GUIDEBOOK FOR

IECQ QC 080000

HAZARDOUS SUBSTANCES PROCESS MANAGEMENT

Funded by SME Development Fund

工業貿易署
Trade and Industry Department

Organizers

香港工業總會
FHKI Federation of Hong Kong Industries

香港綠色製造聯盟

Implementation Agent

HKPC

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Design and Production: **i.Link Group Limited**
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Acknowledgements

We would like to acknowledge the following organizations for their support and contribution for this Industry Experience Sharing (in alphabetical order):

- Fook Tin Technologies Limited
- Gibson Innovation Limited
- Golden Cup Printing Co. Ltd.
- Hasbro, Inc.
- Leo Paper Group
- Print-Rite Holdings Limited
- SGS Group
- Techtronic Industries Company Limited
- Tonly Electronics Holdings Limited
- Tusen Lee Group (Holdings) Co. Ltd.

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Published: August 2015

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SME DEVELOPMENT FUND PROJECT

"A Support Programme for Assisting Hong Kong SMEs to Effectively Achieve Hazardous Substances Compliance through Adoption of IECQ QC 080000 Hazardous Substances Process Management System"

ABOUT THIS GUIDEBOOK

The Hong Kong Green Manufacturing Alliance (HKGMA) in association with the Hong Kong Productivity Council (HKPC), has implemented a 18-month support programme, aiming to spur industry wide actions on the awareness and adoption of the IECQ QC 080000 Hazardous Substance Process Management for SMEs. A variety of activities have been carried out, such as seminars, industry consultation visits, workshops, and outreach to local industrial associations or professional institutes. Serving as practical reference for the industries, this Guidebook covers topics on essential requirements on the standard, procedures to identify key hazardous substances free processes and develop controls, documentation and auditing requirements, introduction of typical certification process, as well as industry cases for experience sharing.

PREFACE

In recent years, regulatory requirements on the use of hazardous substances in products have grown increasingly stringent, and new compliance requirements are continually being introduced. In response to these compliance challenges, the International Electrotechnical Commission (IEC) launched IECQ QC 080000 Hazardous Substances Process Management (HSPM) in 2005. The HSPM system provides comprehensive international specifications to assist manufacturers and suppliers in developing management processes to identify, control, quantify, and report any hazardous substances contained in their products. With this systematic disclosure and control scheme on hazardous substances compliance issues in place, customers and end-users also benefit by knowing more about the hazardous substances free status of a particular product.

Many overseas buyers continue to incorporate the elements of the IECQ QC 080000 HSPM System into their sourcing requirements. They also request that suppliers integrate these elements into their own operations and undertake third-party certification to demonstrate product safety compliance.

Unlike their overseas counterparts, however, most SMEs in Hong Kong are not fully aware of the effectiveness of the IECQ QC 080000 HSPM system in ensuring compliance with international regulations on hazardous substances. They may still rely on an ad-hoc approach such as testing sample products upon request, which can be costly and ineffective in the long run.

To aid Hong Kong SMEs wanting to adopt QC 080000 (latest version released in 2012) to meet emerging requirements of global buyers and to enhance their market competitiveness, the Hong Kong Green Manufacturing Alliance (HKGMA) in association with the Hong Kong Productivity Council (HKPC), launched an 18-month support programme (the Support Programme) to help industry:

- Understand the importance and added-value of an effective hazardous substances management programme
- Acquire a practical understanding of the IECQ QC 080000 HSPM System
- Learn the principles and essentials of implementing an IECQ QC 080000 HSPM System
- Adopt the IECQ QC 080000 HSPM System in order to enhance market competitiveness

The Support Programme offers seminars, industry consultation visits, e-Fact sheets, workshops, industry outreach and a practical bilingual Guidebook (this Guidebook) for SMEs. This Guidebook includes an overview of the essential standards, procedures, processes, controls, audit requirements and documentations needed to achieve IECQ QC 080000 certification, and also looks at best industry practices and general processes. The Guidebook is available in both printed form and on the HKGMA website for easy access.

On behalf of the HKGMA, I wish to express my appreciation to those supporting organizations who have shared their valuable experience so generously with us. I hope that this Guidebook will be of immense benefit to the industry in understanding and implementing their own HSPM System, to enhance their competitiveness and achieve success in the global market.

Mr. Yan Zhao Jia, Robert
Chairman
Hong Kong Green Manufacturing Alliance

CHAPTER 1: OVERVIEW AND STATUS OF IMPLEMENTATION OF IECQ QC 080000 HSPM

1. Regulation Requirements for the Control of Hazardous Substances in Different Regions (EU, China and US)

Hazardous substances have become a growing concern in manufacturing, especially in industries that produce toys, consumer electronics and electrical appliances. With the aim to eliminate unsafe products and reduce the number of product recalls due to hazardous substances, different regions around the world have devised regulatory requirements for electrical products and components to restrict or prohibit the use of toxic substances.

1.1 Waste Electrical and Electronic Equipment (WEEE) Directive (Directive 2002/96/EC)

In the EU, a number of directives focused on the control of hazardous substances and chemicals have been imposed. The Waste Electrical and Electronic Equipment Directive (WEEE Directive) was introduced in 2003. Producers are responsible for taking back, treating and/or recycling WEEE. Member countries, distributors, producers, and other entities are also required to fulfill certain requirements related to the design, sorting, collection, and recycling of WEEE. Other places such as South Korea had launched the Act for Resource Recycling of Electrical and Electronic Equipment and Vehicles in 2008, which contains elements of WEEE/Restrictions of Hazardous Substances (RoHS). In 2012, the WEEE Directive was

revised to include a few amendments. Among them, large electrical and electronic retailers in the member states are now obliged to accept small WEEE items from consumers, without requiring them to buy a new product.

1.2 Restriction of Hazardous Substances (RoHS) Directive (Directive 2002/95/EC)

In 2006, the Restriction of Hazardous Substances (RoHS Directive) Directive was ratified to ban the use of six hazardous materials (Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated biphenyls and Polybrominated diphenyl ethers) in electrical and electronic equipment and is now a mandatory requirement for all member states of the EU.

To allow flexibility, RoHS directive includes over 80 exemptions for products with certain expiration dates. In late 2007, Mainland China's version of the RoHS came into force. In 2013, RoHS 2 Directive (Directive 2011/65/EU) took effect and expanded the labeling requirements to include all electrical and electronic equipment, cables and spare parts, with full compliance required by 2019. In addition, manufacturers are obliged to apply for exemptions if needed and to carry out any necessary assessments related to the exemptions.

1.3 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Implemented in 2008, the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) directive is designed to protect human health and the environment from certain harmful chemicals. Under REACH, all companies manufacturing or importing chemicals in quantities equal to or greater than one tonne per year into the EU market are required to register their substances with the European Chemicals Agency (ECHA). With each registration, the ECHA will evaluate and check the chemical information submitted by the relevant company and examine

its testing proposals. In addition, carcinogens, mutagens, substances toxic to the reproductive system and substances that are persistent, bio-accumulative and toxic, very persistent and very bio-accumulative or of equivalent concern may be identified as Substances of Very High Concern (SVHC) and will be added to the Authorization Candidate List. SVHCs that are included in the Authorization List will need to apply for an authorisation for each use of that substance.

1.4 Hazardous Substances Legislation in the United States

Compared to Europe and Asia, the United States started regulating hazardous substances in 1985 when California Proposition 65 passed. Since 1985, many consumer products have been reformulated to eliminate the toxic chemicals identified by California Proposition 65. The California Electronic Waste Recycling Act was also enacted to reduce the use of cadmium, hexavalent chromium, lead and mercury in certain electronic products sold in the state. Nationally, the Consumer Product Safety Improvement Act (CPSIA) granted power to the U.S Consumer Product Safety Commission (CPSC) to regulate the safety of all products, whether imported for sale or made in the U.S. The Act also helps to protect children under the age of twelve against harmful levels of lead and phthalates from child-related products.

2. Background and Development of IECQ QC 080000

The IECQ QC 080000 is the Hazardous Substances Process Management (HSPM) standard developed by the International Electrotechnical Commission (IEC) in conjunction with the Quality Assessment System for Electronic Components (IECQ) created in 2005. The IECQ Hazardous Substance Process Management (HSPM) QC 080000 Certification is applicable to any industry manufacturing electrical and electronic components as well as related materials, both internally produced and outsourced. Based on ISO 9001/TL 9001/TS 16949, the IECQ QC 080000 aims to minimize or eliminate the production of hazardous substances to satisfy RoHS, WEEE and other customer-specific requirements.

The IECQ QC 080000 applies a process management approach to implement and maintain hazardous substances free (HSF) products and production processes. It allows companies to develop ways to identify, control, quantify and report the amounts of hazardous and toxic substances in the products they manufacture or supply. Using third-party assessments, such as laboratory testing, the system also allows outside suppliers to demonstrate that their electrical and electronic components and products are free of specific hazardous substances, to meet local, national and international requirements.

