

IECQ HSPM QC 080000 Requirement Understanding

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



▶ Marvin Ng

▶ July 28th, 2006

 UL International Ltd.
Underwriters
Laboratories Inc.



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Introduction



▶ Marvin Ng

❖ UL Lead Assessor for ISO9001, ISO14001,
RC14001, Medical Devices

▶ Kindly keep mobile close during the lesson



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Overview

- ▶ RoHS & WEEE Directives.
- ▶ What is QC080000 IECQ HSPM.
- ▶ Background of QC080000 IECQ HSPM.
- ▶ Benefits of QC080000 IECQ HSPM Certification.
- ▶ Understanding of the Standard QC 080000 IECQ HSPM
- ▶ Case Study

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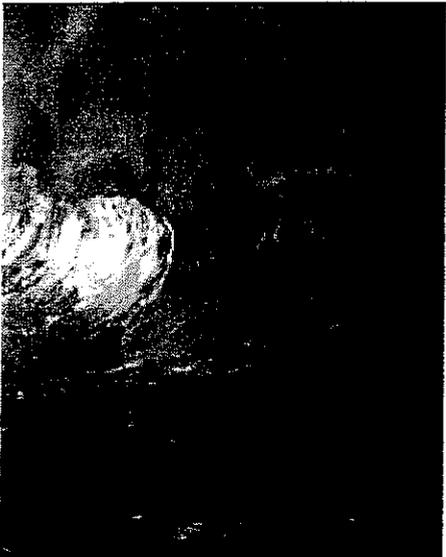


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RoHS is coming!

“
 RoHS Directive is
 a tidal wave that's
 about to wash over
 the electronics
 industry
 ”

*Electronics
 Business-Online
 Magazine*



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Are you ready ?



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RoHS Directives

RoHS Directive




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RoHS Directives

Directive 2002/95/EC
of the European
parliament and the
council of 27
January 2003 on the
Restriction of the
use of certain
Hazardous
Substances in
Electrical &
Electronic equipment



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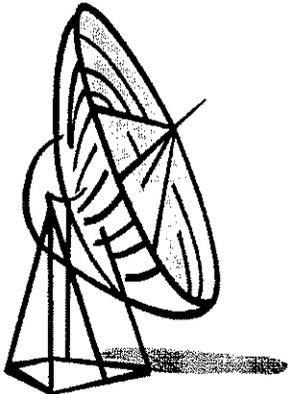


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Scope of RoHS Directives

- ▶ RoHS regulations apply to
 - ❖ All EEE put on the European market on or after 1 July 2006
 - ❖ All EEE which falls into any of the eight broad categories listed in annex 1A of WEEE directive

• Source :RoHS Directive (2002/95/EC), Article 2.1.2.2



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RoHS Directive- Hazardous substances

1. Lead(Pb)
2. Cadmium(Cd)
3. Mercury(Hg)
4. Hexavalent Chromium(Cr+6)
5. Polybrominated Biphenyl Ether(PBB)
6. Polybrominated Diphenyl Ether(PBDE)
 - Source : RoHS Directive (2002/95/EC), Article 4.1



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Restricted or Banned?

- ▶ **Restricted, not banned.**
 - ❖ Total avoidance possible?
 - ❖ Certain concentration values tolerated.
 - Source :Commission Decision of 18 August 2005 amending directive 2002/95/EC, (2005/618/EC), Point **No.1**



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Maximum Concentration value in PPM

▶ Lead	1000 ppm
▶ Cadmium	100 ppm
▶ Mercury	1000 ppm
▶ Hexavalent Chromium(Cr+6)	1000 ppm
▶ Polybrominated Biphenyls(PBB)	1000 ppm
▶ Polybrominated Diphenyl Ether (PBDE)	1000 ppm



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Addition of other substances ?

Very Likely !!

' On the basis of a proposal from the commission, the European Parliament and the council shall decide, as soon as scientific advice is available, and in accordance with the principles on chemicals policy as laid down in the sixth community environment action program, on the prohibition of other hazardous substances and the substitution thereof by more environment-friendly alternatives which ensure at least the same level of protection for consumers'

▪ Source : RoHS Directive (2002/95/EC), Article 4.3

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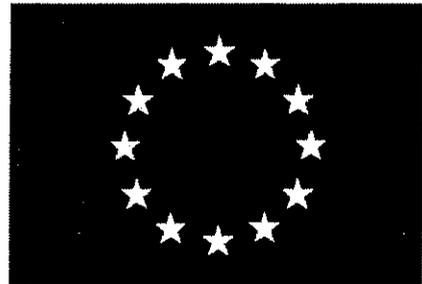
Risk of Non-compliance

- ❖ Broken of relationship to Customer
- ❖ Product Banned to ship to Europe, Huge Penalty
 - Manger go to Jail
- ❖ Broken of Company Reputation



WEEE Directives

WEEE Directive



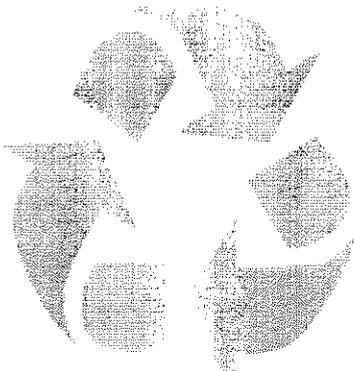


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WEEE Directive

- ▶ Directive 2002/96/EC of the European Parliament and the council of 27 January 2003 on Waste electrical and electronic equipment (WEEE)



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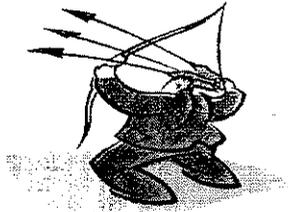


