与有害物质过程管理体系认证实施规则

TZ 按照国际管理体系认证标准 ISO/IEC 17021-1 进行管理体系认证。本文件为认证过程中从申请到再认证所需的所有关键控制提供了一个框架。本文件旨在为有害物质过程管理体系（QC080000）认证注册的申请、获得和保持提供指导。本文件的内容是 STZ 有关认证注册的规定中的公开部分，请申请组织在申请前仔细阅读并遵照执行。

1. 认证申请
   1. 申请认证注册的组织应具备以下条件：
      1. 申请组织应该是一个有独立责任的法人，或者法人授权的设计者、制造商、供应商、修理者、或者产品的维护者；
      2. 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；
   2. 申请认证组织的职责：

The responsibilities

* + 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 organization shall have the responsibilities, specified in Sub clause 7.2.3 of IECQ 03 -1 and the following.

1. 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要求时提供该文件化质量管理体系的副本；

The organization 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.

1. 组织应指定具备 IECQ QC 080000 中要求的技术能力的管理者代表；

The organization shall nominate a Designated Management Representative (DMR) with demonstrated technical competence as defined in IECQ QC

080000 Specification.

1. 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 organization shall implement and maintain qualified internal auditors and maintain records of qualification and on-going requalification.

1. 组织的内审员资格：

The organization internal auditor qualifications

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 内审员课程或者研讨

Shall have attended and successfully passed an IECQ HSPM internal auditor training course or workshop.

* + 1. 组织应始终符合 IECQ 体系和方案的要求；

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

* + 1. 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 organization 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

* + 1. 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 organization 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；

* + 1. 申请组织需承诺按时缴纳规定的费用；

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

* + 1. 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。

The organization shall upon the termination or suspension of an IECQ certificate, immediately discontinue the use of the IECQ logo on all materials and refrain from making or implying any statement of IECQ certification or approval. No further release under IECQ can take place.

* 1. 申请认证所需资料：

Application Material

* + 1. 当组织充分理解 STZ 的认证规章后可提交 HSPM 申请书，STZ 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 STZ 拒绝了组织的认证申请则告知组织拒绝的理由；

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

* + 1. 申请应至少包含以下内容：

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

* + - 1. 准确识别申请认证的预期活动范围;

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

* + - 1. 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;

* + - 1. 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 organization seeking approval shall submit or make available the following documentation (non-exhaustive) for review by the assessment team:

* 质量手册

Quality 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 ISO/IEC 17025 认可报告(如果需要)。

Registration report(s) covering al l Clauses of ISO 9001 or equivalent QMS and/or ISO/IEC 17025 accreditation report (if required)；

文件应该以纸质或者电子格式提供，电子格式应提供常用的文件格式，如 PDF。

The documentation may be provided in paper form or electronic format. The electronic format shall be provided in a commonly used file format e.g. PDF.

1. IECQ HSPM 认证流程

IECQ HSPM Certification procedure

* 1. 一阶段

Stage 1

* + 1. 为验证组织是否符合 IECQ QC 080000 的适用要求，应在现场或场外对文件和过程进行第一阶段的审查。

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.

* + 1. 下列情况，一阶段必须在客户现场进行

The stage 1 shall be carry out on site where the following situation,

* + - 1. 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;

* + - 1. 组织的规模较大，且组织结构复杂（大于 1000 人）；

Large (more than 1000 employees) and complex organizational structure;

* + - 1. 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

* + 1. 第一阶段应对以下内容进行审核：

The stage 1 shall include the follows

* + - 1. 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《管理体系文件审核报告》；

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;

* + - 1. 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;

* + - 1. 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 has operated its hazardous substances management system for more than 3 months;

* + - 1. 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 relevant laws and regulations requirements and compliance;

* + - 1. 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.

