INTERNATIONAL ELECTROTECHNICAL COMMISSION

QC 080000 (IECQ HSPM)

Second edition
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IEC Quality Assessment System for Electronic Components (IECQ)

Electrical and Electronic Components and Products Hazardous Substance Process Management System Requirements (HSPM)

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Electrical and Electronic Components and Products Hazardous Substance Process Management System Requirements (HSPM)

FOREWORD

This IECQ 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 Specification is a supplement to and exists in concert with the ISO 9001-2000 Quality Management System (QMS) framework for the comprehensive, systematic, and transparent management and control of processes pursuant to HSF goals. This document is based on the EIA/ECCB Standard 954 *Electrical and Electronic Components and Products Hazardous Substance Free Standard and Requirements* to serve as guidance for manufacturers in the fulfillment of HSF and customer requirements which may include regulatory requirements such as Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on Waste Electrical and Electronic Equipment (WEEE).

Note:
Legislation exists or is pending in a number of jurisdictions around the world that will require the elimination of a specified list of hazardous substances (HS), including lead, mercury, cadmium, hexavalent chromium, poly-brominated biphenyls (PBB), and poly-brominated diphenyl ethers (PBDE) from a wide range of products. As a result, producers and users of electrical and electronic components must be able to know that their products either are hazardous-substance free (HSF); or, if the products are not HSF, the quantitative amounts of HS that are present.

The processes used to identify, control, quantify, and report the HS content in an electrical or electronic component, or an element thereof, must be defined and understood in sufficient detail to assure all concerned 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 requirements and regulations; to allow efficient and effective compliance checks; that it can be implemented by producers and users in many different locations; and to allow harmonization of compliance and enforcement methods. Above all, they must minimize technical barriers to the trade of products around the world.

0 Introduction

This Specification is intended for use by:

1. manufacturers, suppliers, repairers, and maintainers of products to develop processes to identify, control, quantify, and report the amounts of HS in the products they manufacture or supply; and
2. customers and users of the products to know the HSF status of a product, and to understand the processes by which it is determined.

1 Scope

This Specification defines the requirements for establishing processes to identify and control the introduction of hazardous substances (HS) into its products. In the event that hazardous substances are introduced into the products, this Specification defines the requirements for implementing processes to test, analyze, or otherwise ascertain the HS content, and to make it available to the customer. Documented processes shall be within the organization's business and quality management systems.

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

2 Normative References

ISO 9001:2000, *Quality Management Systems – Requirements*

ISO 10005:1995, *Quality Management – Guidelines for quality plans*

ISO 10006:1997, *Quality management – Guidelines to quality in project management*

ISO 19011, *Guidelines on quality and/or environmental management systems auditing*

IEC QC 001002-3, *Rules of Procedure, Part 3: Approval procedures*

AS 9100, *Quality Systems Aerospace Model for Quality Assurance in Design, Development, Production, Installation and Servicing*

TL 9000 *Quality Management System (QMS) Requirements*

ISO 13485 *Medical devices — Quality management systems — System requirements for regulatory purposes*

3 Terms and Definitions

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

HS Hazardous Substance refers to any material as listed in the WEEE or RoHS and any additional customer requirements as prohibited from usage and is interchangeable with Restricted Substances.

HSF Hazardous Substances Free refers to the reduction or elimination of any material as listed in the WEEE or RoHS directives or other applicable standards or regulations.

Information services provider refers to an entity or organization that analyzes, monitors, or provides information for use in conjunction with designing, procuring, manufacturing, maintaining or supporting products for which the lead content should be known.

May indicates a course of action that is permissible within the limits of this document.

Product customer refers to an entity or organization that purchases a product, either for use or re-sale.

Product maintainer refers to an entity or organization that is responsible for keeping a product available for service, after it has been placed in service.

Product manufacturer refers to an entity or organization that manufactures a product or set of products for which the hazardous substances content must be known on a quantitative basis.

Product repairer refers to an entity or organization that repairs or restores a product to service after it fails in service.

Product supplier refers to an entity or organization that (a) distributes a product obtained from a manufacturer to a subsequent customer or user; or (b) integrates a manufactured product into a higher level product that is supplied to a subsequent customer or user.