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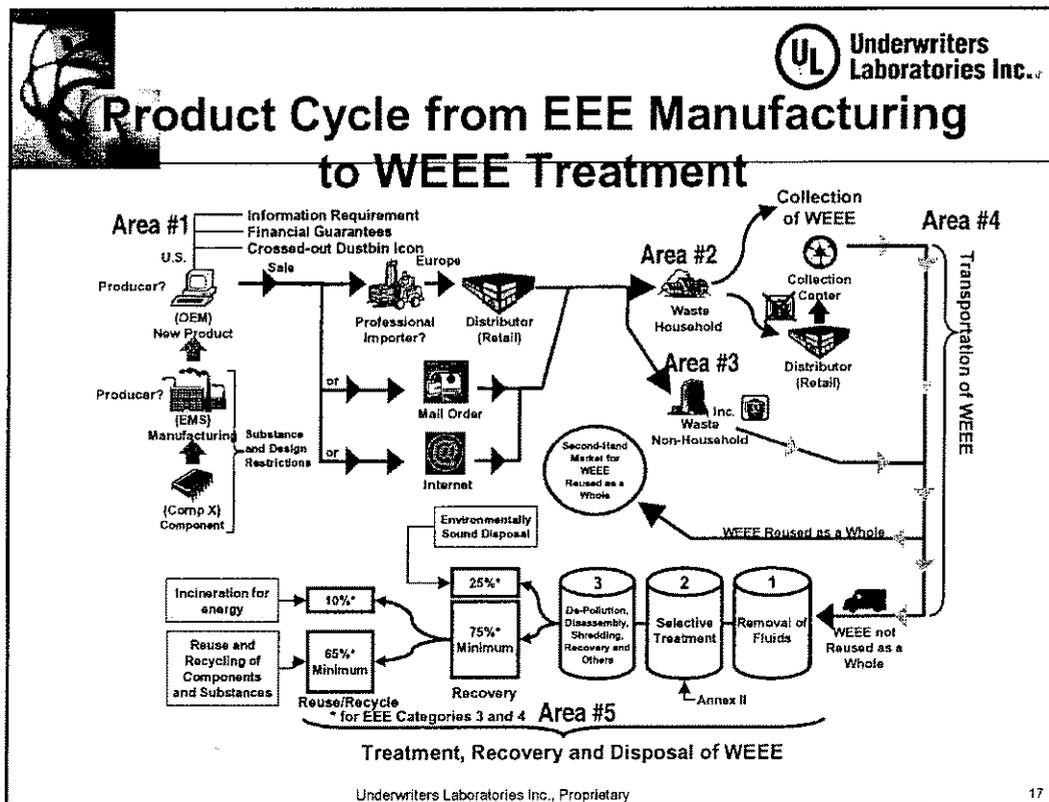


Objective of WEEE directive

- ▶ **Priority:** Prevention of WEEE
- ▶ Reduce disposal of waste by
 - ❖ Reuse
 - ❖ Recycling
 - ❖ Other forms of waste recovery
- ▶ Improves Environmental performance of all operators involved in life cycle of EEE



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Scope of WEEE

- Same as that of RoHS directive
- All EEE which falls into any of the eight broad categories listed in annex 1A of WEEE directive.

WEEE 類別	產品
大家電	烹調用具, 微波爐, 冷氣機, 冰箱 等
小家電	烤麵包機, 時鐘, 手錶, 咖啡機, 吹風機 等
資訊與通訊器材	迷形電腦, 個人電腦, 印表機, 電話, 傳真機 等
消費性電子產品	收音機, 電視機, 攝影機, 播放機, 電子樂器 等
燈具	非家用之螢光管, 霓虹燈 等

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Scope of WEEE

WEEE 類別	產品
電器和電子工具	電鑽，電鋸，割草機，衣車 等
玩具 娛樂 及 運動器材	電動汽車/火車，手提電子遊戲機，跑步機，划船器
醫療儀器	放射治療機，心臟儀器 等 用於偵測、治療或減輕疾病、受傷或殘障的器材
監控儀器	煙霧偵察機，溫度偵察機 等
自動販賣機	熱飲販賣機，糖果販賣機，代幣販賣機

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Product design- WEEE point 1

- ▶ Producers - Design & Produce EEE for
 - ❖ For Repair
 - ❖ Possible upgrading
 - ❖ Reuse
 - ❖ Easy dismantling & recovery
- Reuse and recycling of WEEE, their components & materials!

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Product design- WEEE point 2

- ▶ Do not prevent WEEE being reused unless there is
 - ❖ environment and /or
 - ❖ safety requirement

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Recycling Objective

- ▶ Objective for collecting, recycling and reuse of WEEE on 31 Dec 2008

產品種類	再使用率和回收率 (reuse / recycling)	再生率 (recovery)
1. 大型家電用品	75 %	80 %
2. 小型家電用品	50 %	70 %
3. 資訊及通訊設備	65 %	75 %
4. 消費性電子產品	65 %	75%
5. 照明設備	50 %	70 %
6. 電動工具	50 %	70 %
7. 玩具、休閒及運動設備	50 %	70 %
8. 醫療設備	?	?
9. 監控儀器	50 %	70 %
10. 自動販賣機	75 %	80 %

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Are you really ready?



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Consideration

- ▶ Compliance to the directive are through isolated sample testing and self declaration
- ▶ Do you feel confident when you sign the Self-declaration?
- ▶ Quality Assurance is capable to ensure compliance of Hazardous substance requirements solely?
- ▶ Do you think you understand the risk of noncompliance based on the isolated test report?

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What is QC 080000 IECQ HSPM

Electrical and Electronic Components and Products Hazardous Substance Process Management System Requirements



World-wide approval and
certification program for
electronic components (IECQ)

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What is QC 080000 IECQ HSPM

- ▶ An internationally agreed-upon IECQ Technical specification for Certification by 3rd party assessors that an **organization's processes to manage, minimize and/or eliminate** hazardous substances meet the highest standards.
 - ❖ Incorporates as applicable RoHS, WEEE, SB-50, Green Process & the Principles of a Quality Management System.



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What is QC 080000 IECQ HSPM

- ❖ Solution must be Process-Based
- ❖ Achieved only with effective integration of management disciplines.
- ❖ Designed to be Comprehensive in scope.
- ❖ Dynamic in nature.



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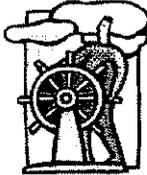


Background of QC 080000 IEQC HSPM

- ▶ Effect of the RoHS and WEEE directives.



- ▶ Developed by industry to provide a comprehensive framework.



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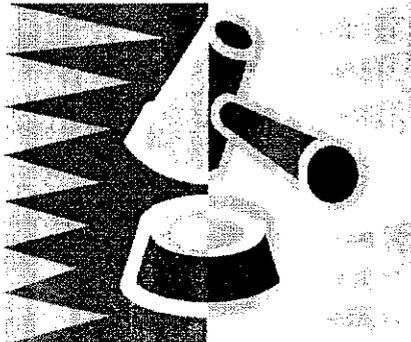


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RoHS is coming Soon!

RoHS Implementation Date

1 July 2006



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Are you really ready?

Are you ready for RoHS?

Yes

What's the Risk level?