* + - 1. 审查客户持有的 9001 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 audit report of 9001 held by the organization and look for evidence of that requirements are duly met and where no Non-Conformances remain outstanding

* 1. 第二阶段审核

Stage 2

当一阶段识别的薄弱项已经解决，可实施第二阶段审核，第二阶段审核应到客户现场进行并覆盖以下方面：

Where the weakness identified during stage 1 have been solved, the stage 2 audit shall be carried out on the site and cover the following aspects:

* + 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； Evidence of compliance with all requirements of applicable standards or other regulatory documents;
    2. 依据客户的关键绩效目标和指标，对绩效进行监视，测量，报告和评审情况； Monitor, measure, report and review the performance according to the customer's key performance objectives and indicators;
    3. 客户遵守法律法规的情况；

Compliance with the rules and regulations

* + 1. 客户对产品以及生产过程中有害物质的管控情况；

Control of the hazardous substances in the products and in the production

process;

* + 1. 内审和管理评审；

Internal audit and management review

* + 1. 针对客户方针的管理职责；

Responsible for the management of policies

* + 1. 管理体系相关因素之间的联系。

The connection between the relevant factors of the management system.

* + 1. 接受现场审核时客户最高管理者和管理者代表管理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 and the DMR shall attend the opening meeting and close meeting during the stage 2

* + 1. 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（保密除外）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 (except confidential) 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;

* + 1. 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 STZ（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 records a system operation that is not in conformity with the relevant standards or the organization's system documents, the organization shall immediately develop a corrective action plan and implement it as planned. Submit written proof that the plan has been implemented to STZ (pass leader) within 30 days. If the audit team believes that the written verification is difficult, or there is serious inconformity, it may require on-site verification and extend the rectification time, but the extended time is generally not more than 3 months.

* + 1. 现场审核结束，审核组会将一阶段和第二阶段审核资料（包括组织为证明不合格项已得到纠正的资料）上交 STZ。STZ 在审查资料后按程序作出认证决定，此决定有三种可能的结果：

At the end of the site audit, the audit team will submit audit files (including the materials that the organization has demonstrated that the nonconformance has been thoroughly corrected) to STZ .After technical review, STZ makes final decision on certification in accordance with the procedures. There are three

possible outcomes of this decision:

* + - 1. 给予认证注册；

Grant certification registration;

* + - 1. 在补充材料或补充审核后，给予认证注册；

After supplementary materials or supplementary audit, give certification registration;

* + - 1. 拒绝认证注册。

Refuse the registration

被认证审核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，STZ 做出的认证决定是客观的、公正的。

The organization audited shall understand that the outcome of the certification decision is ultimately dependent on the certification materials provided by the client or through the audit team, and that the certification decision made by STZ is objective and fair.

1. 认证注册

Grant certification registration;

* 1. 认证决定作出后，STZ 会在 IECQ 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。

STZ will register in the IECQ's online system after the technical review, the main while issue the certificate. However, the client should note that if the audit related fees are not paid, it will affect the issuance of the certificate.

* 1. STZ 向获证客户发放的证书上有组织的名称、地址和认证范围、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TZ 的财产，在因任何原因终止注册时，证书持有者应依照 STZ 的要求予以归还。

The certificate issued by STZ shall include the name, address, scope of certification, 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 recognition mark on the certificate. Certificates are the property of TZ and, in the event of cancellation of registration for any reason, certificate holders shall return them as requested by STZ.

* 1. 证书是获证客户的管理体系达到了认证标准要求的证明文件。获证客户可以将证书

连同标志向客户的顾客们展示以取得他们的信任，但获证客户不得将证书或标志用于产品上或暗示顾客该产品已通过了认证。证书上的 IECQ 及 TZ 两种标志在使用上还有不同的规定。获证客户应按 STZ《认证与注册标志使用说明》的具体要求正确使用。

Certificate is the certification of the client’ s management system to meet the requirements of the certification standards. Clients may display the certificate together with the logo to their customers to gain their trust, but shall not use the certificate or logo on the product or imply to customers that the product has been certified. The IECQ and TZ marks on the certificate have different regulations on the use of them. The client shall use the certification and registration marks correctly according to the specific requirements of STZ "Instructions for the Use of Certification and Registration Marks".

