上海英格尔认证有限公司

Shanghai Ingeer Certification Assessment Co., Ltd.

QMS、EMS、OHSMS认证管理程序

QMS, EMS and OHSMS Certification Management Procedure

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1 目的 Objective

本文件用于指导上海英格尔认证有限公司（以下简称ICAS）开展质量管理体系（含建筑施工企业质量管理体系、医疗器械企业质量管理体系）、环境管理体系、职业健康安全管理体系认证活动，以保证英格尔认证有关的活动具有一致性、连续性和可追溯性。

This document is designed to be a guide for Shanghai Ingeer Certification Assessment Co., Ltd.(hereinafter referred to as 'ICAS') to carry out quality management system (including quality management system of engineering construction auditees and quality management system of medical device auditees), environmental management system, occupational health and safety management system certification activities to ensure the consistency, continuity and traceability of the certification-related activities.

2 范围 Scope

本文件适用于ICAS对认证过程相关活动的控制。This document applies to ICAS's control over relevant certification process activities.

3 职责 Responsibilities

- 市场部负责认证申请的处理、信息的提供、报价、客户满意度调查及其它必要的协调工作;
- 审核部负责合同评审，审核方案策划，审核调度负责审核组委派、审核行程的安排;
- 审核组长负责审核过程的计划编制和审核执行;
- 注册部负责合同评审结果的确认、审核计划的确认、认证决定的协调及安排、证书的制作、发放和管理。
- 技术资源部负责技术领域分析及划分、对参与管理和实施审核与认证人员进行专业能力评定、专业能力发展策划（如见证的安排）及必要的审核作业指导书的制定;
- 监管部负责认证文件的更新发布。
- Market department is responsible for dealing with the certification application，provision of information, quotation, organization satisfaction survey and other necessary coordination works;
- Audit department is responsible for contract reviewing, planning of audit programme; audit assignments are responsible for the appointment of audit group and the journey arrangement;
- Audit team leader is responsible for preparing audit process plan and conducting the audit;
- Registration department is responsible for the confirmation of contract review result and audit plan, the coordination and arrangement of the audit decision and the making, issuing and management of the certificate;
- Technical resources department is responsible for the analysis and division of technical areas, professional competence evaluation of personnel who participates in management and undertakes audit and certification, planning for professional competence development (such as arrangements of witness), and preparation for necessary audit working instruction;
- Regulatory department is responsible for the renewal and issuing of certification document;

4 认证基本流程 Basic process of certification

a) 认证申请;
b) 合同评审;
c) 申请受理及签订合同;
d) 审核方案策划
e) 审核策划
f) 初次认证审核实施;
g) 认证决定;
h) 监督审核;
i) 再认证。

a） Certification application;
b） Contract review;
c） Application acceptance and signing contract;
d） Planning for audit programme;;
e） Audit planning;
f） Implementation of initial certification audit;
g） Certification decision;
h） Surveillance audit;
i） Recertification;

5 认证依据及技术领域划分原则 Certification basis and principle of technical area division

QMS认证依据：GB/T 19001《质量管理体系要求》进行质量管理体系认证（或依据《工程建设施工企业质量管理规范》GB/T50430及GB/T19001《质量管理体系 要求》开展工程建设施工企业质量管理体系认证，或依据ISO 13485《医疗器械 质量管理体系 监管的目的要求》进行医疗器械企业质量管理体系认证）。并参照CNAS-TRC-012:2017 《管理体系认证机构认证业务范围分类指南》，划分认证业务技术领域。

EMS认证依据：GB/T 24001-2016/ISO 14001:2015进行环境管理体系认证。参照CNAS-TRC-012:2017 《管理体系认证机构认证业务范围分类指南》，划分认证业务技术领域。

OHSMS认证依据：GB/T 45001-2020/ISO 45001:2018进行职业健康安全管理体系认证，参照CNAS-TRC-012:2017《管理体系认证机构认证业务范围分类指南》,划分认证业务技术领域。

QMS certification basis: according to ISO9001 *Quality Management System - Requirements* and standards above, or make the certification of quality management of engineering construction auditees according to GB/T50430 *The Guide for Quality Management of Engineering Construction Auditees* and ISO9001 *Quality Management System - Requirements),* or conduct quality management system certification of medical device auditee according to ISO 13485 *Medical Device Quality Management System Objective and Requirement for Supervision*. And divide technical area of certification business according to IAF ID1:2014 & Statistical classification of economic activities in the European

Community，NACE rev2..

EMS certification basis: conduct environmental management system certification according to ISO14001:2015. And divide technical area of certification business according to IAF ID1:2014 & Statistical classification of economic activities in the European Community，NACE rev2..

OHSMS certification basis: ISO 45001:2018. And divide technical area of certification business according to IAF ID1:2014 & Statistical classification of economic activities in the European Community，NACE rev2..

6 认证程序Certification procedure

6.1 认证申请Certification application

6.1.1 申请认证组织应按ICAS要求，提供以下申请信息或资料:

a) 申请认证的范围（申请认证的范围应包含在营业执照经营范围内）；
b) 申请组织寻求认证的管理体系标准或其他要求;
c) 认证申请书，包括申请组织的生产经营或服务活动等情况的说明;
d) 法律地位的证明文件（包括：组织营业执照、事业单位法人证书、社会团体登记证书、非企业法人登记证书、党政机关设立文件等）的复印件
e) 组织管理体系覆盖的活动所涉及法律法规要求的行政许可证明、资质证书、强制性认证证书等的复印件;
f) 若管理体系覆盖多场所活动，应附每个场所的法律地位证明文件的复印件（适用时）；并说明各多场所活动、活动管理（或分包）情况;
g) 管理体系相关的文件化信息如已编制的管理手册、管理制度;
h) 管理体系覆盖的产品或服务的质量标准清单;
i) 申请组织与申请认证的领域相关的一般信息，包括其活动，人力与技术资源，以及适用时，其在一个较大实体中的职能和关系;
j) 接受与管理体系有关的咨询的情况;
k) 申请组织所有影响管理体系符合性的外包过程的信息;
l) 说明是否已获得其他认证机构的认证或已接受过其他认证机构的审核;
m) OHSMS认证申请方还需提供所识别的与过程有关的主要的危险源和OHS风险，在过程中所使用的主要危险材料以及任何适用的OHS法规中的有关的法律义务、组织场所内及组织场所外的工作人员的详细信息;
n) 其他与认证审核有关的必要文件。

市场部收到认证申请要求时，应在当天或最迟于第二个工作日将《认证申请表》(MFP1488)及公开文件以适当的方式提供给申请方，同时要求组织在提交申请表的同时提交认证范围内的产品生产/服务的流程;

The organization that applies for certification shall provide the following applying information or

materials as required by ICAS:

a) The applied scope of certification (scope applied shall be within the scope of business licenses);

b) Management system standard or other requirements which the applicant is seeking certification;

c) Application form, including the explanations of production and operation or service activity of the organization;

d) Proof photocopy of legal status, certificate of legal institutions, social organizations and non-corporate registration certificate and document of party or government organizations; photocopy of organization code certificate;

e) Photocopies of the administrative licensing certificate, qualification certificate and compulsory certificate as required by the statutory and regulatory requirements which is related to the activity covered by organization's management system.

f) If management system covers multi-site activity, a proof copy of every site's legal status shall be added (if applicable); explain each multi-site activity and outsourcing of activities;

g) Relevant documentation information of the management system such as the already prepared management manual and management requirements

h) Quality standard list of the product or service covered by the management system

i) General information about the organization and fields of certification, including activities, human and technical resources and the function and relationship of a larger entities when applicable;

j) The situation for accepting consults related to management system;

k) All information of outsourcing process influencing management system conformity for application organization.

l) Specify if certification from other certification organization has been obtained or audit conducted by other certification organization has been received.

m) The information provided to the Certification Body by the authorized representative of the applicant organisation on its processes and activities shall also include the identification of the key hazards and OHS risks associated with processes, the main hazardous materials used in the processes, and any relevant legal obligations coming from the applicable OHS legislation. The application shall contain details of personnel working on, as well as working away from the organisation's premises.

n) Other necessary documents related to audit.

After receiving certification application requirement, market department shall provide the *Certification Application Form* (MFP1488) and public document in an appropriate way to applicant at the right day or no later than the second working day, and require organization to submit application form and process of product production or service at the same time.

6.2 合同评审 Contract Review

6.2.1 合同评审 Contract review

审核部合同评审人员负责合同评审，市场业务人员予以协助。

收到认证申请时，应对认证申请及补充信息进行评审确认，以确保：

a) 申请资料齐全，申请组织从事的活动符合相关法律法规的规定，信息充分，可以受理；

b) 认证要求已有明确说明并形成文件，且已提供给申请组织；

c) 考虑了申请的认证范围、申请组织的运作场所、完成审核需要的时间和任何其他影响认证活动的因素；

d) 已确认申请组织申请的认证范围包含在其营业执照规定的经营范围内；

e) 解决了认证机构与申请组织之间任何已知的理解差异；

f) ICAS有能力并能够实施认证活动；

g) 考虑了申请的认证范围在ICAS认证业务范围以内且有能力组织认证审核；考虑了申请组织的运作场所、完成审核需要的时间和任何其他影响认证活动的因素（语言、安全条件、对公正性的威胁等）；

h) 保持了决定实施审核的理由的记录；

在依据ICAS制定的技术领域风险等级分类的基础上，根据具体组织的具体状况，合同评审人员可以适当将该认证项目的技术等级或风险类别予以降低或升高后再行进行评审；评审结果须经ICAS指定的人员予以批准后方可实施，并应将评审理由记录下来。

Contract review personnel form audit department shall be responsible for the contract review and market sales personnel shall assist with it.

When receiving certification application, it shall review and verify the application and supplementary information to ensure that:

a) The application material shall be complete; activities which the organizations engaged in shall comply with the provisions of relevant laws and regulations and the information shall be complete, and then can be audited;

b) Certification requirement has been explained explicitly, documented and provided to the organization;

c) The applied certification scope, operational site, time to complete the audit and any other influence factor are considered;

d) The scope of certification which had been confirmed from the organization shall be within its business scope on business license;

e) Comprehension difference has been solved between certification authority and the organization;

f) ICAS is capable of implementing certification activity;

g) The certification scope, operation-site and time required to complete the audit and other factors which affect the certification activity, such as language, safety condition and threat to impartiality;

h) Keep record of reason for implementing the audit;

The level of risk in the technical field classification basis based on ICAS, according to the specific conditions of specific clients, contract review personnel can be appropriately the technical level/ risk categories of this project to reduce or increase the after review; the results shall be specified

by the ICAS staff to be approved, and shall review the reason is recorded.

6.2.2 应急合同评审 Emergency contract review

当受审核方在审核现场提出变更需求如申请扩大认证范围、缩小认证范围等时，审核组长应要求受审核方填写《变更申请》单，及时提交给客服人员，由其将变更申请交给合同评审人员，合同评审人员根据专业变更、场所及有效人数实际情况及时作出评审（原则上完成评审的时间不超过现场审核时间的八分之一）：

1） 原审核组具备专业能力、且无需增加审核人日数时，审核部向审核组下达针对变更要求的审核任务派遣书；审核组长修订审核计划，使其包括原审核任务和变更后的审核任务的所有审核计划内容。经ICAS确认后执行新审核计划。

2） 原审核组具备专业能力，但需增加审核人日数时，审核部综合考虑该审核组可予以安排的审核时间，就变更的部分下达单独的审核任务派遣书；审核组长依据派遣书编制审核计划，该审核计划对应于变更后的审核任务。经ICAS确认后执行新审核计划。

3） 原审核组不具备审核能力时，审核部安排具备专业审核能力的审核组，并与受审核方协商确定补充审核的日期，下达补充审核的审核任务派遣书；补充审核的审核组长依据派遣书编制审核计划，该审核计划对应于补充审核的审核任务。经ICAS确认后执行新审核计划。

If auditee requests for changes on-site such as expanding certification scope, reducing certification scope etc., then audit team leader shall ask the auditee to fill out ‘Application for Change’ form and submit it to the customer service staff who would then submit it to contract reviewer. Contract reviewer would conduct review based on the actual situation such as change of profession, sites and effective number of people (in principle, time for completing the review shall be no more than 1/8 of on-site audit time):

1) If original audit team has professional competence and there is no need to increase man day, audit department would send audit assignments notice with respect to the request for change; audit team leader makes audit plan and make sure it contains plans for any audits including original audit task and audit task after change. New audit plan would be carried out once ICAS has confirmed.

2) If original audit team has professional competence, but there is need to increase man day, audit department would send independent audit assignments with respect to the change considering audit time the audit team can possibly allocate; audit team leader makes audit plan based on the task assignments notice, and this audit plan corresponds to audit task after change. New audit plan would be carried out once confirmed by ICAS.

3) If original audit team does not have professional competence, audit department shall arrange a audit team with professional audit competence, negotiate date for supplementary audit with the auditee and send audit assignments notice for supplementary audit. Supplementary audit team leader makes audit plan based on the assignments notice, this audit plan corresponds to supplementary audit. New audit plan would be carried out once ICAS has confirmed.

6.3 申请受理及签订合同 Acceptance of application and signing contract

6.3.1 认证申请的受理 Acceptance of certification application

对符合上述要求的申请方，市场部可决定受理认证申请；对不符合上述要求的，市场部应通知申请组织补充和完善，或者不受理认证申请。

市场部应完整保存认证申请的审查确认工作记录。

Upon meeting the above requirements, the market department may decide to accept certification applications; if not, the market department shall notify the applicant organization to supplement and complete, or does not accept certification application.

Market department shall store the whole record of the certification application.

6.3.2 签订合同 Signing contract

6.3.2.1 合同评审通过后，市场部在收到申请的当天或最迟不超过第二个工作日内，分别根据《认证审核人天表及收费标准》对认证活动进行报价；

After passed the contract review, market department shall quote on the different certification activity according to *Audit Man day Form and Charging Standard* on the day of receiving the application or no later than the second working day.

6.3.2.2 市场部收到申请方的报价确认后，与申请方签订《管理体系认证合同书》（MAP0312），并于当天或最迟不超过第二个工作日内将《管理体系认证申请表》（MFP0389）和相关申请材料转交审核部。

After receiving conformation of the quotation, market department shall sign the 'Management System Certification Contract' (MAP0312) with the applicant and transfer the *Certification Application Form For Management System* (MFP0389) as well as relevant application document to audit department on the day or on the second working day at least.

6.4 审核方案的策划 Planning of audit programme

6.4.1 审核方案策划人员对认证项目的整个认证周期制定审核方案；审核方案应覆盖全部的管理体系要求，策划的审核活动用以正式受审核方的管理体系符合认证依据的标准或其他要求。The audit programme planner prepares an audit plan for the entire certification cycle of the certification project; The audit programme shall cover all management system requirements, and the planned audit activities shall be used to confirm the standards or other requirements on which the management system review and certification of the auditee is based.

6.4.1.1 初次认证审核方案应包括两阶段初次审核、认证决定之后的第一年与第二年的监督审核和第三年在认证到期前进行的再认证审核。第一个三年的认证周期从初次认证决定算起。以后的周期从再认证决定算起。The audit programme for the initial certification shall include a two-stage initial audit, surveillance audits in the first and second years following the certification decision, and a recertification audit in the third year prior to expiration of certification. The first three-year certification cycle begins with the certification decision. Subsequent cycles begin with the recertification decision.

6.4.1.2 如果组织已获得认证或接受了其他机构的审核，对审核方案做出任何调整则应收集充足的、可验证的信息，以证明调整的合理性，并记录该调整。If the organization has received certification or audited by other CB, audit assignments shall collect sufficient and verified information

to make changes for the rationality of the change, and record it.