No

What's your status?



supplier declaration

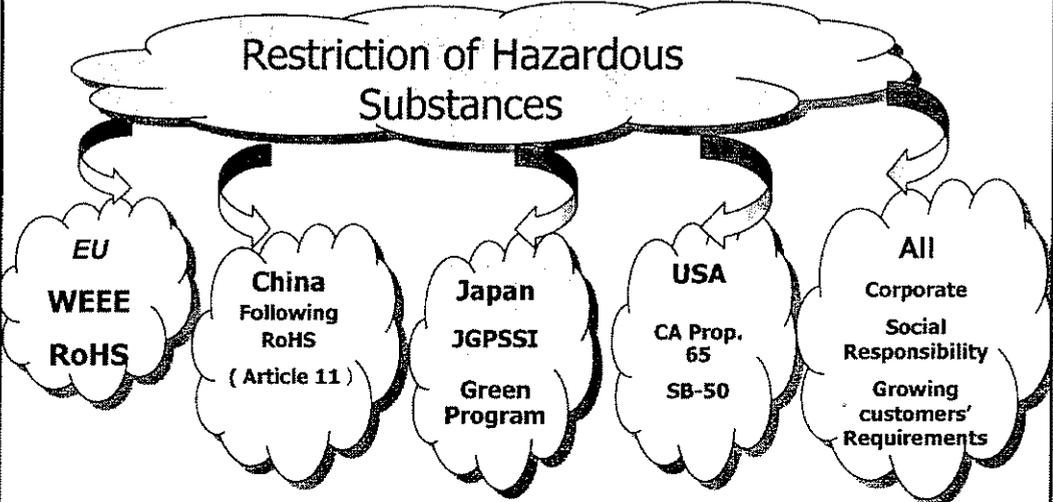
Product test reports

material test reports

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NEW! **Challenges!!**



Restriction of Hazardous Substances

- EU**
WEEE
RoHS
- China**
Following
RoHS
(Article 11)
- Japan**
JGPSSI
Green
Program
- USA**
CA Prop.
65
SB-50
- All**
Corporate
Social
Responsibility
Growing
customers'
Requirements

Compliance Is Not An Option...It Is a Necessity

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Challenges

- ▶ More and more legislation concerning electronic waste and hazardous substances!!
 - ❖ China (Mar. 1, 2007)
 - ❖ California, US (July 1, 2007?)
 - ❖ Japan (JGPSSI)



- ▶ Growing customer requirements for
 - ❖ Green products
 - ❖ Green procurement
 - ❖ Green processes

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QC 080000 IEQC HSPM

A guidance for Manufacturers in the fulfillment of regulatory and customer HSF requirements.



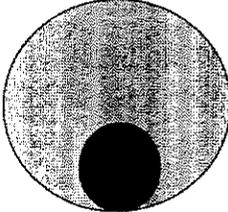
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QC 080000 complements ISO 9001

- ▶ **ISO 9001:2000** Standard provides a framework for optimization of business and quality management systems.



- ▶ **QC 080000 HSPM** was written to fit into that framework.

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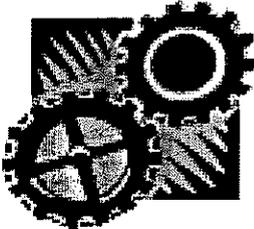


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QC 080000 Strengthens ISO 9001

- ▶ **QC 080000 HSPM** is a supplement to ISO 9001-2000 Quality Management System.



- ▶ **Strengthens** the principles and practices.
- ▶ **Further directs** the Application to the management of hazardous substances.

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IECQ HSPM Certification Benefits

- ▶ IECQ Accreditation **satisfy regulators** that processes are free of Hazardous Materials.
 - ❖ Organization that can manufacture according to IECQ HSPM standard receive a certificate as proof.
- ▶ Tell the global marketplace that you have **the processes in place to properly manage your products for HSF.**



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IECQ HSPM Certification Benefits

- ▶ Assures Global Market Access and creates a Competitive Advantage!
- ▶ Assures Compliance with laws & highest industries' Standards.
- ▶ Opportunity to Save Costs!
 - ❖ Often replaces lengthy surveys from customers.
 - ❖ Reduces Testing requirements.



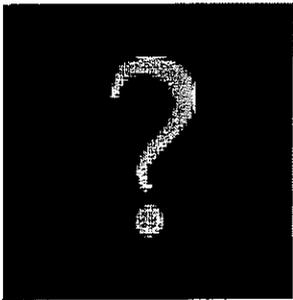
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Lost ?



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QC 080000 HSPM

Key Elements of the Standard QC 080000 HSPM

1. Purpose	1. Design and Development
1. Scope	1. Purchasing
1. Reference Documents	1. Verification of Purchased Product
1. Terms and Definitions	1. Production and Service
1. Special Requirements	1. Identification and Traceability
1. Management Responsibility	1. Handling of Hazardous Substances
1. Records	1. Measurement, Analysis and Improvement
1. Management Review	
1. Resource Management	
1. Product Realization	

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Applicability

- ▶ Who should use this specification?
 - ▶ Manufacturers, suppliers, repairers, and maintainers of products
 - ❖ To develop processes to identify, control, quantity, and report the amounts of HS in their products
 - ▶ Customers and users of the products
 - ❖ To know the HSF status of a product, and to understand how HSF status was determined

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Case Study 1

- ▶ A company develops software as a subcontractor for use to run a semiconductor manufacturing facility
 - ❖ Do they need to seek QC080000 IECQ HSPM compliance?

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Definition

- ▶ HSF – Hazardous Substance Free
- ▶ HS – Hazardous Substance
- ▶ RS – Restricted Substance

- ▶ What's the difference of RS to HS in QC080000?

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Definition

- ▶ **Shall** – Indicate a mandatory requirement to be followed in order to confirm to this document
- ▶ **Should** – indicates that, among several possibilities, one is recommended as particularly suitable; or a certain course of actions is preferred but not required
- ▶ **May** – indicates a course of action that is permissible within the limits of this document

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Other Terms and Definition

- ▶ Information Services Providers ----- > ?
- ▶ Product customer
- ▶ Product maintainer
- ▶ Product manufacturer
- ▶ Product repairer
- ▶ Product user
- ▶ HSF Hazardous Substance Free
- ▶ HS Hazardous Substance
- ▶ Restricted Substance
- ▶ Shall/Should/May

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Question

▶ Who is who?

