented information in format and through channels acceptable by the customers and legal authorities, such as HS analysis report or data of chemical composition;

g) control of their own external providers to ensure HSF conformity.

NOTE Special care should be taken with new providers to ensure they understand the full requirements.

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production under controlled conditions, as applicable:

a) the availability of documented information that defines:

1) the HSF characteristics of the products to be produced, or the activities to be performed;

2) preventive measures for processes that have the potential of contamination by or mixture with HS;

b) the use of specified materials and technology, infrastructure and environment for the operation of processes;

c) the implementation of monitoring and measurement activities at appropriate stages to verify that HSF criteria for control of processes, and HSF acceptance criteria for outputs or products, have been met;

d) the implementation of actions to prevent human error possibly introducing HSF risks.

8.5.2 Identification and traceability

The organization shall identify the HSF status of outputs with respect to monitoring and measurement requirements throughout processes of product provision.

The organization shall label products according to legal, customer or organization's own requirements with regard to HS control.

The organization shall control the unique identification of the outputs where necessary, and retain documented information necessary to enable traceability.

Processes that include any HS shall be uniquely identified and controlled to prevent HSF product from contamination by HS.

8.5.3 Property belonging to customers or external providers

The organization shall ensure the HSF conformity of the materials and components from external providers are verified prior to use, including external providers that are designated by customers.

When the HSF characteristic of the property is found nonconforming, the organization shall report this to the customer or external provider and relevant documented information retained.

8.5.4 Preservation

The organization shall preserve the outputs and products to ensure HSF conformity to requirements:

a) the organization shall protect the HSF characteristic of product;
b) the organization shall ensure the integrity of any labelling and identification used to specify the HSF conformity of the products;
c) HSF conforming and nonconforming materials, components and products shall be segregated, clearly identified, and handled according to defined processes;
d) intermediate outputs or products are released correctly for HSF production;
e) documented information related to the storage and the use of HSF nonconforming products shall be retained.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products with regard to HS control.

The organization shall retain appropriate documented information as evidence of HSF conformity for the purpose of demonstrating product and services conformity to the legal or customer requirements. Documented information shall be retained for at least a period requested by relevant legal or customer requirement. The effectiveness and validity of this documented information shall be evaluated in a defined period.

The organization shall ensure the sound basis on which the declaration of HSF conformity is based.

The organization shall cooperate with the legal authorities or customers, at their request, on any action taken to ensure compliance with HSF requirements.

NOTE 1 Post-delivery activities with regard to HS control can include but not limited to making available and providing HS data and relevant documented information, withdrawing or recalling products under request and other action requested.

NOTE 2 Examples of documented information here can include but not limited to technical documentation and declaration of conformity dossiers, supplier declaration, contractual agreement, material declaration, or test report.

8.5.6 Control of changes

The organization shall review, verify where necessary, and control changes that would possibly change the HSF characteristic of products, to ensure continuing conformity with HSF requirements.

Where required by applicable legal and customer requirements, changes shall be reported to and approved by the customers before implementation.

The results of the review, verification and approval of changes shall be retained as documented information, as well as the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that HSF requirements for the product have been met, and the documented information, identification, declaration of HSF conformity or HS information, labelling are attached correctly with the product before release of products and services where applicable.

HSF outputs or products are released according to applicable requirements.

8.7 Control of nonconforming outputs

8.7.1 The organization shall identify HSF nonconforming outputs, segregate them from conforming outputs and prevent them from unintended use or delivery unless otherwise allowed by appropriate legal authorities or customer.

When HSF nonconforming outputs are detected after delivery, the organization shall inform customers or notify legal authorities according to legal or customer requirements. Nonconforming products shall be traced and withdrawn from the customer or recalled from the market under request.

External provider(s) associated with the HSF nonconforming outputs shall be identified and informed of the nonconformity to ensure corrective measures are taken.

8.7.2 The organization shall retain documented information that:

a) describes the HSF nonconformity, including the HS detected, the material or outputs containing the HS, and the processes associated with the HS;
b) describes relevant external providers and customers identified;
c) describes the actions taken;
d) demonstrate customer’s approval of the delivery, if applicable.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured for identification of HSF conformity (e.g. the materials and HS to be tested) and provision of data on HS or chemical composition where necessary, taking into consideration the potential material risks and process risks, legal and customer requirements on HS testing and data provision;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, taking into consideration the legal and customer requirements on HS testing, such as IEC 62321 and EN 62321 for HS regulated by EU RoHS;

c) when the monitoring and measuring shall be performed, taking into consideration the HSF characteristics of materials and processes and the potential risks without timely detection, as well as the legal and customer requirements on HS testing.