In 2012, the IECQ QC 080000 Specification was revised and upgraded. In addition to restricting hazardous substances in products, the 2012 version put more emphasis on management requirements such as compliance assessment, preparation of self-declarations, preparation of technical files and product control. The new version also incorporates more regulatory requirements such as China RoHS, REACH, CPSIA, toy directive and battery directive. The new version is also better aligned and consistent with ISO 9001:2008.

Figure 1.1 Timeline of hazardous substances control regulations and standards

3. Relationship between ISO 9001, ISO 14001 and IECQ QC 080000

Similar to other common environmental systems, the IECQ QC 080000 uses a process management approach instead of a product based approach to control the level of hazardous substances in compliance with worldwide legal requirements. Further to that, HSF objectives, policy and control procedures have to be established to meet the relevant requirements.

Despite some similarities between the three standards, the IECQ QC 080000 follows the methodology of ISO 9001 instead of ISO 14001. Since its aim is to meet legal requirements and maintain HSF products, ISO 9001 provided a more suitable approach when setting up the system. The below table clarifies the differences between the three standards in terms of their system focus, scope and strategy.

Content	IECQ QC 080000	ISO 9001	ISO 14001
System Focus	Hazardous substances control	Meeting customer's requirements and quality expectations	Significant environmental aspects control
Scope	Electrical product production process. Control of hazardous substances regulated by international directives	All areas of a business, e.g. training, facilities, people and services	Effluent emitted to the environment during business operations
Strategy	Set HSF Objectives and Policy	Establish quality objectives and targets and a quality management plan	Identify significant environmental aspects and set objectives; control and monitor plan

Table 1.1 Comparisons between IECQ QC 080000, ISO 9001 and ISO 14001 management systems

4. Benefits of Adopting IECQ QC 080000

The IECQ QC 080000 offers a systematic methodology for any size organization, including small and medium enterprises (SMEs), to establish a hazardous substances management system. The benefits of the system and include:

- Overcome green trade barriers in the global market by fulfilling RoHS Directive, WEEE Directive, REACH and other legal requirements
- Reduce product recall risk

- Lower product testing costs through process control
- Provide frameworks to control hazardous substances throughout the production process including the supply chain
- Demonstrate corporate commitment to implement best practices to protect the environment through minimizing hazardous substances
- Enhance company reputation

Benefits of adopting the IECQ QC 080000 are demonstrated in Chapter 3: Industry Experience Sharing.

5. Certification Number of IECQ QC 080000

The demand for the HSPM is growing. According to the IECQ database, over 2500 IECQ QC 080000 certifications have been issued worldwide as of March 2015, and nearly all of those certifications originated in Asia (99%). The remaining one percent came from the European Union, North America and South America. The below graph illustrates the worldwide distribution of IECQ QC 080000 certifications.

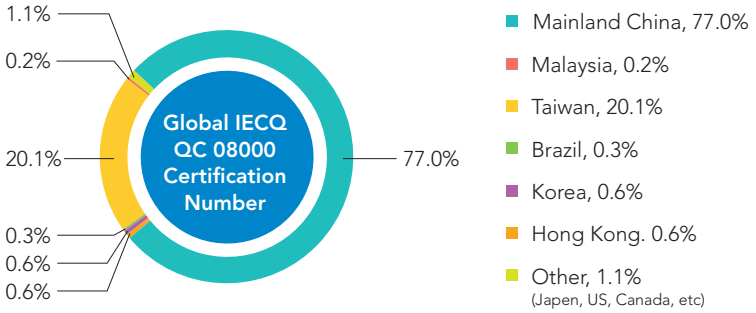

Figure 1.2 Global IECQ QC 080000 certification number distribution

6. Structure of this Guidebook

This publication has been prepared as a useful handbook for the electrical and electronic components manufacturing industry by introducing the background and development of the IECQ QC 080000 (Chapter 1), creating a practical preparation and implementation plan for establishing a Hazardous Substance Process Management System (Chapter 2), highlighting best practices that can help companies to manage and eliminate hazardous substances in their products (Chapter 3), and providing detailed certification process and auditing requirements (Chapter 4).

CHAPTER 2: OVERVIEW OF IECQ QC 080000 HAZARDOUS SUBSTANCES PROCESS MANAGEMENT SYSTEM (HSPM)

The main purpose of adopting an HSPM System is to help an organization improve its management of hazardous substances in a systematic manner.

Similar to other ISO management system standards such as ISO 9001, ISO 14001 and ISO 50001, IECQ QC 080000 HSPM is based on a continual improvement framework. An overview is given in the figure below:

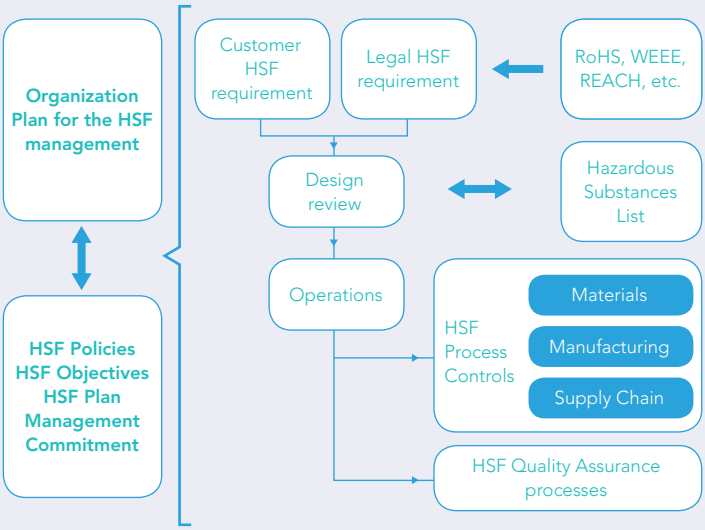

Figure 2.1 The basic structure for the achievement of HSF operations

Before introducing the detailed requirements of IECQ QC 080000 HSPM, there are some key concepts to understand, according to the following definitions and standards:

The definition of hazardous substances (HS) means: any substance, regulated by applicable legal or customer requirements which prohibit, restrict, reduce its use and/or require notification of its existence, that will inherently do harm to human health, public safety and/or the environment. HS can vary across different organizations and in different regions. The most common examples of HS can be obtained from the RoHS Directive, which specifies 6 types of prohibited substances (i.e. Pb, Hg, Cd, Cr6+, PBB, and PBDE).

Therefore, the ultimate goal of establishing an IECQ QC 080000 HSPM System is to achieve HSF - Hazardous Substances Free.

In addition, it is important to know the terminologies specified in the requirements, including **Shall**, **Should** and **May**, which can help readers to understand the level of compliance required:

a.) Whenever the standard says **SHALL**, it indicates a mandatory requirement.

b.) The word **SHOULD** indicates that the standard or the requirement is recommended as a suitable/preferred option among several possibilities.

c.) In the case of the word **MAY**, the standard or requirement is permissible within the limits specified by the standard.

It should also be noted that the requirements of the IECQ QC 080000 standard should be read in conjunction with ISO 9001 for a fuller understanding of the scheme. The below section highlights the key elements of IECQ QC 080000 requirements. Examples are illustrated for reference.

1. General Requirements

This section explains the importance of ISO 9001 in establishing the HSPM System as well as the need to build up a management cycle for managing hazardous substances. The general requirements also provide a framework for an organization to establish an effective management strategy. To fulfill this mandate, IECQ QC 080000 requires an organization to commit to a "Plan-Do-Check-Act" Cycle. From identifying the specific processes to be managed relevant to HSF goals, establishing criteria that will be used to determine the effectiveness of an organization's HSF process management, to conducting routine monitoring and measuring, all aspects of the cycle are needed to achieve success.

1.1 Documentation Requirements

The documentation requirements describe how records, policies and other related documentation are to be maintained as part of the IECQ QC 080000 system:

1. Communication of information - Documents such as policy directives are an important way for organizations to communicate their commitment to both regulatory organizations and potential customers. As a usual practice, organizations who are IECQ QC 080000-certified will upload their HSF policy to the company website and/or include their HSF requirements during the purchasing process.

2. Evidence of conformity - Documents also serve an important purpose during third-party inspections when organizations need to demonstrate their capability in managing HS.

3. Knowledge sharing - All proper procedures used to manage HS can be recorded so that best practices can be disseminated within an organization or to external stakeholders.

The three major documents in the IECQ QC 080000 System are: HSF policy, HSF objectives and HS list. An organization should draft these three documents to properly reflect their customers' interests and business needs. An example of a company HS list is included below for reference. To begin, an organization should consult relevant legislation such as RoHS Directive to compile a preliminary list of HS. Then customers' requirements can be added to the list. The organization should also document which components or raw materials could potentially be on the HS list.

1.2 Management Responsibility

The management responsibility section outlines the roles of top management within the IECQ QC 080000 HSPM System. The involvement of top management fosters the effective establishment of HSPM and ensures that a consistent approach and message are applied throughout an organization. Such participation also encourages commitment from other key members of the organization. In addition to providing general support, these key members must provide the resources (time, personnel, funding, materials, etc.) to involve people in the process. All HSF policies and objectives should be approved by top management or management representatives. Furthermore, top management should ensure that their employees fully adopt the principles of HSPM and are committed to reducing and/or eliminating HS.

