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Restricted substances management systems for electrical and electronic products - Requirements

电子电气产品限用物质管理体系 要求

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Restricted substances management systems for electrical and electronic products - Requirements

1 Scope

This document specifies the requirements for the restricted substances management system of organizations related to the production of electronic and electrical products, including organizational environment, leadership, planning, support, operation, performance evaluation and improvement.

This document is applicable to the evaluation of restricted substance management systems for various types and sizes of organizations, which are related to the production of electrical and electronic products.

Note: Organizations related to the production of electrical and electronic products include manufacturers, suppliers, repairers, maintainers, service providers of electrical and electronic products and their supply chains.

2 Normative references

This document has no normative references.

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Electrical and electronic products

Equipment and supporting products that rely on current or magnetic fields to generate, transmit, measure such current and magnetic fields, whose rated working voltage does not exceed 1500 V for direct current and 1000 V for alternating current.

[Source: GB/T 26572-2011, 3.2]

3.2

Restricted substances

Substances that are restricted for use in electrical and electronic products by laws,

The organization shall continuously determine, monitor, review the information of these interested parties and their related requirements.

4.3 Determine the scope of the restricted substance management system

The organization shall determine the boundaries and applicability of the restricted substance management system to determine its scope.

When determining the scope, the organization shall identify:

- a) Various external and internal factors mentioned in 4.1;
- b) Requirements of interested parties mentioned in 4.2;
- c) Products and services of the organization.

If all the requirements of this document are applicable to the scope of the restricted substance management system determined by the organization, the organization shall implement all the requirements of this document.

The scope of the organization's restricted substance management system shall be available and maintained as documented information. The scope shall describe the types of products and services covered. If the organization determines that certain requirements of this document are not applicable to the scope of its restricted substance management system, the reasons shall be stated.

Conformity to the requirements of this document may be claimed only if the requirements determined to be inapplicable do not affect the organization's ability or responsibility to ensure the management of restricted substances in its products and services and do not affect the enhancement of customer satisfaction.

4.4 Restricted substance management system and its processes

4.4.1 The organization shall establish, implement, maintain, continually improve a process-based restricted substance management system, including the required processes and their interactions, in accordance with the requirements of this document.

The organization shall determine the processes required for the restricted substance management system and their application throughout the organization and shall:

- a) Determine the required inputs and expected outputs of these processes;
- b) Determine the sequence and interaction of these processes;
- c) Determine and apply the necessary criteria and methods (including monitoring, measurement and related performance indicators) to ensure the effective operation and control of these processes;

- d) Determine the resources required for these processes and ensure their availability;
- e) Assign responsibilities and authorities for these processes;
- f) Address risks and opportunities as required in accordance with 6.1;
- g) Evaluate these processes and implement necessary changes to ensure that the expected results of these processes are achieved;
- h) Improve processes and restricted substance management system.
- **4.4.2** To the extent and degree necessary, the organization shall:
 - a) Maintain documented information to support the operation of processes;
 - b) Retain documented information to ensure that its processes are carried out as planned.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment to the restricted substances management system by:

- a) Being accountable for the effectiveness of the restricted substances management system;
- b) Ensuring that the management policy and management objectives of the restricted substances management system are established and appropriate to the organizational context and consistent with the strategic direction;
- c) Ensuring that the restricted substances management system requirements are integrated into the organization's business processes;
- d) Promoting the use of a process approach and risk-based thinking;
- e) Ensuring that the resources required for the restricted substances management system are available;
- f) Communicating the importance of effective restricted substances management and compliance with the restricted substances management system requirements;
- g) Ensuring that the restricted substances management system achieves its intended results;

- h) Engaging, guiding, supporting personnel to contribute to the effectiveness of the restricted substances management system;
- i) Driving improvement;
- j) Supporting other relevant managers in exercising leadership within their areas of responsibility.