6.4.1.3 对审核活动的要求还包括:

1）现场审核应安排在认证范围覆盖的产品生产或服务活动正常运行时进行。

2）如果受审核方体系包含多个现场或多个临时场所，且这些场所都处于该申请组织授权和控制时，根据组织填写的《多现场 多场所信息征询表》（MFP0350），制定合理的抽样方案以确保对各场所管理体系的正确审核。该抽样方案应考虑到不同场所的活动是否存在可能对质量管理产生显著影响的区域性因素，如果是，则不能进行抽样。

对于多场所或含有临时场所的组织，应考虑:

是否具有利用信息和通信技术进行远程审核;

多场所运做组织应确定组织总部作为其实施认证的合同方;

所有场所在一个统一控制和管理的管理体系下运行;

应将单一场所的审核发现视为整个体系的情况，并应实施相应的纠正。

3）发生“扩大审核范围”的情况，策划审核方案时应明确：是否需要根据所扩大的部分增加审核要求，并对可能增加的要求在《审核方案》中进行明示。

4）策划OHSMS的审核，需考虑：（1）从合规性的角度确定客户的管理体系的能力，以确保其满足适用的法律、法规和合同要求；（2）OHSMS应包括组织控制下或施加影响的、对组织的 OHSMS绩效有影响的活动，产品和服务。组织的OHSMS应覆盖其控制的临时场所，例如建筑工地，不论其位于何处。

Requirements for audit activities also include:

1）On-site audits shall be processed during the certified products production or service activities at normal operation.

2）If the auditee system includes multi-site or multiple temporary sites, where are under control of the organization, it shall formulate reasonable sampling scheme to ensure the correct audit of management system according to Multi-site Multi-location Information consultancy Form (MFP0350) filled out by the organization. The sampling scheme shall take into account whether the activities in different places may have a significant impact on the quality of management, and if any, it cannot be sampled.

For the organization with multi-site or temporary site, the following shall be considered:

The computer-assisted audit technology is used for remote audit or not;

Multi-site operational organization shall determine the headquarters as the contract of the certification;

All sites is run in a management system under unified control and management;

The audit findings of the single site shall be regarded as of the whole system; and related correction shall be taken.

3）If ‘expanding of audit scope’ happens, the planning of the audit programme shall specify whether audit requirements shall be added based on the expanded part, if so, state the possible

requirements in the “audit programme”.

4）To plan OHSMS's audit, we need to consider: (1) determine the ability of the customer's management system from the perspective of compliance to ensure the client meets applicable statutory, regulatory and contractual requirements; (2)The OH&SMS shall include activities, products and services within the organization’s control or influence that can impact the organization’s OH&SMS performance. Temporary sites, for example, construction sites, shall be covered by the OH&SMS of the organization that has control of these sites, irrespective of where they are located.

6.4.2 确定审核人天和审核时间 Determination of audit man day and audit time

ICAS根据申请组织提交的信息，梳理清其规模、特性、业务复杂程度、管理体系覆盖的范围、认证要求和其承担的风险等因素，核算并确定审核人天，审核人天数的确定见根据CNAS-CC105:2020制定的ICAS《QMS（EMS/OHSMS）认证审核人天表及收费标准》。

确定审核人天时，还要考虑以下项目：

a) 申请方的管理体系是否主要以电子化（“e-based”）过程和文件为主；
b) 是否进行联合审核或一体化审核；
c) 管理体系范围内活动的分包情况；
d) 是否依据多个管理体系标准进行认证；
e) 如果组织采用轮班作业，考虑在轮班工作中发生的活动对审核策划的影响
f) 与组织的产品、过程或活动相关联的风险
g) 是否具有利用信息和通信技术进行远程审核
h) 是否存在对产品实现关键过程的外包
i) 以前审核的结果；
j) 如果客户在另一个组织的场所提供服务，则ICAS英格尔应验证客户的OHSMS是否涵盖这些场所外的活动（尽管另一个组织具有其OHSMS的责任）。在确定审核时间时，ICAS英格尔应考虑定期审核这些员工工作的场所。如何确定审核哪些场所应被记录下来，作为确定审核时间的理由。

其中一阶段的审核所需要的时间应考虑组织的产品的复杂程度，文件的复查程度，通常不超过总人天的三分之一。

ICAS shall consider the factors such as the size, characteristics, complexity of the business, scope of its management system, certification requirements and the risk it undertakes according to the information provided by the applicant, and therefore calculate and confirm the audit man day. The confirmation of the audit man day number shall be referred to the ICAS’s *QMS (EMS/OHSMS) Audit Man day and Charge Standard* which is prepared according to IAF MD5:2019.

The following items shall be taken into consideration when determining the audit man day:

a) If applicant’s management system is e-based and file-based;
b) If combined with audit, joint audit or integrative audit;
c) Outsourcing of activities within the scope of management system;

d) Whether to conduct certification according to multiple management system standards;
e) If organization adopts shift work, it shall be considered the impact the activity occurred during shift work may cause on the audit plan
f) Risk related to the organization's product, process or activity;
g) Whether computer-assisted audit technology is used for remote audit;
h) Whether there is outsourcing of the key process of the product
i) Previous audit results;
j) If the client provides services at another organisation's premises, ICAS shall verify that the client's OH&SMS covers these offsite activities (notwithstanding the OH&SMS obligations of the other organization). In determining the time to be spent for audit, ICAS shall consider to audit periodically any organization site where these employees work. How to determine which sites to be audited should be recorded as reasons for determining audit time.

The time required for the stage one audit shall consider the complexity of the company's product and the review degree of the document. Usually it would not be more than one-third of the total man day.

6.4.2.1 认证风险的判定 Determination of certification risk

不宜在审核方案策划阶段将高风险的风险等级降低、宜待一阶段完成后根据现场实际情况进行降级处理。方案策划人员在综合各方面的因素后确定审核所需人天（如审请方有倒班运作，且不同的班次的生产过程不同,不得进行抽样。若不同的班次审核过程类似但存在有差异之处，审核人天需覆盖对差异性进行审核的时间）及认证专业范围。任何等级降低或提高、人天减少或增加的理由均应给予记录。

各认证范围复杂程度，风险等级的划分：按ICASP14、ICASP12的要求执行。

It is not recommended to downgrade the high risk level when planning for the audit programme, degradation of risk level shall be considered after completion of stage 1 based on the actual situation on-site. Planning personnel of the program will determine required audit man day (e.g. if applicant company works in shifts and different shifts have different manufacturing process, then sampling is inappropriate; if different shifts are similar but differences still exist, the audit man day shall include time for differences audit) and certification professional scope after taking all sorts of factors into consideration. Reasons for upgrading or downgrading any level and increasing or decreasing man day shall all be recorded.

The division of the complexion of each certification scope and its risk level: according to the requirements of the ICASP14 and ICASP12;

6.4.2.2 采用信息和通信技术进行远程审核的时间满足CNAS-CC14:2019及CNAS-CC105:2020要求，对拟认证的职业健康安全管理体系所覆盖的活动复杂性和规模以及场所间差异加以识别作为抽样程度的基础；

Time spent by remote control of ICT shall meet the requirements of IAF MD4:2018 and IAF MD5:2019; the identification of complexity and scale of activity covered by OHSMS that is to be certified as well as difference between locations shall be taken as the foundation of sampling degree.

6.4.2.3 当组织申请的认证范围只包含设计和销售，应评价该组织是否包含生产外包过程。通常情况下：如果该组织销售的是其自己自行设计的产品，并将该产品的生产外包，则该组织必须对其生产外包的过程加以控制，对该组织的生产外包过程的审核是必须的，并在证书中注明生产外包

When the applied certification scope of auditee only includes design and sell, it shall be evaluated that whether there is outsourcing in the manufacture process. Generally: if the auditee sells self-designed products and outsources its manufacture, then the auditee shall take control of the outsourcing manufacture process. The audit of such outsourcing manufacture process is a necessary and it will be declared in the certificate about the outsourcing manufacture.

6.4.3 多场所的抽样 Multi-site sampling

如果受审核方所申请认证的管理体系包含多个现场或多个临时场所，且这些场所都处于该申请组织授权和控制时，根据组织填写的《多现场/多场所 信息征询单》（MFP0350），审核组对每一生产场所实施现场审核，以确保审核的有效性。

审核方案应包括两阶段初次审核，第一年与第二年的监督审核和第三年在认证到期前进行的再认证审核。审核方案的确定和任何后续调整应考虑组织的组织规模、其管理体系，服务过程的范围与复杂程度，以及经证实的管理体系有效性水平和以前审核的结果。

现场审核应安排在认证范围覆盖的产品生产或服务活动正常运行时进行。

对于OHSMS覆盖多个场所的情况，应基于与活动和过程的性质相关的OHS风险程度的评价，确定认证范围内的每个场所可否抽样。如果有多个场所没有涵盖相同的活动、过程及 OHS 风险，抽样不适用。虽然一个场所与其他场所有类似的过程或制造类似的产品，但ICAS英格尔应考虑每个场所的业务活动 （技术、设备、使用和存储的危险材料的数量、工作环境、场所等）之间的差异。当允许抽样时，认证机构应确保将被审核的场所样本具有被审核组织现存的过程、活动和OHS风险的代表性。

If the management system applied by the auditee contains multiple sites or multiple temporary sites, plus all these sites are under the authority and control of the applicant; then audit team shall conduct on-site audit to each production-site according to the *Multi-site/Multi-location Information consultancy Form* (MFP0350) filled out by the organization in order to ensure the effectiveness of the audit.

Audit programme shall include a two-stage initial audit--surveillance audits for the first year and second year, and recertification audit prior to certification expires in third year. Determination and any subsequent adjustments of the audit programme shall consider the size of the organization, its management system, the range of products and processes and complexity, as well as the level of effectiveness of proven management system and the results of previous audits.

On-site audits shall be conducted during the normal operation of product production or services activities which are within certification scope.

In the case of OHSMS operated over multiple sites it is necessary to establish if sampling is permitted or not based on the evaluation of the level of OHS risks associated to the nature of activities

and processes carried out in each site included in the scope of certification. Where there are multiple sites not covering the same activities, processes and OHS risks, sampling is not appropriate. Although a site performs similar processes or manufactures similar products to other sites, the CAB shall take account of the differences between the operations of each site (technology, equipment, quantities of hazardous materials used and stored, working environment, premises etc.). When sampling is permitted ICAS shall ensure that the sample of sites to be audited is representative of processes, activities and OHS risks that exist in the organization to be audited.

6.4.4 初次审核分一阶段和二阶段两个阶段的审核，为了实现一阶段目标（如6.6.2.1所述），一般情况下，一阶段需要现场进行，不进行一阶段的现场审核的情况见6.6.2.3。

Initial audit includes stage 1 audit and stage 2 audit. In general, in order to achieve the objective of stage 1 (stated in 6.6.2.1), stage 1 audit shall be on-site audit. Refer to 6.6.2.3 for situation without on-site stage one audit.

6.5 审核前的准备 Preparation before audit

6.5.1 确定审核目的、范围和准则 Determination of audit objective, scope and criteria

6.5.1.1 认证范围的确定Determination of certification scope

为了让各种性质的组织有充分的灵活度来确定其质量管理体系，环境管理体系，职业健康安全管理体系认证证书范围，以反映出他们的商业需要与不同的运行情况，防止组织把应该包含在质量管理体系，环境管理体系，职业健康安全管理体系的运行要素从认证范围中删除。

证书的范围的确定依据以下因素:

- 申请人简况，如组织特征，名称，法律地位，以及有关的人力和技术资源，以及界定组织输入，输出的职责界限;
- 有关质量管理体系、环境管理体系、职业健康安全管理体系覆盖活动的一般信息;
- 对标准或其他规范性文件的说明，以及质量管理体系、环境管理体系以及职业健康安全管理体系及能源管理体系核心要素的文件;
- 与不完全包含在质量管理体系、环境管理体系以及职业健康安全管理体系范围中服务活动的接口直至认证的职业健康安全管理体系中予以证明（如：他们包含在危险源的识别与评价中）;
- 宜考虑组织许可范围和提供服务的场所。

认证范围中关于产品或服务活动的描述，应使用专业、规范的词语。当申请方提交的范围描述使用“行业内习惯用语”或“约定俗成的说法”时，合同评审人员宜建议其按技术标准或中国经济活动分类中关于产品的说明名称来命名。

认证范围的确定在合同评审阶段可以初步进行，如在第一阶段审核结束后，认证范围与合同评审阶段的范围偏差时，审核组长应通知审核部，以便审核对人天，资源配备等进行调整。

In order to make the organization have sufficient flexibility to determine its QMS, EMS and OHSMS certification scope reflecting their business needs and different operating conditions, and prevent organization from removing the operational elements included in

QMS, EMS and OHSMS from the certification scope.

The following factors are used to determine the scope:

- Brief introduction of applicant, for example, organization characteristics, name, legal status and relevant human and technical resources and the limited responsibility of input or output of organization;
- Information of activities covered by QMS, EMS and OHSMS management system;
- Explanations of normative reference and main documents of QMS, EMS, OHSMS management system;
- If service activities are not all included in QMS, EMS, OHSMS management system, please give proof, for example, they are involved in the identification and evaluation of hazard;
- It is appropriate to consider the certification scope and site providing service of the organization;

The description of products or service activity within the certification scope shall use professional and standard terms. If the description of scope uses the 'common wording in the industry' or 'conventionalized wording', contract review personnel is supposed to suggest it to name it according to technical standard or the product description in the Chinese economy activity categories.

Determination of certification scope can carry out initially at the contract review stage. If there is a deviation between certification scope and contract review after the completion of the stage 1, audit head shall inform audit department and make adjustment of man day and resource allocation.

6.5.1.2 审核目标由审核部负责确认。审核范围和准则包括任何更改应由审核部在市场部的协助下与申请认证组织商讨后确定。Audit objective is determined by audit department. Audit scope and criteria including any changes shall be determined by audit department after negotiation with organization applying for the certification under assistance of market department.

6.5.2 审核组的组成和派遣 Composition and Assignments of the Audit Team

6.5.2.1 决定审核组的规模和组成时，应考虑下列因素：

a) 审核目标、范围、准则和估计的审核时间；

b) 是否是结合、一体化审核或联合审核；

c) 实现审核目标所需的审核组整体能力；

d) 认证要求（包括任何适用的法律、法规或合同要求）；

e) 语言和文化。

f) 审核组成员以前是否审核过该组织的管理体系。

In deciding the size and composition of the audit team, consideration shall be given to the following:

a) audit objectives, scope, criteria and estimated audit time;

b) whether the audit is a combined, joint or integrated;

c) the overall competence of the audit team needed to achieve the objectives of the audit;

d) certification requirements (including any applicable statutory, regulatory or contractual requirements);

e) language and culture.

f)whether members of the audit team have audited the management system of this organization.

