



苏州莱标标准认证有限公司  
Suzhou LQA Standard Certification Co., Ltd.

有害物质管理体系认证控制程序  
SOP for IECQ HSPM Certification Management

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# 有害物质管理体系认证 控制程序

SOP for IECQ HSPM Certification Management

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## 文件修改履历 Revision list

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A0	首版发布 First Published	2020.02.02	黄宏量 Richard Huang	周延冲 Civen zhou	
B0	根据 IECQ 评审结果, 不符合 NCR10/OBS, 进行修订部分内容; 策划了一套 IECQ HSPM 审核专用表单 According to feedback from IECQ Assessment (NCR10/OBS), revised the part of context, A set of dedicated forms are designed for IECQ HSPM Certification activity	2022.9.15	黄宏量 Richard Huang	周延冲 Civen zhou	

## 1 目的 purpose

在进行与 IECQ 相关的认证活动中, LQA 应严格遵守所有包括 IEC CA01, IECQ 01S, IECQ 02, IECQ 03-1, IECQ 03-2, IECQ 03-5, ISO/IEC17021-1, ISO 19011:2018 和相关的认可要求。

When conducting IECQ activities, LQA shall strictly comply with all applicable requirements. These are primarily defined in IECQ CA01, IECQ 01S, IECQ 02, IECQ 03-1, IECQ 03-2, IECQ 03-5, ISO/IEC17021-1, ISO 19011:2018 and associated IAF and/or CNAS Mandatory documents.

本文件旨在为有害物质过程管理体系 (IECQ HSPM 方案) 认证注册的申请、获得和保持提供指导。本文件的内容是 LQA 有关认证注册的规定中的公开部分, 请申请组织仔细阅读并遵照执行。

The purpose of this document is to provide guidance for the application, acquisition and maintenance of certification and registration of the Hazardous Substances Process Management (IECQ HSPM Scheme). The content of this document is a public part of LQA rules regarding certification activities, which should be carefully read and complied with by the applicant organization.

## 2 适用范围 Scope

适用于对有害物质过程管理体系的认证注册的申请、获得和保持。

This SOP is applied to application, acquisition and maintenance of certification and registration of IECQ HSPM.

## 3 职责 Responsibilities

3.1 业务部负责收集申请组织的资料;

Marketing dept is responsible for collecting the information of the application organization,

3.2 审核部负责合同评审, 特别是技术方面的评审、审核活动的策划、管理和实施;

Audit Dept is responsible for contract review, particular the technical aspect, planning and management of the audit activities

3.3 审核组长负责实施现场和/或非现场审核, 编制审核计划和审核报告, 对不符合项进行跟踪和验证;

The audit team leader is responsible for implementation of on-site and/or off-site audit, preparing an audit plan and audit report, tracking and verification of non-conformity

3.4 技术部负责现场审核流程完成后的技术评审和认证决策。

Technical Dept is responsible for the technical review and making certification decision after the completion of the

on-site audit process.

### 3.5 总经理或其授权人负责批准和颁发证书

GM or their authorized person is responsible for the approval and issuing the certificate

## 4 审核依据、申请组织 Audit Criteria, and Applicant

### 4.1 审核依据 Audit Specifications

#### 4.1.1 IECQ QC 080000 有害物质过程管理体系要求;

IECQ QC 080000 Hazardous Substance Process Management System Requirements (IECQ HSPM)

#### 4.1.2 IECQ QC 080000 的附件 A 和附件 B,

即欧盟 RoHS 指令及其已发布的修订本, 和/或中国 RoHS 2。

Annex A and Annex B of IECQ QC 080000, i.e., EU RoHS Directive and its published amendments, and/or China RoHS 2.

#### 4.1.3 客户指定的要求

Customer specific requirements

### 4.2 申请组织 Applicant/organization/client

#### 4.2.1 申请认证注册的组织应具备以下条件:

The applicant should meet the following conditions:

4.2.2 申请组织应是电工组件产品的制造商、供方、修理方、维护方和服务提供方（及其供应链）。组织应该是一个有独立责任的法人，或者经法人授权；

The applicant shall be a manufacturers, suppliers, repairers, maintainers and service providers (and their supply chain) of electrotechnical component products.

This applicant shall be a legal entity or an authorized organization with independent responsibilities.

4.2.3 申请组织应建立并实施了 ISO 9001 质量管理体系或者等同的质量管理体系；

The applicant shall have developed and implemented an ISO 9001 quality management system (QMS) or equivalent QMS.

