A Symphony of Synergy: How Certification to the IECQ HSPM Specification Works in cConcert with the IPC Lead Free Certification Program

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The IPC's Lead Free program addresses one of the 6 Hazardous Substances regulated by the RoHS directive. Certification to the QC 080000, the IECQ HSPM Specification, addresses the other 5 Hazardous Substances called out by RoHS thus addressing all 6 of the restricted substances. The synergy of applying both systems allows a company to accomplish total due diligence.

Directive 2002/95/EC of the European Parliament and of the Council was published on 27 January 2003.

Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (commonly known and referred to as RoHS) went into effect July 1, 2006.

The RoHS directive was established by the European Union in order to reduce waste harmfulness, and restrict certain types of hazardous substances from being imported into the EU. The directive bans the following six substances, above the noted concentration levels, in electrical and electronic equipment:

Substance	Max Concentration
Lead – Pb	**0.1%**
Mercury – Hg	**0.1%**
Cadmium – Cd	**0.01%**
Hexavalent Chromium – Cr(VI)	**0.1%**
Polybrominated biphenyls – PBB	**0.1%**
Polybrominated diphenyl ethers - PBDE	**0.1%**

In May 2006, the European Union published a guidance document intended to assist companies as they attempt to comply with the EU RoHS directive. Key issues addressed within the Guidance include the establishment of a Compliance Assurance System (CAS) and establishment of the underlying principles that might be used to guide member states that make up the European Union in RoHS enforcement. Also addressed by the guidance document are the type of documentation that 'producers' (within the specific definition given in Article 3 of the Directive) might be advised to keep, the ways in which Member State enforcement authorities might use such documentation to check for RoHS compliance, the ways in which sample preparation, and analytical testing might be employed to avoid inconsistent enforcement decisions between Member States.

RoHS Guidance Document Summary

The guidance document has two primary intentions. First, it was established to assist Member States with national enforcement of the RoHS Directive. Second, it was established to provide clarity to industry on how producers may demonstrate compliance with its requirements.

Through the RoHS guidance document, two routes toward compliance are established that incorporate some combination of product testing and process management.

Specifically addressed by the Guidance Document is the requirement for the management of suppliers to a producer. It is not enough to simply accept Certificates of Compliance from suppliers to demonstrate that incoming materials are in compliance with the RoHS directive. A producer is required to manage the supplier through on site audits, and an overall system to ensure compliant materials are received.

What other Legislations are there?

Directive 2002/96/EC of the European Parliament and of the Council published a directive on 27 January 2003 Regarding Waste Electrical and Electronic Equipment. This directive is commonly referred to as WEEE.

In the state of California, Senate Bill (SB) 50 lists 700+ chemicals with adverse impacts, including lead, antimony trioxide, DEHP & cadmium. Products (with exemptions) with >300 ppm lead in outer contact surface layer must be labelled. Customer notification via letter except for consumer customers applies to all firms that sell or resell to CA retail consumers.

In the country of China Article 11 (the Chinese equivalent of RoHS) (draft) lists management and control of pollution by eliminating pollutants and requiring recycling of electronic information products. The Draft developed by Ministry of Information Industry expands scope of EU RoHS and says China is on track to have most stringent standards worldwide and likely will become de facto standard to design to Applies to ALL producers/importers of electronic products "Womb-to-tomb" scope. Packaging must be non-toxic, biodegradable and recyclable. Products must be labelled with names, content levels, and recyclability of harmful materials. Products not properly marked will not be allowed past customs.

Other US & Global HSF Legislation
Maine, California, and 10 US States have Pending Legislation and this number continues growing every day! International legislations in this arena include China, Japan, Australia, and Korea

How can a company demonstrate compliance?
International Electro technical Commission published a standard regarding Hazardous Substance Process Management – QC 080000.
Formally published as QC 080000 IECQ HSPM 2005
Electrical & Electronic Components and Products Hazardous Substance Process Management System Requirements, this document aids a company in establishing a process based compliance system, in line with the guidance established by the European Union.