6.5.2.2审核调度根据申请人所从事的业务性质及根据技术领域划分表确定的专业能力要求委派审核组。审核组的委派要能确保:

a) 审核组如果仅有一名审核员，该审核员应有能力履行适用于该审核的审核组长职责并有能力完成满足整个审核组的能力要求。

b) 审核过程中具有合理数量的专职认证人员和技术专家和（或）翻译人员。技术专家和翻译人员应在审核员的指导下工作。使用翻译人员时，翻译人员的选择要避免他们对审核产生不正当影响。

c) 任务书中必须明确每个审核组成员的作用，如组长，专业审核员、技术专家和（或）翻译人员、观察员、实习审核员，以便审核组准确安排审核计划;

d）一阶段审核员的委派：审核组应至少有一位相关技术领域的审核员；一阶段审核组长与二阶段审核组长宜为同一人。

e）二阶段审核员的委派，应满足以下条件:

- 审核组应至少有一位相关技术领域的审核员；审核员不具备相应专业时，需聘请技术专家支持;
- 审核组内至少有一位经ICAS评定过的可担任审核组长的审核员;
- 审核组成员不得与该审核项目有利益冲突;
- 见证审核员可以是审核组成员，可以担任审核组长；见证实习审核员升审核员时应与被见证的人员为同一组参加审核；对审核员或审核组长进行内部能力确认时，至少有一小时要与被见证审核员一起进行审核;
- 审核组能满足组织要求的语言能力;
- 审核组成员之间有协同合作的能力;
- 当需要采用计算机技术辅助进行远程审核时，或对以电子化过程和文件为主的管理体系时，要派遣具有相应运用计算机技术审核能力和了解信息安全方面要求的审核员。需要将审核组报技术资源部对其特殊技能进行评价认可后方可执行。
- 实习审核员数量不得超过正式审核员的总数;
- 观察员不应作为审核组成员。

Audit team assignments shall be based on the business applicant undertakes and professional competence requirements determined from the Table of technical areas to assign audit team. The assignments of audit team shall ensure the following:

a) If audit team just has one auditor, the auditor shall be able to fulfill the responsibility of the team leader and has ability to meet the whole requirements of the team.

b) During the audit process, there are a reasonable number of full-time certification personnel, technical experts and/or translators. Technical experts and translators are supposed to work under the guidance of auditors. Translators shall be avoided the improper influence on the audit.

c) In the assignments book it shall specify the role of each member of the audit team, such as team leader, professional auditor, technical experts and (or) translators, observers and auditors-in-training in order for the audit team to arrange the audit plan accurately;

d) The appointment of stage 1 auditor: it shall have at least one auditor from relevant technical area; audit team leader of stage 1 and stage 2 shall be the same person.

e) The auditor appointment for stage 2 shall meet the following requirements:

- There shall be at least one auditor with profession of relevant technical areas in audit team; When there is no auditor with technical ability, technical experts are needed;
- There shall be at least one auditor in audit team who has been assessed by ICAS and can serve as the team leader within the audit team ;
- There are no conflicts of interests between team members and the audit project;
- Witness auditor can be member of audit team who can act as audit team leader. When witness auditor-in-training is promoted to auditor, he/she shall participate in audit with personnel being witnessed in the same group; when conducting internal witness of auditor or audit team leader, he/she shall have at least one hour participating in the audit with auditor being witnessed;
- Audit team's linguistic competence can meet organization's requirements ;
- Competence in cooperation among team members;
- When using computer technology for remote audit or auditing electronically process and file-based management system, auditors with the corresponding audit capability and information security need to be sent. The audit team needs to be reported to technical resource management department, evaluated its special skills and then implemented.
- The number of interns cannot exceed that of regular auditor;
- Observer shall not be a member of audit team;

6.5.2.3审核组长在与审核组商议后，应向每个审核组成员分配对特定过程、职能、场所、区域或活动实施审核的职责。所进行的分配应考虑到所需的能力、有效并高效地使用审核组以及审核员、实习审核员和技术专家的不同作用和职责。在审核进程中，为确保实现审核目的，可以改变工作分配。

After discussing with the audit team, audit team leader shall assign each member of audit team responsibilities for the implementing audit to specified process, function, location, region or activity. The assignments shall take into account the necessary competence and make use of the different roles and responsibilities of audit team, auditor, auditors-in-training and technical experts effectively. In the process of audit, assignments of work can be changed to ensure the achievement of audit objectives.

6.5.3 审核计划 Audit Plan

6.5.3.1 总则 General

审核组长在编制《审核计划》（MFP0311）时应参照组织管理体系相关的职能分配表（组

织有提供时）和《审核组派遣通知书》（MFP0308）合理安排审核时间和人员。审核组长或其指定的人员与审核组成员协商，对具体的过程、职能、或活动等的审核工作分配给审核组成员。审核工作的分配应考虑充分利用资源和时间，任务分配后，审核组长应对计划进行审核确认，《审核计划》（MFP0311）应具有一定的灵活性，以允许更改。随着现场审核活动的进展，审核范围的更改可能是必要的，并注意以下事宜：

a) 审核时间每天每人8小时，每天每人加班不可超过1.5小时；
b) 审核计划由审核组长完成。若由于种种原因无法由审核组长完成，由机构指定的具有编制审核计划能力的其他人员辅助完成，由审核组长在现场审核前或现场时确认，必要时于现场进行适当调整，并于现场在审核计划上签字确认。调整不得违反上述要求，审核计划的编制责任始终在审核组长；
c) 市场部业务人员是计划的总协调，应在计划首先上签署业务人员的姓名，以便与顾客沟通；
d) 审核计划需经审核部复核，由复核人员签批方可发送给组织，并征求组织的同意；
e) 应以过程审核的方式进行计划，对不同部门的关键条款进行抽样，根据产品特性、复杂程度及认证范围决定对各部门的抽样量及分配审核任务。抽样应覆盖所有要素和所有部门；
f) 对部门和条款的审核时间安排应根据组织规模和生产服务的性质来合理安排。（如：对QMS的8.5.1条款审核时间应比8.2.1的时间长；生产成熟产品的组织和开发新产品的组织在对QMS的8.2条款审核的时间上也应有区别）；
g) 在审核计划中应明确主要职能部门和作业现场（项目名称或现场）的审核安排，应满足多场所审核时对体现不同职能或作用的场所的覆盖要求；
h) ISO9001、ISO14001、ISO45001标准之第八章必须安排专业审核员进行审核；OHSAS18001标准之4.4.6/4.4.7/4.5.1条款必须安排专业审核员进行审核；ISO13485标准之7.1/7.3/7.5/7.6/8.2.4/8.3条款安排专业审核员进行审核。
i) 初次认证审核时应在计划中体现“文审问题确认”、“删减条款合理性确认”、“顾客抱怨”；
j) 监督审核时“上次不符合的整改验证”、“认证证书和标志的使用”应体现；
k) 采用信息和通信技术的远程审核计划，应满足CNAS-CC14：2019及CNAS-CC105：2016要求；
l) 新进审核员初次见证为现场见证，且见证审核员与被见证审核员至少有1小时以上针对部分条款分在同组审核。
m) 实习审核员不可单独审核；
n) 观察员不可执行审核；
o) 技术专家应做为审核关键过程的审核员的技术支持；为审核员提供技术咨询。不能把技

术专家当审核员。为严肃保密性，技术专家陪同过程中的个人记录应交审核员留存，并归档；

p) 见证审核员为审核员见证时，不可同时审核；但为审核组长见证组长能力时，可作为审核组成员同时参加审核；

q) 同一审核组不能连续对同一家组织连续审核两个认证周期。

While preparing the 'Audit Plan'(MFP0311), audit team leader shall considerorganization's function allocation table (if provided by the organization) as well as *Assignments Notification of Audit Team(MFP0308) to reasonably arrange the time and personnel*. Audit leader or personnel appointed by him consult with members for process, function and activity to distribute audit work to auditors. Distribution of auditing work shall consider making full use of resource and time, after distributing work audit leader or personnel appointed by him shall audit the plan. 'Audit Plan'(MFP0311) shall be flexible enough to make allow the alternation. With the development of on-site audit, the scope may be changed and following issues need to be noted:

a) Audit time is 8 hours per person per day; time of extra work is no more than 1.5 hours;

b) Audit plan shall be completed by audit team leader. If audit team leader cannot complete the plan for some reason, it shall be completed by other person appointed by the company. The audit team leader shall make the confirmation before on-site audit or while on the site. It shall be revised when necessary and sign to confirm on the audit plan while on the site. The revision shall not violate the above requirements which would be the team leader's responsibility otherwise.

c) Sales personnel of the market department are the chief coordinators of plan. Service staff name shall be signed on plan to communicate with organization firstly;

d) Audit plan shall be reviewed by audit department and sent to organization after signing conformation and ask for the organization's agreement;

e) Planning with the method of process audit and sample from key clause in different department; based on the product's characteristic, complexity and certification scope to determine the sampling number of each department and distribute the audit mission. Sampling shall cover all elements and all departments;

f) Audit time of department and clause shall be arranged according to organization's scale and service's characteristic. For example, audit time of QMS in clause 8.5.1 shall be longer than 8.2.1; there is a distinction of audit time of auditee with mature products and developing new products in terms of QMS in clause 8.2;

g) Specify audit arrangement of main functional department and working site (project name or on-site) in audit plan and meet the coverage requirement of main functional site in multi-site audit;

h) The chapter eight of ISO9001 and ISO14001 and ISO45001 standards, professional auditor shall be arranged for the audit to clause 4.4.6/4.4.7/4.5.1of OHSAS18001, and professional auditor shall be arranged for the audit to 7.1/7.3/7.5/7.6/8.2.4/8.3 of ISO13485 ;

i) During the initial certification audit, 'document problem confirmation', 'conformation of reasonability of clause deletion' and 'organization complaint' shall be shown in the plan;

j) During surveillance audit, 'conformation of correction of last nonconformity', 'use of certification certificate and mark' shall be shown. For the audit of the auditee that is recovered from suspension, 'audit of the activity during suspension of this auditee' shall be shown in the audit plan;

k) Time spent by remote control of computer shall meet the requirements of CNAS-CC14:2019 and CNAS-CC105:2020;

l) The first witness of a new auditor is on-site witness; witnessed auditor and to-be-witnessed auditor shall audit partial clause at the same team at least one hour.

m) Auditor-in-training can not audit alone;

n) Observer can not audit;

o) Technical experts must be accompanying with auditor in main region, who should provide technical consultancy to auditor and make signature to confirm. Technical expert is not an audit. In order to keep confidentiality, personnel record during the process of technical expert's accompanying shall be retained and archived;

p) Witnessed auditor can serve as member of the audit team, who cannot be auditor at the same time as a witnessed auditor, while he can be auditor when he is a leader;

q) The same audit team can not review continuously the same auditee for two certification cycles;

6.5.3.2 审核计划编制 Preparing the audit plan

审核计划中应包括:

a) 审核目的;

b) 审核准则;

c) 审核范围;

d) 拟审核的组织和职能单元或过程;

e) 现场审核活动的日期和地点;

f) 现场审核活动预期的时间和期限，包括于受审核方管理层的会议及审核组会议;

g) 审核组成员的作用、职责、身份及联系方式;

The audit plan shall include:

a)the audit objectives;

b)the audit criteria;

c)the audit scope;

d)organizational and functional units or processes to be audited;

e)date and location of the on-site audit activities;

f)the expected time and duration of on-site audit activities, including auditee's management meeting and audit team meeting;

g)the roles, responsibilities, identities and contacts of audit team members;

6.5.4 审核组任务的沟通 Communication of audit team tasks

审核部应将《审核组派遣通知书》（MFP0308）在认证审核之前同时发放给组织及审核组，征求组织及审核组成员的意见，以避免利益冲突。如果组织反对审核组或审核组成员，声明有

利益冲突，应立即调整审核组成员。

审核组成员在审核前应与审核组长进行信息沟通，审核调度或审核组长负责确认后勤的安排，如交通方法、路线图、接车等事宜。审核派遣通知中应说明至少以下事项：

- 审核组所有成员在审核中的作用、姓名及联系电话；
- 受审核方名称、审核的所有地址、联络人姓名及联系方式；

现场审核活动开始前，审核计划应当经审核委托方评审和接受，并提交受审核方。受审核方的任何异议应在审核组长、受审核方和审核委托方之间予以解决。任何经修改的审核计划应在继续审核前征得各方的同意。

Audit department shall send a 'Assignments notice of the audit team'(MFP0308) to the organization and audit team before documents review, and ask for suggestion of them to avoid conflicts of interests. If the organization objects to audit team or members of the team and declares there are conflicts of interests, the audit team members shall be adjusted immediately.

Members in audit team shall communicate with leader before auditing. Audit assignments or audit leader is responsible for logistic arrangement, such as transport, route map and pick-up. The assignments notice shall at least specify the following matter:

- Functions in auditing, name and phone number of all members;
- Auditee's company name, audit address, coordinator's name and contact information;

Audit plan shall be reviewed and accepted by client and submitted to auditee before on-site audit. Any dissent of aduitee shall be solved by audit leader, auditee and client. Any modification of audit plan shall obtain all parts' agreements before implementing.

6.6 初次认证审核 Initial Certification Audit

6.6.1 原则 Principle

初次审核分两个阶段实施：第一阶段和第二阶段。一阶段一般情况下不存在终止审核的情况；当审核组认为其不具备二阶段审核条件时，在一阶段审核结论中明确记录。

The initial certification audit of a management system shall be conducted in two stages: stage 1 and stage 2. Termination of audit usually does not happen in stage 1, therefore, if audit team considers the organization is not qualified for stage 2 audit, there shall be explicit recorded in the audit conclusion of stage 1.

6.6.2 第一阶段审核 Stage 1 audit

6.6.2.1 第一阶段的目的是通过了解组织的管理体系，策划第二阶段审核的关注点，并通过审查组织的以下方面，了解组织对第二阶段的准备状态：

a) 审核组织的文件化的管理体系信息；

b) 评价申请组织的运作场所和现场的具体情况，并与申请组织的人员进行讨论，以确定第二阶段审核的准备情况；

c) 评价管理体系运行过程中是否实施了内部审核与管理评审，确认管理体系是否已有效运行并且超过3个月；

d) 确认申请组织建立的管理体系覆盖的活动内容和范围、申请组织管理体系涉及的有效人数、活动过程和场所，遵守相关法律法规及技术标准的情况；

e) 审查第二阶段审核所需资源的配置情况，并与申请组织商定第二阶段审核的细节；

f) 结合申请组织方针和目标，了解其审核准备状态，识别对目标的实现具有重要影响的关键点，为策划第二阶段的审核提供重点；

The objective of stage 1 is to prepare the focus point for stage 2 audit by gaining the knowledge of the body's management system as well as to understand the body's preparation status for the stage 2 by examining the body's following aspects:

a) review the client's management system documented information;

b) evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2;

c) review the operation of management system to determine whether internal audit and management review have been carried out, and determine whether its management system has been operated effectively for more than 3 months;

d) determine content and scope covered by applicant's management system, effective number of people, process of activities and sites, and its compliance with legal, regulatory and technical standards requirements;

e) review the allocation of resources for stage 2 and agree the details of stage 2 with the client;

f) provide a focus for planning stage 2 by gaining a sufficient understanding of the client's management system and site operations in the context of the management system standard or other normative document;

6.6.2.2 为实现上述目的，在第一阶段审核中，获取与受审方管理体系有关的关键绩效和重要运行要素的适当信息。

a) 审核组织的管理体系文件化信息，如有任何问题应在现场与组织进行充分的沟通，需要整改处应明确ICAS的要求；

b) 现场查验受审核方的资质证件的原件，若未能见到原件的，必须及时将该信息传递到机构，由机构协调，通过网络或其他渠道验证组织真实信息；

c) 审查组织理解和实施标准要求的情况、适用的法律法规要求，特别是体系成文信息中描述的产品或服务、部门设置和负责人、生产或服务过程等是否与申请组织的实际情况相一致；以及对管理体系的关键绩效效果或重要的因素、过程、目标和运作的识别情况；

d) 审查第二阶段审核所需要资源的配置情况，并与组织商定第二阶段审核的细节；

e) 结合可能的重要因素充分了解组织的管理体系和现场运作，以便为策划第二阶段审核提供关注点；

f) 评价组织是否策划和实施了内部审核与管理评审，确认管理体系是否有效运行3个月以上；

g) 确认管理体系的实施程度能否证明组织已经为第二阶段审核做好了准备；

h) 一阶段审核的结论和组织需要整改的问题写入《管理体系文审、一阶段审核结论及问题清单》（MFP0374）；

注：审核组务必在第一阶段审核结束后明确告之组织：如果组织针对一阶段提出的问题未在二阶段审核前自行采取必要的措施，可能会导致二阶段审核不通过。

特殊情况下，当有充分理由时，部分第一阶段可以不在现场进行，但应提供证据证明第一阶段的上述目标全部实现。

In order to achieve the above objective, during the stage 1 audit, obtain appropriate information on the key performance and important operating element related to the auditee's management system.

a) Audit organization's documented information of its management system and discuss with organization on the site if any problem arises, ICAS shall make its requirements explicit where rectification is needed;

b) Examine the original copy of auditee's qualification certificate on the site. It shall be notified to the body if the original copy is failed to be obtained, and the body shall make arrangement to verify company's authentic information by other methods such as internet.

c) Examine organization's understanding and implementation of requirements of standards and applicable statutory and regulatory requirements, especially products or services described in the documented information, department settings and responsible persons and whether process of production or services are consistent with actual situation of the applying organization; identification of key performance or significant factors, process, objectives and operation of management system;

d) Examine the configuration of resource required by the stage 2 audit; and confirm the details for the stage 2 audit with organization;

e) Get to know fully about organization's management system and its on-site operation with regard for possible significant element to provide key point for preparing stage 2 audit;

f) Evaluate whether organization has prepared and implemented internal audit and management audit; and whether management system has been operated effectively for more than 3 months.

g)Determine whether implementation of the management system could prove that organization is ready for the stage 2 audit;

h) Conclusion of stage 1 audit and problems that organization needs to correct shall be recorded in "Management system document review, stage 1 audit conclusions and problems list"(MFP0374);

Note: Audit team must notify the organization of the following once stage 1 audit has completed: if organization fails to take necessary action against problems raised during stage 1 before stage 2, which may lead to failure of stage 2 audit.