### 4.3 申请组织的职责 The responsibilities of the applicant

#### 4.3.1 申请组织应承担 IECQ 03 -1 第 7.2.3 款规定以及以下职责:

The applicant shall have the responsibilities, specified in Sub clause 7.2.3 of IECQ 03 -1 and the following.

a) 组织应按照 IECQ QC 080000 的要求保持并记录质量管理体系, 其中包含 IECQ 03-1 中的“IECQ 质量管理体系要求”, 并在认证机构为认证目的的要求时提供该文件化质量管理体系的副本;

The applicant shall maintain and document a QMS in accordance with the requirements of IECQ QC 080000 which encompasses the requirements of “IECQ Quality Management System requirements” IECQ 03-1 and make available copies of that documented QMS should the IECQ CB require it for certification purposes.

b) 组织应指定具备 IECQ QC 080000 中要求的技术能力的管理者代表,其职责应符合 IECQ03-1 的要求;

The applicant shall nominate a Designated Management Representative (DMR) with demonstrated technical competence as defined in IECQ QC 080000 Specification, and responsibilities as defined in IECQ 03-1.

c) 组织应实施并保持有资格的内审员, 并保持资格和持续再确认的记录。

The applicant shall implement and maintain qualified internal auditors and maintain records of qualification and on-going re-qualification.

d) 申请组织的内审员资格:

The applicant internal auditor qualifications of an applicant

参加并成功的通过了质量管理体系内审员课程

shall have attended and successfully passed a QMS internal auditor course.

参加并成功的通过了 IECQ HSPM 内审员课程或者内审员能力要求

shall have attended and successfully passed an IECQ HSPM internal auditor training course or performance of internal auditor.

#### 4.3.2 组织应始终符合 IECQ 体系和 IECQ HSPM 方案的要求;

The applicant shall at all times comply with the requirements of the IECQ System and IECQ HSPM Scheme(s);

4.3.3 组织应授予认证机构的代表在正常工作时间内进入其认证范围内正在进行工作的场所和/或场所, 以审查系统、过程、测试方法和记录。必要时, 这些访问权应包括为核实终止认证的程序所需的任何商定的访问。

The applicant shall give the representatives of the IECQ CB access, during normal working hours, to the premises and/or sites in which work being performed within the scope of their certification is being carried out for the purpose of examining systems, processes, methods of test, and records. These access rights shall include, where necessary, any agreed visits needed to verify that the procedures for the termination of certification have been carried out.

#### 4.3.4 组织应促进认证机构任何就影响认证范围的操作方面对其供应商进行评估的安排;

The applicant shall facilitate any arrangement allowing the IECQ CB to conduct assessment at the supplier upon aspects of operations having influence on the scope of certification;

#### 4.3.5 申请组织需承诺按时缴纳规定的费用;

The applicant must undertake to pay the fees as determined by the content of the application on time.

#### 4.3.6 当 IECQ 证书终止或中止时, 组织应立即停止在所有材料上使用 IECQ 标志, 并不得做出或暗示任何 IECQ 认证或批准的声明。

When the status of IECQ Certificate is on the termination or suspension, this applicant shall immediately discontinue the use of the IECQ logo on any materials and refrain from making or implying any statement of IECQ certification or approval. No further release under IECQ can take place.

### 4.4 申请认证所需资料: Application Material

4.4.1 当组织充分理解 LQA 的认证要求后可提交《管理体系认证申请书》, SLQA 初步了解申请组织的情况并对申请书进行评审, 评审后决定是否受理该组织的认证申请。如果通过申请评审双方将签订认证合同, 如果 LQA 拒绝了组织的认证申请则告知组织拒绝的理由;

After the applicant (Client) has fully understood the LQA rules related to certification registration and submitted the "Application for management System Certification" to LQA, LQA will decide whether to accept the application through review. If LQA is unable to accept the organization's application for certification, LQA shall provide the organization with reasons for its refusal.

#### 4.4.2 申请应至少包含以下内容:

The application submitted by the applicant shall indicate as a minimum the following:

##### a) 准确识别申请认证的预期活动范围;

Accurately identifying the intended scope of activity for which certification is applied for;

##### b) 组织开展活动的各场所的详细信息;

The full details of the location(s) where the organization conducts its activities;

c) 寻求批准的组织应提交或提供下列文件（非详尽的）供审核组评审；

The applicant seeking approval shall submit or make available the following documentation (non-exhaustive) for review by the assessment team:

- ⚙ 有害物质管理手册 Hazardous Substances Management Manual;
- ⚙ 管理评审程序 Management Review Procedure;
- ⚙ 内部审核程序 Internal Assessment Procedure;
- ⚙ 纠正和改进程序 Corrective/Improvement Action Procedure;
- ⚙ 涵盖 ISO 9001 或同等质量管理体系的所有条款的审核报告和/或审核计划(适用时)。  
Registration report(s) covering all Clauses of ISO 9001 or equivalent QMS, and/or audit plan When applicable;
- ⚙ 有害物质控制清单; Master list of HS
- ⚙ 其它必要的 HSPM 控制文件; HSPM documented requirements

文件应该以纸质或者电子格式提供，电子格式应如 PDF,JPG 的文件格式。

The provided documentation shall be in paper or electronic. The electronic format could be in PDF or jpg.

## 5 IECQ HSPM 认证流程 IECQ HSPM Certification procedure

### 5.1 一阶段审核 Stage 1 examination

5.1.1 为验证组织是否符合 IECQ QC 080000 的适用要求，应在现场或非现场对文件和过程进行第一阶段的审核。

A Stage 1 examination of the documentation and processes to verify the organization's compliance with the applicable requirements of IECQ QC 080000 shall be conducted on site or off site.