- ❖ 3M
- ❖ Sony
- ❖ IBM

- A) Product Customer
- B) Product Manufacturer
- C) Product Supplier

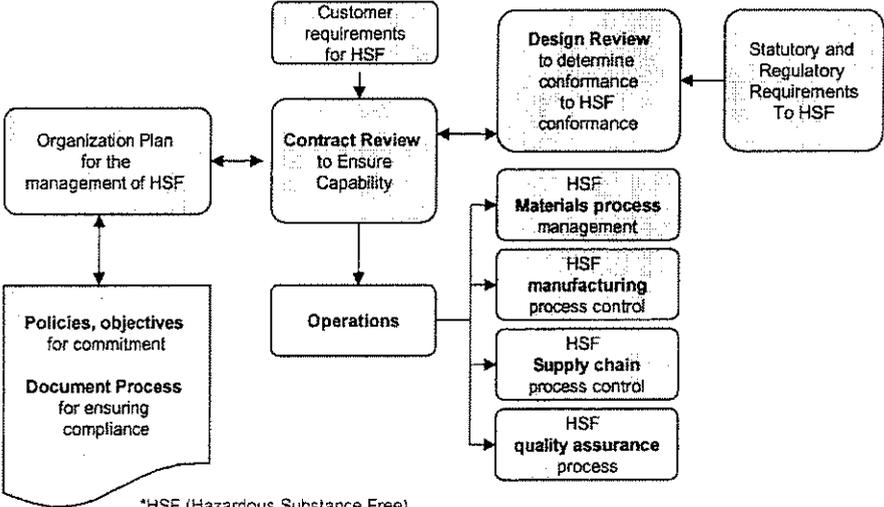
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Basic HSPM Processes



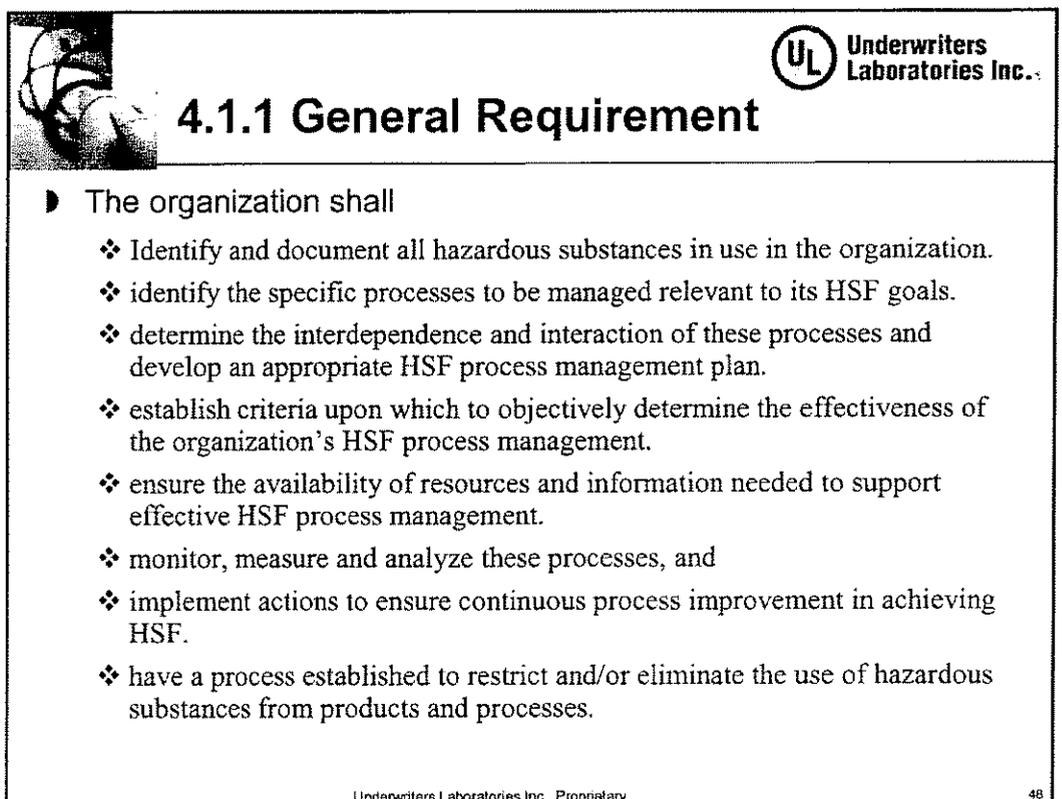
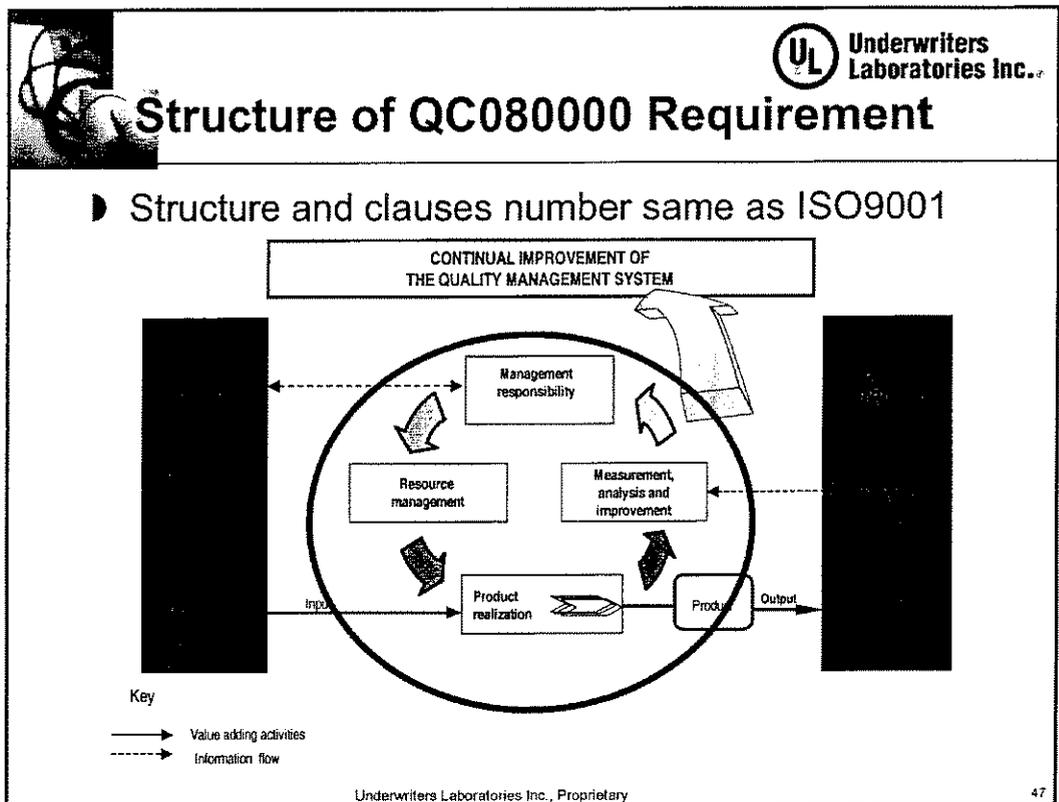
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graph TD
    CR[Contract Review to Ensure Capability] --> OR[Organization Plan for the management of HSF]
    OR --> CR
    CR --> OP[Operations]
    CR --> DR[Design Review to determine conformance to HSF conformance]
    CR --> HSM[HSF Materials process management]
    CR --> HMF[HSF manufacturing process control]
    CR --> HSC[HSF Supply chain process control]
    CR --> HQA[HSF quality assurance process]
    CR --> CRR[Customer requirements for HSF]
    CRR --> CR
    DR --> CR
    SR[Statutory and Regulatory Requirements To HSF] --> DR
    PO[Policies, objectives for commitment] --> OR
    DP[Document Process for ensuring compliance] --> OR
    