In special condition, if there are sufficient reasons, part of stage 1 can be off site, however, evidence shall be provided to demonstrate that all the above objectives of the stage 1 are achieved.

6.6.2.3 以下情况可以考虑不进行一阶段的现场审核：

a) ICAS市场人员或审核员已经对组织进行过拜访或预评估，对组织关于6.6.2.1中的一阶

段审核的目的和要求已经达成，并出具与一阶段现场审核报告等效的拜访报告；或:

b) 受审核方已获得其他经认可的认证机构颁发的相应管理体系的有效认证证书，通过对其文件、资料的审查和转换前的评审，可确认受审核方的管理体系运行成熟，并可依据收集的信息，足以完成第二阶段审核的策划，并达到一阶段的审核目的和要求；或:

c) 受审核方已获得本机构颁发的其他有效的认证证书，对受审核方所申请的管理体系认证有充分了解、资料的审查可确定审核范围和第二阶段的审核重点，并达到一阶段的审核目的和要求；或:

d) 受审核方有充分的证据可证明其产品/服务技术特性明显、过程简单，通过对其文件资料审查，认为其认证风险低，并达到一阶段的审核目的和要求。如：环境、职业健康安全管理体系的风险为三级，质量管理体系的产品/服务不涉及国家强制的要求，人身安全等，通过对受审核方提交的文件、资料的审查，可作出是否能进行二阶段审核的判定。

For the following situation, stage 1 audit might be considered not necessary:

a) ICAS market personnel or auditor have conducted visit or pre-assessment to the organization; and have been familiar with the stage 1 objective of auditee in 6.6.2.1, visiting report shall be issued; or:

b) if auditee has obtained certificate of relevant management system issued by other certification body which has been accredited through examination of its documents and materials and review conducted prior to transfer, it can be determined whether auditee's management system is mature; meanwhile, information gathered can be used for stage 2 audit plan and achieving audit objectives of stage 1; or:

c) if auditee has been issued other management system certificate by ICAS, activities scope, organizational structure and process can be obtained via previous audit, and scope of audit and audit focus for stage 2 can be determined through examination of its documents and materials, and objectives and requirements for stage 1 can be met;or:

d) If auditee has sufficient evidence to show that its has obvious features and simple process of its product/service technique, then through examination of its document, it can be regarded as low-risk, such as: environment and occupational health and safety management system are considered to be level three or limited; product/service of QMS are not related to compulsory requirements by the nation or personal safety etc.; through examination of document and material submitted by the auditee, decision can be made on whether to conduct stage 2 audit and whether the audit objectives and requirements for stage 1 can be met.

6.6.2.4 一阶段不需要在现场进行时，应在审核方案中说明理由，必须在相应的审核任务书中进行说明；一阶段审核派遣书应在二阶段现场审核日前下达，以便审核组及时安排和完成非现场审核工作。

Stage 1 does not require to be carried out on-site, and reasons shall be given in the audit programme and explained in the relevant audit assignments book. Assignments book for stage 1 audit shall be issued before the on-site audit date of stage 2 in order for audit team to arrange and complete off site audit jobs.

6.6.2.5一阶段不进行现场审核时，仍需填写一阶段审核报告。此时，审核组须先将《管理体系文审、一阶段审核结论及问题清单》（MFP0374）填写完成并提交ICAS审核部，审核部收到该文件后方可进行二阶段的审核派遣。一阶段审核报告可在审核结束时一起提交。

Stage 1 audits are undertaken off site. However, stage 1 audit report shall still be filled out. Meanwhile, audit team shall complete *List of Conclusions and Problems from Management Documentation Review and Stage 1 Audit*(MFP0374); and submit to ICAS's audit department who can only assign stage 2 audit upon receipt of this document. Stage 1 audit report can be submitted when audit finishes.

6.6.2.6 一阶段审核计划中，可以不安排正式的首末次会议，但在审核计划中应体现出在审核开始和结束时有与受审核方进行沟通、确认的过程和时间。

In the audit plan of stage 1, the formal opening meeting and closing meeting may not be arranged, but the process and time of communication and confirming with the auditee at the beginning and end of the audit shall be reflected in the audit plan.

6.6.3 第二阶段审核 Stage 2 audit

6.6.3.1 二阶段的审核目的：评价组织管理体系的实施情况，包括有效性。

第二阶段审核应在现场进行，并至少覆盖以下方面：

a) 确定申请认证组织管理体系，适用的管理体系标准或其他规范性文件的所有要求的符合性及证据。确认其体系覆盖的范围及活动的管理及控制情况。
b) 依据关键绩效目标和指标（与适用的管理体系标准或其他规范性文件的期望一致），对绩效进行监视、测量、报告和评审确保申请认证组织持续实现其目标的有效性；
c) 评价管理体系确保组织满足适用的法律、法规及合同要求的能力。
d) 评价管理体系绩效中与相关法律法规和行业标准的符合情况；
e) 组织的管理过程的运作控制；
f) 确认内部审核和管理评审是否有效；
g) 确认实现管理方针的管理职责的适宜性；
h) 确认规范性要求、方针、绩效目标和指标、适用的法律法规要求、职责、人员能力、运作、程序、绩效数据和内部审核发现及结论之间的联系。
i) 适用时，识别管理体系的潜在改进区域。
j) 管理体系的规范性要求、方针、绩效目标和指标、适用的法律法规要求、职责、人员能力、运作、程序、绩效数据和内部审核发现及结论之间的联系。
k) 确认在第一阶段审核中识别出的重要审核点的监视、测量、报告和评审记录的完整性和有效性。
l) 确认其实际工作记录是否真实。对于审核发现的真实性存疑的证据应予以记录并在做出审核结论及认证决定时予以考虑（记录在审核报告中）。

The purpose of stage 2: evaluate the implementation of organization's management system including effectiveness.

The stage 2 shall take place at the site(s) of the client. It shall include at least the following:

a) Determine certification applying organization's management system as well as the conformity and its proof for any requirements from applicable management system standard or other normative document. Determine scope covered by its system and management and control over its activity.

b) Based on key performance objective and factor (consistent with expectation of applicable management system standard or other normative document), conduct surveillance, measurement, report and review against performance to ensure applying organization's effectiveness to continual achieve its objective.

c) Evaluation of management system to ensure organization's competence to meet applicable laws, regulations and contract requirements.

d) Evaluate the conformity of management system performance with relevant laws and regulations as well as industrial standard

e) Operational control of organization's management process

f) Determine whether internal audit and management review are effective;

g) Determine the applicability of realizing management policy's management duty;

h) Determine the relations among normative requirement, policy, performance objective and factor, applicable regulatory and statutory requirements, responsibilities, personnel competence, operation, procedure, performance data and internal audit findings and conclusions.

i) If applicable, identify potential improvement area of management system.

j)Relations among management system's normative requirement, policy, performance objective and factor, applicable regulatory and statutory requirements, responsibilities, personnel competence, operation, procedure, performance data and internal audit findings and conclusions.

k) Determine the completeness and effectiveness of supervision, measurement, report and review record of key audit point identified during stage 1 audit.

l) Determine whether its actual work record is authentic. Evidence found in the audit that shows doubts of authenticity shall be recorded and considered when making audit conclusion and certification decision (in the audit report).

6.6.4 准备工作文件及审核开始前的准备 Preparing work document and preparedness prior to the audit

6.6.4.1 审核组成员应评审与其承担的审核任务,准备必要的工作文件，例如：抽样计划、查询相关法规法律文件等。对于带有"*"的行业，ICAS应搜集相关的法规及标准。如，对于34.03.00中的建筑工程监理应至少搜集以下法规及标准： Members of audit team shall review and undertake their audit tasks, prepare for the necessary work document, such as: sampling plan, research of relevant statutory and regulatory document etc.. For industry with '*', ICAS shall collect relevant laws and standards. For constructional engineering supervision in 34.03.00, it shall at least collect the following laws and standards:

- 建筑法及建筑监理的法规； Construction law and regulations of construction supervision;
- 工程监理单位资质管理办法； Method of managing engineering supervision unit's

qualification;

- 工程建筑监理条例；Supervision regulation for engineering construction;
- 工程建设监理规定等。Supervision standard for engineering construction etc.

6.6.4.2 有技术专家参加的审核，审核组长应请技术专家向审核组介绍必要的专业知识和关键控制点，并请技术专家在现场审核完成前填写《□现场审核专业交底及指导培训记录/□非现场审核专业交底记录》。For audit where technical experts participate in, team leader shall ask technical experts to introduce necessary professional knowledge and key control point to the audit team, plus ask technical experts to fill out '□explanation of on-site audit profession/□explanation record of non-on-site audit profession ' prior to on-site audit.

6.6.4.3 审核员代表 ICAS 的形象，应装束整洁、稳重，以正装为宜。 Auditor represents ICAS's image and he/she shall be well groomed, preferably in formal dress.

6.6.4.4 审核组长在实施审核前就审核活动中观察员的到场及理由与申请认证组织达成一致。审核组长应确保观察员不影响或不干扰审核过程或审核结果。

Audit team leader shall reach an agreement with organization who applies for certification on observer's presence and reasons before starting the audit. Audit team leader shall ensure that observer would not affect or disturb audit process or audit result.

6.6.4.5 每个审核员宜由一名向导陪同，除非审核组长与组织另行达成一致。审核组长应确保向导不影响或干扰审核过程或审核结果。

Each auditor shall be accompanied by a guide unless audit team leader reaches an agreement with organization otherwise. Audit team leader shall ensure that the guide would not affect or disturb audit process or audit result.

6.6.5 文件化信息的审核 Audit of documentation information

根据ISO 9001、ISO 14001、ISO 45001以及GB/T50430、ISO13485标准要求，需形成文件的信息和为确保管理体系有效性所需的形成文件的信息，以及转版过程中所作的工作，应要求组织在现场审核前（或一阶段审核时）及时提供给ICAS，审核员应及时进行文审。

初次认证审核时，文件审核结果应总结写入《管理体系文审、一阶段审核结论及问题清单》中，并要求受审核方最迟在第二阶段现场审核前完成对相关问题的整改，以便在第二阶段现场审核前或现场审核开始时能予以确认。

其他审核类别（如再认证或扩大范围审核）需要进行文件化信息的审核时，文件审核结果应总结写入《管理体系文审、一阶段审核结论及问题清单》对应的文审栏目中，并在现场审核实施前对整改结果做出确认。若仍未有效整改的，现场审核时开具不符合项报告。

According to requirements of standards ISO 9001:2015, ISO 14001:2015、ISO 45001：2018 and GB/T50430, ISO13485, information required to be documented and information for ensuring the effectiveness of management system, and works have been done during transition shall all be provided to ICAS before on-site audit (or stage 1 audit) . Auditor shall conduct document review without undue delay.

During initial certification audit, result of document audit shall be written in *List of Conclusions and Problems from Management Documentation Review and Stage 1 Audit*; and auditee is required to complete correction of relevant problems no later than stage 2 on-site audit, so that it may be

confirmed before or upon stage 2 on-site audit.

When audit of documented information is required for other audit categories(e.g. recertification or audit scope extension) , result of documentation review shall be written in relevant sections of "Management system document review, stage 1 audit conclusions and problems list", and result of corrections shall be conformed before on-site audit is conducted. If no effective correction is confirmed, nonconformity report shall be issued on the site.

6.6.6 现场审核的实施 Conducting the on-site audit

管理体系审核使用过程审核的方法，在每个部门的审核应体现以下6个步骤:

a) 创造良好的审核氛围;

b) 确定审核的基础信息（如被审核部门的环境/危险源因素、目标、指标和方案、职责、架构、文件、资源、在生产的产品或提供的服务）

c) 识别过程，特别是关键控制点和验证作法与文件要求的一致性;

d) 寻找证据（人证、物证、文件、运行记录和过程业绩等）;

e) 检查回顾（每个部门审核结束前，每个审核员应回顾和检查所审核的项目，确保没有遗漏的应审的项目、是否有需要在其它部门进一步确认的事项或需其他审核组成员在其它部门需确认的事项、是否已就审核发现已经与受审核方充分沟通等）;

f) 结束审核。

Method of process audit used during management system audit shall include the following 6 steps during audit of each department:

a) Create fine environment for audit;

b) Determine the basic information for audit(such as department's environmental/hazardous elements, objective, factor and programme, responsibilities, frame, document, resources, product being manufactured or service being provided)

c) Process of identification especially consistency of key control point and method of verification with which required in the documentation;

d) Evidence tracking (witness, evidence, documentation, operational record and performance of process etc.)

e) Examination and looking back （each auditor shall look back and examine all the audit project before the end of each department's audit to ensure that there is no missed project to be audited, to check if there is matter to be further confirmed in other department or matter to be confirmed by other audit team member in other department, and whether sufficient negotiation has been made with auditee on audit findings etc.);

f) Closing audit.

6.7 审核活动 Audit activities

6.7.1 召开首次会议 Conducting the opening meeting

会议的主要目的是简要解释将如何进行审核活动。

会议由审核组长主持，审核组成员、受审核方最高管理层、受审核的职能或过程负责人参

加，参会所有人员（包括审核组成员）应在《签到表》（MFP0312）上签到，由审核组长保存记录。申请组织要求时，审核组成员应向申请组织出示身份证明文件。

首次会议上应由审核组长主导介绍包括以下内容，并让组织有提问的机会。召开首次会议时应包括下列要素的确认，详细程度可与组织对审核过程的熟悉程序相一致：

- 双方介绍参会人员；包括简要介绍其角色；
- 介绍审核性质、审核目的、审核依据；与组织确认认证范围，并向组织解释审核将根据确认的范围进行抽样；与组织确认审核范围内是否有法律所禁止的产品；
- 与组织确认审核场所，如果有固定多现场或临时场所，且受审核方在申请时未向机构申报，应请组织填写《□多现场 □多场所信息征询表》（MFP0350），在这种情况下，审核组长应合理调整审核计划，确保审核覆盖所有场所；审核组长认为涉及现场/场所抽样或审核人天不足时，应通知审核部；
- 确认审核组和组织之间的正式沟通渠道；
- 确认审核计划及其任何变化，以及与组织的其他相关安排，例如，末次会议的时间、地点、参加人员，审核组和受审核方管理层之间的临时会议以及任何新的变动；
- 确认审核组所需的资源和设施（临时办公、通讯、交通工具、劳动保护）；
- 宣布保密承诺和确认有关保密事宜；宣布公正性声明；
- 确认审核和工作的安全事项、应急和安保程序（存在时）；
- 介绍陪同人员的作用并安排落实（向导、见证、联络）；
- 简要介绍审核活动如何实施；
- 说明现场审核结论是推荐性结论；说明严重不符合项、轻微不符合项和观察项的定义及处理方法，以及对现场审核的影响程度；
- 说明可能终止审核的条件。
- 确认审核组长和审核组代表ICAS对审核负责，并应控制审核计划（包括审核活动和审核路径）的执行；
- 说明审核所用的抽样方法和审核程序；
- 确认审核所使用的语言（必要时）；
- 关于审核过程发生争议时的处理程序；
- 确认在审核中将告知组织审核进程及任何关注点；
- 安排受审核方领导讲话；询问组织是否有问题；

为便于检查首次会议内容是否有缺漏，ICAS编制了《首次会议查检表》（MFP0313）。

The main purpose of the meeting is to simply explain how to conduct the audit activity.