5.1.2 下列情况，一阶段必须在客户现场进行

The stage 1 examination shall be carried out on site where the following situation exists,

a) 客户是多场所或者有临时场所，客户的产品或者服务过程复杂；

There are multiple sites or temporary sites and the customer's product / service scope is complex;

b) 组织的规模较大，且组织结构复杂（大于 1000 人）；

The size of the organization is Large (more than 1000 employees) and with complex organizational structure;

c) 客户不允许提供体系文件以供评审;

Due to the management requirements of customers, relevant system documents are not allowed to be provided, and such documents have a great impact on the second-stage audit

### 5.1.3 第一阶段应对以下内容进行审核:

The stage 1 shall include the follows

a) 审核管理体系文件,并初步确认企业实际情况是否与管理体系文件描述一致,需形成《HSPM 体系文件审核报告》;

Review the management system documents, and preliminarily confirm whether the actual situation of the client is consistent with the description of the management system documents. The CRF shall be generated and formed;

b) 确认受审组织已获得 ISO9001 或等效质量管理体系证书,并在有效期限内;

Confirm that the organization has obtained the certificate of ISO9001 or equivalent quality management system, and within the valid period;

c) 确认受审组织有害物质管理体系运行超过 3 个月以上;

Confirm that the organization under trial run has operated its hazardous substances management system for more than 3 months;

d) 审核管理体系覆盖的活动内容和范围、员工人数、活动过程和场所等必要信息,体系是否完整识别了相关的过程和有害物质信息,以及相关的法律法规要求和遵守情况;

Review the content and scope of activities covered by the management system, the number of employees, the activity process and locations and other necessary information, whether the system has fully identified the relevant process and hazardous substance information, as well as the conformity of relevant laws and regulations requirements;

e) 审查第二阶段审核所需资源的配置情况,与客户商定第二阶段审核的细节。

Review the allocation of resources required for the stage 2 and negotiate with the client on the details of the second stage audit.

f) 审查客户持有的 ISO9001 的审核报告,并寻找符合所有要求的证据以及没有未关闭的不符合项。

Review the ISO9001 audit report of the client, look for evidence of compliance with all requirements and verify no Non-Conformity is open.



## 5.2 第二阶段审核(现场) Stage 2 Audit (on-site)

当一阶段识别的问题项已经解决, 第二阶段审核才可以启动。第二阶段审核应到客户现场进行并覆盖以下方面:

Where the non-conformities identified during stage 1 have been solved, the stage 2 audit will be conducted on the site and cover the following aspects:

5.2.1 与适用的管理标准或其他规范性文件的所有要求的符合情况及证据,IECQ QC 080000 的附录 A 和附录 B;

Evidence of compliance with all requirements of applicable standards or other regulatory documents, such as Annexes A and B of IECQ QC 080000;

5.2.2 根据客户的关键绩效目标和与 HSF 要求相关的指标, 进行监控、测量、报告和审查绩效;

Monitor, measure, report and review the performance according to the customer's key performance objectives and indicators relevant to HSF requirements;

5.2.3 客户对产品以及生产过程中有害物质的管控情况,以及对所有相关运营过程的 HS 控制;

Control of the hazardous substances in the products and in the production process, as well as HS control on all relevant operation processes

5.2.4 内审和管理评审;

Internal audit and management review

5.2.5 针对 HS 方针和 HSF 目标的管理职责;

Responsibility assigned for HSF policy and HSF objectives management

5.2.6 管理体系过程之间的控制关系。

The control between the process of the management system.

5.2.7 现场审核时, 客户最高管理者和管理者代表、体系涉及的部门负责人均应出席首次会议和末次会议;

The top management, the DMR and department leader involved in shall attend the opening meeting and closing meeting during the stage 2 on site audit

5.2.8 在现场审核中, 客户应允许审核员无限制地接触与所申请注册范围有关的业务、场所和文件, 并为审核组提供办公场所。涉及多场所的项目, 审核应覆盖每个场所;

During the on-site audit, the client shall allow the auditor to have unlimited access to the business, site and documents related to the scope of registration applied for, and provide office space for the audit team. For projects involving multiple sites, the audit should cover each site;

5.2.9 IECQ HSPM 审核组观察可能被认为对受审组织有用改机机会/观察项, 可以在审核过程中口头提出, 不应作为结果或评论写在 IECQ HSPM 报告或后续跟踪事项中。这种口头提供的意见也不可以在末次会议上提供或提出。

While there may be occasions where an observation may be deemed useful to the company such observations may be given verbally throughout the assessment but shall not be included as a result or commentary within the IECQ HSPM report or the assessor's assessment trail(s). Such verbally provided observations shall not be given or presented at the closing meeting.

5.2.10 当审核员记录到了体系运行与相关标准或与该组织体系文件有不符合时, 组织应立即制订纠正措施计划, 并按计划实施。在 30 日内向 LQA (通过审核组长) 提交该计划已实施完成的书面证明材料。如果审核组认为书面验证有困难, 或有严重不符合时, 有可能要求现场验证并延长整改时间, 但延长的时间一般不超过 3 个月。

When the auditor raised a non-conformity against the relevant standards or the organization's system documents, the organization shall immediately develop a corrective action plan and implement it as planned. Objective evidence of plan implementation shall be submitted to LQA audit team leader within 30 days. If the audit team believes that the off-site verification through a written documents is difficult, or there is a major nonconformity, it may require an on-site verification and extend the rectification time, but the extended time is generally not more than 3 months.