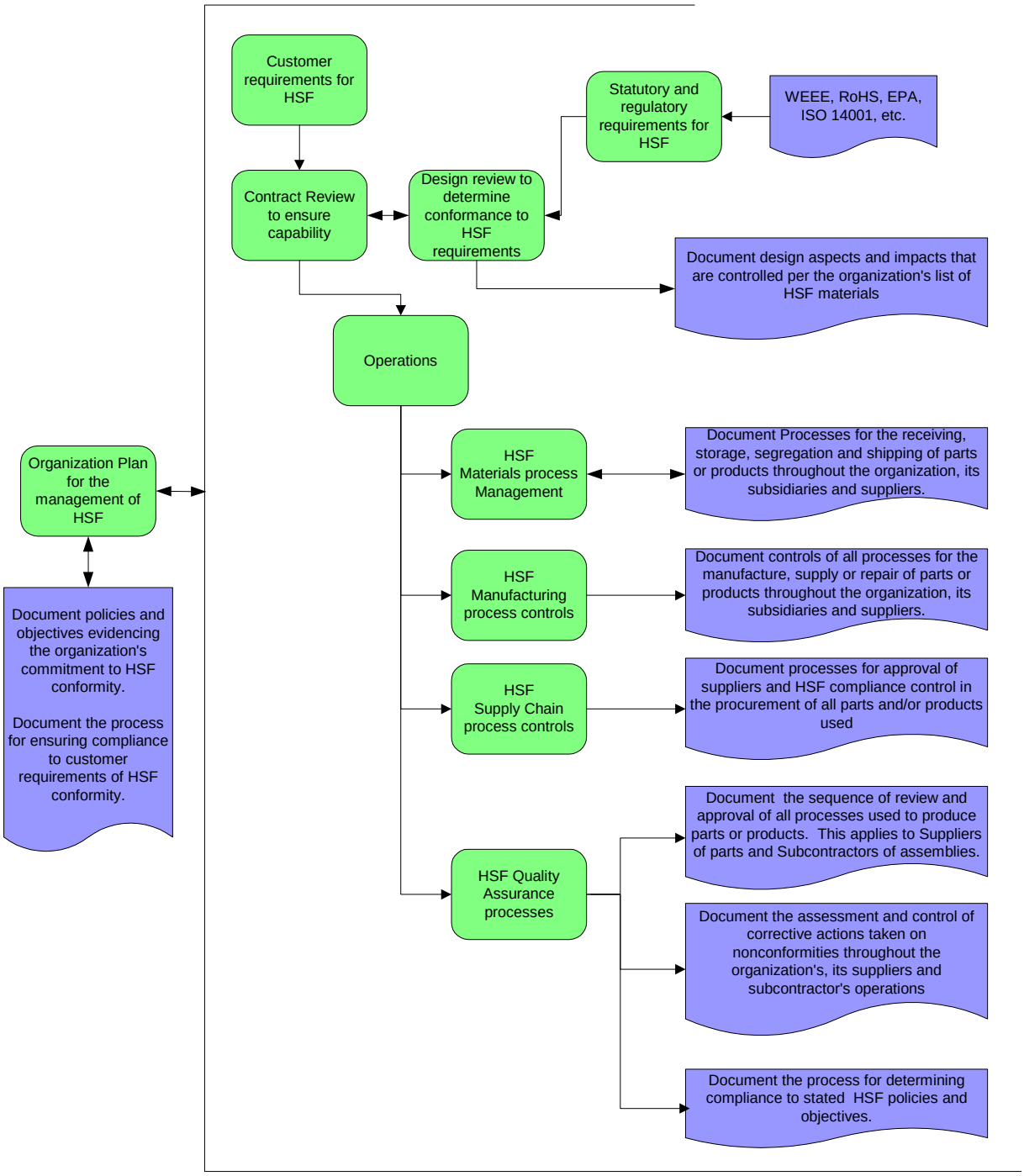
Product user refers to an entity or organization that uses an item after it has been placed in service.

Restricted Substance refers to any material as listed in the WEEE or RoHS and any additional customer requirements as prohibited from usage and is interchangeable with HS

Shall indicates a mandatory requirement to be followed in order to conform to this document.

Should indicates that, among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required; or that (in the negative form) a certain course of action is deprecated but not prohibited.

Structure for the achievement of Hazardous Substance Free operations



This model illustrates the minimum requirements of this standard, but does not show processes at a detailed level

4 Quality Management System

4.1 General requirements

The requirements of ISO 9001 shall apply along with the additional requirements below:

4.1.1 General

Each organization shall include in its ISO 9001:2000 mandated quality management system the procedures, documentation, and process management practices necessary to achieve HSF product and production processes.