The organization shall demonstrate, either with its own capability or by external testing facilities, the HSF conformity of its products and services, or by other means where appropriate.

9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations in respect of HS control have been fulfilled.

9.1.3 Analysis and evaluation

The organization shall determine, collect, analyze and evaluate appropriate data and information arising from monitoring and measurement in respect of the performance and effectiveness of the HSPM system.

The results of analysis shall be used to evaluate:

a) HSF conformity of products and the trend;

b) the degree of customer satisfaction in respect of HS control;

c) the performance and effectiveness of the HSPM system;

d) the performance of external providers with regard to HS control;

e) the need for improvements to the HSPM system.

9.2 Internal audit

The organization shall conduct internal audits at planned intervals to provide information on whether the HSPM system conforms to this International Specification and its own HSF requirements, and is effectively implemented and maintained.

The audit programme shall be planned, established, implemented and maintained in consideration of the importance of the processes concerned, changes affecting the organization, and the results of previous audits in respect of HSF aspects.

The frequency with which the processes are audited shall not be less than that of the QMS.

Auditors performing the internal audit shall demonstrate knowledge, as well as the ability to apply this knowledge during the internal audit, in the following areas, at a minimum:

a) understanding of this International Specification;

b) understanding of the organization's applicable legal and customer requirements;

c) understanding the key HS risks with materials and processes;

d) understanding of the principles and limitations of the testing and measurement methods used, or accepted, by the organization;

e) understanding of the testing and measurement results obtained by, or provided to, the organization.

Documented information of how this competence is acquired and assessed shall be retained.

9.3 Management review

9.3.1 General

Top management shall review the organization's HSPM system.

9.3.2 Management review inputs

The inputs of management review shall include:

a) the suitability and realization of HSF policy and objectives;
b) the changes of legal and customer requirements with regard to HS control;
c) identification, use of HS;
d) HSF nonconformities and corrective actions, including audit results;
e) evaluation and feedback from customers on the HS management performance of the organization;
f) any losses due to violation to legal or customer requirements;
g) resources needed for realizing HSF products and processes;
h) improvement opportunities.

9.3.3 Management review outputs

The outputs of management review shall include decisions and actions related to:

a) opportunities for improvement;
b) any need for changes to the HSPM system;
c) resource needs;
d) changes to the competence needed to satisfy 9.3.2 b);
e) changes to the testing, monitoring and measurement equipment needed to satisfy 9.3.2 c).

The results of management review shall be retained as documented information as evidence.

10 Improvement

10.1 General

Improvement in regard of HSF management can apply to both products and processes.

NOTE Absolute HSF is usually not the pursuit of HSPM in case the requirement is restriction or notification of HS rather than prohibition or ban of HS.

10.2 Nonconformity and corrective action

HSF nonconformity shall be identified and addressed with correction or corrective action taken where needed.

Corrective actions shall be appropriate to the effects of the HSF nonconformities encountered.

Documented information shall be retained as evidence of any subsequent actions taken, and the results of any corrective action.

10.3 Continual improvement

The organization shall continually improve the HSPM system in consideration of the results of analysis and evaluation, and the outputs from management review.

Continual improvement in respect of HSPM includes one or more of the following aspects:

a) elimination or reduction of HS content in the products;

b) enhancement of HSF processes to prevent contamination of products;

c) improvement of monitoring processes to detect HSF nonconforming products more effectively and efficiently;

d) improvement of product traceability and recall processes to prevent nonconforming products from entering the market;

e) improvement of change management process;

f) improvement of personnel competence on identification of HS content, design of product processes to prevent contamination, monitoring and measurement processes, etc.