* 1. 一旦 STZ 通知暂停或撤销了组织的注册资格，组织即不得在任何场所使用证书和

标志，继续使用将承担相应的法律责任。

Once STZ notices to suspend or cancel the registration of the organization, the organization shall not use the certificate and mark in any place and shall bear the corresponding legal liability for its continued use.

1. 监督审核

Surveillance

监督审核为现场审核

The surveillance shall be conducted on site.

* 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 ，

* 1. 监督审核每年应进行一次，首次监督审核应在第二阶段最后一天起 12 月内进行。

监督审核应得出符合标准要求的结果；

The Surveillance audit shall be conducted once a year, and the first surveillance audit shall be conducted within 12 months from the last day of the stage 2 surveillance audit should be in line with the standard requirements of results;

* + 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.

* + 1. 监督审核应包括以下内容：

Surveillance audit shall include the following contents:

1. 内审和管理评审；

Internal audit and the management review

1. 对上次审核中确定的不符合采取的措施；

Verify the corrective action

1. 投诉的处理；

Complain and appeals

1. 管理体系实现目标的有效性

The effectiveness of the management system objective

1. 持续改进活动的进展；

Continuous improvement

1. 产品、生产过程有害物质管理等持续的运作控制；

The HS control of products and the production process

1. 管理体系变更情况；

The changes of management system

1. 认证标志的使用。

The logo and the marks

当客户完成现场的监督审核，依据监督组长给出正面结论，最终由认证决定进行技术评审后， 客户可以继续保持认证资格，STZ 会以书面（或者邮件）的方式通知客户。

When the client completes the on-site supervision and audit, based on the positive conclusion made by the supervisor, the final technical review is decided by the certification, the client can continue to maintain the certification qualification, and STZ will notify the client in writing (or email).

* 1. 若客户不能在规定期限内接受监督审核，IECQ 证书应被暂停，暂停期限不超过 6 个月， 期间若按要求完成监督则恢复证书，否则逾期撤销证书。

If the client can’t accept the surveillance audit within the specified period, the IECQ certificate shall be suspended. Suspension for failure to accept a surveillance visit shall not exceed six months, after which, the certificate shall be restored if all requirements have been met, or withdrawn.

1. 再认证

Re-certificate

* 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.

* 1. 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 recertification audit and that all scheduled surveillance assessments have been successfully completed.

* 1. 再认证审核的目的是确认实施的过程和程序整体上与 IECQ 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 recertification audit is to confirm the continued conformity and effectiveness of the implemented processes and procedures to the IECQ Scheme requirements as a whole, and its continued relevance and applicability for the scope of certification

* 1. 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)。

Recertification 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).

* 1. 再认证审核需覆盖所有场所

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

* 1. 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 carry out on site, the audit team shall review as follows

* + 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.

* + 1. 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 management system can fully cover the scope of certification after the client has undergoing changes.

* + 1. 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。

Understand the policies, objectives and performance data of the client management system, and whether they promote the realization of client policies and objectives.

* + 1. 通过再认证审核发现的不符合，客户应采取纠正和纠正措施并提供依据。在规

定的时间提供给 STZ（审核组长）验证。

If the non-conformance is found through recertification audit, the client shall take corrective actions and provide evidence. Provide to STZ for verification within the specified time.

* + 1. 审核组长负责将审核资料交 STZ，以便 STZ 做出更新认证的决定。

The audit team leader is responsible for submitting the audit materials to STZ so that STZ can make a decision to renew the certification.

1. 特殊审核

Special Surveillance

* 1. 有下列情况时认证机构应对客户实施特殊的监督审核

A special surveillance visit shall be conducted by the IECQ CB in situations where:

1. 组织搬迁

An organization has relocated;

1. 一个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; An organization has been taken over or acquired by another organization which may have resulted in changes to personnel, management and/or management system procedures;
2. 管理者代表变更，认证决定应该确认当客户管理者代表发生变更时是否需要一个特殊的监督访问

An organization changes its DMR; The IECQ CB will determine if a special surveillance visit is to be conducted when an organization changes its DMR.