5.2.11 现场审核结束, 审核组提交审核报告, 包括现场审核报告和/或文件审核报告, 组织为证明不合格项已得到纠正的资料)

After the completion of on-site audit process, the audit team will submit audit report and other evidence, including SAR and/or CFR, and the materials that the organization has demonstrated that the nonconformity has been completely corrected.

5.3 在做出审核决定前, 机构应对对审核报告和不符合纠正计划及其整改情况进行技术评审。Before certification decision make, a technical review on the audit report and corrective plan and corrective evidence of NCR shall be conducted.

5.4 在审查资料后, 由认证决定人员作出认证决定, 此决定有三种可能的结果:

After the technical review, LQA makes final decision on certification by certification decision maker. There are three possible outcomes of this decision:

a) 给予认证;

Granting certification;

b) 在补充材料或补充审核后, 给予认证;

Need further materials or supplementary audit, and Granting certification;

c) 拒绝认证。

Refusing certification

技术评审和认证决定人员不能是参与审核的人员

Both technical reviewer and certification decision maker are different from those who carried out the audits

5.5 机构将告知客户最终的认证决定和决定理由，特别是拒绝认证的理由。被认证的客户应理解到认证决定的结果最终取决于客户提供的或通过审核组提供的证明材料，LQA 做出的认证决定是客观的、公正的。

LQA will notice the client about the result and reason of certification decision, specially for refusing certification, The client shall understand that the result of the certification decision is ultimately dependent on the evidence provided by the client or through the audit team, and that the certification decision made by LQA is objective and impartiality.

## 6 认证注册 Granting of certification;

6.1 认证决定作出后，LQA 会在 IECQ/CNCA 官网上向社会发布客户的注册情况，将获证客户列入注册名单。同时向客户发放正式的认证证书。但获证客户应注意，如果审核的相关费用未交清，将会影响证书的发放。

LQA will Register in the IECQ's online system and CNCA online system after the technical review, and issue the certificate to client. However, the client must note that if the fees are not paid, it will affect the release of the certificate.

6.2 LQA 向获证客户发放的证书上有组织的名称、地址和认证范围（包含企业的经营业务范围以及所认证的有害物质法规/指令的范围）、注册日期、有效期（证书有效期一般为三年）和证书编号。证书上还将有相应的认可标志。证书是 LQA 的财产，在因任何原因终止注册时，证书持有者应依照 LQA 的要求予以归还。

The certificate issued by LQA shall include the name, address, scope of certification (Includes the scope of business activities of the client and the scope of certified hazardous substances regulations/directives), date of registration, validity period (the validity period of the certificate is generally three years) and certificate number of the organization. There will also be a corresponding Accreditation mark on the certificate. Certificates are the property of LQA and, in the event of cancellation for any reason, the holder shall return per requested by LQA

6.3 证书是客户根据 IECQ HSPM 方案的技术和质量体系要求和适用的法规标准，识别和控制引入有害物质（HS）的实施过程的认证。客户可以向其客户展示 IECQ 合格证书，包括 IECQ 和 LQA 的标志获得他们的信任，但不得将 IECQ 合格证书或 IECQ 和/或 LQA 的标志使用在产品上或暗示客户产品已经经过认证。IECQ 合格证书上的 IECQ 和 LQA 标识有不同的使用规定。客户应根据 IECQ 01A

和莱标公司的程序规定的要求, 正确使用 IECQ 和/或 LQA 的证书和标识

Certificate is the certification of the client's implemented processes to identify and control the introduction of hazardous substances (HS) into its products in accordance with the technical and quality system requirements of the IECQ HSPM Scheme and applicable legislative criteria. Clients may show the IECQ Certificate of Conformity that includes the logos of both IECQ and LQA to their customers to gain their trust, however but shall not use the IECQ Certificate of Conformity or the logos of IECQ and/or LQA on the product or imply to customers that the product has been certified. The IECQ and LQA logos on the IECQ Certificate of Conformity have different regulations on the use of them. The client shall use the certificate and the logos of IECQ and/or LQA correctly according to the applicable requirements of IECQ 01A and LQA "SOP for the Use of Certification and Registration Marks.

6.4 一旦 LQA 通知 IECQ 认证组织暂停或取消 IECQ 认证, 认证组织应不再将其组织描述为“IECQ 认证”, 也不得在任何地方使用 IECQ 认证细节、IECQ 合格证书或 IECQ 和/或 LQA 的标志, 包括在已交付/提供的产品/服务, 合格声明 (DoC) 或自我合格声明 (SDoC), 继续使用将承担相应的法律责任。

Once LQA notifies the suspension or cancellation of an IECQ Certified organization, the IECQ certified organization shall no longer describe their organization as “IECQ Certified”, nor shall they use the IECQ Certification details, the IECQ Certificate of Conformity or the logos of IECQ and/or LQA in any places, including any declaration of conformity (DoC) or self-declaration of conformity (SDoC) of dispatched/provided products/services and shall bear the corresponding legal liability for its continued use.