1.3 HSF Policy

The section on HSF policy explains how an organization can demonstrate its commitment through company policies and show its willingness to effectively manage HS. In general, a company's HSF policy could be integrated into the ISO 9001 policy on quality management.

1.4 HSF Objectives

The HSF objectives are measurable targets that an organization can use to assess the effectiveness of its HSF policy. Objectives should include a timeline, as appropriate, for the elimination of HS in products. In addition to specifying the quantity of HS in products, an organization should also incorporate staff training as well as customer feedback in its HSF objectives. With that in mind, an organization should also consider its individual business needs when establishing HSF objectives.

1.5 Responsibility, Authority and Communication

After establishing HSF policies and objectives, an organization should define the roles and responsibilities of its personnel for achieving company objectives within the timeline. In addition to ISO 9001 standards, an organization could consider adding additional roles, responsibilities and requirements to the existing manuals on HSPM. An example is given below:

Department	Function(s)
General Manager	Set up overall HSF plan
HR Department	Identify needs of HS training programme
Engineering Department	Identify ways to improve product design
QC Department	Test HS Directive content of products
Procurement Department	Buy RoHS Directive compliant materials
Production Department	Implement HSF Plan
Sales Department	Understand clients' HSF needs

Table 2.1 Example of the roles and responsibilities on HSPM

The IECQ QC 080000 HSPM System also requires that an organization's top management appoints a management representative to oversee all matters related to HS performance of both the organization and its suppliers. The representative will also need to ensure effective internal communication between departments so that each department understands its roles and responsibilities in achieving HSF. Sample types of internal communication include: meetings, notices, reminders and internal memos. All internal communication should be properly recorded for knowledge sharing or third-party audits.

1.6 Management Review

This section outlines the disclosure and reporting requirements of the IECQ QC 080000 HSPM system in relation to a organization's HSF plan.

The management review should include any decisions or reports related to:

- Continuing suitability, adequacy and effectiveness of HSPM
- Non-compliance issues due to changing legal or customer requirements, use of hazardous substances or other HSF abnormalities
- Corrective action taken for HSF nonconformities and the current status of such action
- HSPM audit reports
- Customer comments and feedback
- Recommendations for improvement
- Allocation and adequacy of resources for HSF processes and products

Since the amount of hazardous substances in a product is a key indicator of quality, the management review of a organization's IECQ QC 080000 HSPM System can be held concurrently with its evaluation of ISO 9001. Periodic management reviews will also help an organization to identify ways to improve its HSF plans and procedures.

2. Resource Management

The establishment of an IECQ QC 080000 HSPM System requires resources that might differ from normal business operations. Section 6.1 of the IECQ QC080000 standard outlines the resources an organization might need for HS management. Here are the major components that the IECQ QC 080000 System requires:

1. Raw materials - organizations may need to purchase new raw materials that comply with regulations.

2. Machinery - some traditional equipment may not be suitable for producing HSF products, as they might cause contamination (e.g. lead) in products. Organization may need to upgrade old equipment or purchase new machinery.

3. Testing equipment - some organizations may need to purchase testing equipment such as XRF for testing HS levels in products for internal control or sampling.

4. Manpower - the capabilities needed for designing and producing HSF products can be different to that for traditional products.

5. Product registration/administration costs - after successfully producing HSF products, organizations may choose to register their products with local and global certification schemes and costs may be incurred for such schemes.

Top management is advised to provide adequate resources for the above components to achieve an effective HSPM system:

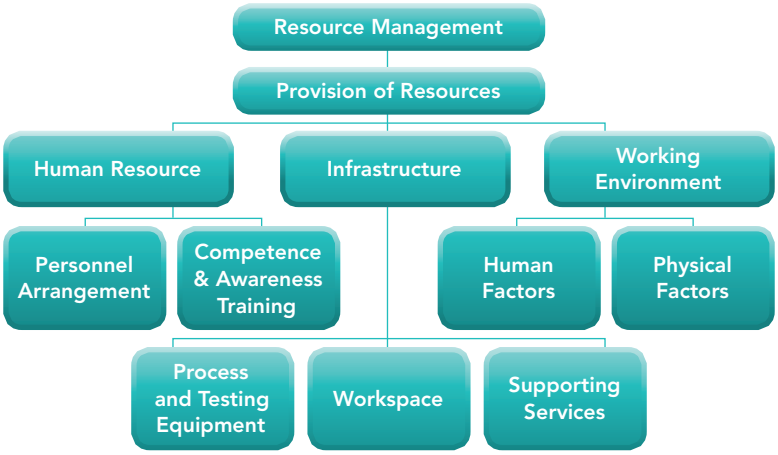

Figure 2.2 Overview of resource management

2.1 Human Resources

A competent workforce is essential to successfully implementing an organization's HSPM and manufacturing HSF products. Proper training to encourage and ensure the competency of personnel is an important element in the IECQ QC 080000 HSPM System. An organization should always review the skill levels and general awareness of its staff. In HS management, a whole range of employees would benefit from supplementary training, such as:

1. Supply Chain Officers - Employees who manage supply chains may be required to assess whether incoming materials fulfill their organizations' HSF requirements. This may involve reading and analyzing testing reports, compliance declarations, material safety data sheets, agreements, etc. In some cases, it may involve auditing and carrying out due diligence of suppliers to ensure their self-declarations are valid. The work may require a high degree of competence in HS management.

2. Internal Testing Personnel - If an organization decided to test the HS levels of incoming materials, relevant personnel would need to understand the HS list and any testing requirements.

3. Warehouse Logistics Administrator - In warehouses that store both non-HSF and HSF products, the logistics administrator will need to be strict about labelling products and materials and handling general classifications as well as the control and movement of materials and the traceability of out-going materials in order to prevent any mix-up between non-HSF and HSF products.

4. Production Site Workers - All workers will need to be skilled with new machinery to achieve HSF.

5. Product designers - The quality of any product is of high importance. Thus designers will need to factor in HSF requirements at the product design stage. As such, they will need to source and utilize alternative materials that would meet HSF objectives while not affecting the functionality and quality of a product.

2.2 Infrastructure and Work Environment

The infrastructure and work environment requirements should also be considered during the resource management process. The infrastructure listed below is essential in meeting HSF process and product requirements.

- Warehouse
- Process equipment

- Hardware and software for testing equipment
- Data computing systems
- Communication and information systems

The care and upkeep of the above components is critical for preventing HS contamination. Company premises, equipment and systems should be maintained regularly, and any repairs or maintenance should be logged and recorded. The work environment should always be clean and tidy, so that the risk of cross-contamination is kept to a minimum.

3. Product Realization

According to ISO 9001, product realization is the term used to describe the stages that an organization goes through to develop, manufacture, and deliver finished goods or services. An effective Quality Management System (QMS) includes a comprehensive approach to getting from the product concept to the finished product. In the IECQ QC 080000 HSPM System, the product realization requirement focuses on how to integrate HSF properties in to an existing product realization process. Similar to general requirements and resource management, there are documentation requirements for the efforts that organizations make to achieve HSF processes.

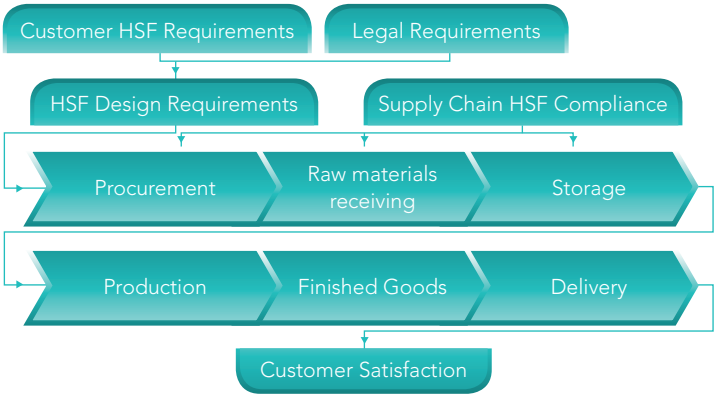

Figure 2.3 Typical Process of Product Realization

3.1 Customer-related Process

The section on customer-related processes is very similar to the section in ISO 9001. In ISO 9001, requirements for customer-related processes ask that an organization determine its own product requirements. These requirements may come from customers, laws, regulations, and generally-accepted standards within an organization's industry or market. As for the IECQ QC 080000 HSPM System, an organization will need to determine HS-specific requirements. There are various ways for an organization to determine HS-specific requirements from customers, including purchase agreements, customers' environmental policies, customers' green procurement specifications, as well as other requirements such as RoHS and WEEE Directives.

After gathering a product's preliminary HS requirements, both customers and organizations need to review these HS requirements to be certain that customers understand them, and that organizations meet these requirements. This review must fulfill the three requirements mentioned in clause 7.2.2 (a) to (c) of the IECQ QC 080000 HSPM standard. This review is similar to the one in ISO 9001 and can be conducted at the same time.

Customers also need to be fully aware of the impact caused by any HS in products. To meet this requirement, an organization should deliver information on a product's MSDS, its compliance declaration, HS testing report, etc. Some organizations have even established an online platform so customers can access all pertinent information at once. These requirements can be fulfilled on top of the ISO 9001 management system.