5.1.2 Customer focus

Top management shall demonstrate its leadership and commitment to customer focus by ensuring that:

- a) Applicable legal and regulatory requirements and customer requirements for restricted substance characteristics are determined, understood, continually met;
- b) Risks and opportunities that may affect product and service conformity and the ability to enhance customer satisfaction are identified and addressed;
- c) Efforts to enhance customer satisfaction are consistently made.

5.2 Policy

5.2.1 Establishment of policy

Top management shall establish, implement, maintain a restricted substances management policy that:

- a) Includes a commitment to comply with legal and regulatory requirements and to meet customer requirements;
- b) Is appropriate to the purpose and context of the organization and supports its strategic direction;
- c) Provides a framework for establishing restricted substances management objectives;
- d) Includes a commitment to continual improvement of the performance of the restricted substances management system.

5.2.2 Communication policy

The restricted substances management policy shall:

- a) Be maintained as documented information and available;
- b) Be communicated, understood, applied within the organization;
- c) Be available to relevant interested parties, as appropriate.

b) How to:

- 1) Integrate and implement these measures in the restricted substance management system process (see 4.4);
- 2) Evaluate the effectiveness of these measures.

The response measures shall be commensurate with the potential impact of risks and opportunities on the compliance of products and services with restricted substance characteristics.

The organization shall maintain and retain documented information related to the results of the risk and opportunity identification process, including all identified restricted substances contained in its products and processes, introduced directly or indirectly, or may be introduced.

Note: Opportunities include the adoption of new practices, new materials, new technologies, the introduction of new products, the establishment of new partners, etc., which will lead to the reduction (or elimination) of restricted substances to meet the needs of the organization or its customers.

6.2 Planning of restricted substance management objectives and their achievement

6.2.1 The organization shall establish management objectives for relevant functions, levels and processes required for the restricted substance management system.

The objectives shall:

- a) Be consistent with the restricted substance management policy;
- b) Be measurable; and, where appropriate, include a timeline for the reduction or elimination of restricted substances identified and used in processes or products;
- c) Take into account applicable requirements;
- d) Be related to the compliance of products and services with restricted substance characteristics and to enhancing customer satisfaction;
- e) Be monitored;
- f) Be communicated;
- g) Be updated as appropriate.

The organization shall maintain documented information on restricted substance management objectives.

6.2.2 When planning how to achieve restricted substance management objectives, the

organization shall determine:

- a) What is to be done;
- b) What resources are required;
- c) Who is responsible;
- d) When it will be completed;
- e) How the results will be evaluated.

6.3 Planning of changes

When the organization determines that changes to the restricted substances management system are needed, the changes shall be implemented in a planned manner (see 4.4).

The organization shall identify:

- a) The purpose of the change and any potential impact that may affect products and services on applicable laws, regulations and customer requirements;
- b) The impact on the integrity of the restricted substances management system;
- c) The availability of resources;
- d) The allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources required to establish, implement, maintain, continually improve the restricted substances management system.

The organization shall identify:

- a) The capabilities and limitations of existing internal resources;
- b) The resources that need to be obtained from external providers.

7.1.2 People

The organization shall determine and provide the necessary people to effectively

monitoring and measurement resources are fit for purpose.

7.1.5.2 Measurement traceability

Measurements of restricted substance properties shall be traceable and measuring equipment shall:

- a) Be calibrated and/or verified against measurement standards traceable to international or national standards at specified intervals or before use. When such standards do not exist, documented information as the basis for calibration or verification shall be retained;
- b) Be identified to determine its status;
- c) Be protected to prevent the invalidation of the calibration status and subsequent measurement results due to adjustment, damage or attenuation.

When measuring equipment is found to be unfit for its intended use, the organization shall determine whether the validity of previous measurement results has been adversely affected and take appropriate action if necessary.

7.1.6 Organizational knowledge

The organization shall determine the necessary knowledge to operate processes and obtain products and services that meet the requirements for restricted substance properties.

This knowledge shall be maintained and available to the extent required.

In response to changing needs and trends, the organization shall review existing knowledge and determine how to acquire or access more necessary knowledge and knowledge updates.