## 7 监督审核 Surveillance

监督审核为现场审核

The surveillance shall be conducted on site.

7.1 在证书有效期内获证组织为保持注册资格, 必须满足以下条件:

In order to remain the registration during the validity period of the certificate, the certified organization must meet the following.

7.2 监督审核不得超过每年 (间隔 12 个月-至少一个日历年), 初始认证后的第一次监督审核不得超过认证决定日起的 12 个月 (主场所的认证决定日期为所有场所的永久认证周期日期)。监督审计应产生符合或不符合 IECQ HSPM 方案和审核标准的结果。该组织持有的 IECQ 证书的每个场所都需要每年对所有有害物质管理流程和 IECQ QC 080000 的相关条款进行监督评估, 不允许对流程或场所进行抽样。

Surveillance audits shall not be greater than annually (12 months apart - at least once a calendar year), with the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date

(the certification decision date of the Master site forms the permanent certification cycle date for all sites). Surveillance audits should produce the results of either complying or not complying with the IECQ HSPM Scheme and the audit criteria. Each location of the IECQ Certification held by the organization will require a surveillance assessment to all IECQ HSPM processes and relevant clauses of IECQ QC 080000 annually, no process or location sampling allowed.

#### 7.2.1 合同约定的金额应付监督审核费用和年金费用。

The surveillance audit fee and annuity fee shall be paid in accordance with the Contract.

#### 7.2.2 监督审核应包括所有的有害物质体系管理过程，尤其包括以下内容：

Surveillance audits shall include all processes of IECQ HSPM system of the organization, particularly focusing on the following contents:

- a) 内审和管理评审； Internal audit and the management review
- b) 对上次审核中确定的不符合采取的措施； Effectiveness verification of the corrective action of the NCR(s) during the previous audits
- c) 投诉的处理； Complain and appeals
- d) 管理体系实现目标的有效性 The effectiveness of the HSF objectives of management system
- e) 持续改进活动的进展； Continuous improvement
- f) 基于风险的思维,与 HSF 符合性相关的核心过程的策划和实施；  
Risk-based thinking in the planning and implementing the core processes relevant to HSF conformity
- g) 最高管理人员和过程控制其关键作用人员的 HSF 意识；  
HSF awareness of top management and key personnel in the processes;
- h) 产品和过程中的 HS 控制，以及所有相关操作过程中的 HS 控制；  
The HS control of products and the process as well as HS control in all relevant operation processes;
- i) 管理体系变更情况； The changes of management system
- j) IECQ 和 LQA 认证标志的使用。 The use of IECQ logo and LQA logo

当现场监督审核完成后，审核组长给出积极正面荐结果。审核文件包应进行独立的技术审查，并根据审查的结论和正面推荐结果，最终决定是否维持认证。LQA 将以书面（或电子邮件）通知客户继续认证的决定

Where the on-site surveillance audit process is completed, and the audit team leader has made a positive recommendation. The audit package shall undergo independent technical review with the final decision on maintaining the certification based on the conclusion of the review and a positive recommendation. LQA will notify the client in writing (or email) on the decision of continued certification

## 8 再认证 Re-certification

8.1 IECQ 的证书需要每三年更新一次, 除非执行 IECQ 基本规则和程序规则中规定的终止权利。如果组织不打算更新其认证证书, 应在到期前不少于 60 天以书面形式通知认证机构。

IECQ Certificates shall be renewed at least once every three years, unless the termination rights provided for in the IECQ Basic Rules and Rules of Procedure are exercised. If an organization does not intend to renew its certification, it shall notify the IECQ CB in writing of its intentions not less than 60 days prior to its renewal date.

8.2 每三年更新 IECQ 认证/批准的条件是成功的再认证审核和所有策划的监督审核已成功完成。

Renewal of the IECQ Certification / Approval at the three year interval shall be on the condition of a successful re-certification audit and that all scheduled surveillance assessments have been successfully completed.

8.3 再认证审核的目的是确认实施的过程和程序整体上与 IECQ HSPM 方案要求的持续符合性和有效性, 以及其对认证范围的持续相关性和适用性

The purpose of the re-certification audit is to confirm the continued conformity and effectiveness of the implemented processes and procedures to the IECQ HSPM Scheme requirements as a whole, and its continued relevance and applicability for the scope of certification

8.4 当管理体系或实施的过程和程序发生重大变化时, 再认证审核活动可能需要进行详细的文件评审(第一阶段审核), 客户、或管理体系或实施的过程和程序运行的环境(例如, 立法的变更)。

Re-certification audit activities may need to have a detailed document review (stage 1 audit) in situations where there have been significant changes to the management system or implemented processes and procedures, the client, or the context in which the management system or the implemented processes and procedures are operating (e.g. changes to legislation).

8.5 再认证审核需覆盖所有场所

All sites covered by the IECQ Certification / Approval shall be assessed

8.6 再认证审核需到客户现场进行, 审核内容主要包括:

The re-certificate assessment shall be carried out on site, the audit team shall review as follows

8.6.1 根据认证客户管理体系符合性及内部和外部的变更情况, 通过对客户绩效数据分析, 内审, 管理评审等信息的评价, 了解客户的管理体系有效性保持。

According to the compliance of the certification, client management system and internal and external changes, through the client performance data analysis, internal audit, management review and other information evaluation, to understand the effectiveness of the client management system maintenance.