What is QC 080000?
QC 080000 is an internationally agreed-upon IECQ technical specification for certification by 3rd-party assessors. An audit verifies that a company's processes to manage, minimize and/or eliminate hazardous substances meet the highest standards. This incorporates as applicable RoHS, WEEE, SB-50, green process, etc and the principles of a QMS. It was developed originally from the US standard EIA/ECCB 954.

What is QC 080000 IECQ HSPM?
The standard is based on the belief that achievement of HSF products & production processes cannot be realized without effective integration of management disciplines. A total solution must be process-based. In the same philosophy that once said "One can't "inspect in" quality", similar belief and principle applies and "One can't "test out" HSF."

How was QC 080000 Created?
With a number of regulations published and known, there was not a clear path for producers to use to demonstrate compliance with multiple standards and directives. At the time that QC 080000 was initially written, several pieces of legislation were published. In particular:
EU Directive - RoHS
EU Directive - WEEE
California SB50 – AB 2022(pending)
China Article 11 (~ RoHS)
China Article 12 (~WEEE)
Other regulations are imminent in Japan, Korea, Australia, and additional US states.

A team was formed to generate a process based standard that would allow a producer to leverage the management principles of an implemented quality management standardized system.

How does QC 080000 Work?
It is comprehensive in scope and includes management of all HS processes regardless of HSF requirements a company is trying to meet. It is designed to satisfy company HSF requirements and country HSF regulatory requirements to reduce or replace government compliance testing and numerous company-specific audits.

QC 080000 and ISO 9001
IECQ HPSM is an "add on" to the producers Quality Management System (QMS). ISO 9001 (or other quality management system standards such as AS 9100, TS 16949, TL 9000) provides a blueprint for optimization of business and quality management systems. IECQ HSPM was written to fit into that blueprint and strengthen adherence to the principles and practices prescribed by the International Organization of Standardization (ISO). It also directs their application to the management of hazardous substances.

What does QC 080000 look like?
The sections of the QC 080000 were intentionally set up to align with ISO 9001.
The specific sections of the standard are:
0 Introduction
1 Scope
2 Normative Reference
3 Terms and definitions
4 Quality Management System
5 Management Responsibility
6 Resource Management
7 Product Realization
8 Measurement Analysis and Improvement

To facilitate integration of HS process management with a company's QMS, these sections and their subsections use the same numbering as ISO 9001:2000

Steps to Certification
A company must first establish a quality management system that is either registered or assessed and found to be compliant. Quality management standards include ISO 9001, AS9100, TS16949, TL9000, etc.

A producer should obtain training that is specific to the management of Hazardous Substances in accordance with the QC 080000 standard. The system is then built, and demonstrated as compliant with a full round of internal audits of the system.

A producer can then apply to Certification Body for registration to IECQ QC 080000. The registration process will typically include a preliminary documentation review followed by an On-Site Registration Audit (typical duration of 1.5 – 7 days based on a company's size and management system).

Successful registration will result in the presentation of an internationally recognized certificate, and inclusion on the IECQ website of certified companies. Status of the system will be monitored through on-going Annual Surveillance.

National Standards Authority of Ireland

Your Global Registrar

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IPC + IECQ = Due Diligence

- The IPC's Lead Free program addresses **one** of the 6 Hazardous Substances regulated by the RoHS directive. Certification to the QC 080000, the IECQ HSPM Specification, addresses the ***other 5*** Hazardous Substances called out by **RoHS**.
- The synergy of applying both systems allows a company to accomplish total due diligence.

What is RoHS?