The organization shall

a) Identify and document all hazardous substances in use in the organization.
b) identify the specific processes to be managed relevant to its HSF goals.
c) determine the interdependence and interaction of these processes and develop an appropriate HSF process management plan.
d) establish criteria upon which to objectively determine the effectiveness of the organization's HSF process management.
e) ensure the availability of resources and information needed to support effective HSF process management.
f) monitor, measure and analyze these processes, and
g) implement actions to ensure continuous process improvement in achieving HSF.
h) have a process established to restrict and/or eliminate the use of hazardous substances from products and processes.

4.1.2 Relationship with ISO 9001

The intention of this document is that HSF process management is to be congruent with the elements of ISO 9001:2000 international Standard.

4.1.3 Outsourcing

Where an organization chooses to outsource any process that affects its products' HSF characteristics, and accept into its operations the product of processes outside its own operations, the organization shall ensure management of and control over such processes.

4.2 Documentation requirements

The requirements of ISO 9001 shall apply along with the additional requirements below:

4.2.1 General

The quality management system documentation shall include
a) The HSF requirements shall be an integral part of the organization's quality management system and shall include
b) a list of all hazardous substances used within the organization.
c) statements of HSF policy and objectives with inclusion of a timeline for elimination of use of all hazardous substances, as appropriate
d) in the organization's quality manual a section on the HSF process management plan and objectives and reference to HSF documented procedures
e) documented procedures as required by the organization's HSF process management plan with control of all such documents executed as required by section 4.2.4 of the ISO 9001:2000 international Standard.
f) records of the organization's HSF process management performance.

Note: Consistent with the ISO 9001:2000 international Standard, “documented procedures” means that the procedure is established, documented, implemented and maintained. Additionally, the extent of documentation required is specific to the size of the organization, complexity of processes, and the competence of personnel.

5. Management Responsibility

5.1 Management Commitment

The requirements of ISO 9001 shall apply along with the additional requirements below:

Top management shall provide evidence of its commitment to the development and implementation of practices consistent with achieving HSF products and production processes and the continuous improvement of such by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.
b) establishing the HSF policy.
c) ensuring that HSF objectives are established.
d) including HSF in management reviews, and
e) providing resources to ensure progress toward HSF products and production processes.
f) ensuring the list of hazardous substances is communicated throughout the organization.
g) Determining HSF requirements.

5.2 Customer focus

Top management shall ensure that customer HSF requirements are determined, are met and included in the measure of customer satisfaction.

5.3 HSF Policy

Top management shall ensure that the HSF policy is appropriate for the purpose of the organization, and

a) includes a commitment to comply with requirements and continually improve the effectiveness of the HSF management practices.
b) provides a framework for establishing and reviewing HSF objectives.
c) is communicated and understood within the organization, and
d) is reviewed for continuing suitability.

5.4 Planning

The requirements of ISO 9001 shall apply along with the additional requirements below:

5.4.1 HSF objectives

a) Top management shall ensure that HSF objectives are established at relevant functions and levels within the organization. The HSF objectives shall be measurable and consistent with the HSF policy.
b) The HSF objectives shall include a timeline, as appropriate, for the elimination of hazardous substances identified and used in processes or products including procured products.

5.4.2 HSF planning

Top management shall ensure that

a) the practices required to achieve HSF are integrated into the quality management system planning and are elements in the quality objectives, and
b) the continuity of the HSF effort is maintained as improvements and changes are executed.

5.5 Responsibility, authority and communication

The requirements of ISO 9001 shall apply along with the additional requirements below:

5.5.1 Responsibility and authority

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

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes, procedures, and practices are established pursuant to achieving HSF goals.
b) reporting to top management on the organization's performance pursuant to the HSF plan and needs and recommended improvements in execution.
c) ensuring that HSF related requirements and responsibilities are communicated and understood throughout the organization.
d) ensuring the awareness in supplier organizations of their HSF related requirements and responsibilities.

5.5.3 Internal Communication

a) Top management shall ensure that the organization's personnel are informed of performance effectiveness and issues as relate to the HSF policies and execution plan.
b) Hazardous substances information shall be communicated, as required throughout the organization.

5.6 Management review

The requirements of ISO 9001 shall apply along with the additional requirements below:

5.6.1 General

Top management shall include and report on, during the regular management reviews, activities related to the HSF plan with regards to identification, use of hazardous substances, nonconformance's and corrective actions.