3.2 Design and Development

Generally speaking, during design and development, an organization should consider the HS content of the raw materials, the compatibility of raw materials with production equipment, and the potential impact of the production process on the HS content of the final product. An organization can reference the "Design for the Environment" concept proposed by the Environmental Protection Agency (EPA), which provides a step-by-step guide for developing environmentally friendly products, from a product's life cycle perspective.

Similar to ISO 9001, HSF design and development inputs refer to both customers' needs and any legal requirements that might influence the HSF design of products. After considering HS requirements, design results or plans (i.e. output) should include sufficient information for third-parties to verify that a design has fulfilled HSF requirements, and provide information on the procurement of raw materials as well as production processes and usage. All design output should be recorded and documented.

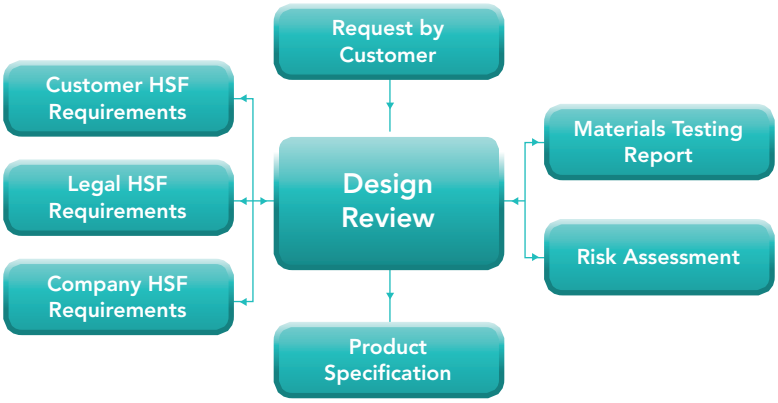

Figure 2.4 Summary graph showing HSF design and development

3.3 Purchasing of HSF Products

An organization's outsourcing activity can affect the HS characteristic of its products. Thus, it is important that an organization employs a risk-based strategy to select suppliers. For example, suppliers could be classified into three types:

1. Type A - incoming materials have a **critical** impact on the HS content of products

2. Type B - incoming materials have an **important** impact on the HS content of products

3. Type C - incoming materials have a **minor** impact on the HS content of products

With this in mind, an organization should prefer Type A suppliers when purchasing raw materials. The above classification is based on the potential risk factors inherent in incoming materials. Alternatively, an organization could classify suppliers according to their quality and environmental performance:

1. Type A - Preferred suppliers with a good track record in material quality

2. Type B - Normal suppliers with a reasonable track record in material quality

3. Type C - Non-qualified suppliers with a poor track record in material quality

This classification system can be achieved by regular evaluation of suppliers via questionnaires and spot-checks.

The selection of suppliers is only the first step an organization takes to verify the safety and quality of incoming materials. IECQ QC 080000 does not require organizations to purchase their own testing equipment, but it does require organizations to institute a management procedure for any incoming high-risk materials. If resources are adequate, organizations could consider purchasing their own testing equipment to confirm claims made by suppliers.

3.4 Production and Service Provision

To adequately manage HS, an organization must plan overall production, installation and service processes and also provide an orderly working environment. Some organizations might manufacture HSF products and non-HSF products at the same time. These organizations may need to pay special attention to production stages and service provisions. To fulfill safety requirements, these organizations need to provide adequate information regarding production, installation, and service processes that will help avoid contamination and cross-contamination between HSF and non-HSF products. All processes that could lead to contamination must be identified and monitored to ensure that HSF objectives are met.

Identification and traceability using labelling and zoning are ways to avoid cross-contamination. Proper storage and preservation of products might also be required if the HS characteristics of any products are liable to change over time, due to humidity or salinity, for example.

3.5 Control of Monitoring and Measuring Devices for HSF Characteristics

An organization should determine whether any measuring equipment is needed for the internal control of HSF products. If such equipment is purchased by an organization, regular equipment calibration and maintenance should be carried out to ensure continued accuracy and precision.

4. Measurement, Analysis and Improvement

According to the IECQ QC 080000 standard, regular measurement, analysis and enhancement are important ways to gauge the effectiveness of the HSPM and to monitor the system's compliance status. Periodic reviews of customer satisfaction, internal audits, production processes and product quality are required.

These requirements are very similar to those in ISO 9001. Internal auditing is especially important to make sure that all IECQ QC 080000 elements are correctly in place and consistently applied across an organization as shown in the below figures.

Preparation work for an internal audit:

Figure 2.5 Preparation for an internal audit

The typical procedure for an internal audit:

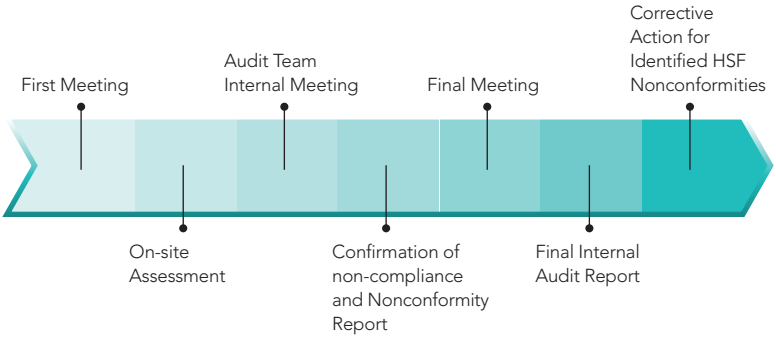

Figure 2.6 Typical process for an internal audit

4.1 Control of HSF Nonconforming Products

The IECQ QC 080000 standard also sets out how an organization must respond when non-conforming products are detected in different phases. For example, an organization should develop procedures to identify non-conforming products and prevent their exportation or approval. An organization should also establish procedures for the handling of non-conforming products after export. An organization's record of non-conformance can provide a basis for future analysis and the continuous improvement of the HSPM system.

4.2 Analysis of HSF Data and Continuous Improvement

The IECQ QC 080000 standard requires organizations to collect and analyze HSF data to identify ways to improve performance. Data may also be used as evidence since it provides a record of an organization's efforts to manage HS. Similar to the ISO 9001 system, IECQ QC 080000 also requires that an organization strive for continuous improvement. The management reviews of ISO 9001 and IECQ QC 080000 can be held concurrently so that top management receives a thorough perspective on overall product quality.

In general, an organization should address actual and potential non-conformities by taking corrective and preventive actions in the following areas:

- Reviewing non-conformities or potential non-conformities
- Determining causes of non-conformities or potential non-conformities
- Evaluating the need for action to ensure that non-conformities do not occur or recur
- Determining and implementing appropriate action as needed
- Maintaining records of corrective actions and preventive actions
- Reviewing the effectiveness of any corrective or preventive action taken
- Reporting the progress of HSF corrective actions during management reviews

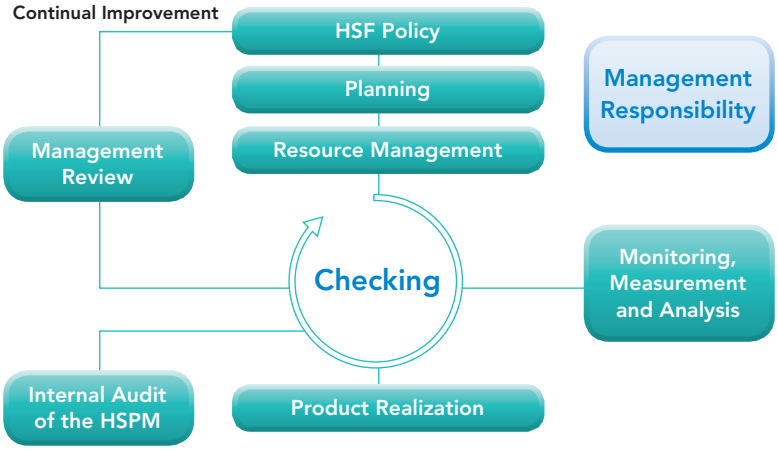

Figure 2.7 Overview of the HSPM System's Structure

CHAPTER 3 INDUSTRY EXPERIENCE SHARING

This chapter collates the practical experiences from a number of selected companies in developing and implementing IECQ QC 080000 HSPM, from which their success factors, challenges and lessons learnt are illustrated to provide insights to those who plan to adopt IECQ QC 080000 HSPM in their energy management strategy.

Five cases are presented following the alphabetical order:

- **Fook Tin Technologies Limited**
- **Leo Paper Group**
- **Print-Rite Holdings Limited**
- **Techtronic Industries Company Limited**
- **Tusen Lee Group (Holdings) Co. Ltd.**

FOOK TIN TECHNOLOGIES LIMITED

Overview of the Company

Fook Tin Technologies Limited ("Fook Tin") was established in 1963. The company specializes in the design, manufacturing, marketing and distribution of electronic products including consumer scales, medical devices and commercial weighing instruments. To ensure the product quality and protect the environment, Fook Tin has been certified in the ISO 9001 Quality Management System and the ISO 14001 Environmental Management System.