### 8.6.2 客户在经历各种变更后, 管理体系是否能完全覆盖认证范围。

Whether the HSPM system can fully cover the scope of certification after various changes relevant to the HSF conformity having been undergone by the client.

### 8.6.3 了解客户管理体系的方针, 目标和绩效数据, 是否促进了客户方针, 目标的实现。了解客户的 HSPM 体系的 HSF 方针、HSF 目标和绩效数据, 以及它们是否促进 HSF 符合性的达成。

Understand the HSF policy, HSF objectives and performance data of the client's HSPM system, and whether they contribute to the achievement of HSF conformity.

### 8.6.4 再认证审核发现的不符合, 客户应采取有效的纠正和纠正措施, 在规定的时间内提供客观证据给 LQA 的审核组长, 进行验证。

If the non-conformance is found through recertification audit, the client shall take effective correction and corrective actions and provide objective evidence to LQA audit leader for verification within the specified and agreed time frame.

### 8.6.5 审核组长负责提交审核包进行技术审核, 然后提交技术委员会进行认证更新决定。

The audit team leader is responsible for submitting the audit package for technical review and then to the technical committee for certification renewal decision.

## 9 特殊审核 Special Surveillance

### 9.1 有下列情况时应对客户实施特殊的监督审核

A special surveillance audit shall be conducted by LQA in situations where:

- a) 认证组织搬迁  
a certified organization (client) has relocated
- B) 认证组织已被其他组织接管或收购, 可能导致人员、管理和/或管理体系程序的变化;  
a certified organization (client) has been taken over or acquired by another organization which may have impacted or resulted in changes to personnel, management structure and/or HSPM system procedures;
- c) 认证组织(客户)变更其管代。LQA 应评估新的 DMR 的技术和行政能力, 以确定是否要进行特别的现场审核。  
a certified organization (client) changes its DMR. LQA will assess the technical and administrative competence of the new DMR to determine if a special on-site audit is to be conducted.
- d) LQA 有正当理由关注认证组织是否持续符合 IECQ 的相关要求。  
LQA has just cause for concern regarding a certified organization (client) continued compliance with the

requirements of IECQ HSPM Scheme..

## 9.2 较短时间通知客户的审核

### Short-notice audit

对于以下几种情况, LQA 可能需要在较短时间内通知客户,安排一次特殊审核:

LQA may need to notify the client at short notice to arrange a special visit as follows

a) 对投诉进行调查

Investigation for appeals

b) 对认证资格被暂停的认证组织进行追踪。

Tracking certified organizations (clients) whose IECQ Certification has been suspended.

## 10 证书的转换 Transfer of IECQ HSPM Certificate of Conformity

当莱标收到 IECQ 证书的持有者希望将自己的“有效”证书转入时,应符合以下要求:

Where LQA receives a desire/request from an IECQ Certified Organization (that holds “Current” status IECQ Certification) to transfer from their present Certificate issuing IECQ CB to LQA, the following shall apply:

10.1 证书持有者应该按照 IECQ03-01 的 9.2 和 9.3 的要求向新的认证机构提出正式的认证申请;

Formal application shall be submitted by the applicant client to LQA in accordance with IECQ 03-1 9.2 & 9.3

10.2 收到申请的 IECQ 认证机构应从客户处获得最新的 IECQ 监督审核报告,并进行正式的技术评审,以确保没有未关闭的不符合项;

LQA shall request and receive from the applicant client a full copy of the latest IECQ HSPM surveillance assessment report (CRF & SAR) and the previous IECQ HSPM re-certification assessment report (CRF & SAR) along with full details of any raised NCR's, and conduct a formal technical review, ensuring there are no outstanding NCRs.

10.3 如果对最近的 IECQ HSPM 监督审核报告 (CRF&和 SAR)和先前的 IECQ HSPM 再认证评估报告 (CRF&SAR)的技术审查确认完全符合 IECQ HSPM 方案和审核标准,且没有未完成的 NCR,则可签发一份新的 IECQ 认证证书,涵盖审核报告中列出的相同标准、活动范围和现场,而无需进行现场审核。

Where the technical review of the latest IECQ HSPM surveillance assessment report (CRF & SAR) and the previous IECQ HSPM re-certification assessment report (CRF & SAR) confirms full compliance with the IECQ HSPM Scheme and scope criteria and no outstanding NCRs, then a new IECQ Certification maybe issued covering the exact same criteria, scope of activity and site(s) listed in the assessment reports without the need for a site visit.