6. Resource Management

6.1 Provision of resources

The requirements of ISO 9001 shall apply along with the additional requirements below:

The organization shall determine and provide the resources needed to implement and maintain HSF processes and products

6.2 Human resources

The requirements of ISO 9001 shall apply along with the additional requirements below:

6.2.1 General

Personnel performing work affecting HSF product shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting HSF product quality,
b) provide training specific to the HSF plan for the identification, use, and elimination of hazardous substances.
c) evaluate the effectiveness of the actions taken,
d) ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the HSF objectives, and
e) maintain appropriate records of education, training, skills and experience.

6.3 Infrastructure

The requirements of ISO 9001 shall apply along with the additional requirements below:

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

7 Product Realization

7.1 Planning of HSF process and product realization

The requirements of ISO 9001 shall apply along with the additional requirements below:

The organization shall plan and develop the processes needed for HSF product realization.

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

a) quality objectives and requirements for the HSF product;
b) the need to establish HSF processes, documents, and provide resources specific to the HSF product;
c) required verification, validation, monitoring, inspection and test activities specific to the HSF product and the criteria for product acceptance. This shall include information services providers as appropriate;
d) documented procedures or work instructions for processes that include the use of restricted substances to include prevention where the possibility of contamination exists.

e) records needed to provide evidence that the HSF realization processes and resulting product meet requirements.
f) The output of this HSF planning shall be in a form suitable for the organization's method of operations.

Note: A document specifying the HSF processes (including the product realization processes) and the resources to be applied to a specific product can be referred to as a quality plan.

7.2 Customer-related process

The requirements of ISO 9001 shall apply along with the additional requirements below:

7.2.1 Determination of requirements related to the HSF product

The organization shall determine

a) HSF requirements specified by the customer,
b) HSF requirements not stated by the customer but necessary for specified or intended uses, where known.
c) HSF statutory and regulatory requirements related to the product, and
d) any additional HSF requirements determined by the organization.

7.2.2 Review of HSF requirements related to the product

The organization shall review the requirements related to the HSF product. This review shall be conducted prior to the organization's commitment to supply HSF product to the customer and shall ensure that;

a) HSF product requirements are defined, and
b) the organization has the ability to meet the HSF defined requirements.
c) any use of or possibility of contamination or mixing of processes or product that contain restricted substances shall be communicated to the customer.
d) Records of the results of the HSF review and actions arising from the review shall be kept and maintained.

7.3 Design and development

The requirements of ISO 9001 shall apply along with the additional requirements below:

7.3.1 HSF design and development planning

The organization shall plan and control the design and development of HSF product.

In planning the design, the use of any restricted substance shall be identified in the documentation and a plan for control and eventual replacement/elimination of the part.

7.3.2 HSF Design and development inputs

Inputs relating to HSF product requirements shall be determined and records maintained.

HSF inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 HSF Design and development outputs

The HSF outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

When the design requires the use of a restricted substance a documented procedure shall be developed for the control, identification, monitoring and measurement of the process/product to include subcontracted product.

7.3.4 HSF Design and development review

At suitable stages, systematic reviews of the design and development shall be performed in accordance with the HSF plan.

7.3.5 Design and development verification

The requirements of ISO 9001 shall apply

7.3.6 Design and development validation

The requirements of ISO 9001 shall apply

7.3.7 Control of HSF design and development changes

HSF design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.

7.4 Purchasing of HSF products

The requirements of ISO 9001 shall apply along with the additional requirements below:

a) The organization shall ensure that procured product conforms to HSF requirements.
b) the organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's HSF requirements.
c) the organization shall ensure that any HSF part/material is free from possible contamination with a restricted substance.
d) procurement of restricted substances shall be clearly identified on the purchase document and upon receipt of the material.
e) Verification of HSF purchased product
f) The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified HSF purchase requirements.
g) The procurement route of purchased goods shall be fully understood and any process that has the possibility of contamination by restricted hazardous substances shall be fully identified. A documented procedure shall outline the procurement activities related to the HSF process.
h) Establish a documented procedure for the inspection and identification of Hazardous substances included in purchased goods. The hazardous substance shall be identified by the type in the inspection data.
i) included shall be a process to handle an abnormality/nonconformance.
j) If the processes are combined with each other a documented procedure shall be established to differentiate between parts.