- **Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the**

- **R**estriction **of the use o**f **certain H**azardous **S**ubstances

  in electrical and electronic equipment

RoHS: Restriction of Hazardous Substances

- To reduce waste harmfulness, bans the following six substances, above the noted concentration levels, in electrical and electronic equipment

Substance	Max Concentration
Lead – Pb	**0.1%**
Mercury – Hg	**0.1%**
Cadmium – Cd	**0.01%**
Hexavalent Chromium – Cr(VI)	**0.1%**
Polybrominated biphenyls – PBB	**0.1%**
Polybrominated diphenyl ethers - PBDE	**0.1%**

by Weight in Homogenous Material

Key Date: Compliance by July 1, 2006

RoHS Enforcement

RoHS Enforcement

Guidance Document

Version 1 – issued May 2006

http://www.rohs.gov.uk/Docs/Links/RoHS%20Enforcement%20Guidance%20Document%20-%20v.1%20May%202006.pdf

This Guidance Document has been developed through discussions within the "EU RoHS Enforcement Authorities Informal Network".

It should be noted that the document is informative and advisory, but has no legal authority.

Individual Member State RoHS enforcement authorities are bound by their own national legal structures and can only apply this guidance within the confines of those structures.

Key issues addressed within the Guidance include:

- The underlying principles that might be used to guide RoHS enforcement
- The type of documentation that 'producers' (*within the specific definition given in Article 3 of the Directive1)* might be advised to keep
- The ways in which Member State enforcement authorities might use such documentation to check for RoHS compliance
- The ways in which sample preparation and analytical testing might be employed to avoid inconsistent enforcement decisions between Member States

RoHS Guidance Document Summary

This document has two primary intentions: -

• to assist Member States with national enforcement of the RoHS Directive;

And

• to provide clarity to industry on how producers may demonstrate compliance with its requirements.

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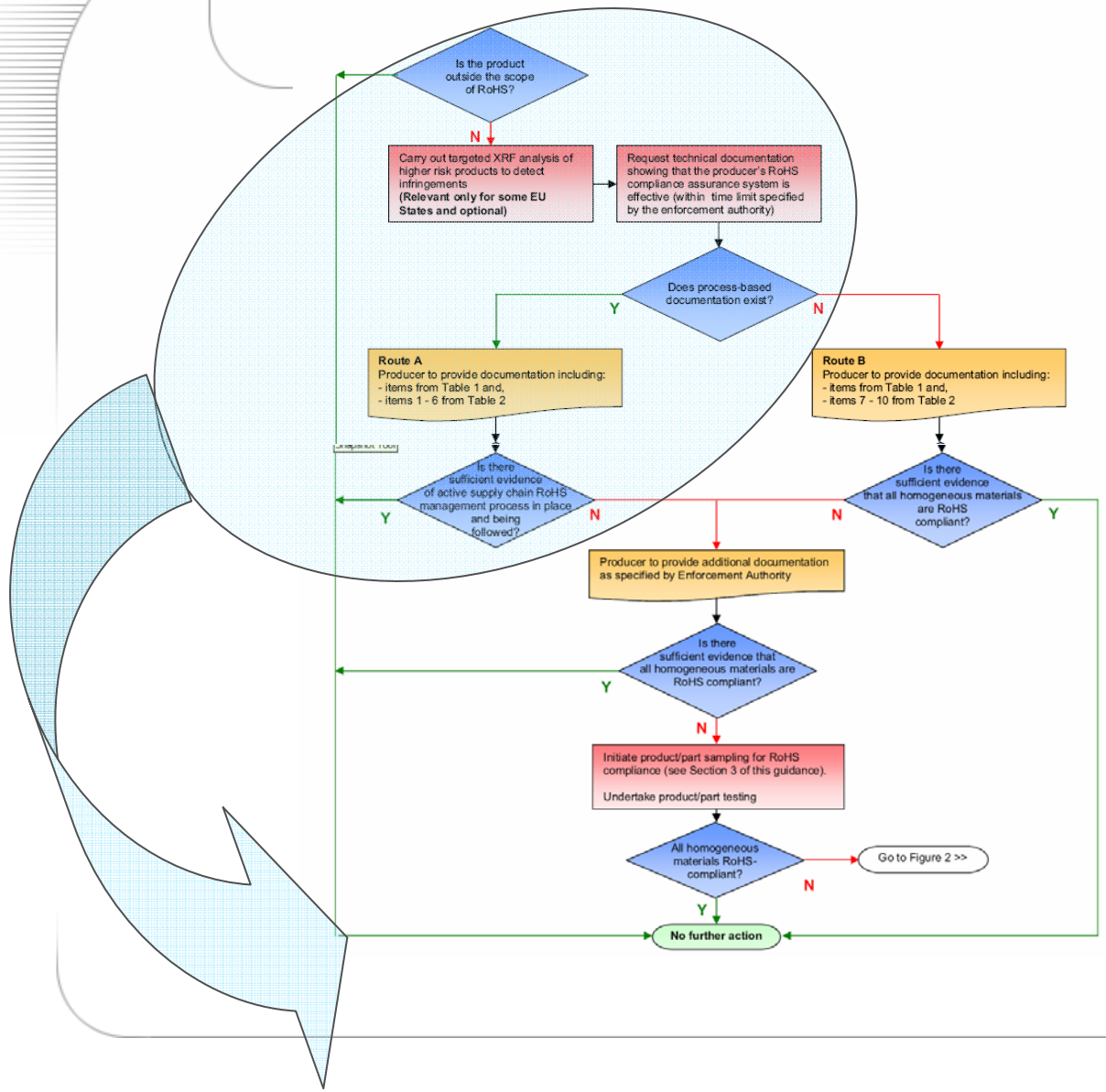
RoHS Guidance Document Summary