LQA 颁发的 IECQ 证书应与之前颁发的 IECQ 认证 (证书) 的效期范围和有效期相一致,即“原始发行”和“效期”应与之前持有的 IECQ 证书相匹配。此外,如果作为 IECQ 认证的一部分存在分现场证



书, 则“添加分现场证书”的日期应与之前持有的 IECQ 认证附加现场证书相匹配。

The LQA issued IECQ Certificate shall line up with the time frame of the previous issued IECQ Certification (certificate(s)) for the next surveillance audit and expiration date, i.e., the “Original Issue” and “Expiration” shall match that of the previous held IECQ Certification. Additionally, where Additional Site Certificates exist as part of the IECQ Certification the “Site Added” dates shall match that of the previous held IECQ Certification Additional Site Certificate

10.4 如果在技术评审时发现未被关闭的不符合项, 则应该在签发新的证书之前, 关闭不符合, 可能需要根据不符合的严重程度实施现场审核

Where at the end of the technical review of the latest surveillance assessment report NCRs are revealed these shall be closed prior to the issuing of a new Certificate. This may require a site visit depending on the severity of the NCRs

## 11 暂停、撤销 Suspension and cancellation

11.1 如果出现以下情况, HSPM 证书将被 LQA 撤销:

An IECQ HSPM Certificate may be cancelled by LQA if:

- a) 未支付应付费用; There is non-payment of outstanding fees;
- b) 证书发布存在错误; It has been issued in error;
- c) 证书持有者申请撤销; The holder requests cancellation;
- d) 当有误导性的使用证书时, 如果企业不能在 LQA 提出整改要求后 2 周内实行这方面的整改措施, IECQ 证书应被撤销;

It is used in a misleading way, the IECQ Certificate shall be cancelled if the Organization fails to take corrective action in this respect within 2 weeks of being requested to do so by LQA;

- e) IECQ 获证组织不再符合 IECQ 体系的要求;

The IECQ Certified Organization no longer complies with the requirements of IECQ HSPM Scheme;

f) IECQ 获证组织的质量体系, 相关的程序或过程不再能提供充足的信心去证实他们的活动范围可以符合 IECQ HSPM 方案规定的要求。

The IECQ Organization’s quality system, associated procedures or processes no longer provide adequate confidence that their scope of activities can be conducted in accordance with requirements of IECQ HSPM Scheme

11.2 当 IECQ 证书被取消时, LQA 到 IECQ 系统的代表应尽快通知 IECQ 秘书, 而 LQA 证书管理责任人应根据 IECQ OD 015 在 IECQ 在线证书系统中记录证书变化状态。

When an IECQ Certificate has been cancelled, the LQA representative to IECQ System shall notify the IECQ Secretary as

soon as possible and the personnel in charge shall record the status change in the IECQ on-line Certificate System in accordance with IECQ OD 015.

## 12 证书的暂停 Suspension

12.1 如果有理由认为基于以上所示的原因对 IECQ 证书所进行的撤销只是暂时的, 并且证明他们在短暂的延迟后可以采取改进措施, 则此 IECQ 证书应被 LQA 暂停。一般情况下, 暂停期限不得超过 1 个月。

The IECQ certificate shall be suspended by LQA if there is reason to believe that the cancellation of the IECQ certificate for the reasons set out in 11 above is only temporary and that they can be improved after a short delay. In general, the suspension period shall not exceed one month.

12.2 LQA 应给 IECQ 证书获证企业发出适当的关于暂停的通知, 并应给出理由。

LQA shall give suspension notice to the IECQ Certificated Organization with reason(s).

12.3 当 IECQ 认证被取消或暂停时, 认证组织不得再将其描述为“IECQ 认证”, 也不得在任何地方使用 IECQ 证书细节、IECQ 合格证书或 IECQ 和/或 LQA 的标志, 包括已交付/提供的产品/服务的合格申明 (DoC) 或自我合格申明 (SDoC)。应尽快完成相应的改进措施。

When an IECQ Certification has been cancelled or suspended, the IECQ certified organization shall no longer describe their organization as “IECQ Certified”, nor shall they use the IECQ Certification details, the IECQ Certificate of Conformity or the logos of IECQ and/or LQA in any places, including any declaration of conformity (DoC) or self-declaration of conformity (SDoC) of dispatched/provided products/services. The corresponding improvement measures should be completed as soon as possible..

## 13 申投诉 Appeals and complaints

13.1 包括获证组织在内的任何 LQA 的利益相关方, 都有权在任何认证阶段对 LQA 的决定提出申诉或投诉。

Any interested party of LQA, including the certified organization, has the right to file an appeal or complaint against the LQA decision at each stage of certification process.

13.2 当获证组织对认证决定有异议时, 本机构接受获证组织的申诉, 并按规定的流程或程序进行处理、并及时进行处理, 在 60 日内将处理结果形成书面通知送交获证组织。

If any client has any appeal to the certification decision, LQA accepts it and timely deal with it per a defined process or procedures, and will send back the written results to this client within 60 days.

13.3 若申诉人认为 LQA 机构未遵守认证相关法律法规或认证规则, 可以向 IECQ MC、国家认监委, 甚至升级至 IEC CAB。

If the appellant considers that LQA fails to comply with the relevant certification laws and regulations or certification rules, it may complain with the IECQ MC, CNCA and if required escalate this matter to IEC CAB.

13.4 在现场审核期间, LQA 审核员/员工将通知客户关于申投诉的流程。申投诉渠道包括:

LQA auditors/ personnel are responsible for informing the clients of the appeal process during the on-site audits.