Meeting is hosted by audit team leader, and team members, top management of auditee, person in charge of functions or processes that are to be audited will participate in. Everyone(including members of audit team) who participates in the meeting shall sign on the

'Sign-in sheet'(MFP0312) and audit team leader shall keep the record. If applicant organization requires, members of audit team shall show identities to the applicant organization.

Audit team leader shall guide and introduce the following information and give the organization opportunity for questions. The confirmation of following elements shall be confirmed during opening meeting, and level of specificity of which shall be consistent with organization's familiarity with audit process:

- Introduce the attendees which includes introduction of their roles;
- Introduce characteristic, purpose and basis of auditing; explain to organization that making samples shall base on the affirmative scope; determine whether forbidden products are included in the scope;
- Determine audit sites with organization. If there are fixed multi-site or temporary sites which are not reported by the auditee to the body during application, the organization shall fill out □Multi-site □Multi-location Information consultancy (MFP0350), under such circumstance, audit team leader shall adjust the audit plan and ensure all sites; if team leader consider that site sampling or audit man day is inadequate, he/she shall inform audit department;
- Determine the formal communication channel between audit team and organization;
- Determine audit plan and any changes to it as well as other relevant arrangements of the organization, such as time, site, attendee of closing meeting and interim meeting and any new change of audit team and management of auditee;
- Confirm necessary resources and facilities (temporary working, communication, vehicle and labor protection);
- Declare confidentiality commitment and erasure confidentiality matters;
- Confirm safety matters in audit and work, emergency and safety procedure, if existing;
- Introduce function of accompany personnel and put into practice (guide, witness and contact) ;
- Introduce briefly how to implement audit activity;
- Specify that the on-site audit conclusion is recommendation conclusion; specify the definition of and dealing method for major nonconformity, minor nonconformity, and observation as well as the level of influence on the on-site audit
- Specify possible conditions for terminating the audit;
- Determine that audit team leader and audit team represented for ICAS are responsible for auditing, and take control of the implementation of audit plan (including audit activity and audit route);
- Specify the sampling method and audit procedure used in the audit;
- Confirm language used in auditing when necessary;
- The dealing process of dispute occurred in the audit;
- Confirm that audit process and any focus have been informed to organization.
- Arrange a speech from the leader of auditee party and ask if the organization has any questions;

'Opening Meeting Checklist' (MFP0313) is prepared for checking if there is omission in the content of the opening meeting by ICAS.

6.7.2 审核中的沟通Communication during the audit

6.7.2.1 根据组织的审核范围及复杂程度，审核组长应安排必要的沟通渠道及沟通方式；Audit group leader shall arrange necessary communication channel and method according to scope and complexity of organization's audit;

6.7.2.2 审核时间超过一天以上时，审核组长应每天组织审核组内部进行一次简短的会议，以便：

a) 交换信息；

b) 评定审核进展情况；

c) 必要时，重新分配审核组成员的工作。

If the audit time is more than one day, group leader shall organize a brief meeting everyday in audit team so as to:

a) Exchange information;

b) Evaluate progress of audit;

c) Reallocate auditor's work when necessary.

6.7.2.3 视组织规模及其复杂程度，审核组长应定期向组织通报审核进展情况及相关情况。Group leader shall inform audit progress and related information to organization regularly according to the scale and complexity of organization.

6.7.2.4 审核组成员在审核中发现重大不符合时，应及时报告审核组长，并由组长与组织沟通。If there is a major nonconformity, the auditor shall report to group leader in time and the leader communicates with organization.

6.7.2.5 审核组成员如发现超过范围之外的引起关注的问题时，应当指出并向审核组长报告，必要时，应通报组织。If auditor find problems over the scope, he shall point it out and report to leader, if necessary, to tell the organization.

6.7.2.6 当获得的审核证据显示审核目的无法实现，或显示存在紧急和重大的事件、事故，例如安全风险、突发的生产过程事故、环境事故时，审核组长应与审核部取得联系,并同组织商量确定补救措施或终止审核。补救措施可以考虑以下方式：

a) 重新安排审核时间及审核计划；

b) 修改审核计划，对存在重大不符合项的相关区域另外安排时间跟踪审核；

c) 改变审核目的及审核范围。

If the audit evidence obtained shows that audit objective can not be achieved or there is emergent and significant incident and accident; such as safety risk, unexpected accident during production process and environmental accidents; then group leader shall contact audit department and determine remedial actions or terminate the audit. Remedial actions can consider the following:

a) Re-arranging audit time and plan;

b) Modifying audit plan and arranging time for follow-up audit of area with major nonconformities;

c) Changing audit objectives and scope.

6.7.2.7 当现场审核时，出现组织管理体系涉及的有效人数、名称、地址或/及审核范围变更，审核组长负责与ICAS审核部取得联系并填写《变更申请》表，由组织签字确认后传回给公司审核部进行评审。 审核部审核方案管理人员负责变更的评审，对于认证业务范围的变更或/及组织

人数的变更应确定下述事宜后决定应采取的措施:

a) 认证业务范围的变更

- 评估审核组成员的业务能力;
- 评估认可的业务范围;
- 征求组织的意见。

b) 组织管理体系涉及的有效人数的变更

- 审核人天的变更
- 审核计划的调整
- 征求组织的意见

During on-site audit, if there are changes of effective number of staff, name, address and/or audit scope that are involved in organization's management system, then audit team leader is in charge of contacting ICAS's audit department and fill out the form of *Application for Change* which shall then be signed and confirmed by the auditee and be returned to audit department for review. Personnel of audit department for managing audit programme is in charge of reviewing the change. For change of certification business scope or/and staff number, necessary actions shall be determined after confirming the following matters:

a) Changes of certification business scope
   - Assess professional competence of audit members;
   - Assess accredited business scope;
   - Ask for organization's opinion.

b) Changes of effective number of staff that is involved in organization's management system
   - Change of audit man day
   - Adjustment of audit programme
   - Ask for organization's opinion.

6.7.2.8 任何审核组成员如发现其所审部门实际没有分配给其要素活动，应随时通知审核组长。

If any audit team member finds that the department being audited is not actually allocated with element activity, he/she shall immediately notify audit team leader.

6.7.2.9 审核组长应召集审核组成员对审核过程中的发现在末次会议前进行讨论并综合评价，确定构成不符合项时，应经审核组长确认同意后，方可向受审核方提出，当审核员与审核组长就不符合项产生争议时，审核员现场应服从审核组长的安排。事后可将该争议提报ICAS管理委员会裁定。

Audit team leader shall gather audit team members to conduct discussion and overall comments on findings during audit process before the closing meeting; if nonconformity is determined, it can only be raised to the auditee after confirmed and agreed by the audit team leader; if there happens to be disputes on the nonconformity between auditor and team leader, auditor shall submit to the team leader's arrangement on the site. The disputes can be submitted to the ICAS management committee for verdict afterwards.

6.7.2.10 现场审核发现人数严重失实导致审核无法按计划完成时，应首先填写《变更申请》表，

由组织签字确认，传回审核部以便审核部重新进行审核人天的确认，审核组长负责与组织协调补救措施。

If audit fails to be completed as planned due to the inconsistency of staff number with facts found during on-site audit, form of *Application for Change* shall be filled out first and which shall be signed by the auditee and sent back to audit department in order for audit department to determine the audit man day once again; audit team leader is in charge of arranging remedial actions with auditee.

6.7.2.11 当与组织就不符合项发生分歧时,审核组应首先虚心听取组织的解释，决不可武断或以自己以往的经验要求组织，应努力以适当的、富有建设性、专业的方式解决与组织之间的分歧；如组织的解释合理，可取消发生争议的不符合项。如争议无法解决，应向组织解释ICAS有关《申诉、投诉、争议程序》（ICASP06）对争议的处理方法。

When there is a dispute over nonconformity with organization, audit team shall listen to organization's explanation modestly first and shall not request organization arbitrarily by experience; team shall deal with the dispute in a constructive and professional way; if organization's explanation is reasonable, the nonconformity may be eliminated. If dispute can not be solved, audit team shall explain handling method in *Appeal, Complaint and Dispute Procedures*（ICASP06）to the organization.

6.7.2.12 若审核组内部或与受审核方之间发生无法处理或协调的异常/突发事件，审核组长应立即上报总经理。

If abnormal/emergency events happen within the audit team or with the auditee which can not be dealt with or negotiated the audit team leader shall immediately report to the managing director.

6.7.3 信息的搜集和验证和记录 Collection, verification and record of information

6.7.3.1 审核组成员应在其承担的审核工作内，根据审核计划、用抽样的方式进行信息的收集，使之成为审核证据。信息的来源可以是:

a) 与员工和其他人员的交谈。当非审核人员(如顾问)代替被审核人员不断回答问题时，相关审核组员应给予适当的制止;

b) 对活动、周围工作环境和条件的观察;

c) 文件，如：方针、目标、计划、程序、标准、指导书、规范、图样、合同、营业执照、许可证、产品强制性检验报告、订单等;

d) 数据的汇总、分析、和业绩指标;

e) 组织抽样方案的信息、抽样和测量过程的信息;

f) 其他方面的报告，如：组织抱怨、反馈等;

g) 计算机数据库和网站;

h) 记录;

The audit team members shall collect information with a sampling approach in its audit work according to the audit plan, sources of information can be:

a) Talk with employee and other staff. If non-auditor (e.g consultant) answers to the

questions on behalf of auditor, then relative audit team member shall stop him/her.

b) Observation on activity, surrounding working condition and environment;
c) Documents, such as policy, objectives, plan, program, standard, and guide book, criterion, drawing, contract, business license, license and mandatory product inspection report and order form;
d) Summary and analysis of data as well as performance factor;
e) Information of organization sampling scheme, sampling and measurement process;
f) Other reports, such as organization complaints and feedback etc.;
g) Computer database and website;
h) Records;

6.7.3.2 审核记录Audit Records

所有记录包括从申请、合同评审、任务书、文件审核报告、审核计划等所有与审核相关的记录和文件，审核部均应将原件以电子档案或书面形式予以保留在公司，审核组或任何其它人员不可将原件带离公司。

采用计算机技术进行远程审核时，要详细记录以下信息:

a) 采用何种计算机辅助技术进行的远程审核;
b) 远程审核项目、远程地址;
c) 对方参加远程审核参加人员;
d) 调用的文件和记录名称;
e) 通过视频或电话等审核的人员名称和职务;
f) 符合/或不符合的关键证据。

All records include application, contract review, mission book, document audit report, audit plan and all records and documents related to audit. Audit department shall retain the origin copy in electric or written way in company. Audit team or other staff can not take origin copy away from company.

When using computer for remote audit, the following details shall be recorded:

a) What is the use of computer-aided technology to conduct remote audit;
b) Remote audit items and address;
c) Participants of remote audit in opposite side;
d) Documents and record name;
e) Name and duty of the personnel who audit by video or telephone;
f) Key evidence of conformity/ nonconformity

在OHSMS审核时，审核组应面谈以下人员：负有OHS法律责任的管理者；负责OHS的员工代表；负责监视员工健康的人员，如医生和护士。还有管理人员、长期和临时员工。宜面谈的其他人员：从事与预防OHS风险相关活动的管理人员和员工，和承包方的管理者和员工。面谈的人员、身份、远程面谈的理由等，按审核记录表单要求予以记录。若采取了远程方式，远程面谈的理由应被记录;

记录中应避免涂改液或其它方式覆盖原始记录，必须纠正时，可以以划改的方式修正，并由原记录人签字。

审核记录使用的文字为中文，特殊情况下，经批准可使用外文。审核记录应体现审核证据，证据可以是人证、物证、质量记录等。如：具有可追溯的抽样（产品名称和批号等），面谈的人员姓名和见证人等。

应当记录具体的不符合和支持的审核证据;符合要求和支持的审核证据的记录应简明扼要，具有唯一可追溯性。

应注意以下事项：

a) 初次认证时，对QMS的第八章条款的审核应覆盖认证范围内的所有不同类的产品（即：所有不同类的产品都应审核到）；监审时可酌情抽样；记录应具有可追溯性；对于停止或无在生产的产品、尚未完成所有阶段的产品、尚没有订单的产品、可搜集其它证据，例如：人员资质、设备能力等，以能证明其有能力生产；但应在审核流转单中予以注明，以确保该认证项目在监督审核整个周期内覆盖到所有认证范围。

b) 适用时，QMS的8.6条款审核记录应体现认证范围内的不同类别的产品的出厂依据/标准，必要时，要收集产品3C认证、强制性标准执行情况的证据（包括型式试验、国家/地方/行业的抽查报告等），如受审核方不能提供3C或其它强制性标准执行情况的证据，则应记录不能提供的原因，及受审核方目前的计划;

c) 如有外部供方提供的产品或服务过程，要记录外部提供的产品名称或服务，及其控制情况；（若组织认证产品范围的产品形成过程全部外包，该外包单位应视为组织的多场所，并到现场进行审核做好记录）；

d) 不符合项报告的描述应清楚、准确且具有可追溯性，应包含不符合发现场所、审核发现描述、不符合依据;

e) 凡审核计划要求审核的条款不能漏审；在各部门首页记录表编制栏上审核员应签字。末次会议前的审核组会议上，审核组长应安排审核组成员互相确认审核记录无漏审现象，并将所有审核记录交审核组长归档。

During OHSMS audit, the audit team shall interview the following persons: the manager with OHS legal responsibility; Employee representative in charge of OHS; People responsible for monitoring the health of employees, such as doctors and nurses. There are also managers, permanent and temporary staff. Other personnel should be interviewed: managers and employees engaged in activities related to OHS risk prevention, and managers and employees of the contractor.Interview personnel, identity, reasons for remote interview, etc. shall be recorded according to the requirements of the audit record form. Reasons for the remote interview should be recorded.

Audit record shall use Chinese but foreign language can be used in special circumstance. Record shall reflect audit proof which can be witness, physical evidence and quality record, such as a traceable sample (product name and batch number), personnel name and witness etc.

Specific nonconformity and audit evidence shall be recorded; records that meets requirements and supporting audit evidence shall be concise and with a unique traceability.

Notice following matters:

a) In the initial certification, audit to clauses in Chapter 8 of QMS shall cover all varieties of products within the certification scope (which means that all different kinds of products shall be audited); in the surveillance audit, sampling can be used as appropriate; record shall have traceability; for product which has stopped producing or is not being produced, which has not completed all stages and which has no order, other evidence may be collected; such as: personnel qualification, ability of instrument; to prove its production ability, however, it shall be noted in the audit circulation sheet to ensure that this certification project covers all certification scope in the whole cycle of surveillance audit.

b) Audit record of article 8.6 in QMS shall represent different products' basis or standard when leave the factory. If necessary, to collect evidence of 3C certification and implementation of mandatory standard, including type test, national/regional/industrial spot check report. If auditee can not provide 3C or implementation situation of other compulsory standard, the reason for failing to provide shall be recorded as well as the current plan of the auditee party;

c) If there is process of product or service provided by external party, it shall record the name of the product or service provided externally as well as it s control status; (if organization's product within the scope of certification product is all outsourced, then the outsource company shall be regarded as organization's multi-site, and where on-site audit shall be carried out and be recorded.

d) nonconformity records shall be clear, accurate and traceable, and shall include site where the nonconformity is found, description of auditing and evidence of nonconformity;

e) Audit plan requires that there shall be no clause fails to be audited. Auditor shall sign on the first page of record. In the audit team meeting before closing meeting, audit team leader shall arrange members to examine with one and other and sign to confirm that there is no omission in audit record. The audit team leader shall archive the audit record.