1. 有正当理由关注一个组织是否持续符合 IECQ 的相关要求。

The IECQ CB has just cause for concern regarding an organizations continued compliance with the relevant IECQ Schemes requirements.

* 1. 较短时间通知客户的审核

Short noticed audit

对于以下几种情况，STZ 可能需要在较短时间内通知客户,安排一次特殊审核：

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

1. 对投诉进行调查

Investigation for appeals

1. 对认证资格被暂停的客户进行追踪。

Tracking customers whose certification has been suspended.

1. 证书的转换

Transfer of IECQ HSPM Certificate of Conformity

如果 IECQ 证书的持有者希望将证书转换至另外一家认证机构，应符合以下要求：

Should there be a desire for an IECQ Certificate holder company to transfer their IECQ Certificate from their Certificate issuing IECQ Certification Body to another IECQ Certification Body, the following shall apply.

* 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 to the newly selected IECQ Certification Body in accordance with 9.2 & 9.3

* 1. 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；

The IECQ Certification Body receiving the application shall obtain a full copy of the latest IECQ surveillance assessment report from the client and conduct a formal technical review, ensuring there are no outstanding NCRs

* 1. 如果最近的一次监督审核报告的技术审查确认没有未完成的不符合项，则可以签发

一份新证书，覆盖监督报告中所列的活动范围和场地，而无需现场审核。

Where the technical review of the latest surveillance assessment report confirmed no outstanding NCRs then a new Certificate maybe issued covering the scope of activity & site(s) listed in the assessment report without the need for a site visit

**备注：**新证书应与之前颁发的证书下一次监督访问的时间框架和有效期一致，也就是说，

“原始签发”和“有效期”至少应与之前颁发的 IECQ 认证相匹配。

Note: The new Certificate shall line up with the time frame of the previous issued Certificate for the next surveillance visit & expiration date, i.e. as a minimum the “Original Issue” and “Expiration” dates shall match that of the previous held IECQ Certification.

* 1. 如果在技术评审时发现有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

1. 暂停、撤销

Suspension and cancellation

* 1. 证书的撤销 Withdrew
     1. 如果出现以下情况，HSPM 证书将被 TZ 撤销：

An HSPM Certificate may be withdrawn by TZ if:

1. 未支付应付费用；There is non-payment of outstanding fees;
2. 证书发布存在错误；It has been issued in error;
3. 证书持有者申请撤销； The holder requests cancellation;
4. 当有误导性的使用证书时，如果企业不能在 TZ 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 withdrawn if the Organization fails to take corrective action in this respect within 2 weeks of being requested to do so by TZ;

1. IECQ 获证组织不再符合 IECQ 体系的要求；

The IECQ Certified Organization no longer complies with the IECQ System requirements;

1. 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 体制的要求。

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 IECQ Scheme requirements.

* + 1. TZ 应给 IECQ 证书获证企业发出适当的关于撤销的通知，并应给出理由。

TZ shall give due notice to the IECQ Certificated Organization of such cancellation and shall give the reason(s).

* 1. 证书的暂停 Suspension
     1. 如果有理由认为基于以上 12.1 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 TZ 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 TZ if there is reason to believe that the cancellation of the IECQ certificate for the reasons set out in 12.1 above is only temporary and that they can be improved after a short delay. In general, the suspension period shall not exceed one month.

* + 1. TZ 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。

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

* 1. 当一张 IECQ 证书被撤销或暂停，企业不应再描述他们的企业是获得 IECQ 认证的也不应再使用 IECQ 的标志，并应尽快完成相应改进措施。

When an IECQ Certificate has been cancelled or suspended, the Organization shall no longer describe their organization as "IECQ Certified", nor shall they use the IEC IECQ logo.

8. 4 企业应有权针对 IECQ 证书的撤销或暂停提出申诉。

The Organization shall have the right to appeal, in accordance with the national arrangements, against the cancellation or suspension of the IECQ Certificate.