```

*HSF (Hazardous Substance Free)

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4.1.2-1

4.1.2 Documentation Requirement

- ▶ HSF requirements shall be an integral part of the organizations' QMS and shall include
 - ❖ A list of all HS used in the organization
 - ❖ Statements of HSF policy and objectives with timeline for elimination of use of all hazardous substances, as appropriate
 - ❖ a section on the HSF process management plan and objectives and reference to HSF documented procedures documented in QM
 - ❖ Documented procedure as required by the organization's HSF process management plan and control as 4.2.3 required
 - ❖ Records of the organization's HSF process management performance

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Document and Record Control

- ▶ Same as ISO9001:2000 required



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5.1 Management Commitment

- ▶ Top Management shall provide evidence of commitment to development and implementation to achieving HSF products and production processes and continual improvement by
 - ❖ Communicate to organization the important of meeting customer, statutory & regulatory requirements
 - ❖ Establishing HSF policy
 - ❖ Ensure HSF objectives established
 - ❖ Include HSF in management review
 - ❖ Provide resources to ensure progress on HSF products and process
 - ❖ Ensure list of HS communicated throughout the organization
 - ❖ Determine HSF requirements

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5.2 Customer Focus

- ▶ Ensure Customer requirement are determine and met **and included in the measure of customer satisfaction**

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5.3 HSF Policy

- ▶ HSF Policy appropriate for the purpose of the organization
- ▶ Include commitment to comply with requirements and continually HSF mgt practice improvement
- ▶ Provide framework for establishing and reviewing HSF objective
- ▶ Communicated and understood within the organization
- ▶ Reviewed for continuing suitability

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5.4.1 HSF Objective

- ▶ HSF objectives are established at relevant functions and levels
- ▶ Measurable, consistent with HSF policy
- ▶ Include a timeline, as appropriate, for elimination of HS identified and used in process and product, include procured products.

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5.4.2 HSF Planning

- ▶ HSF practice are integrated into the QMS planning and are elements in the quality objectives
- ▶ Continuity of HSF effort is maintained as improvements and changes are executed

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5.5.1 Responsibility and Authority

- ▶ HSF related responsibility and authorities are defined and communicated within organization

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5.5.2 Management Representative

- ▶ Top management appoint
- ▶ Have responsibility and authority that include
 - ❖ Ensure process, procedure and practices established to achieving HSF goal
 - ❖ Report about organization's performance
 - ❖ Ensure HSF requirement and responsibility communicated
 - ❖ Ensure awareness in supplier organization of their HSF related requirements and responsibilities

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5.5.3 Internal Communication

- ▶ Top Management shall
 - ❖ Ensure the organization's personnel are informed of performance effectiveness and issues as related to HSF policy and execution plan
 - ❖ HS information be communicated throughout the organization

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5.6 Management Review

- ▶ Other ISO9001 requirements applied with following additional requirements
- ▶ During regular management review, Top management shall include and report on activities related to HSF plan related to
 - ❖ HS identification,
 - ❖ use of HS,
 - ❖ Nonconformance
 - ❖ Corrective Action

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Case Study 2

- ▶ During the audit, you found in management review meeting minutes that purchasing department manager was not joined in the meeting but the company purchased many HS parts.
 - ❖ Is it an nonconformance?
 - ❖ Please justify your answer by reference particular clause and statement in QC080000 requirements

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Case Study 3

- ▶ A Company manufactures digital toys and sell to Europe. The company implemented HSPM. It is observed that from the HS list shows that there are totally 15 HSs used in their product and processes. They have eliminated 5 out of 6 HS that is required by EU and remain lead, which have a timetable to reduce it below 100ppm by 2010.
 - ❖ Is it RoHS complaint?
 - ❖ Provided that the company have good HSPM. Do they able to be certified to QC080000?

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6 Resources Management

- ▶ 6.1 Provision of resources
- ▶ 6.2 Human Resources
- ▶ 6.3 Infrastructure

- ❖ Resources management in an HSF environment requires the addition of **Technical knowledge** of HS to the QMS requirements

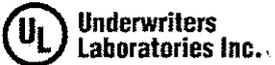
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6.1 Provision of resources

- ▶ Organization shall determine and provide resources needed to implement and maintain HSF processes and product

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6.2 Human Resources

- ▶ 6.2.1 – Personnel performing work affecting HSF product shall be competent based on
 - ❖ Education
 - ❖ Training
 - ❖ Skill
 - ❖ Experience
- ▶ 6.2.2 – Organization shall
 - ❖ Determine necessary competence
 - ❖ Provide training specific to HSF plan
 - ❖ Evaluate effectiveness
 - ❖ Ensure personnel aware relevance & importance of their activities, & how they contribute to achievement of HSF objective
 - ❖ Maintain record of education, training, skill and experience

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6.3 Infrastructure

- ▶ Shall determine, provide and maintain infrastructure needed to achieve conformity to HSF process and product requirements

❖ Technical knowledge may be required in auditing this section

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7.1 Planning of HSF process & Product Realization

- ▶ Shall plan and develop processes needed for HSF product realization
- ▶ Following shall be determined in HSF product realization
 - ❖ Quality objectives and requirements for HSF product
 - ❖ Need of establishing HSF processes, document and resources needed
 - ❖ Required verification, validation, monitoring, inspection, test activities for HSF product with criteria for product acceptance, include IS as appropriate