6.7.3.3 审核组长在审核过程中应随时检查审核组成员是否按照ICAS程序要求使用文件。

The audit team leader shall always check in the audit process whether the team members use files in accordance with the procedures of ICAS.

6.7.3.4 实习审核员指导对实习审核员的活动和审核发现最终负责，实习审核员不能单独编写审核记录。

Auditor instructor-in-training shall be responsible for the auditor-in-training's activity and final audit findings, auditor-in-training shall not prepare audit record by him/herself.

6.7.4 审核结束前的准备Preparation before the end of audit

6.7.4.1 形成审核发现 Generating audit findings

审核组成员根据审核准则对审核记录的完整性进行确认,以确保审核充分性和完整性，并评价审核证据，形成审核发现。例如EMS审核时，除了注意关注重大环境因素的识别和管理外，同时还应关注可能对工作环境造成污染影响的环境因素的识别和管理。可以在审核报告中识别和记录改进机会。

Audit team members confirm the integrity of the audit by using audit criteria for ensuring the adequacy and completeness of the audit, evaluating audit evidence, generating the audit findings. Such as EMS audit, except for paying attention to identification and management of significant environmental element, identification and management of environmental element which may cause pollution to the work environment shall be paid attention to as well. Improvement opportunity may be identified and recorded in the audit report.

6.7.4.2 审核组长应在结束会议之前，召开审核组内部会议，审核组应：

a) 针对审核目的,评审审核发现及审核过程中所发现的其它信息;

b) 考虑审核过程中不确定的因素，对审核结论达成一致;

c) 根据管理评审、内部评审的适宜性及本次审核发现，及确保审核的连续性，对下次监督审核的需关注的部门和要素、过程提出建议;

d) 确定任何必要的跟踪活动;

The audit team leader shall arrange audit team internal meeting before the closing meeting. Audit team shall:

a) Other information regarding to audit objective and review audit that is found during the audit process

b) Consider uncertain factors during audit process and reach agreement on audit conclusion;

c) Make suggestion on department factors and process of next audit according to suitability of management review and internal review and this audit finding and continuity of the audit;

d) Determine necessary follow-up activity;

6.7.4.3 审核组应就不符合项与组织沟通，确认审核证据的准确性，并使组织理解并接受。审核组长应尝试解决审核组与组织之间关于审核证据或审核发现的任何分歧意见，未解决的分歧点应予以记录。

a) 针对审核目的，评审审核发现及审核过程中所发现的其它信息;

b) 考虑审核过程中不确定的因素，对审核结论达成一致;

c) 根据管理评审、内部评审的适宜性及本次审核发现，及确保审核的连续性，对下次监督审核的需关注的部门和要素、过程提出建议;

d) 确定任何必要的跟踪活动;

e) 确认审核方案的适宜性，或识别任何需要的修改（例如范围、审核时间或日期、监督能力）。

The audit team shall communicate with the organization on the nonconformity, confirm the accuracy of audit evidence and let the organization understand and accept it. Audit team leader shall try to solve any disagreements and opposite opinions on the audit evidence or audit findings between audit team and organization; the unsolved disagreement point shall be recorded

a) Other information regarding to audit objective and review audit that is found during the audit process

b) Consider uncertain factors during audit process and reach agreement on audit conclusion;

c) Make suggestion on department factors and process of next audit according to suitability of

management review and internal review and this audit finding and continuity of the audit;
d) Determine necessary follow-up activity;
e) Ensure the suitability of audit programme or identify any modification, such as scope, audit time or date, supervising capability.

6.7.4.4 审核组成员应分别将所发现的不符合项记录于《不符合项报告》（MFP0314）中，并对不符合项分级。不符合项报告中对不符合要清晰陈述，并详细标识不符合所基于的客观证据。在形成不符合项报告前，应与组织说明不符合，以确保证据准确且不符合得到理解。但不向组织提示不符合的原因或解决方法。

审核报告中应记录不符合以及所对应的审核准则。

Audit team member shall record the nonconformity found in the 'nonconformity Report' (MFP0314) and rate it. In the nonconformity report, it shall be clearly specified and notify the objective evidence it is based up on in details. Before the report is formed, organization shall be notified with the nonconformity to ensure that evidence is correct and nonconformity is being understood. However, reasons or solving method shall not be disclosed to the organization.

nonconformity and its corresponding audit criteria shall be written in the report.

6.7.4.5 得出审核结论Audit Conclusion

审核组通过6.7.4.2的讨论，对审核中收集的所有信息和证据进行分析，以评审审核发现并就审核结论达成一致，形成审核结论。审核结论应包含以下内容:

a) 管理体系与审核准则的符合程度;
b) 管理体系的实施、保持和改进的有效程度;
c) 内审、管理评审的适宜性、充分性、有效性和改进方面的能力;
d) 有关管理体系实施中最重要的正面和负面的总结;
e) 审核组的结论;
f) 必要时，提出建议。

审核报告中的最终推荐结论应覆盖本次审核派遣的任务，这些任务可能包括了:

1）初次认证——推荐认证注册、不推荐认证注册

2）监督、再认证——推荐保持认证注册、不推荐保持认证注册、推荐暂停证书、推荐撤销证书

审核结论有以下以下几种形式:

- 推荐注册/ 维持证书: 当审核发现只存在轻微不符合，且都已采取纠正措施并经验证后，初次认证和再认证时，推荐注册；监审时，推荐保持注册;
- 有条件推荐注册/维持证书: 当审核发现存在严重不符合时；已制定不符合纠正计划并实施了部分纠正措施后，根据情况有条件推荐/维持。
- 推荐证书暂停: 监督审核时，现场发现获证组织有违反法律法规的情况，或发生了质量/环境/安全事故；现场审核发现上次开具的不符合项超过一个月仍未实施有效的纠正措施;

■ 推荐撤消证书：证书暂停后超过六个月仍未对不符合包括严重不符合项采取有效的纠正措施。

■ 不推荐注册：

1. 受审核方的管理体系有重大缺陷，不符合认证标准的要求以及合规性要求。
2. 发现受审核方存在重大质量安全问题或有其他与产品和服务质量相关严重违法违规行为。

After discussion of clause 6.7.4.2 by the audit team, it shall generate the audit conclusion which includes the following:

a) The conformity level between management system and audit criteria;

b) The effectiveness of the implementation, maintenance and improvement of management system;

c) Suitability, sufficiency, effectiveness of internal audit and improvement ability;

d) The most important positive and negative conclusion in the implementation of FSMS;

e) The conclusion of audit team.

f) Make suggestion when necessary.

The final recommendation conclusion in the audit report shall cover tasks assigned in this audit, these tasks may include:

1) Initial certification -- recommend certification registration, not recommend certification registration

2) Surveillance, recertification -- recommend maintain certification registration, not recommend maintain certification registration, recommend suspending certificate, recommend withdrawing certificate

The audit conclusions may be in following forms:

- Recommend registration or maintaining certificate : When there is just minor nonconformity in the audit finding and corrective actions have been taken and verified, then recommending registration after initial certification and recertification and maintain registration after surveillance audit;
- Recommend registration or maintaining certificate with conditions: when there is major nonconformity in audit finding and correction plan of nonconformity has been made and part of the corrective action has been implemented, then recommend/maintain with conditions based on the situation.
- Recommend suspending certificate: during surveillance audit, if there is breach of laws and regulations of the certified organization on-site or there are quality/environmental/safety accident; it is found during on-site audit that nonconformity issued last time has not been taken effective corrective actions for more than a months;
- Recommend withdrawing certification: no effective corrective actions have been adapted to major nonconformity for more than six months after suspension of certificate.
- Not recommend registration:

1. There are major defects in auditee's management system, which does not meet requirements of

certification standard and compliance requirements.
2. It is found that the auditee has major quality safety issue or other major violations of rules and laws.

6.7.5 召开末次会议 Conducting the closing meeting

审核组与组织的管理层一起召开正式的末次会议，并要求与会人员签到。由审核组长主持，并以受审核方能够理解和认同的方式提出审核发现和结论,包括关于认证的推荐性意见。审核组长可使用《末次会议查检表》（MFP0316）检查末次会议要说明的项目，以免遗漏有关的事项。必要时，可以解释审核发现和对审核标准的理解。

末次会议主要内容:

- 审核情况报告：主要是确认本次审核的范围、确认不符合报告、管理体系的综合评价、确认审核结论、审核报告的分发等;
- 重申抽样方法;
- 说明并确认受审核方针对不符合项进行纠正和纠正措施的时间要求(如进行再认证应规定在认证终止前实施纠正与纠正措施的时限,从而使新的认证周期在上一个认证周期结束前已经生效）;
- 说明 ICAS 处理不符合及验证整改情况的过程（包括自行验证整改、审核组验证整改、ICAS 注册部评定、ICAS 总经理批准、发证（初审）/资格保持（监督）过程）;
- 说明 ICAS 有关服务、及审核后活动;
- 监督审核要求;
- 认证证书和标志的使用要求;
- 重申公正性声明、保密承诺;
- 受审核方信息沟通的要求;
- 需要澄清的问题;
- 说明投诉处理过程和申诉过程。

OHSMS审核时，应要求组织代表邀请负有OHS法律责任的管理者，负责监视员工健康的人员、负责OHS的员工代表参加末次会议；参加会议的人员应签到；未到的应记录缺席的理由。

末次会议时组织应有机会提出问题。审核组与组织之间关于审核发现或结论的任何分歧意见应得到讨论并尽可能获得解决。任何未解决的分歧意见应在审核报告中予以记录并提交ICAS注册部。

Closing meeting shall be the formal meeting attended by both audit team and management of the organization and it requires the attendees to sign. The whole audit team, relevant leaders and personnel form auditee party shall participate. It is hosted by audit team leader and the audit findings and conclusion is issued in a way that is understandable and agreed by the auditee party. Audit team leader could use ‘Closing Meeting Checklist’ (MFP0316) to prevent some relevant part from being omitted. When necessary, there shall be explanation for audit findings and understanding of audit standard.

Main contents of closing meeting:

- Audit report: determine audit scope, nonconformity, and comprehensive evaluation of management system, audit conclusion and distribution of audit report;
- Re-affirm sampling method;
- Specify and confirm the time requirements for correction and correction actions against the nonconformity taken by the auditee (specify limited time of implementing corrective measurement before certificating when make recertification so as to make new certification take into effect before the ending of last certification);
- Specify the process of nonconformity dealing process and verification of correction (including voluntary verification of correction, verification of correction by the audit team, ICAS registration department assessment, ICAS managing director's approval and process of certificate issue (initial audit)/qualification maintenance (surveillance);
- Specify relevant ICAS service and activities after audit;
- Requirements for surveillance audit;
- Requirement of use of certificate and marking;
- Reaffirm impartiality statement and confidentiality commitment;
- Requirements of auditee information communication;
- Problems that are to be clarified;
- Explain processing procedure of complaints and appeal.

During OHSMS audit, the organization representative shall be required to invite the manager with legal responsibility for OHS, the person responsible for monitoring the health of employees, and the employee representative responsible for OHS to attend the end meeting; Participants should sign in; Reasons for absence should be recorded.

The organization shall have opportunity to ask questions during the closing meeting. Any disagreements on the audit findings or conclusion between audit team and organization shall be discussed and solved as much as possible. Any unsolved disagreements shall be recorded in the audit report and be submitted to ICAS registration department.

6.7.6 现场审核结束前审核信息及审核文件的收集 Collection of audit information and audit documents before the end of on-site audit

审核组长负责以上审核信息的收集及并根据《审核文件检查表》（MFP0309）对相关审核文件进行收集并按要求完成签字盖章确认的手续。Audit team leader is responsible for collecting relevant audit documents according to *Audit document checklist* MFP0309 and complete the process of confirmation such as signature and stamp as required.

6.7.7 审核报告 Audit report

审核报告由审核组长负责编制，并对审核报告的内容负责。审核报告中的信息应确保能为认证决定提供充分信息，这些信息的要求体现在ICAS质量管理手册中。

ICAS客服人员或其他指定人员将审核报告提交组织，并保留签收或提交的证据。

Audit team leader is responsible for the preparation of the audit report and its content. The audit report may be attached with necessary evidence or record of related truth for the certification which includes words or photos, videos and other audio materials. The information in the audit report shall

ensure that it could provide sufficient information for the certification decision and requirements for this information shows in the quality management manual of the organization.

ICAS service personnel or other appointed personnel shall submit the audit report to organization organization and keep evidence of signing or submission.

6.7.7.1 编制审核报告时，应按报告中提示的栏目，须逐项评价组织对管理体系覆盖的过程和活动的管理及控制情况；

When preparing audit report, for each item in the report, it shall be evaluated in regards to the organization's management and control of processes and activities covered by management system

6.7.7.2 监督审核和再认证时，重点关注并记录获证组织的变更情况、不符合项纠正措施有效性、认证证书和认证标志的合规引用情况；

During surveillance audit and recertification, special attention shall be paid to the following and record shall be made: the changes of organization with certification, effectiveness of corrective actions of nonconformity, compliance of reference of certification certificate and certificate mark.

6.7.7.3 再认证审核前，需对该获证组织上一认证周期的管理体系运行绩效进行评价；再认证审核时需对上一认证周期管理体系运行绩效评估的薄弱环节予以关注。

Before recertification, operation of certified organization's management system during previous certification cycle shall be evaluated;and recertification audit shall pay attention to weak links shown in the performance evaluation of management system for previous period.

6.7.7.4 关于"管理体系审核综述"栏的三个选项"符合"、"基本符合"、"不符合"的选择与描述内容。The selection and description of the three options in the "Management System Audit Overview" column: "Conform", "Mostly conform", and "Not conform".

1）勾选"符合"，就是指审核这方面的内容后，认为都符合要求，即，未开出任何不符合项或观察项；

2）勾选"基本符合"，是指在对应的这方面，尚存在一点或一些不足、或开具了观察项；

3）勾选"不符合"，是指在对应的这方面，开具了不符合项（包括轻微不符合和严重不符合）；

审核组如果选了"基本符合"，除了对这方面管理情况的正面评价以外，还应简单描述希望受审核方改进或提高的地方，或者是观察项的内容；选了"不符合"时，既要描述不符合项涉及到的负面评价；也要有对这一方面管理的正面总结。当没有任何负面评价或提出改进建议的时候，即认为这一方面的评价结果为"符合"。

1) Selecting "Conform" means that after reviewing this aspect, it is deemed that all requirements are met, that is, no non conformities or observations have been made;

2) Select "Mostly conform" to indicate that there are still some deficiencies or observation items in the corresponding point;

3) Selecting 'Not conform' means that a non conformity item (including minor and severe non conformity) has been issued in the corresponding point;

If the audit team selects "Mostly conform", in addition to a positive evaluation of the management situation in this point, it should also briefly describe the areas where the auditee hopes to improve or improve, or the content of the observation items; When selecting 'Not conform', it is

necessary to describe the negative evaluation involved in the non compliant item; There should also be a positive summary of this aspect of management. When there are no negative evaluations or improvement suggestions, it is considered that the evaluation results in this aspect are "Conform".

6.7.8 不符合项的原因分析、处理及验证的方式 Cause analysis, handling and verifying method of nonconformity

审核组长或审核组长指定的开出不符合项的审核员或ICAS确认过的有能力的人员负责跟踪不符合项的整改，确保不符合项在规定的时间内的有效整改(ICAS指定人员可以通过审查组织提供的文件，或在必要时实施现场验证来验证纠正和纠正措施的有效性，不符合的解决提供支持的证据应予以记录，对不符合的解决进行审查和验证的证据应予以记录，有必要时请审核员确认，并将审查和验证的结果告知组织)。

Audit team leader or personnel making nonconformity appointed by him or designated by organization is responsible for closing nonconformity, and ensure nonconformity has reformed in the fixed time (personnel designated by organization can review organization's documents and verify validity of corrective measurements on-site when necessary. Evidence provided for solving nonconformity shall be recorded, make auditor confirm if necessary. Inform organization of the result of reviewing and verifying.)