Managing hazardous substances in its products is one of Fook Tin's top priorities. In 2006, Fook Tin was the first company in the world to be certified under the IECQ QC 080000 Hazardous Substances Process Management (HSPM) standard.

Pioneer Experience

Setting HS Management Objectives and Engagement

Planning is always the first step for all management systems, and Fook Tin recognized the importance of setting up Hazardous Substances Management Objectives. Starting in 2005, the company's senior management conducted thorough research on the Restriction of Hazardous Substances (RoHS) directive. Since RoHS compliance requires cooperation from suppliers, Fook Tin trained about 100 suppliers in RoHS requirements.

Supplier Monitoring

Fook Tin has used the Material Safety Data Sheet (MSDS) provided by suppliers to identify incoming materials that have a higher risk of containing restricted substances. The company will pay special attention to these materials and conduct internal tests to confirm their compliance. It also requires suppliers to provide RoHS test reports of incoming materials every six months.

Integrating Management Systems

Fook Tin did not appoint external consultants to implement IECQ QC 080000 HSPM. Instead, it used its rich experience in ISO 14001 and ISO 9001 compliance, incorporating hazardous substances management principles into existing system manuals. This enabled the company to achieve its certification efficiently.

Internal Audit

Fook Tin ensured that all proper practices are in place and all staff are following the right procedures by conducting an internal audit every three months. This has identified potential nonconformities for Fook Tin, and has given the company confidence that it can pass an external audit at any time.

The Benefits

Fook Tin has used its IECQ QC 080000 HSPM certification to meet buyers' requirements, saving around HKD 300,000 in annual testing costs. This proves the level of confidence that customers have in Fook Tin's hazardous substances management process.

By fulfilling the requirements of IECQ QC 080000 HSPM, Fook Tin has also improved and reviewed its product design process, using fewer materials to produce the same product. Improved design has saved 5-15% of production costs per product.

Recommendations to SMEs

Fook Tin recommends that all SMEs establish and implement IECQ QC 080000 HSPM, especially those who already have ISO 14001 and ISO 9001 certificates in place. The company's experience shows that external consultants are not always required if a management system is already in place. For SMEs with more resources, Fook Tin also recommends investing in testing equipment such as an X-ray fluorescence (XRF) analyzer. This will enable them to test the conformity of incoming materials as necessary.

LEO PAPER GROUP

Overview of the Company

Established in 1982, Leo Paper Group ("the Group") is a global printing communications company that prints books, games, bags, gifts and packaging for its business clients. The Group has its three factories in Guangdong, Heshan and Shanghai, and also maintains 10 global distribution locations. It employs over 15,000 staff members worldwide.

Environmental responsibility is an important goal for the Group, which makes every effort to be a responsible manufacturer. It has certified its main factory, Heshan Astros Printing Ltd, for management standards including IECQ QC 080000, ISO 14001 and ISO 17025.

As part of its continued effort to reduce use of hazardous substances and lower its environmental and health risks, the Group also established its hazardous substances process management (HSPM) system in 2010. Created under IECQ QC 080000, HSPM helps to keep the Group's production processes and products free of restricted substances and other contaminants. In 2012, the Group upgraded the system by adding customers' specific requirements, along with legal regulations for selected countries.

Pioneer Experience

To help implement the HSPM, the Group set up its Product Safety Committee and Product Safety Policy. The Committee consists of senior managers from departments including sales, quality control, procurement and the Group's in-house laboratory.

The Group also supports the HSPM with several control points at different stages of the production lifecycle:

Collect Product Requirements and Safety Information

To ensure product compliance and customer satisfaction, the Group collects essential product information, including the product users' age, import countries' regulations, and standard requirements. The Product Safety Team can then propose a safer product design if necessary, or make other recommendations based on legal requirements and customer needs.

Material Development and Testing

During the material research and development stage, all materials to be used must undergo a comprehensive chemical risk assessment to prevent potential hazards.

Procurement

To minimize potential risk, the Group conducts safety and conformity assessments during the quotation stage. Suppliers must submit a Material Safety Data Sheet (MSDS) for the product, along with testing reports. The supplier must also submit a safety declaration for the product. When the products arrive, the Group samples products at random for compliance with safety requirements.

In-house Production Control

The Group sets clear procedures on stocking and labelling within its factories to prevent misuse of hazardous substances. Pollution prevention procedures and material tracking systems also prevent cross contamination.

Continual Improvement

The Group regularly assesses its system, and records the assessment reports to ensure the compliance of its manufacturing process with safety and environmental requirements. It also regularly trains all of its employees and its suppliers in existing and new product safety requirements in major import countries such as EU and the U.S. Training sessions also update trainees on upgraded versions of the HSPM.

The Benefits

By implementing the IECQ QC 080000 HSPM procedures, the Group is able to lower the risk of incidents and product recall. Records show that no product safety incidents happened since implementation of IECQ QC 080000 HSPM. The management system has also increased the Group's competitiveness by lowering testing costs, which has boosted customer satisfaction and loyalty.

PRINT-RITE HOLDINGS LIMITED

Overview of the Company

Print-Rite Holdings Limited ("Print-rite") owns a group of subsidiaries specialising in the printer consumable supply and services industry. Among these companies, six of them manufacture more than 4,000 products, including ribbons, inks, inkjet printer cartridges, laser printer cartridges, toners, rollers, and chips.

Print-rite focuses on technological innovation. Its subsidiaries own 2,200 patents worldwide, made possible via their substantial investment in R&D. All of these achievements help Print-rite to assume the leading role in its industry.

A collection of sustainability policies underpins Print-rite's commitment to corporate social responsibility. All of its products are manufactured in modern, well-equipped plants certified with ISO 9001, ISO 14001 and IECQ QC 080000 standards.

Pioneer Experience

Integration with ISO 9001 Quality Management System

Print-rite first implemented the IECQ's HSPM standard in 2007. The company worked hard to develop the internal expertise necessary to implement the standard, forming a team focused on HSPM that secured IECQ QC 080000 certification in 2008. It also drew on its existing knowledge of ISO 9001 to successfully integrate hazardous substances management into its ISO 9001 manuals.

Use of IT to facilitate hazardous substance identification

Hazardous substances control regulations have tightened worldwide, and the list of hazardous substances is expanded frequently. Compliance with IECQ QC 080000 requires a company to maintain a hazardous substances list. This list must be regularly updated to remain compliant with the latest regulations.

Print-rite integrates an IT tool with its existing Enterprise Resource Planning (ERP) system to identify high-risk materials during the manufacturing process. This tool significantly improves the efficiency of Print-rite to control the risk level and quality of a wide range of products.

Design for the Environment

Product design often entails the use of certain hazardous substances, but Print-rite regularly reviews and refines its design and manufacturing processes, identifying opportunities to reduce their use. The company also frequently contacts suppliers to identify new, safer materials to use.

The Benefits

IECQ QC 080000 HSPM certification has enabled Print-rite to build an awareness of its hazardous substances status directly into its management processes. This process extends outside the company and all the way through its supply chain, because Print-rite requires its suppliers to control the levels of hazardous substances in their products according to international regulations such as RoHS, WEEE and REACH.

Suppliers must provide evidence of their compliance with Print-rite's product quality requirements or be disqualified. Holding them accountable in this way lowers the risk of violating regulatory requirements.

Recommendations to SMEs

Print-rite recommends that SMEs developing a HSPM system to collect all the relevant legal requirements on hazardous substances and establish a hazardous substance list in the early stage of development.

Print-rite also recommends that SMEs seek advice from external consultants when they do not have past experience in establishing management systems such as ISO 9001 or ISO 14001. Lastly, the company encourages SMEs to choose and work with suppliers that share the same value of promoting product quality and controlling hazardous substances.

TECHTRONIC INDUSTRIES COMPANY LIMITED

Overview of the Company

Founded in 1985, Techtronic Industries Company Limited ("TTI") is a manufacturing and trading company specialising in power tools, outdoor gardening tools, floor care appliances. It serves consumer and professional users in the home improvement, hardware, repair, and construction industries. Sales market based primarily in North America and Europe, the company employs a workforce of over 20,000 staff members worldwide, including those at its production facility in mainland China.

TTI is committed to sustainable leadership and promoting environmental protection. As such, the company has obtained the following certifications and accreditations:

- ISO 14001 Environmental Management System
- ISO 9001 Quality Management System
- IECQ QC 080000 Hazardous Substances Management System (HSPM)
- ISO 14064 Greenhouse Gases Quantification at Organization Level

Pioneer Experience

Clear HSF Policy and Top Management Commitment

TTI follows IECQ QC 080000 requirements, identifies and controls all hazardous substances (HS) that might make their way into its products and production process. These substances include prohibited substances listed in various European regulations and directives (RoHS 2011/65/EU, WEEE 2012/19/EU, REACH 1907/2006/EC, PAHs ZEK 01.4-08) and US ones (California's CP65).

The top management of TTI is also well aware of the importance of hazardous substances management. As such, the company appointed its QSA & EHS director to oversee process control, training and supplier management.