 - ❖ Documented procedures or work instructions for processes that include use of RS to include prevention possible contamination
 - ❖ Record needed for HSF realization processes & product meets requirements
 - ❖ Output of this HSF planning shall in format suitable to organization

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7.2.1 Determination HSF product requirements

- ▶ Shall determine
 - ❖ HSF requirements specified by the customer
 - ❖ HSF requirements not stated but necessary for specified or intended uses, where known
 - ❖ HSF statutory and regulatory requirements to product
 - ❖ Additional HSF requirements determined by organization

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7.2.2 Review of HSF requirement

- ▶ Shall review requirement related to HSF product, review shall conducted prior commit to supply HSF product and shall ensure that
 - ❖ HSF product requirements defined
 - ❖ Organization have ability to meet HSF defined requirements
 - ❖ Any use of or possibility of contamination or mixing of processes or products that contain RS shall communicated to customer
 - ❖ Records of result of HSF review and actions arising be kept and maintained

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7.3 Design and Development

- ▶ Shall plan and control the design and development of HSF product
- ▶ 7.3.1 Design plan
 - ❖ Identify & document any RS used
 - ❖ Plan for control & eventual replacement / elimination of RS parts
- ▶ 7.3.2 Design input
 - ❖ Design & development input relating to HSF product requirement shall be determined and record maintained
 - ❖ Input shall be reviewed for adequacy
 - ❖ HSF product requirements shall be complete, unambiguous and not in conflict with each other

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7.3 Design and development

- ▶ 7.3.3 Design output
 - ❖ Shall in a form that enable verification against the inputs
 - ❖ Outputs shall be approved prior to release
 - ❖ When design requires a RS, **documented procedure** for control, identification, monitoring and measurement to include subcontracted product
- ▶ 7.3.4 Design verification
 - ❖ Systematic review of design & development shall be performed at suitable stage, according to HSF plan
- ▶ 7.3.7 Control of design changes
 - ❖ Changes shall be reviewed, verified, validated and approved prior to implementation

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7.4 Purchasing of HSF product

- ▶ Procured product shall conform to HSF requirement
- ▶ Supplier shall be evaluated and selected based on the ability to supply product in accordance with the organization's HSF requirements
- ▶ Assurance any HSF part/material is free from possible contamination with RS
- ▶ Procured restricted substances shall be clearly identified on the purchase document and upon receipt of the material
- ▶ Verification of the HSF purchased product
- ▶ Establish and implement inspection or other activities necessary to ensure purchased product meet specified HSF purchased requirements

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7.4 Purchasing of HSF product

- ▶ Procurement route of purchased goods shall be fully understood and documented in a procedure
- ▶ Any process during procurement that has the possibility of contamination by restricted HSs shall be identified
- ▶ Establish a documented procedure for the inspection and identification of HS included in purchased goods
- ▶ HSs shall be identified by type in the inspection data
- ▶ A process to handle an abnormality or nonconformance shall exist
- ▶ If processes are combined with each other, a documented procedure to differentiate between parts shall exist

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7.5.1 Control of HSF production & service provision

- ▶ HSF production and service provision shall be planned under **control condition** include,
 - ❖ HSF information that describe the product
 - ❖ HSF work instruction
 - ❖ Suitable HSF equipment
 - ❖ Use and implementation of HSF monitoring & measurement
 - ❖ Implementation of HSF release, delivery & post-delivery process control
 - ❖ **Identification & documentation** of possible contamination processes
 - ❖ **Documented operational procedures** that define preventive measures to eliminate contamination

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7.5.2 Validation of HSF process

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

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7.5.3 HSF identification & traceability

- ▶ Where appropriate, identify HSF product by suitable means throughout **product realization**
- ▶ Processes including any RS shall be uniquely identified and segregated to prevent combination with HSF product
- ▶ Identify HSF product status with respect to monitoring and measurement requirements
- ▶ Where traceability is a requirement, control and record the unique identification of product

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7.5.4 Handling of Hazardous Substances parts

- ▶ A documented procedure for the handling and storage of hazardous substances is required
- ▶ This procedure shall include records of receiving and shipping and records showing HSs are segregated and managed separately

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7.6 Control of monitoring & measurement devices for HSF processes

- ▶ Determine
 - ❖ the monitoring & measurement to be undertaken
 - ❖ the monitoring and measuring devices needed to provide evidence of conformity of HSF product to determined requirements
- ▶ Establish process to ensure monitoring and measurement are carried out consistent with the HSF monitoring and measurement requirements

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Case Study 4

- ▶ Considering you are performing internal audit based on QC080000 requirements. You interview a clerk in Receiving. She knows parts marked "RoHS compliant" go in one area and parts without the mark go in another. She has no idea what RoHS is.
 - ❖ Is it violated the QC080000 requirement?
 - ❖ What specific clause might this situation violate?

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Case Study 5

- ▶ You work in Procurement for a company that outsources the manufacturing of its PWB for the small kitchen appliances it sells. Your manager thinks that compliance to WEEE, RoHS, and HSPM is your vendor's concern.
 - ❖ What do you think? Is it right?
 - ❖ How will you response to your manager?

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8 Measurement, analysis & improvement

- ▶ 8.1.1 Organization
 - ❖ Shall plan and implement the monitoring, measurement, analysis & improvement processes needed to demonstrate conformity to HSF requirements