7.5 Production and service provision

The requirements of ISO 9001 shall apply along with the additional requirements below:

7.5.1 Control of HSF production and service provision processes

The organization shall plan HSF production and service provisions under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of HSF information that describes the characteristics of the product,

b) the availability of HSF work instructions, as necessary,
c) the use of suitable HSF equipment,
d) the availability and use of HSF monitoring and measuring devices,
e) the implementation of HSF monitoring and measurement, and
f) the implementation of HSF release, delivery and post-delivery process controls.
g) processes that have the possibility of contamination are identified and documented.
h) operational procedures are documented and define preventive measures to prevent possible contamination.

7.5.2 Validation of HSF processes for production and service provision

The organization shall validate HSF processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any HSF processes where deficiencies become apparent only after the product is in use or the service has been delivered.

7.5.3 HSF identification and traceability

a) Where appropriate, the organization shall identify the HSF product by suitable means throughout product realization.
b) Processes that include any restricted substance shall be uniquely identified and segregated to prevent combination with HSF product.
c) The organization shall identify the HSF product status with respect to monitoring and measurement requirements.
d) Where traceability is a requirement, the organization shall control and record the unique identification of the product.

7.5.4 Handling of hazardous substances parts

There shall be a documented procedure for the handling and storage of hazardous substances. This procedure shall include records of receiving and shipping; and records showing hazardous substances are segregated and managed separately.

7.6 Control of monitoring and measuring devices used in HSF processes

The requirements of ISO 9001 shall apply along with the additional requirements below:

a) The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of HSF product to determined requirements.
b) The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the HSF monitoring and measurement requirements.

8. Measurement, analysis and improvement

8.1 General

The requirements of ISO 9001 shall apply along with the additional requirements below:

8.1.1 Organization

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity to HSF requirements.

8.2 Monitoring and measurement of HSF processes

8.2.1 Customer satisfaction

The requirements of ISO 9001 shall apply along with the additional requirements below:

8.2.2 Internal Audit

The organization shall conduct internal assessments at planned intervals to determine whether the organization's Hazardous Substance Free processes conform to the requirements of this national standard and to customer specifications, and are effectively implemented and maintained.

Note: See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance

8.2.3 Monitoring of Restricted Substances Processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the Restricted Substance processes including processes of suppliers/subcontractors and information services providers where the possibility of the use of a restricted substance is identified

How these processes are to be controlled, monitored and measured shall be documented.

8.2.4 Monitoring and measurement of Restricted Substance Product

The organization shall establish a documented procedure to monitor and measure the Restricted Substances of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the HSF plan.

Evidence of conformity with acceptance criteria for Restricted Substances shall be maintained. Records shall indicate the person(s) authorizing release of product.

Product release and delivery shall not proceed until the required reviews have been satisfactorily completed.

8.3 Control of nonconforming HSF product

The requirements of ISO 9001 shall apply along with the additional requirements below:

The organization shall ensure that products which do not conform to HSF product requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall deal with nonconforming product by one or more of the following ways:

a) There shall be a clear procedure to handle situations when nonconforming products that contain restricted substances are detected and to prevent products that contain restricted substances from being shipped unless otherwise allowed.
b) Records of the nature of nonconformities and subsequent actions taken shall be maintained and clearly identified as to what restricted substance was detected
c) When nonconforming HSF product is detected after delivery or use has started, the organization shall take action to notify customers according to contract agreements or company process management policy.

8.4 Analysis of HSF data

The requirements of ISO 9001 shall apply along with the additional requirements below:

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the HSF process management system.

The analysis of data shall provide information relating to:

a) customer satisfaction
b) conformity to product requirements
c) characteristics and trends of processes and products including opportunities for preventive action, and suppliers' performance.
d) continuous improvement efforts for the elimination of the all hazardous substances, as applicable.

8.5 Improvement of HSF process management system

The requirements of ISO 9001 shall apply along with the additional requirements below:

8.5.1 Continual Improvement

The organization shall continually improve the effectiveness of HSF process management through the use of the quality policy, quality objectives, assessment results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action for identified HSF nonconformances

a) The organization shall take action to eliminate the cause of HSF nonconformities in order to prevent recurrence.
b) A HSF documented procedure shall be established to define requirements for
c) reviewing HSF nonconformities (including customer complaints)
d) determining the causes of nonconformities,
e) evaluating the need for action to ensure that HSF nonconformities do not recur,
f) determining and implementing action needed,
g) records of the results of action taken,
h) reviewing corrective action taken, and
i) reporting the status of all HSF corrective actions for management review.