Annex A
(normative)

EU RoHS requirements

IECQ QC 080000 Clauses	IECQ HSPM system requirements considered to satisfy RoHS
4.1 Understanding the organization and its context	The organization shall monitor and review changes to the EU RoHS requirements, such as the addition of HS, the changing exemptions, the updating of testing methods, etc. These shall be identified and followed in an appropriate timeline.
4.2 Understanding the needs and expectations of interested parties	The organization shall monitor and review customer requirements originated from EU RoHS. These shall be identified and followed in an appropriate timeline.
4.3 Determining the scope of the HSPM system	The organization shall clearly state EU RoHS is covered within its scope and managed by the implementation of IECQ HSPM.
5.1.2 Customer focus	Top management shall demonstrate leadership and commitment with respect to customer focus that they understand the EU RoHS requirements clearly for placing product on the market.
5.3 Organizational roles, responsibilities and authorities	Where an authorized representative is appointed by the organization, the obligations of HSF compliance of products and the drawing up of technical documentation shall not form part of the authorized representative's mandate.
6.1 Actions to address risks and opportunities	The organization shall demonstrate how risk-based thinking has been applied throughout the whole operation to ensure the HSF compliance of products and services.
6.2 HSF objectives and planning to achieve them	The organization shall ensure special attention is paid to timelines set by EU RoHS for the restriction of specific substances and exemptions while setting HSF objectives.
7.4 Communication	The organization shall demonstrate how communication shall be carried out where applicable: (a) organizations who consider or have reason to believe that EEE which they have placed on the market is not in conformity with EU RoHS shall immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken; (b) organizations, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with EU RoHS, in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with EU RoHS. Where an "authorized representatives" is appointed by the organization, the "authorized representatives" shall be provided with EU Declaration of Conformity and the technical documentation at the disposal of national surveillance authorities for 10 years following the placing on the market of the EEE, and all the information and documentation necessary to demonstrate the conformity of an EEE with EU RoHS. The organization shall demonstrate, where the organization is outside of EU and a final EEE is exported to EU through importers in EU, that their importer has been provided with the EU Declaration of Conformity and the technical documentation.

IECQ QC 080000 Clauses	IECQ HSPM system requirements considered to satisfy RoHS
7.5.1 General	Where organization is a manufacturer as defined by RoHS, the documented information shall be prepared: a) technical documentation; b) EU Declaration of Conformity in accordance with annex VI of EU RoHS; c) CE marking.
7.5.2 Creating and updating	While creating the technical documentation, EN 50581 and module A of Annex II to Decision No 768/2008/EC shall be followed. While creating EU Declaration of Conformity, the format shall be in accordance with annex VI of EU RoHS. While using CE marking, it shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008, where applicable.
7.5.3 Control of documented information	The organization shall retain and able to provide proof of product conformity and the technical documentation to the customers for 10 years following delivery to the customers, where applicable.
8.3.5 Design and development outputs	Where organization is a manufacturer as defined by RoHS, the organization shall draw up the required technical documentation, an EU Declaration of Conformity and affix the CE marking on the finished product.
8.3.6 Design and development changes	The organization shall take into account the changes in product design or characteristics, and changes in the harmonized standards or in technical specifications by reference to which conformity of EEE is declared.
8.5.2 Identification and traceability	Where applicable, the CE marking shall be affixed visibly, legibly and indelibly to the finished EEE or to its data plate. Where that is not possible or not warranted on account of the nature of the EEE, it shall be affixed to the packaging and to the accompanying documents. The CE marking shall be affixed before the EEE is placed on the EU market. Where applicable, the organization shall ensure that their EEE bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE. Where applicable, the organization shall ensure that its products bear its name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE, or where that is not possible, on its packaging or in a document accompanying the EEE.
8.7 Control of nonconforming outputs	Organizations who consider or have reason to believe that EEE they have placed on the market is not in conformity with EU RoHS shall immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw it or recall it, if appropriate, and immediately inform the competent national authorities of the EU Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
9.1.3 Analysis and evaluation	The organization shall ensure that if tests and measurements are used to demonstrate compliance with EU RoHS, the test and measurement methods are in accordance with EN 62321-1 or its equivalent.

Annex B
(normative)