Below are the communication paths:

LQA <http://www.lqa-cert.com/> Email: [info@lqa-cert.com](mailto:info@lqa-cert.com)

IECQ <https://www.iecq.org/> Email: [info@iecq.org](mailto:info@iecq.org)

CNCA <http://www.cnca.gov.cn/>

发生的费用由申诉方预先支付, 最后按实际责任比例进行摊销。具体操作见《LQAP007 投诉、申诉控制程序》

The expense estimate shall be paid in advance, and finally amortized in proportion to the actual liability. Details refer to the SOP - Complaint and Appeal Procedure

## 附录 A 相关记录 Record or Report

序号 SN	表格编号+版本号 Form No (w/ Version No)	中文记录名 Record name in Chinese	英文记录名 Record name in Chinese
1	LQA-JL-17-01-01	IECQ HSPM 认证申请表	IECQ HSPM Certification Application
2	LQA-JL-17-02-01	IECQ HSPM 体系分场所信息表	IECQ HSPM Multi-sites information Sheet
3	LQA-JL-17-03-01	IECQ HSPM 体系认证申请评审单	IECQ HSPM Certification Application Review
4	LQA-JL-17-04-01	IECQ HSPM 认证组织信息变更通报表	IECQ HSPM Certified Organization notification
5	LQA-JL-17-05-01	管理体系认证合同	Certification Contract
6	LQA-JL-17-06-01	IECQ HSPM 审核方案策划管理表	IECQ HSPM Audit Programme Planning and Managing
7	LQA-JL-17-07-01	IECQ HSPM 审核通知	IECQ HSPM Audit Notice to Client
8	LQA-JL-17-08-01	IECQ HSPM 审核委托书	IECQ HSPM Audit Assignment Letter
9	LQA-JL-17-09-01	IECQ HSPM 证书确认函	IECQ HSPM Certificate Confirmation Letter
10	LQA-JL-17-10-01	IECQ HSPM 审核计划	IECQ HSPM Audit Plan
11	LQA-JL-17-11-01	IECQ HSPM 专业引导培训记录	Technical guided training records for IECQ HSPM Audit

12	LQA-JL-17-12-01	公正性声明及保密承诺 (IECQ HSPM)	Impartiality statement and confidentiality commitment(IECQ HSPM)
13	LQA-JL-17-13-01	IECQ HSPM 会议记录单	Minutes of meetings (IECQ HSPM)
14	LQA-JL-17-14-01	首末次会议签到表(IECQ HSPM)	Opening/Closing Meeting Attendance Sheet (IECQ HSPM)
15	LQA-JL-17-15-01	IECQ HSPM 检查表	IECQ HSPM Checklist
16	LQA-JL-17-16-01	IECQ HSPM 不符合报告	IECQ HSPM Nonconformity Report
17	LQA-JL-17-17-01	IECQ QC 080000 第一阶段报告 (CFR)	IECQ QC 080000 Compliance Report Form (CRF) Stage 1 Report
18	LQA-JL-17-18-01	IECQ HSPM 第二阶段审核报告 ( SAR )	Site Assessment Report (SAR) Stage 2
19	LQA-JL-17-19-01	IECQ HSPM 技术评审表	IECQ HSPM Technical Review form
20	LQA-JL-17-20-01	IECQ HSPM 认证决定评定表	IECQ HSPM Certification Decision Form
21	LQA-JL-17-21-01	IECQ HSPM 现场审核信息反馈表	Feedback form of IECQ HSPM on-site audit
22	LQA-JL-17-22-01	IECQ HSPM 审核方案调整确认表	IECQ HSPM Audit Scheme Change Approval Form

## 附录 B - IECQ HSM 审核人日- Man days

认证组织员工数 Certified entity number of employees	现场审核人日 Initial assessments on-site days	再认证现场审核日 Re-certification assessments on-site days	初次文件审核人日 再认证文件审核人日 Initial assessment document review days. Re-certification document review as necessary	年度监督审核 人日 Annual surveillance days
1 - 75	2	2	0.5	1.5
76 - 150	3	2.5	0.5	2
151 - 600	4	3	1	3
601 - 1 000	5	4	1	3
1 001 - 2 000	5	4.5	1	4
2 001 - 3 000	6	5	1	4
3 001 - 4 000	7	6	1	5
4 001 - 8 000	8	6.5	1	5
8 001 - 15 000	8	7	1	6
15 001 - 20 000	9	8	1	6

应根据每个组织机构/场所的员工人数确定审核所需的总人日，并且不得将所有场所的员工总数相加。

the total man days shall be determined based on the number of employees at each of organization's facility/location(s) and shall not combine the total number of employees for all sites.

以下所示时间的增加或减少可能会由于上述因素或以下因素的组合而发生变化，但不得超过 30%。报告中对以下所示时间的任何更改均应有正当理由

The increase or reduction in the times shown below may be altered due to the factors above or combinations of, but not by more than 30 %. Any change to the times shown below shall be justified in the report.

详见 IECQ 03-5 © IEC 2018 HSPM 规则 附录 A

detail refer to IECQ 03-5 © IEC 2018 Annex A