Staff Engagement to Enhance HSF Awareness

TTI trains its staff in HS management. This training process is extensive, covering departments including incoming quality control, R&D, purchasing, production, warehousing and marketing. It backs up this training with a combination of employee awareness materials, including quality manuals and standard operation instructions. The company also reminds staff about the importance of HS management using posters and notices.

In 2014, TTI demonstrated its commitment to ensuring that the HS objectives are closely followed by setting 100% targets on incoming and outgoing quality controls. It also set a 100% acceptance rate for HSF process checks.

Supplier Management with Advanced Technology

TTI also manages the HS content of the finished goods or materials from suppliers that it uses in its manufacturing processes. During research and development, it requests a HSF Declaration of Conformity document and a HS Test Report from material suppliers. These help to ensure that the materials provided comply with the HSF requirements.

To complement this documentary proof, TTI also has an in-house chemical analysis laboratory for testing the HS content of materials. The lab uses sophisticated technical equipment to accurately determine the HS content of materials concerned. This includes X-ray Fluorescence (XRF) Spectrometers, Gas Chromatography–Mass Spectrometry (GC/MS), and Inductively Coupled Plasma (ICP) Spectrometry.

Building on Excellence

Instead of using external consultants in establishing IECQ QC 080000 HSPM, TTI relied on its own rich heritage in ISO 14001 and ISO 9001 compliance. The company integrates the HSPM framework with its existing environmental and quality management framework, saving time and resources in developing the required management guideline and manuals.

To achieve IECQ QC 080000 certification, companies must be audited by an accredited third party certification body. The certification cost will depend on the company's size and the complexity of its business. In 2013, TTI paid approximately RMB 35,000 to renew its IECQ QC 080000 certification. The certification has enhanced the company's product quality and reduced redundant testing processes for clients.

TSUEN LEE GROUP (HOLDINGS) CO. LTD.

Overview of the Company

Tsuen Lee Group (Holdings) Co. Ltd. ("Tsuen Lee") was established in 1982 in Hong Kong. Tsuen Lee has become one of the global leading manufacturers in the toy and household products industry with more than 15,000 employees worldwide. Its main factories are located at Jiangxi, Shenzhen, He Yuen and Zhongshan. Spanning a total area of 550,000 square meters, these plants are equipped with modernized, environmentally-friendly and energy-efficient production equipment and facilities.

Tsuen Lee is committed to product quality and environmental protection, and the company strives to ensure that its products are manufactured in a responsible manner. Since 1994, it has received environmental management certifications including:

- ISO 9001 Quality Management System (1994)
- OHSAS 18001 Occupational Health and Safety Management System (1999)
- ISO 14001 Environmental Management System (2001)
- IECQ QC 080000 Hazardous Substances Process Management (HSPM) (2007)

All of these efforts have cemented Tsuen Lee's position as a leader in sustainable product development and customer well-being.

Pioneer Experience

Effective Internal Control

Internal control is a fundamental component of IEQC QC 080000 HSPM. To meet the standard, companies must create procedures to ensure that products meet product quality and hazardous substances requirements.

To respond to these needs, Tsuen Lee built an in-house chemical testing laboratory. All high-risk raw materials purchased must pass the relevant tests before going into the manufacturing process. This internal control is critical to detect hazardous substances among raw materials that are supposed to be RoHS compliant.

Commitment from the Top

Compliance is a core component of Tsuen Lee's business philosophy. Its management team has created a dedicated department to oversee all compliance-related matters, including hazardous substances management. Senior management places such importance on environmental quality that the company's director of compliance reports directly to the executive director on product compliance matters.

The Benefits

Tsuen Lee's efforts in implementing IECQ QC 080000 HSPM has increased customer satisfaction on product quality and significantly reduced product recalls. The company strongly believes that the substantial investment made in chemical testing equipment and facilities is worthwhile, because these internal control measures have reduced the potential financial loss associated with product recalls and customer complaints. More importantly, Tsuen Lee has earned its customers' trust, and demonstrated leadership in corporate social responsibility in its industry.

Recommendations to SMEs

Tsuen Lee recommends that SMEs attach higher importance to hazardous substances management. They should regard the investment in setting up management systems as part of an ongoing sustainability management strategy that will deliver long-term value.

Tsuen Lee also emphasizes the importance of senior management commitment and responsibility towards hazardous substances management. SMEs should continue to acquire new knowledge on compliance, and keep updated about the latest market trends in order to enhance their competitiveness in this evolving economy.

CHAPTER 4 CERTIFICATION PROCESS AND AUDITING REQUIREMENTS

By acquiring the IECQ QC 080000 Certification, an Organisation demonstrates to customers that their products, services, processes and related materials conform to internationally-recognised standards and specifications with regard to hazardous substances control.

IECQ Certification Bodies (IECQ CB) are independent groups endorsed by both the IECQ Conformity Assessment Bodies Committee and the IECQ Management Committee. IECQ CB have full authority to conduct IECQ QC 080000 certification assessments, evaluations and surveillance activities. They then issue IECQ QC 080000 Certificates to those applicants who comply with the IECQ QC 080000 HSPM requirements and supporting IECQ Operational Documents.

It should be noted that IECQ CB can develop their own certification process in line with IECQ guidelines. Any organisation seeking IECQ certification (the Organization) should refer to the agreement with the relevant Certification Body for details of the certification process.

This chapter illustrates a typical IECQ QC 080000 HSPM certification process in accordance with the requirements of the IECQ HSPM Scheme, which includes Hazardous Substances Process Management Requirements (IECQ 03-5), Basic Rules for IECQ system management (IECQ 01) and General Requirements for all IECQ Schemes (IECQ 03-01).

1 IECQ QC 080000 Certification Process

The typical certification process is illustrated in the following diagram:

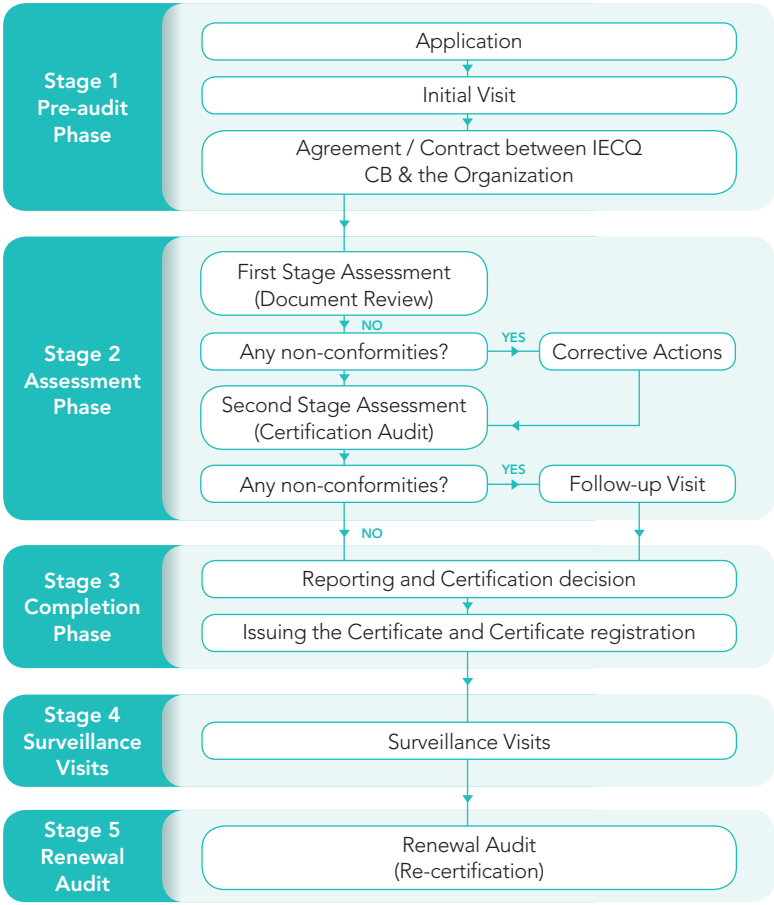

Figure 4.1 Typical certification and audit process

Stage 1 – Pre-audit Phase

1.1 Application

The Organisation can contact any approved IECQ CB for IECQ QC 080000 certification. The IECQ CB will normally begin with a preliminary questionnaire to the applicant to collect relevant information. This questionnaire helps the IECQ CB to understand the background and profile of the Organization, and more importantly, to determine whether the Organization can meet the basic audit requirements. IECQ CB can then identify the audit scope of activity relevant to the required certification and the amount of time needed for the certification process.

1.2 Initial Visit

Some IECQ CB may conduct an initial visit to evaluate the current situation and readiness of the Organization for certification. The initial visit allows the IECQ CB to better understand the Organization's processes, activities and procedures involving hazardous substances.

1.3 Agreement/Contract between IECQ CB & the Organisation

IECQ CB will submit to the Organization a quotation specifying the audit plan (i.e. audit scope, procedures, details of assessment team, time allocation, etc.) and associated fee for the certification process.

The assessment team members are determined by IECQ CB. It normally consist of the following personnel who evaluate general IECQ HSPM elements and manage the whole certification process, electrical and electronic component experts (if necessary), and specialists who can provide specific knowledge and understanding of the Organisation's industry and product lines.