Note: The organization's knowledge of the restricted substance management system includes, but is not limited to:

- a) Applicable laws, regulations and customer requirements for the restricted substance characteristics of the products and services provided by the organization;
- b) Restricted substance risks and their control in the materials that make up the products and services;
- c) Process risks and their control;
- d) Measurement methods and their constraints;
- e) Understanding of restricted substance measurement results and their meaning.

7.2 Competence

The organization shall:

- a) Determine the required competence of personnel working under its control who perform work that affects the performance and effectiveness of the restricted substance management system;
- b) Ensure that these personnel are competent based on appropriate education, training or experience;
- c) Take actions to obtain the required competence when applicable and evaluate the effectiveness of the actions;
- d) Keep appropriate documented information as evidence of personnel competence.

Note: Required capabilities include, but are not limited to:

- a) Identify, understand, apply applicable laws, regulations, customer requirements;
- b) Design and development of products that meet restricted substance characteristics requirements;
- c) Select, evaluate, use, manage external suppliers;
- d) Identify new materials;
- e) Perform risk analysis on processes, products, services or materials provided internally or externally and the restricted substance management capabilities of external suppliers;
- f) Restricted substance measurement;
- g) Communication of restricted substance characteristics;
- h) Preparation of restricted substance characteristics technical documentation.

7.3 Awareness

The organization shall ensure that persons working under its control are aware of:

- a) The restricted substance management policy;
- b) Relevant management objectives;
- c) Their contribution to the effectiveness of the restricted substance management system, including the benefits of improved performance;
- d) The consequences of non-compliance with the restricted substance management

- a) Documented information required by this document;
- b) Documented information determined by the organization to be necessary to ensure the effectiveness of the restricted substance management system;
- c) Documented information required by applicable laws, regulations, customers.

Note: Documented information includes but is not limited to:

- a) Supplier declaration or contractual agreement on product compliance with restricted substance characteristics;
- b) Product technical documentation/archives;
- c) List of restricted substances contained or potentially introduced into the product;
- d) Material safety data sheet for the product;
- e) Material declaration for electrical and electronic products;
- f) Restricted substance test reports.

7.5.2 Creation and updating

When creating and updating documented information, the organization shall ensure appropriate:

- a) Identification and description (e.g., title, date, author, index number);
- b) Format (e.g., language, software version, diagram) and media (e.g., paper, electronic);
- c) Review and approval to maintain suitability and adequacy.

7.5.3 Control of documented information

- **7.5.3.1** Documented information required by the restricted substance management system and this document shall be controlled to ensure that:
 - a) It is available and applicable where and when required;
 - b) It is properly protected (e.g., from disclosure, improper use or loss).
- **7.5.3.2** To control documented information, the organization shall perform the following activities, as applicable:
 - a) Distribution, access, retrieval, use;
 - b) Storage and protection, including maintaining readability;

- c) Change control (e.g., version control);
- d) Retention and disposal.

The organization shall appropriately identify and control documented information from external sources that is determined by the organization to be necessary for the planning and operation of the restricted substance management system.

Documented information retained as evidence of conformity shall be protected from unintended changes.

8 Operation

8.1 Planning and control of operation

To meet the requirements of restricted substance management and implement the measures identified in Chapter 6, the organization shall plan, implement, control the required processes (see 4.4) by the following measures:

- a) Determine the restricted substance characteristics requirements for products and services;
- b) Establish criteria for:
 - 1) Processes;
 - 2) Acceptance that meets the restricted substance characteristics requirements;
- c) Determine the resources required to meet the requirements of restricted substance management;
- d) Implement process control in accordance with the criteria;
- e) Determine, maintain, retain documented information to the extent and extent necessary:
 - 1) Ensure that the process has been carried out as planned;
 - 2) Confirm that products and services meet the restricted substance characteristics requirements.

The output of the plan shall be suitable for the operation of the organization.

The organization shall control changes to the plan, review the consequences of unexpected changes, take measures to mitigate adverse effects as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4), to

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