6.7.8.1 不符合项的定义：缺少或未能实施和保持一个或多个管理体系的要求，或根据所得到的客观证据足以怀疑组织所提供产品或服务质量的情况。 Definition of nonconformity：lack or not implement and keep the requirements of one or more management system, or doubt the organization's product or service quality according to objective evidence.

6.7.8.2 不符合的分类：严重不符合、轻微不符合、观察项Classification of nonconformity: major nonconformity, minor nonconformity, observation

a) 严重不符合：缺少或未能实施/保持一个或多个标准条款的要求，或在同一个要素中很多个次要缺失导致某个要素的失控。

组织的环境/职业健康安全管理体系不能满足以下（不仅限于以下）对合规性的要求，无法证明组织实现了初次和持续的对合规性的承诺。如：

- 在管理方针中含有对遵守运用法律、法规的承诺；
- 组织已全部识别其所有与其环境因素/危险源相关的具体的运用法律法规要求，通过定期评审予以保持；
- 组织已确定如何应用到自己的环境因素/危险源的法律法规，并在整个EMS过程中加以考虑；
- 在目标、指标及方案中已充分识别法律法规要求及其变化；
- 对已发现违规问题，已立即采取纠正措施；
- 已就每一条所运用法律法规的合规性进行评估；
- 组织已证实具有对合规性问题纠正能力；
- 内审已覆盖合规性评价的相关要素

- 管审中已涉及合规性评价的结果。
- 组织遗漏或未能正确识别及评价重要环境因素/重大危险源、对重要环境因素的运行控制全面失效、对组织的环境绩效造成重要影响。

或组织：

- 无法满足质量管理体系相适用的要求（譬如没有投诉处理或培训系统）。
- 无法完成质量管理体系相适应要求。
- 当对后市场数据的调查体现了商品缺陷，不能实施合适的纠正和预防措施。
- 在根据商品标签要求使用机械时，投入市场的产品会对病人和/或使用者引起危险
- 目前流通产品明显不满足组织要求和/或法规要求
- 上次审核中不符合项重复出现

b) 轻微不符合项：单个或孤立地不符合认证要求中某一项条款的要求；或实施中未执行或偏离条款中的要求的。

c) 观察项：观察项为尚无足够证据证明其不符合，或属于潜在不符合、需提请受审核方注意的事项。

a) Major nonconformity:

Lacking or fail to carry out/maintain one or more requirements of standard clause, or several minor missing within one factor causes the loss of control of certain factor.

Organization's EMS/OHSMS can not meet following compliance requirements and can not prove that organization has achieved compliance commitment initial and continuously:

●Compliance with laws and regulations in management policy;

●Organization has identified all requirements of laws and regulations related to environmental factors/hazard source and keep it by reviewing regularly;

●Organization has determined how to apply it to laws and regulations related to environmental factors/hazard source and will consider during the process of EMS;

- Having fully identified requirements and changes of laws and regulations in objectives, index and scheme;
- Taking corrective actions immediately for violated issues;
- Having evaluated compliance of every laws and regulations;
- Having verified that organization has capability to take corrective actions;
- Internal audit cover all relevant elements of compliance evaluation;
- Results of compliance evaluation has involved in regulatory.

●Organization omit or doesn't identify and evaluate main environmental factors, and can not control the operation of environmental factors/hazard source that make great influence on performance.

Or the organization:

●Cannot meet the applicable requirements of QMS, such as no complaints handling or training

system;

- Cannot complete the applicable requirements of QMS;
- Data survey of marketing represents products defection and can not take appropriate action to correct and precaution;
- When using machine according to the requirement of label, products will cause danger to patients or users;
- Current circulated products obviously do not meet organization's requirements and/or regulatory requirements;
- nonconformity in last audit occurs again.

b) Minor nonconformity: not meet the requirement of certain clause in nonconformity isolate; or having not implemented or deviated from the requirement of clause.

c) Observation: no enough evidence to prove nonconformity or belong to potential nonconformity which the auditee shall pay attention to.

6.7.8.3 不符合项的验证方式：Verification method of nonconformity：

a）严重不符合：

监督审核和再认证时，严重不符合项须在15天内将纠正证据和纠正措施提交ICAS，由要求亲自进行书面验证的提出不符合项的审核员或审核组长或由机构指定人员对其首先进行书面验证，并需在必要时指定审核员于现场对纠正措施的有效性进行验证，具体时间应根据审核组与组织方约定的期限。未按审核组与受审核组织约定的时限（初次认证时严重不符合项最长整改期为三个月）提交纠正措施及实施效果的证明材料的，已认证组织作撤消证书处理，初次认证组织作不发证决定。

b）轻微不符合：

初次认证和再认证时，受审核方应在30天内（再认证不符合项实施纠正和纠正措施的时限应在认证证书有效期终止前）提交ICAS纠正和纠正措施及实施效果的证明材料，以便完成不符合项关闭的书面确认，并在必要时指定审核员于现场对纠正措施的有效性进行现场确认。 就无法在短期内完成的纠正措施，由机构指定人员与审核员沟通后决定，其实施的有效性是否可在下次年度审核时确认。凡30天内未提交纠正措施及实施效果的证明材料，已认证组织作暂停证书处理，三个月后仍未提交纠正措施及实施效果的证明材料，已认证组织作撤消证书处理，初次认证组织作不发证决定。监督审核时，受审核方应在30天内提交纠正措施计划，其有效性可在下次监督审核/复评时现场验证。

a) Major nonconformity:

Corrective action for major nonconformity shall be completed within 15 days, and corrective evidence and actions shall be provided to our company, auditor or team leader who had raised the nonconformity and request written verification or someone assigned by body conduct written verification firstly. Also, the body is required to appoint auditor to conduct verification of effective of corrective actions on-site when necessary. For details of the date, it shall follow the date agreed by

organization and audit team. For organization which has failed to provide corrective actions and evidence of its implementation within the agreed timescale (longest period for correction for major nonconformity identified in initial certification is three months), the certified organization shall have a withdrawal; and no issuance of certificate for the initial certification organization.

b) Minor nonconformity:

The applicant shall submit ICAS correction, evidence of corrective action and its implementation within 30 days in initial certification and recertification. The time limit for recertification nonconformity shall confirm by designated personnel before the certificate is valid, and the appointed auditor verify the validity of corrective action on-site if necessary. When corrective action can not be completed in a short time, after communicating with the agency designated personnel and auditors decide whether to confirm the effectiveness of its implementation at the next annual audit. If certified organization has not submitted evidence of corrective actions and output within 30 days, its certificate would be suspended; if it has not submitted evidence of corrective actions and output after 3 months, its certificate would be withdrawn, for organization is certified for the first time, it would not be issued certificate. In the surveillance audit, the auditee shall submit a corrective action plan within 30 days; its effectiveness can be verified on-site during the next surveillance audit / re-evaluation.

6.7.9 不符合项及其纠正措施争议的处理

就不符合项及其纠正措施，发生以下争议时，应按照程序P06《申诉、投诉、争议程序》进行:

- 当组织对审核员提出的不符合项或对审核员就其采取的纠正措施的要求产生无法解决的争议时;
- 当注册评定人员与审核员发生无法解决的争议时;

Dispute Handling of nonconformity and Corrective measurement

For nonconformity and corrective measurement, when there is a dispute, operate according to ICASP06 *Appeal, Complaint and Dispute Handling Procedure*:

- When organization has irresoluble disputes over nonconformity raised by auditors or requirements for corrective actions raised by auditors;
- When there is irresoluble dispute between register evaluation personnel and auditors;

6.7.10 终止审核 Terminate audit

发生以下情况时，审核组应终止审核，并通过填写《终止审核流转单》方式，及时向ICAS报告:

1）审核时发现组织实际情况与申请材料有重大不一致;

2）组织对审核活动不予配合，审核活动无法进行，说明:

3） 其他导致审核程序无法完成的情况，如

组织无法提供以上其生产及经营所需的真实、有效的行政许可；或

组织不能提供其所要求认证的范围内进行生产和提供服务的证据(如组织在现场未进行生产，组织生产设备，工艺，人员无法实现产品的正常生产)；或

认证申请人无法出示拥有其生产场地权利的合法性证据(如组织无法提供真实、有效的购买生

产场地产权合同、场地租赁协议、收购协议等文件)；或

组织无法提供符合EMS认证标准及法律法规要求的环评合法手续（EMS认证适用）。

对于终止审核的项目，审核组应将已开展的工作情况、终止审核的原因写入《终止审核流转单》（MFP0399）中，并经ICAS批准后方可终止审核、离开受审核组织。该《终止审核流转单》将由专人提交给受审核组织。可能造成终止审核的原因见《终止审核流转单》（MFP0399）。

When following situation occurs, audit team shall terminate auditing and report to ICAS by filling out *Conversion Form of Audit Termination*:

1） Major inconsistency is found between auditee's actual situation and what is in the application materials during audit;

2）Auditee does not cope with audit, therefore, audit can not go on, explanation:

3） Other situations that prevent audit procedure from being completed, such as

Auditee could not provide authentic and effective administrative license for production and business it undertakes; or

Auditee could not provide evidence of production and service provision within scope of certification it applied (e.g. Auditee does not perform production on-site, auditee's production facilities, techniques and personnel could not perform the normal production of the product); or

Certification applicant could not provide legal evidence demonstrating it is entitled to its production-site (e.g. Auditee fails to provide authentic and effective purchasing contract of production-sites, renting agreement of the site, acquisition agreement etc.); or

Auditee could not provide legal procedure for environmental assessment as required by EMS certification standard and statutory and regulatory requirements (EMS certification applies).

For audit items that has been terminated, audit team shall write down the work has already been developed and reason for termination into *Conversion Form of Audit Termination* (MFP0399). Audit team can only terminate the audit and leave the organization after ICAS's approval. The *Conversion Form of Audit Termination* shall be delivered to the organization by special person. For reasons which may cause audit termination, see *Conversion Form of Audit Termination* (MFP0399).

6.7.11 审核结案 Audit closeout

一阶段审核的结案:

一阶段审核的审核问题发现以《管理体系文审、一阶段审核结论及问题清单》的形式提供给组织。审核组长在该表单“整改要求”栏中，需明确说明哪些问题需要在二阶段审核前确认后方可进行二阶段审核；哪些可以在二阶段现场时确认，并告知组织。

需在二阶段审核前确认后方可进行二阶段审核的问题包括:

- 组织实际情况与管理体系成文信息描述不一致，特别是体系成文信息中描述的产品和服务、部门设置和职责与权限、生产或服务过程等与申请组织的实际情况有重大差异;
- 被审核的管理体系运行周期不到3个月;
- 发现组织有违反法律法规和强制性标准的情况;
- 发现组织发生了质量、环境、安全事故，且尚在整改期间;

- 其他可能影响实现一阶段审核目的的问题。

一阶段审核结束后，审核组长应首先完成《管理体系文审、一阶段审核结论及问题清单》并及时提交或将审核结果以电话、QQ等联系方式及时通知ICAS审核部。

Closeout of stage 1 audit:

The problem of stage 1 audit is found to be provided to the organization in the form of "management system document review, stage 1 audit conclusion and list of questions". In the "Requirements for rectification" column of the form, the audit team leader should specify which issues need to be confirmed before and after the stage 2 audit, which can be confirmed at the second-stage site, and inform the organization.

The problems that need to be confirmed before the second-stage audit before the second-stage audit can be carried out include:

- The actual situation of the organization is inconsistent with the written information description of the management system, especially the products and services described in the written information of the system, Department settings, responsibilities and authority, production or service process, which are significantly different from the actual situation of the applicant organization.
- The period of operation of the audited management system is less than 3 months.
- Violations of laws, regulations and mandatory standards are found;
- Quality, environmental and safety incidents have been found in the organization, and they are still in the period of correction.
- Other problems which may influence the objective of stage 1 audit.

After stage 1 audit finishes, audit team leader shall first of all complete *List of Conclusions and Problems from Management Documentation Review and Stage 1 Audit* and submit it without delay, or inform the audit result to ICAS registration department via telephone and QQ and so on.

二阶段审核的结案:

审核组应对在第一阶段和第二阶段审核中收集的所有信息和证据进行分析，以评审审核发现并就审核结论达成一致。

- 审核组长或其指定的人员获悉已收到受审核方的整改资料后,审核组长或其委托的人员应在 2 个工作日内对纠正措施实施的有效性和符合性进行确认关闭。纠正措施不满足要求时应于当天立即联系组织向组织说明要求，并跟踪直至关闭为止。审核组长应采取适宜的方法对关闭的不符项确认。
- 对注册部在认证决定过程中提出的问题,审核组长及相关的审核员应有责任作出解释并采取积极的补救措施。

审核结案时，应提交审核报告，审核报告的提交最迟不能超过审核结束后30天，由审核组长负责。

Closeout of stage 2 audit:

Audit team shall analyze all information collected during stage 1 and stage 2 audit, and agree on the findings of review audit and audit conclusions.

- The audit team leader or persons designated by him shall confirm close of effectiveness and compliance of corrective actions in two working days after having informed that the auditee has received information of reforming. If corrective action does not meet the requirements, they shall immediately contact the organization on the same day to explain requirements, and track until closed. The audit team leader shall adopt suitable methods for confirming the nonconformity.
- For the problems put forward by registration department in the process of deciding certification, audit team leader and relevant auditor has responsibility to make explanation and take corrective actions.

Audit report shall be submitted by no later than 30 days after the end of audit when close out audit; audit team leader shall be responsible for it.

6.8 认证决定Certification decisions

6.8.1 认证决定包括授予或拒绝认证、扩大或缩小认证范围、暂停或恢复认证、撤销认证或更新认证。Certification decisions includes granting or refusing of certification, expanding or reducing scope of certification, suspending or restoring certification, withdrawing or renewing certification.

6.8.2 认证决定的人员不是实施审核的人员。Certification decision makers shall not be the personnel who conduct audit.

6.8.3 注册部认证决定人员在做出认证决定前,应完成审查和接受所有不符合项的纠正和纠正措施；应对审核报告进行复核；应确认了是否达到审核目的；最终完成认证决定过程的管理。Before making the certification decision, certification decision maker of registration department shall complete the examination and acceptance of correction and correction actions against all nonconformity; review the audit report; confirm whether the audit objective is achieved as well as complete the management of certification decision making process.

6.8.4 认证决定的流程和管理规定,见《认证决定程序》ICASP10。For the process and management regulations of certification decision, please refer to ICASP10 ‘Certification decision procedure’.

6.9 保持认证Maintaining certification

6.9.1 获证后的监督Surveillance after obtaining the certificate

6.9.1.1 ICAS指定审核方案管理人员对监督活动进行策划，以便定期对管理体系范围内有代表性的区域和职能进行监视。策划时考虑获证组织及其管理体系的变更情况。ICAS appoints audit programme managers to design surveillance activities so that representative areas and functions covered by the scope of the management system are monitored on a regular basis, and take into account changes to its certified client and its management system..