- ▶ 8.2.1 Customer Satisfaction
 - ❖ ISO9001 requirement applied (but focus on HSF product)
- ▶ 8.2.2 Internal Audit
 - ❖ Shall conduct internal assessments at planned intervals
 - ❖ Determine whether the organization's HSF process conform to requirements to
 - This specification
 - Customer specification
 - ❖ Determine system are effectively implemented and maintained
 - ❖ Documented procedure required based on ISO9001 requirement

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8.2.3 Monitoring of RS processes

- ▶ Shall apply suitable methods for monitoring & measurement of RS processes including those of **suppliers** and **information services providers**
- ▶ Document how these processes to be controlled, monitored and measured

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8.2.4 Monitoring & measurement of RS product

- ▶ Documented procedure to monitor and measure RSs in the product to verify that product requirements have been met
- ▶ Maintain evidence of conformity with acceptance criteria for RSs
- ▶ Do not proceed with product release and delivery until the required reviews have been satisfactory completed

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8.3 Control of nonconforming HSF product

- ▶ Shall ensure that products not conform to HSF product requirements are identified and controlled to prevent unintended use or delivery
- ▶ Shall deal with nonconforming product by one or more following ways
 - ❖ Shall be a clear procedure to handle situation when nonconforming products containing RSs are detected & prevent being ship unless allowed
 - ❖ Retain records of the nature of nonconformities, **with RS clear identified**, and subsequent actions
 - ❖ When NC HSF product is detected after delivery or use started, take action to notify customer according to contract agreement or company policy
- ▶ Documented procedure required based on ISO9001

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8.4 Analysis of HSF data

- ▶ Shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the HSF process management system
- ▶ Provide information relating to
 - ❖ Customer satisfaction
 - ❖ Conformity to product requirements
 - ❖ Characteristics and trends of processes and product
 - ❖ Opportunities for preventive action and suppliers' performance
 - ❖ Continuous improvement efforts for elimination of all HSs, as applicable

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8.5.1 Continual Improvement

- ▶ Shall continually improve the effectiveness of HSF process management through use of
 - ❖ Quality policy
 - ❖ Quality objectives
 - ❖ Assessment result
 - ❖ Analysis of data
 - ❖ CA, PA and management review

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8.5.2 Corrective Action

- ▶ Take action to eliminate the cause of HSF nonconformities to prevent recurrence
- ▶ Document procedure shall be established to define requirements for
 - ❖ Reviewing HSF NC (include customer complaint)
 - ❖ Determine cause of HSF nonconformance
 - ❖ Evaluate need for action to ensure that HSF NC do not recur
 - ❖ Determine and implement action taken
 - ❖ Review CA taken
 - ❖ Reporting status of all HSF CA for management review

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Case Study 6

▶ A company that makes outer plastic boxes for electronic equipment needs to comply with RoHS. They have started using RoHS-compliant plastics. However, they also want to use up the non-RoHS compliant plastic regrind they have in their parts.

- ❖ Can they use the regrind in their RoHS-compliant outer boxes?
- ❖ What other issues might they face? Or what processes do they need to re-evaluate?

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Key HSPM Considerations

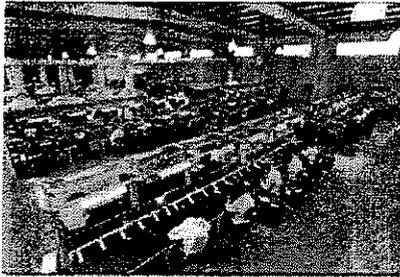
- ▶ Outsourced processes to be controlled and managed if affect HSF characteristics
- ▶ A list of all HS in use
- ▶ Top manager commitment and review
 - ❖ HSF policy and objectives
 - Timeline to eliminate HS (as appropriate)
 - Continual improvements
 - ❖ Met customer requirements and satisfaction
 - ❖ Appoint a competent Management Representative
 - ❖ Review nonconformities and corrective actions

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Key HSPM Considerations

- ▶ Adequate resource provided
 - ❖ Infrastructure
 - ❖ Human
 - Competent personnel
 - Awareness
 - Specific records

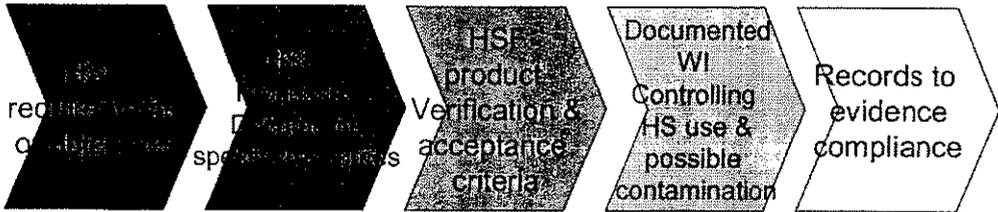


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Key HSPM Considerations

- ▶ Plan and develop needed processes for HSF

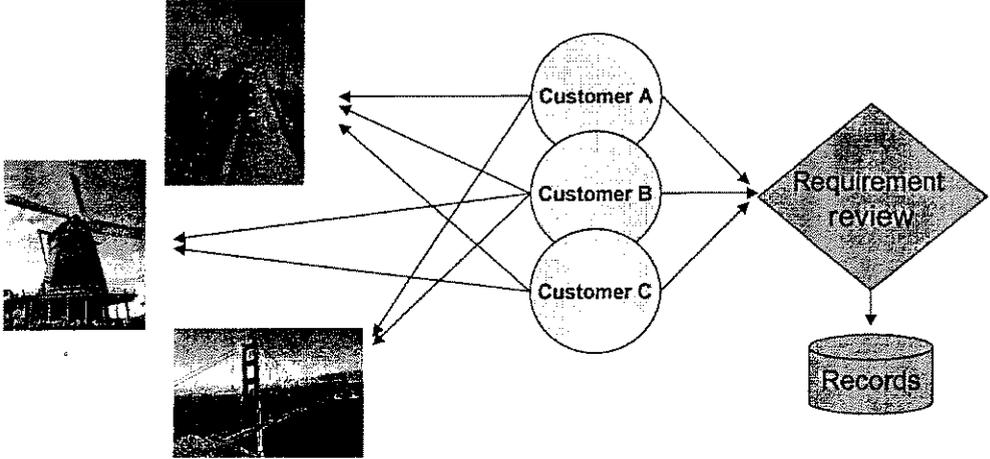


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Key HSPM Considerations

► Determine HSF product requirements



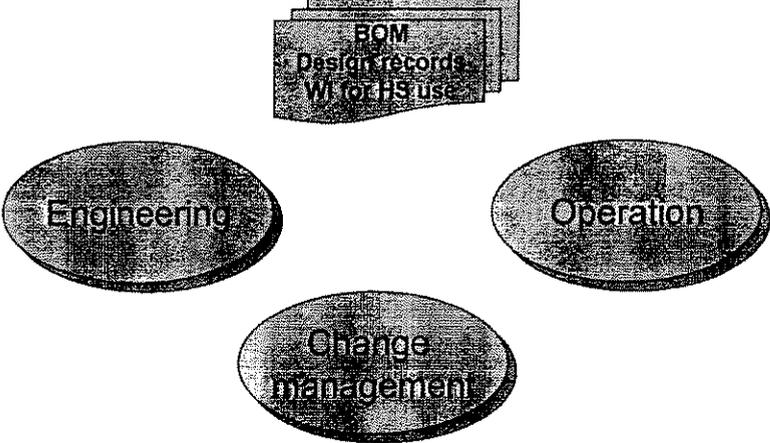
The diagram illustrates the process of determining HSF product requirements. On the left, three product images (a windmill, a bridge, and a structure) are shown. Three customer nodes, labeled Customer A, Customer B, and Customer C, are positioned in the center. Arrows point from each customer to each of the three product images, indicating that all customers have requirements for all products. Additionally, arrows from each customer point to a diamond-shaped node labeled 'Requirement review'. An arrow from the 'Requirement review' node points to a cylinder labeled 'Records', indicating that the review process results in documented records.

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Key HSPM Considerations

► Design and Development Process



The diagram illustrates the Design and Development Process. At the top, a stack of documents is labeled 'BOM', 'Design records', and 'WI for HS use'. Below this, three ovals represent key components: 'Engineering' on the left, 'Change management' at the bottom, and 'Operation' on the right. These components are interconnected, showing the flow of information and processes throughout the design and development lifecycle.

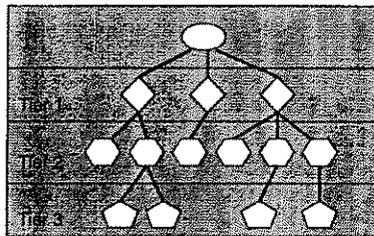
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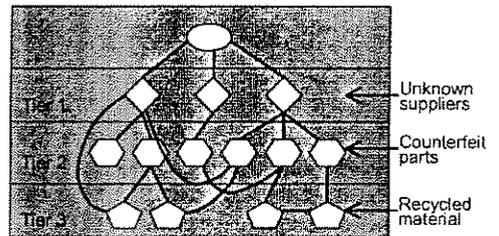
Key HSPM Considerations

Procurement Process

- ❖ Fully understand the procurement route
- ❖ Fully identify any possibility of HS contamination



Conceptual supply chain

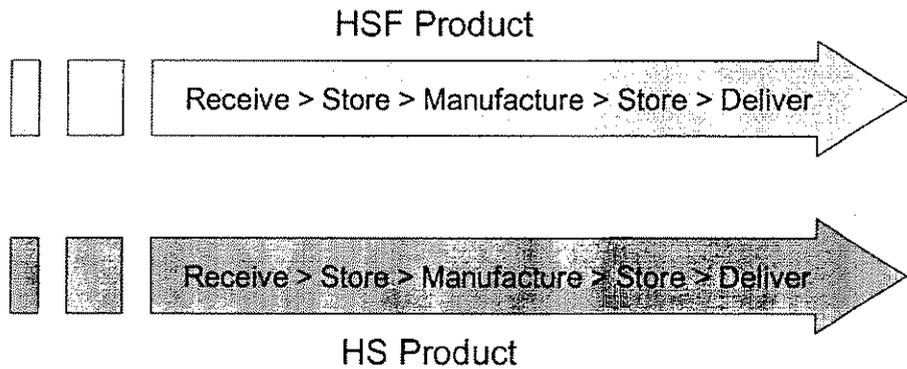


Actual supply chain



Key HSPM Considerations

Plan and control HSF production processes





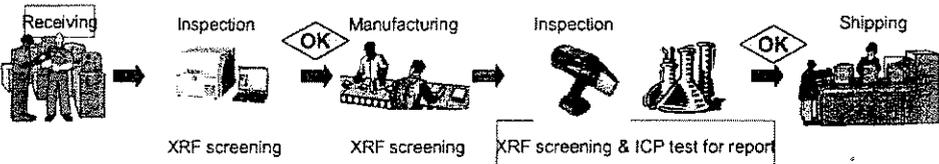


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Key HSPM Considerations

▶ **Monitoring and measurement**

- ❖ HSF product
- ❖ HS process
- ❖ Records with acceptance criteria