RoHS Guidance Document Summary

Table 2 - Typical Compliance Documentation List	
Route A	**Route B**
Process-based Technical Documentation *(Typical information relating to the producer's internal system to ensure RoHS compliance)*	**Product/Part-based Technical Documentation** *(Typical information relating to a product's/part's physical attributes that ensures RoHS compliance of a specific product)*
Compliance Assurance System (CAS)	
1) A definition of the purpose of the system, its essential requirements and specification. This specification should cover compliance both within the company and within the supply chain	7) Producers' or suppliers' warranties /certificates declaring that the use of the restricted substances is within the permitted levels
2) A formally defined process which implements the requirements of the system and is integrated within the organisation's quality and management systems	8) Producers' or suppliers' completed materials declaration for each part (including revision for revised parts) and justification of RoHS categorisation and use of exemptions. These declarations would be limited to the list of RoHS substances, not full materials declarations
3) A technical documentation system (paper and/or electronic) to support the process and measures to assure conformity with the requirements of the system together with necessary training, tools and infrastructure.	9) Analysis report for homogeneous materials in parts/components, (which could be the producers or suppliers own internal or external test results). The test results should refer to homogenous materials in parts/components.

RoHS Guidance Document Summary

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Process-based Technical Documentation *(Typical information relating to the producer's internal system to ensure RoHS compliance)*	**Product/Part-based Technical Documentation** *(Typical information relating to a product's/part's physical attributes that ensures RoHS compliance of a specific product)*
Evidence of Active Control of the CAS	10) Those who use approach B only (SMEs) must also provide evidence that procedures are being followed to show that materials declarations have been assessed to determine if they can be trusted. Enforcement authorities will also need to see documented compliance procedures
4) Results of internal and supplier audits to validate Compliance Assurance System and/or processes. i.e. the supplier's ability to assure compliance.	
5) Evidence that the system is being followed including results of product specific conformance assessments comprising items such as product assessments (including justification of RoHS categorisation and use of exemptions), materials declarations, procurement, inventory and production controls and substance analysis where appropriate	
6) Overview of any internal data system used for the management of RoHS compliance data	

What is WEEE?