Stage 2 – Assessment Phase

2.1 First Stage Assessment (Document Review)

The First Stage Assessment aims to verify the level of compliance with the applicable requirements of IECQ QC 080000 and then identify any non-conformities. IECQ CB normally examine documentation and processes on-site in accordance with the assessment plan. Minor non-conformities may be resolved during the on-site assessment. For major non-conformities, the Organisation must rectify these anomalies, as agreed and accepted by IECQ CB, prior to scheduling the Second Stage Assessment (Certification Audit). IECQ CB will subsequently verify the effectiveness of the corrective actions taken, document all evidence of compliance in an IECQ Compliance Report Form (CRF) and complete both the CRF and IECQ Site Assessment Report (SAR) (see Note 1) before commencing the Second Stage Assessment.

The Organisation and the IECQ CB should reach a common understanding on the scope and schedule of the Certification Audit upon satisfactory review of all documentation.

Typical documents (non-exhaustive) required for review in any First Stage Assessment:

- Master list of hazardous substances
- Documents required for HSPM
- List(s) of all activities to be certified
- List(s) of the locations where activities occur
- Quality Control Manual
- Management Review Records

- Internal Audit Records
- Record of all corrective and preventive action(s) taken subsequent results
- Certificate(s) and Audit Reports of ISO 9001 QMS or equivalent QMS (see Note 2)
- Registration Report for ISO/IEC 17025 accreditation (if required)

2.2 Second Stage Assessment (Certification Audit)

A Certification Audit will only be conducted upon the satisfactory completion of the First Stage Assessment. The Second Stage focuses mainly on assessing the effectiveness of the implemented HSPM procedures and processes as related to the requirements of IECQ QC 080000, IECQ 03-1 and IECQ 03-5. Audit materials will be collected through meetings, interviews, observations, data and record reviews, and sample collecting and testing. As with the First Stage Assessment, the IECQ CB is required to document all evidence of compliance with the IECQ CRF and IECQ SAR.

2.3 Follow-up Visit

The IECQ CB may identify non-conformities during the Certification Audit. They will then require Organisation to develop and implement corrective action(s) to fulfil the IECQ QC 080000 mandate. Follow-up visit(s) may be arranged to ensure that major non-conformities have been properly resolved.

Stage 3 – Completion Phase (Granting of Certification)

3.1 Reporting and Certification Decision

After First and Second Stage Assessments are completed, the IECQ CB will review all relevant audit information and any related documents submitted by the Organisation for a certification decision. If the review is satisfactory, IECQ CB will issue the finalized IECQ CRF and IECQ SAR to the Organization, usually not later than one month after the Certification Audit. IECQ CB will recommend the Organization to receive certification if the intended scope of activity meets with IECQ QC 080000 stated requirements, and non-conformities identified in the assessment phase are resolved.

3.2 Issuing the Certificate and Certificate Registration

The IECQ CB will issue a printed and signed copy of the Certificate of Conformity upon request. Meanwhile, the IECQ CB will register the Certificate with the IECQ on-line Certification System, which is located on the IECQ website (http://www.iecq.org).

Stage 4 – Surveillance Visits

IECQ CB are obligated to conduct periodic surveillance visits after certification. Subject to the decision of IECQ CB, the surveillance visits may be carried out at least once annually. The objective of surveillance is to ensure that the HSPM department of the Organization continues to comply with all certification requirements. IECQ CB are responsible for carrying out on-site assessments at all certified locations to verify continued compliance and to maintain certification. Special surveillance visit(s) will also be arranged in the event of the following changes and/or special conditions:

- Relocation of the Organization
- Changes to the management team and/or management system procedures because of the Organization's acquisition activities
- Alteration of Designated Management Representative (DMR)
- Valid concerns by the IECQ CB about the Organization's compliance with relevant IECQ HSPM requirements.

Stage 5 – Renewal Audit (Re-certification)

The IECQ QC 080000 Certificate must be renewed every three years. Renewal of the Certificate can proceed only if all scheduled surveillance visits and a re-certification audit are successfully completed before the certificate expiry date. An on-site renewal audit should be conducted at each of the Organization's certified locations. The renewal audit focuses on evaluating the Organization's continued compliance with IECQ QC 080000 as well as the organization's effectiveness in implementing HSPM procedures and related processes and the HSPM protocol's continued relevance to the certified scope of work.

2 Certification Requirements

2.1 Applicant Requirements

The majority of applicants are manufacturers, suppliers, designers, repairers and menders who work with hazardous substances and thus required effective HS identification and control systems. In general, an applicant should be able to fulfill the following requirements:

- Appoint a Designated Management Representative (DMR) in the Organization who oversees all issues related to IECQ QC 080000 requirements.

- Ensure that both the QMS and the IECQ HSPM, once established in certified locations, do not change significantly during the certification process, unless the IECQ CB has confirmed in writing that such changes will not affect the Certificate's validity. As stated in the IECQ 03-5:

  "It is expected that changes may be made as a result of continuous improvement practices. However, when such changes result in significant changes to the IECQ HSPM Scheme and its related processes, the IECQ CB shall be notified."

- Comply with IECQ QC 080000 requirements throughout the entire certification validity period.

- Maintain all QMS records as stated in the IECQ QC 080000 HSPM requirements and provide copies of these documents when requested by the IECQ CB.

- Support the audit process. In order to facilitate the inspection of any systems, processes, testing methods and records, the Organization should provide complete site access to assessment and audit teams during normal working hours. The Organization should also facilitate visits and meetings between the IECQ CB and any suppliers who might affect the scope for certification.

- Cease using the IECQ logo on all products, services or materials immediately after the termination or suspension of the IECQ QC 080000 Certificate. The Organization should not assert or imply any statement of IECQ approval and certification in the case of a termination or suspension.

- Renew certificate every three years. The Organization should notify IECQ CB in writing at least 60 days before the renewal date if they intend not to renew the certificate.

2.2 Time Allocation for the Certification Process

The total number of man-days required for certification normally depends on the nature and size of the Organization. The IECQ CB will determine the total man-days required (for two assessments, surveillance visits and a renewal audit) in accordance with the different factors (such as) types of activities to be covered by certification and complexity of the process(es) to be certified.

For Organizations with less than 150 employees, the IECQ CB may conduct document reviews on-site before any certification audit if the organisation agrees with the audit plan prior to the on-site visit.

An integrated IECQ HSPM and ISO 9001 (see Note 2) audit can be performed for Organizations that have established a single management system which is compatible with both standards. If an Organization has not received ISO 9001 certification before, the IECQ CB may perform an integrated IECQ HSPM and ISO 9001 audit concurrently. The possibility exists for a reduction in the total number of man-days required for an integrated audit. Please contact the IECQ CB for further information.

Notes:

Note 1: Different IECQ CB may develop their own reporting systems, which incorporate as a minimum the requirements stated in the IECQ HSPM Compliance Report Form (CRF) and IECQ Site Assessment Report (SAR).

Note 2: Acceptable equivalent QMS includes ISO/TS 16949, AS 9100, International Railway Industry Standard, and TL9000.

REFERENCE

1. Waste Policy and Legislation, European Commission
http://ec.europa.eu/environment/waste/target_review.htm

2. REACH, European Chemicals Agency
http://echa.europa.eu/regulations/reach

3. ISO9001:2008 Quality Management Systems, International Organization for Standardization
http://www.iso.org/iso/iso_9000

4. Consumer Product Safety Commission, the United States
http://www.cpsc.gov/en/

5. IECQ QC 080000: 2012 IECQ Electrical and Electronic Components and Products - Hazardous Substance Process Management System Requirements, International Electrochemical commission Quality Assessment System for Electronic Components, 2014

6. IECQ 03-1 General Requirements for all IECQ Schemes, International Electrochemical Commission Quality Assessment System for Electronic Components, 2012

7. IECQ 03-5 IECQ HSPM Scheme - Hazardous Substance Process Management Requirements, International Electrochemical Commission Quality Assessment System for Electronic Components, 2014

ANNEX A SELF-EVALUATION CHECKLIST

Section 1 to Section 3 of IECQ QC 080000:2012 introduces general description and important definitions of IECQ HSPM. In sections 4 to 8, a list of requirements can be found for evaluating the conformity level of an organization's HSPM system against IECQ QC 080000 standards.

The following Self-Evaluation Checklist (the Checklist) is designed to help SMEs to develop their own HSPM system and is based on IECQ QC 080000 HSPM System Requirements (2012 version, edition 3.0). This Checklist can be used to identify discrepancies between a company's current management practices and the requirements of IECQ QC 080000 HSPM.

The Checklist is for reference only. For certification purposes, organizations should refer to the latest IECQ QC 080000 HSPM standard requirements or seek advice from IECQ Certification Bodies.

General Requirements and Documentation Requirements (refers to section 4.1 – 4.2)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Has the organization implemented and documented ISO 9001 or equivalent (e.g. ISO/TS 16949, AS 9100, IRIS or TL 9000) quality management systems?			
2. Does the quality management systems documentation include: • HSF policy statements and objectives • HSF management plan and procedures in its quality manual • Performance records of the organization's HSF process management • HSF records supporting the legal or customer requirements • A list of all hazardous substances in products			
3. Is the organization able to control all outsourced, HSF-related processes?			