```

    graph LR
      Receiving[Receiving] --> I1[Inspection]
      I1 --- XRF1[XRF screening]
      I1 --- OK1{OK}
      OK1 --> Manufacturing[Manufacturing]
      Manufacturing --- XRF2[XRF screening]
      Manufacturing --- OK2{OK}
      OK2 --> I2[Inspection]
      I2 --- XRF3[XRF screening & ICP test for report]
      I2 --- OK3{OK}
      OK3 --> Shipping[Shipping]
      style I1 fill:none,stroke:none
      style I2 fill:none,stroke:none
      style OK1 fill:none,stroke:none
      style OK2 fill:none,stroke:none
      style OK3 fill:none,stroke:none
      style XRF1 fill:none,stroke:none
      style XRF2 fill:none,stroke:none
      style XRF3 fill:none,stroke:none
    
```

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Key HSPM Considerations

▶ **Control of nonconforming HSF product**

- ❖ Nonconforming handling
- ❖ Prevent from shipping
- ❖ HS detected after delivery or in use
- ❖ Records for HS and actions



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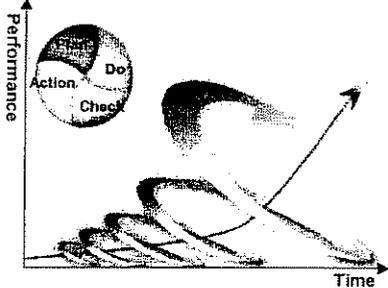
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Key HSPM Considerations

- ▶ Data Analysis and Improvement
 - ❖ Customer satisfaction
 - ❖ Conformity to product requirements
 - ❖ Characteristics and trends of processes and products
 - Preventive action
 - Supplier performance
 - ❖ Continuous improvement
 - efforts to eliminate all HS
 - ❖ Disciplined corrective action
 - Report to management review

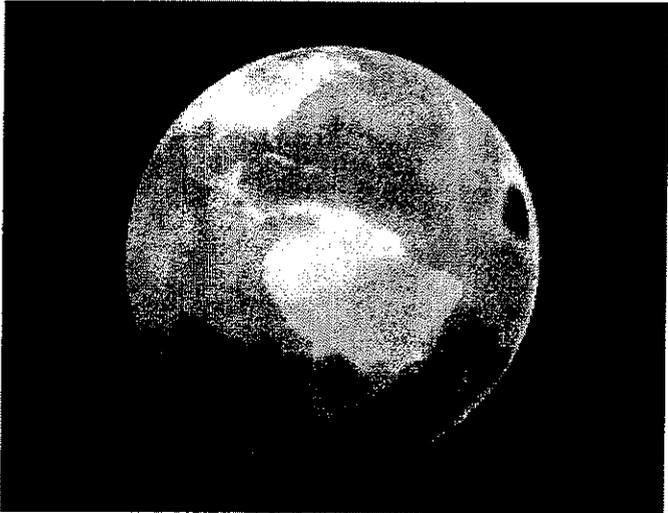


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GLOBAL AIR POLLUTION



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QC080000 Program

- ▶ Company shall have QMS on-hand
- ▶ Audit needed to perform separately but concurrent audit is acceptable
- ▶ Preliminary visit is acceptable upon request

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UL Contact Method



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