- **Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on**
- **W**aste **E**lectrical and **E**lectronic **E**quipment

California Senate Bill (SB) 50

- Lists 700+ chemicals with adverse impacts, including lead, antimony trioxide, DEHP & cadmium
- Products (with exemptions) with >300 ppm lead in outer contact surface layer must be labeled
- Customer notification via letter except for consumer customers
- **Applies to all firms that sell or resell to CA retail consumers**

China (RoHS) Article 11 (draft)

- Management and control of pollution by eliminating pollutants and requiring recycling of electronic information products
- Draft developed by Ministry of Information Industry
  - **Expands scope of EU RoHS**
  - **China on track to have most stringent standards worldwide--Likely will become de facto standard to design to**
- Applies to **ALL producers/importers** of electronic products
- "Womb-to-tomb" scope
- Packaging must be non-toxic, biodegradable and recyclable
- Products must be labeled with names, content levels, and recyclability of harmful materials
  - **Products not properly marked will not be allowed past customs**

US & Global HSF Legislation

- Maine
- California
- 10 US States with Pending Legislation
  - *And growing every day!*

- China
- Japan
- Australia
- Korea

How do you meet them all?

Hazardous Substance Process Management – QC 080000

- **International Electrotechnical Commission**

  QC 080000 IECQ HSPM 2005

- Electrical & Electronic Components and Products **H**azardous **S**ubstance **P**rocess **M**anagement System Requirements

What is QC 080000?

- An internationally agreed-upon IECQ technical specification for certification by 3rd-party assessors that a company's processes to manage, minimize and/or eliminate hazardous substances meet the highest standards
  - Incorporates as applicable RoHS, WEEE, SB-50, **green process**, etc and the principles of a QMS
  - Developed originally from the US standard EIA/ECCB 954
  - On target to become an industry standard within the next 1-1.5 years

What is QC 080000 IECQ HSPM?

- Based on belief that achievement of HSF products & production processes cannot be realized without effective **integration of management disciplines**
  - Solution must be **process**-based
  - Can't "inspect in" quality; Can't "test out" HSF

How was QC 080000 Created?

- EU Directive - RoHS
- EU Directive - WEEE
- California SB50 – AB 2022(pending)
- China Article 11 (~ RoHS)
- China Article 12 (~WEEE)
- Other regulations are imminent in Japan, Korea, Australia, additional US states, etc…

How does QC 080000 Work?

- Comprehensive in scope
  - Management of **all HS processes**
  - Regardless of HSF requirements a company is trying to meet
- Designed to satisfy company HSF requirements and country HSF regulatory requirements
  - Will reduce or replace government compliance testing and numerous company-specific audits

QC 080000 and ISO 9001

- IECQ HPSM is an "**add on**" to the ISO 9001:2000 Quality Management System (QMS)
- ISO 9001 provides a blueprint for optimization of business and quality management systems
  - ***IECQ HSPM was written to fit into that blueprint***
- IECQ HSPM strengthens adherence to the principles and practices prescribed by the International Organization of Standardization (ISO) and directs their application to the management of hazardous substances

Sections of QC 080000 IECQ HSPM

0 Introduction

1 Scope

2 Normative References

3 Terms and Definitions

4 Quality Management System

5 Management Responsibility

6 Resource Management

7 Product Realization

8 Measurement, Analysis and Improvement

To facilitate integration of HS process management with a company's QMS, these sections and their subsections use the same numbering as ISO 9001:2000.

The Steps to Certification

- ISO QMS Registered or ISO Compliant
  - ISO 9001, AS9100, TS16949, TL9000, etc.
- Obtain training
- Build your system
- Apply to Certification Body for registration
- Documentation Review
- On-Site Registration Audit
  - (1.5 – 7 days based on size)
- On-going Annual Surveillance

IEC IECQ

Certificate No. US-HSPM-1002

Issued: April 26, 2006
Revision: N/A
Expiration: April 25, 2009

IECQ Certificate of Hazardous Substance Process Management (HSPM)
applicable to the European Directive 2002/95/EC ("RoHS") requirements

The United States National Authorized Institution (ECCB)
and the Supervising Inspectorate (NSAI) Certifies that

S.W. Electronics & Manufacturing Corporation
"SWEMCO"
1215 N. Church St.
Moorestown, NJ 08057

Has developed and implemented Hazardous Substances Process Management, procedures, and related processes in compliance with the applicable requirements for HSPM organization approval which is in accordance with the Basic Rules IECQ-01 and Rules of Procedure QC 001002-5 "IECQ Hazardous Substance Process Management" of the IEC Quality Assessment System for Electronic Components (IECQ), and with respect to the Specification QC 080000 IECQ HSPM.