Management Commitment (refers to section 5.1)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Does a management representative define, document and review the HSF policies and objectives?			
2. Does management provides resources essential for HSF process management?			
3. Does the organization communicate to its employees all legal and customer HSF requirements?			

HSF Policy (refers to section 5.3)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Does the policy include commitments to: • Continuously improve HSF process management • Comply with applicable legislation and other requirements			
2. Does HSF policy provide a framework for setting HSF objectives and targets?			
3. Is everyone who works for or on behalf of the organization fully aware of the company's HSF policy?			
4. Has the HSF policy been reviewed and updated regularly?			

HSF Objectives and Planning (refers to section 5.4)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have documented HSF objectives been established for relevant functions and levels within the organization?			
2. Are HSF objectives specific, measurable, realistic and understandable?			
3. Are HSF objectives consistent with company HSF policy?			
4. Do HSF objectives include an appropriate schedule to eliminate completely any use of hazardous substances in production processes or products?			
5. Are HSF objectives and practices included in the planning of quality management systems?			
6. Does the organization regularly document and update its HSF action plans?			

Responsibility, Authority, Internal Communication and Review (refers to section 5.5 – 5.6)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have roles, responsibilities and authority for HSF process management been defined, documented and communicated?			
2. Has a management representative been designated to ensure • Compliance with all HSF-related requirements • Communication to top management of HSF plans and performance • Distribution of HSF news and issues throughout the whole organization • Awareness of all HSF-related requirements and responsibilities amongst suppliers			
3. Does the organization communicate its HSF polices and action plans to all personnel?			
4. Does the organization maintain and distribute a list of hazardous substances to the whole organization, (if necessary)?			
5. Do regular management reviews related to HSF process management exist?			

Responsibility, Authority, Internal Communication and Review (refers to section 5.5 – 5.6)			
Requirements	Readiness		
	Yes/No	N/A	Notes
6. Does each management review include decisions or evaluations related to: • The continuing suitability, adequacy and effectiveness of HSF policy and targets • Any non-compliance issues due to updated legal or customer requirements, use of hazardous substances or other HSF nonconformities • Corrective actions undertaken due to HSF nonconformities and their current status • HSPM audit reports • Customers' comments and feedback • Recommendations for overall improvement • Allocation and adequacy of resources for HSF processes and products			

Human Resources (refers to section 6.1 – 6.2)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have all personnel responsible for fulfilling HSF requirements have relevant experience and received the appropriate education, training?			
2. Has the required training associated with the identification, usage and elimination of hazardous substances been identified and communicated?			
3. Has the organization established procedures to insure that all personnel are aware of: • Their roles and responsibilities in fulfilling HSF requirements • The importance of conforming to HSF process management and requirements • How their activities contribute to achieve HSF objectives and targets			
4. Are training records, certificates and licenses maintained to demonstrate competence and aptitude?			

Infrastructure and Working Environment (refers to section 6.3 – 6.4)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Does the organization's infrastructure include (if applicable): • Adequate buildings and workspace • Process equipment • Hardware and software for testing equipment • Data computing systems • Communication or information systems Which elements are needed to conform to HSF process and product requirements?			
2. Has infrastructure been maintained and refurbished regularly?			
3. Does the organization provide a suitable working environment for manufacturing HSF products?			

Planning of HSF Process and Product Realization (refers to section 7.1)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have procedures been established and implemented to meet HSF objectives and product requirements?			
2. Did the organization develop and implement testing and monitoring procedures to assure the quality of its products?			
3. Has the organization considered the actual and potential implications of all processes related to the HSF characteristic of its products? Has the organization taken preventive action as needed?			
4. Are records available to track the conformity and suitability of the organization's HSF product realization processes?			
5. Are procedures in place to monitor any changes to HSF processes and to evaluate any impact the changes may have on fulfilling HSF process and product requirements?			

Determination, Review and Communication of HSF Requirements (refers to section 7.2)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Has a framework been established to identify, define and access all applicable legal HSF requirements as well as HSF requirements applicable to the organization and its customers?			
2. Has the organization determined how the applicable requirements affect its processes and products?			
3. Has the organization reviewed HSF requirements as they relate to complying with legal requirements and other industry and government obligations?			
4. Does the organization conduct HSF reviews and implement follow-up actions on a regular basis?			
5. Has the organization developed and implemented a communication platform to convey to customers the following: • Processes or products that contain hazardous substances • General information requested by their customers • Changes to products that might affect the HSF characteristics of said products and materials			

HSF Design and Development (refers to section 7.3)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Are documents, which identify hazardous substances that might occur in HSF products, classified and organized during the planning stage?			
2. Does the organization document and review all details of HSF product design and development as relates to the HSF legal and customer requirements for HSF products?			
3. Does the organization have a policy in place to collate the work of its HSF design and development teams and to communicate their output externally?			
4. Have procedures related to systemic reviews, verification and validation been established and implemented for use during product design and development stages, so that companies can ascertain the compliance levels of HSF characteristic in its product and process?			
5. Does the organization seek feedback and approval from customers regarding the HSF results of its product design and development?			
6. Has the organization established and implemented a process to identify, document, review, verify and validate any changes to its design and development methods?			

Purchasing of HSF Products (refers to section 7.4)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have criteria for assessing the conformity of a organization's purchased products to HSF requirements been established and implemented?			
2. Have procedures been developed to record and monitor procurement activities related to HSF products?			
3. Have all HSF-related requirements been communicated to suppliers?			
4. In particular, have suppliers been informed of the organization's HSF requirements as they relate to selection and evaluation criteria?			
5. Does the organization evaluate and identify qualified suppliers based on their ability to supply products in accordance with HSF requirements?			
6. Has the organization established and implemented procedures to inspect the compliance levels of purchased products within the specific HSF framework?			

Production and Service Provision (refers to 7.5)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have HSF production and service provisions, and their relation to the conformity of HSF characteristic of products, been identified, planned and controlled with regard to the following: • The prevalence of HSF characteristics in products and relevant HSF work instructions regarding potential contamination from hazardous substances • The availability of appropriate HSF equipment and HSF monitoring and measuring devices • The validation of HSF purchased products for production • The operation of HSF monitoring, measurement, release, delivery and post-delivery process controls			
2. When products cannot be verified or tested for HSF requirements, is the organization able to validate the processes for production and service provisions?			
3. Does the organization identify the HSF status of its products and take action to prevent contamination of those HSF products by hazardous substances during the production process?			
4. Does the organization document and mark its HSF products with proper labels according to legal and customer requirements?			

Production and Service Provision (refers to 7.5)			
Requirements	Readiness		
	Yes/No	N/A	Notes
5. Are procedures in place to identify HSF non-conformity of customer property and to report those findings to customers?			
6. Have procedures been established and implemented to manage and document HSF products with regard to the following considerations: • Keeping HSF products separate from HSF non-conforming products • Maintaining the HSF characteristics of products • Using purchased products in HSF production • Handling HSF non-conforming products			

Monitoring and Measurement (refers to section 8.1 – 8.2)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Does the organization supply suitable monitoring and measuring devices to ensure their products comply with HSF requirements?			
2. Is all monitoring equipment properly maintained and calibrated?			
3. Has the organization developed and implemented controls to monitor procedures that have significant impact in the workplace: • Conformity to HSF legal and customer requirements • Conformity to hazardous substances process management systems • Effectiveness of action plans in achieving improvements • Feedback from stakeholders • Associations that could cause non-conformance, including dealings with suppliers/ subcontractors and information services providers			
4. Are records available to track performance and conformity to key characteristics?			

Internal Audit (refers to 8.2.2)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have internal audit procedures been developed and implemented?			
2. Has an internal audit schedule been developed?			
3. Are internal audits conducted to ensure that HSF process management: • Conforms to established legal and customer requirements • Is effectively implemented and maintained, and improves HSF performance?			
4. Are audit reports and records documented?			

Control of HSF Nonconforming Product (refers to 8.3)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have controls been developed and implemented to identify non-conforming products and prevent them from being exported or approved?			
2. Have procedures been established to handle non-conforming products after export?			
3. Does the organization track these non-conforming products and any corresponding corrective actions?			

Improvement of Hazardous Substance Process Management Systems (refers to section 8.4 – 8.5)			
Requirements	Readiness		
	Yes/No	N/A	Notes
1. Have procedures been established to evaluate the results from monitoring and measurement?			
2. Has the organization established and implemented action plans to improve their hazardous substances process management systems based on these results?			
3. Does the organization address actual and potential nonconformities by taking corrective action and prevention, such as: • Reviewing nonconformities or potential nonconformities • Determining the causes of nonconformities or potential nonconformities • Evaluating the need for action to ensure that nonconformities do not occur or recur • Determining and implementing the appropriate action needed • Maintaining records of corrective actions and preventative actions • Reviewing the effectiveness of the corrective action or preventative action taken • Reporting the progress of HSF corrective actions during management reviews			