China RoHS 2 requirements

China RoHS 2 requirements	IECQ QC 080000 Clauses	IECQ HSPM system requirements considered to satisfy China RoHS
Article 9: EEE designer shall not violate the compulsory standards or other standards stipulated by the laws, administrative regulations and rules when designing the EEE, and on the premise of meeting technological requirements, shall adopt a program in which the substances are harmless or less harmful, easily degraded and easily recycled in accordance with the EEE national standards or industry standards for the restrictions of the use of hazardous substances.	8.3 Design and development of products and services	The organization shall ensure special attention is paid to product design or characteristics changes in the harmonized standards or in technical specifications by reference to which conformity of EEE is declared and shall be taken into account.
Article 10: EEE manufacturer shall not violate the compulsory standards or other standards stipulated by the laws, administrative regulations and rules, and shall adopt the materials, the technique and technology with high resource utilization, easy recycling, environment-friendly, restrict or eliminate the use of hazardous substances in accordance with the EEE national standards or industry standards for the restrictions of the use of hazardous substances. EEE producers shall not deliver or sale the EEE which do not conform to the requirements of China RoHS.	8.5 Production and service provision 7.4 Communication	Manufacturers who use the RoHS mark evidence its product conform to related regulation and rule, shall prevent and control of nonconforming outputs, and in the process such as purchase material, design the technology shall consider fully HSF requirements.
Article 11: The imported EEE shall not violate the compulsory standards or other standards stipulated by the laws, administrative regulations and rules and shall be in accordance with the EEE national standards or industry standards for the restrictions of the use of hazardous substances. The entry-exit inspection and quarantine institutions implement port verification and statutory survey on imported EEE by the law. Customs audited *Customs Clearance of Entry Commodities* issued by entry-exit inspection and quarantine institution and conduct custom clearance formalities by rules.	8.4 Control of externally provided processes, products and services	EEE importer shall declare product conformity to related regulation and rule, pass the inspection by quarantine institutions and get “Import goods declaration form”, then go through the custom formalities by rule.

China RoHS 2 requirements	IECQ QC 080000 Clauses	IECQ HSPM system requirements considered to satisfy China RoHS
Article 12: EEE producers and importers shall not violate the compulsory standards or other standards stipulated by the laws, administrative regulations and rules when making and using the packages of EEE, and shall adopt the non-hazardous, easily degraded and easily recycled materials, and comply with the related national standards or industry standards of packaging utilization.	8.5 Production and service provision 8.7 Control of nonconforming outputs	The EEE packages shall comply with the related standards such as GB/T 1019, GB/T 16288, GB/T 16716.
Article 13: The EEE manufacturer and importer shall mark the hazardous substances contained in EEE when it launches to the market, indicating the name, content and the components contained of hazardous substances, whether they may be recycled, and whether they affect the environment or human health in accordance with the national standards or industry standards for the restrictions of the use of hazardous substances, and shall, if such information cannot be labelled on the products due to the limited product size, shape, surface texture or function, indicate it in the product description. **Article 14:** The EEE manufacturer and importer shall mark the environment-friendly use period on the produced or imported products in accordance with the national standards or industry standards for the restrictions of the use of hazardous substances, and shall, if such information cannot be labelled on the products due to the limited product size, shape, surface texture or function, indicate it in the product description.	8.3.5 Design and development outputs 8.5.2 Identification and traceability	The China RoHS marking shall be affixed visibly, legibly and indelibly to the finished EEE or to its data plate in the form acceptable, the key information include name, content, location, whether its products can recycle, the information of improper use or disposal may affect environment and human health, environment-friendly use period, if applicable. The China RoHS marking shall be subject to the general principles of SJ/T 11364.
Article 15: The environment-friendly use period of EEE can be determined by the manufacturer or importer itself. The relevant industry organizations can, according to technology development level, formulate guidelines on the relevant EEE environment-friendly use period, including the product categories, determine method and the specific period, etc.	8.3.3 Design and development inputs	EEE manufacturer or importer shall determine the environment-friendly use period, encouraged to submitted the period to the ministry of industry and information technology.
Article 16: EEE seller shall not sell EEE in violation of the EEE national standards or industry standards for the restrictions of the use of hazardous substances.	8.6 Release of products and services 8.7 Control of nonconforming outputs	EEE seller shall not place products on the market, which do not conform to national standards or industry standards for the restrictions of the use of HS(s).
Article 17: Management directory shall be adopted to restrict the use of hazardous substances of EEE. Related national departments shall be responsible for establishing, adjusting and releasing the management directory according for actually situation of industry development.	7.5.1 General 7.5.2 Creating and updating	The organization shall have systems that ensure they comply with the management directory established by related national departments.

China RoHS 2 requirements	IECQ QC 080000 Clauses	IECQ HSPM system requirements considered to satisfy China RoHS
Article 18: Government establishes an EEE conformity assessment system for the restriction of the use of hazardous substances. The EEE in the management directory shall meet the EEE national standards or industry standards restriction of the use of hazardous substances, and be managed according to EEE conformity assessment system for the restriction of the use of hazardous substances.	9 Performance evaluation	The organization shall ensure that if tests and measurements are used to demonstrate compliance with the regulatory, statutory, and customer requirements, the tests and measurements are in accordance with GB/T 26125, and SJ/T 11365 or its equivalent.

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