For the following scope of activity
Custom manufacturing and engineering of printed circuit assemblies and complete system builds for the commercial, industrial and military markets.

Issued by Certification Authorities:

ECCB
Electronic Component Certification Board
Signed:
Stanley H. Salot Jr. – President, ECCB
ECCB
PO Box 9041, Midland, Texas 79708
Tel: (432) 697-6970 Fax: (866) 260-6181
Web Site: www.eccb.org

nsai
The National Standards Authority of Ireland
Signed:
Simon Kelly – President, NSAI
NSAI, Inc.
402 Amherst Street, Nashua, NH 03063
Tel: (603) 882-4412 Fax: (603) 882-1985
Web Site: www.nsaiinc.com

The validity of this certificate is maintained through on-going surveillance inspections.
Note: This certificate is valid only in conjunction with the approval document(s). This approval and this certificate may be suspended or withdrawn in accordance with the Rules of Procedure of the IECQ. This certificate remains the property of the body which granted it.

National Standards Authority of Ireland

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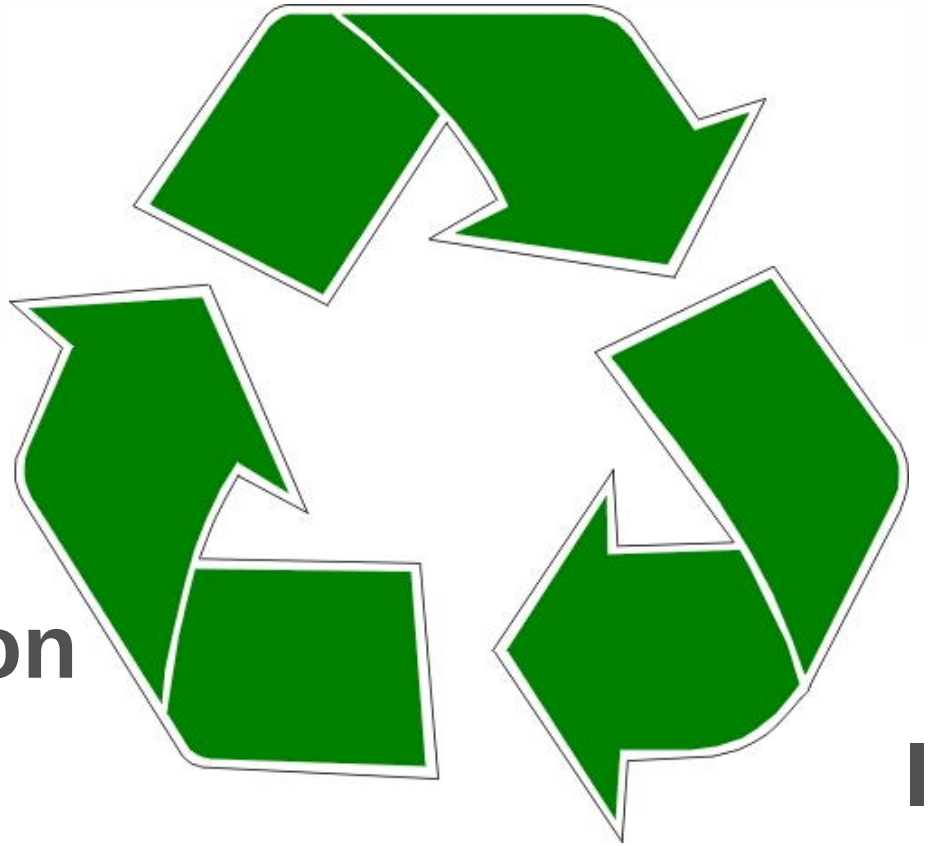
IPC Lead Free



Certification Body

IECQ QC 080000