6.9.1.2 审核方案管理人员负责采取适宜和有效的方法，对于QMS、EMS及OHSMS监督审核应确保监督审核每年至少进行一次，初次认证后的第一次监督审核应在证书签发日起12个月内进行，之后的监督审核不超过上一次审核后12个月（且每个日历年应审核一次）。当已达到监督审核期限而有证据表明获证组织暂不具备实施监督审核的条件时，获证组织需提供相关证明。此时可以适当延长监督审核期限，但最长间隔不能超过15个月。每个星期一，调度应向管理者

汇报年度监督审核安排的状况以及监督审核超期的组织名单。

Audit programme managers are responsible for taking appropriate and effective method. For QMS, EMS and OHSMS, surveillance audit shall conduct at least once a year, first surveillance audit shall be conducted within 12 months from issuing day of certificate. Subsequant surveillence audit shall be conducted within 12 months of last audit (and every audit shall be conducted every calender year). When it's meeting surveillance audit deadline but evidences shows that the certified organization is not qualified for surveillance audit, the certified organization shall provide relevant evidence. Deadline can be extended for surveillance audit, however, it shall not be over 15 months. Every Monday, assignments department shall report to the management person arrangement for annual surveillance audit and list of organizations whose surveillance audit has passed the deadline.

6.9.1.3 监督审核计划应按《审核方案》（MFP0394）关注的部门、活动和区域，审核应覆盖所有的要素，监督计划应参考前次审核的审核发现，与组织管理问题相适宜，并考虑审核的可信性。一个认证周期内的监督审核应覆盖所有部门、过程、活动和区域。每次监督审核应在获证组织现场进行；必审的部门/岗位：最高管理层、管理体系策划部门和主控部门(包括证书和标志的使用管理部门).如原策划部分条款无法执行时，允许调整，但应同时考虑下一次监督审核关注的过程、活动和区域的调整，并在《审核流转单》中予以备注说明。Surveillance audit programme shall be based on the department, activity and regions concerned in the *audit programme* (MFP0394), the audit shall cover all the factors. Surveillance program shall consider the audit findings from last audit and be applicable to the organization's management problem as well as consider the feasibility of the audit. Surveillance audit occurred within one certification cycle shall cover all departments, process, activities and areas. Each surveillance audit shall be conducted on-site where the organization obtained the certificate. The department / position that must be audited : top management, management systems planning department and main control department (including the management department of certificate and mark use); adjustment is allowed when the original plan can not be performed, but it shall also consider the adjustment of processes, activities and areas of the next surveillance audit, and explain in remarks of the 'Audit Flow Sheet'.

6.9.1.4 监督审核组只有一人时，应为有能力履行审核组长责职的专业审核员，如果监督审核由两人或两人以上组成，审核组的派遣应满足本程序6.5.2的要求。 If there is only one person in the surveillance audit team, he/she shall have the ability to fulfill responsibility which is applicable to the professional auditors of audit team leader, if the surveillance audits by two or more members, then assignments of the audit team shall meet requirements of procedure 6.5.2.

6.9.1.5 监督审核 Surveillance audit

监督审核目的是验证获证组织的管理体系如 QMS、EMS、OHSMS 是否持续运行，并考虑组织运作的变化，可能对 QMS、EMS、OHSMS 产生的影响，并确认对认证要求的持续符合性；

监督审核至少应包含下列内容:

a）认证组织的机构、许可要求、主要负责人、产品、工艺、活动、区域、文件化体系等变更情况以及变化情况对质量管理体系、环境管理体系、职业健康安全管理体系运行有效性的影响；

b）实现质量方针、环境方针、职业健康安全方针的重要关键点是否按管理体系的要求在正常和

有效运行;

c）根据组织的质量方针、环境方针、职业健康安全方针分别为强化质量管理体系、环境管理体系、职业健康安全管理体系以全面提高质量绩效、环境绩效、职业健康安全绩效所策划的活动的进展情况;

d）组织是否实施了定期评价法律法规符合性的程序（EMS 及 OHSMS 适用）;

e）与外部相关方交流的信息及其回应（EMS 及 OHSMS 适用）;

f）内部审核及管理评审的结果以及质量管理体系、环境管理体系、职业健康安全管理体系改进的跟踪;

g）对上次不符合的纠正措施效果进行验证，有无遗留问题或再发生;

h）管理体系覆盖的活动涉及法律法规规定的，是否持续符合相关规定；是否发生过重大质量、环境、职业健康安全事故、事件，如发生是如何处理的;

i）是否及时接受和处理投诉；对相关方投诉所采取的措施;

j）总管理目标及各层级质量目标/绩效指标是否实现。目标没有实现的，获证组织在内部管理评审时是否及时调查并采取了改进措施。

k）证书和标志使用或对认证资格的引用是否符合国家及 ICAS 相关的规定等。

The objective of surveillance audit is to verify if the management system of certified client such as QMS, EMS and OHSMS can operate continuously, and the influence that caused by organization operating change on QMS, EMS and OHSMS. Plus determine the continuous conformity of the certification requirement.

Surveillance audit shall at least contain the following aspects:

a. Changes of organization's structure, licensing requirements, principal, products, processes, activities, regional, documentation and other operating systems and influence on the validity of the quality management system, environmental management systems and occupational health and safety management system;
b. Whether significant key points for realizing quality policy, environmental policy and occupational health and safety policy are under normal and effective operation as required by management system
c. Improve quality performance, environmental performance and planning activity of OHSM performance of QMS, EMS and OHSMS according to organization's quality policy, environmental policy and occupational health and safety policy;
d. Whether the organization implements laws and regulations compliance procedure regularly (applicable to EMS and OHSMS);
e. Communicating information with external stakeholders and feedback (applicable to EMS and OHSMS);
f. Result of management review and internal audit and improvement tracing of QMS, EMS and OHSMS;
g. To verify last nonconformity of corrective actions to make sure whether the issues remaining or re-occurs;

h. Whether laws and regulations related in management system covering the activities compliance with the relevant provisions; whether major quality, environment, occupational health and safety accidents, incidents occur, if occur, how to deal; actions of handling complaints;
i. Whether complaints are accepted and dealt with without delay; actions undertaken against complaints from interested parties;
j. Main management objective and quality objective/performance factors of each level are achieved. For objectives that are not achieved, whether the certified organization has undertaken proper investigation and adopted corrective actions during internal management audit.
k. Whether the use of certificate and mark or references of certification qualification to compliance with the relevant provisions of national and ICAS;

6.9.1.6 监督审核报告应包含前次发现的每个不符合事项的整改情况。在审核过程中审核组发现任何导致暂停或撤销认证的不符合或其他情况，审核组长应在审核报告中明确表述。报告中应提出是否继续保持认证证书的意见建议。由独立的具有适当能力的人员负责审核记录及审核报告的复核工作，以确保能否保持认证。

Surveillance audit report shall contain the correction of each nonconformity found last time. If any nonconformity or other circumstances which may lead to suspension or withdrawal are found by audit team during audit process, the audit team leader shall clearly stated it in the audit report. The report give suggestions on whether to maintain certification certificate. Independent and competent personnel shall be responsible for the review of audit records and audit report to ensure whether to maintain certification.

6.9.1.7 如发现体系发生重大变更、发现不符合有关法规要求时或发生可能影响认证基础的变化时，监督活动应根据《认证批准、保持、扩大、缩小、暂停、撤消控制程序》（ICASP11）采取相应的措施; If significant change is found in the system or change may affect certification basis,or inconsistent with relevant regulatory requirements is found, surveillance activity shall take relevant actions according to the 'Procedure for granting, maintaining, expanding, reducing, suspending and withdrawing of certification' (ICASP11).

6.9.2 再认证 Recertification

6.9.2.1 审核调度负责采取适宜和有效的方法确保再认证每三年进行一次，应在认证证书有效期终止前三个月内进行。Audit assignments are responsible for taking appropriate and effective way to ensure re-certificate every three years, the certificate shall be valid for three months prior to the termination of the certificate.

6.9.2.2 审核调度应在再认证前至少三个月，通知市场部客服人员。客服人员负责通知组织，并为下一个认证周期报价格。 Audit assignments inform sales personnel of marketing department at least 3 months before recertification and sales personnel shall inform the organization and quote for the next certification cycle.

6.9.2.3 当管理体系及获证组织的内部和外部环境无重大变更时，再认证审核可省略第一阶段审核，但审核时间应不少于初审计算人日数的2/3。When the certified management system and the organization's internal and external environment without major changes, recertification audit of stage

1 audit can be omitted, but the audit time shall be no less than 2/3 of the number of man day in initial audit.

6.9.2.4 当管理体系、组织或管理体系的运作环境（如法律的变更）有重大变更时，再认证审核活动可能需要有第一阶段。If significant changes happen to the management system, organization or operational environment of the management system (such as change of legislation), recertification needs to include stage 1.

6.9.2.5 再认证审核的策划应基于前一个认证周期内对获证组织的绩效评估情况。编制再认证审核计划时应考虑到对前一认证周期内绩效评估和调阅监督审核报告的工作安排。再认证审核期间审核组应对绩效评估的薄弱环节予以关注并在审核报告中予以记录。Planning for recertification audit shall be based on performance assessment of certified organization during previous certification cycle. preparing of recertification audit shall consider work arrangement for performance assessment and retrival of surveillance audit report of previous certification cycle. During recertification audit, audit team shall pay attention to weak link in the performance evaluation and record it in the audit report.

6.9.2.6 再认证审核的要求和方法与6.6.3第二阶段审核相同；应包括针对下列方面的现场审核：

a) 结合内部和外部变更来看的整个管理体系的有效性，以及认证范围的持续相关性和适宜性；

b) 经证实的对保持管理体系有效性并改进管理体系，以提高整体绩效的承诺；

c) 管理体系在实现获证组织目标和管理体系预期结果方面的有效性。

Requirements of recertification audit are the same to 6.6.3 in stage 2 which shall include the on-site audit of the following aspects:

a) To view the elements of entire management system combined with internal and external changes, as well as continued relevance and adaptability of the certification scope.
b) Commitment to maintaining the effectiveness of the management system and improving the management system which aims to improve the overall performance;
c) Effectiveness of management system in realizing the objective of certified organization as well as management system expected result

6.9.2.7 再认证按照6.8要求作出认证决定，有关条件参见《证书批准、保持、扩大、缩小、暂停、撤消程序》（ICASP11）。

再认证审核报告要求同6.7.7要求，同时应包含调阅以前的监督审核报告、上一周期内历次审核发现的每个不符合的整改情况。公司指定应具有适当能力的认证决定人员独立评审审核文件以及关于受审核方的其他信息，以正确作出认证的决定。对再认证审核中发现的严重不符合项，应按6.7.8要求实施纠正和纠正措施并进行验证，验证应在原证书有效期满前完成。一般不符合项可验证组织制定的纠正和纠正措施计划。

Certification decision of recertification shall be made based on requirements of 6.8, relevant conditions refer to '*Procedure for Granting, Maintaining, Expanding, Reducing, Suspending, and Withdrawing of Certificate*' (ICASP11)

Report of recertification audit is same as required in 6.7.7, meanwhile it shall include retrival of past surveillance audit report, corrections for each nonconformity found from all audits during last

cycle. The company shall have adequate audit personnel with capacity to review files and other information about the auditee independently and make certification decisions correct. For major nonconformity in recertification audit, correction and corrective action shall be implemented according to requirements of 6.7.8 and to verify, the certificate shall be completed before the expiration of the original certificate. For general nonconformity, verification can be applied to correction and corrective action plan made by the organization.

6.9.2.8关于再认证证书的有效期，如果在当前认证证书的终止日期前完成了再认证活动并决定换发证书；或者，在当前认证证书的终止日期前完成了再认证审核且无严重不符合项（此时认证决定日期可能晚于当前认证证书的终止日期），再认证证书的终止日期可以基于当前认证证书的终止日期。证书上的再认证换证日期应不早于再认证决定日期。

如果在当前认证证书终止日期前，ICAS未能完成再认证审核或对严重不符合项实施的纠正和纠正措施未能进行验证，则不应予以再认证，也不应延长原认证证书的有效期。

在当前认证证书到期后，如果认证机构能够在6个月内完成未尽的再认证活动，则可以恢复认证，否则应至少进行一次第二阶段审核才能恢复认证。认证证书的生效日期应不早于再认证决定日期，终止日期应基于上一个认证周期。

With respect to the validity of the recertification, the recertification activity is completed before the termination date of the current certification certificate and the replacement certificate is determined; or, the recertification audit is completed before the termination date of the current certification certificate and there is no serious non conformance (at this time the date of the certificate decision can be later than the termination date of the current certification certificate), the termination date of the recertification may be based on the date of the termination of the certificate. The date of termination of the pre recertification. The renewal date of certificate should not be earlier than the date of re certification.

If ICAS fails to complete recertification audit or to verify the correction and corrective action implemented against major nonconformity, then ICAS shall not perform recertification, or extend the period of validity of original certification certificate.

After the current certificate expires, if CB can complete the unfinished recertification activity within six months, then it can renew the certification. Otherwise, it can only be resumed after another stage 2 audit. The effective date of certification certificate shall be no earlier than decision date of recertification, and expiry date shall be based on previous certification cycle.

6.9.2.9 证书超期失效后，组织可在原有认证合同的基础上重新申请认证。审核部应按初审策划审核方案，要求安排文审及其全过程、全要素的审核。在考虑到对组织管理体系了解的基础上、在确保审核有效性的前提下可适当减少审核时间及安排一阶段的非现场审核。对管理体系的了解、应建立在所收集的信息的基础上，所收集的信息应是充足的、可验证的。所有审核时间的调整及其理由应予以记录。审核费用应按实际人天及时调整，该类审核应按初次审核要求重新发证。证书的生效日期应不早于认证决定日期。

After the certificate loses efficiency, organizations can re-apply for certification on the basis of the original certification of the contract. Audit department shall arrange document review and whole process and all elements of the audit according to requirement of initial audit plan. On the basis of understanding organization management system, and under the premise of ensuring the effectiveness of the audit, it may be appropriate to reduce audit time and arrange for a non-site audit of first-stage. Understanding of the management system shall be established on the basis of the gathered information; the information collected shall be sufficient and verifiable. All the adjustments of audit time and the

reasons shall be recorded. The audit fees shall be timely adjusted according to actual man day, such audit shall require recertification regarded as initial audit. The effective date of the certificate shall be no earlier than the decision date of the recertification. End date shall be based on the last certification cycle.

6.9.2.10 对于接受了再认证申请，但在当前证书终止日期前，未完成再认证审核或对严重不符合项实施的纠正和纠正措施未能进行验证，则不应予以再认证，也不应延长原认证证书的有效期，市场部客服人员应向组织发出告知书，要求组织停止使用认证资格和认证标准及其宣传。在满足认证要求的条件下，该类审核应按初次审核要求重新发证。

If recertification audit has accepted but recertification audit fails to be completed or correction and corrective action against major nonconformity fail to be verified, then it shall be given recertification or extend the expiry date of original certification certificate. Marketing department shall issue notification to require organizations to stop using accreditation and certification standards and their propaganda. Supplementary arrangements shall be arranged when necessary. Under the condition of meeting the certification requirements, such audit shall require recertification regarded as initial audit.

6.9.2.11 再认证时若发现有严重问题可能造成严重不符合时，审核组应及时通知机构，经评审确定终止审核或改为一阶段。

If serious problems have been found during recertification which may cause major nonconformity, audit team shall notify the organization without delay. Audit can be terminated or changed to stage 1 after assessment.

6.9.3 特殊审核 Special audit

6.9.3.1 扩大认证范围 Expanding certification scope

对于已授予的认证，ICAS应对获证组织扩大认证范围的申请进行评审，策划并实施必要的审核活动，并在该审核活动中验证获证组织的管理体系的适宜性和有效性，以作出是否可予扩大的决定。扩大认证范围的审核活动可单独进行，也可和对获证组织的监督审核或再认证一起进行。扩大认证范围的部分应按全要素全过程进行审核。

审核组在编制审核计划时注意，对于拟扩大范围涉及的产品和服务应作全要素的审核；在作出审核结论时，应明确说明对于拟扩大的认证范围是否予以推荐。

For the awarded certification, ICAS shall conduct review of the application for expanding certification scope by the certified organization, plan and implement necessary audit activity, verify the application and effectiveness of the certified organization’s management system during the audit activity in order to make the decision on whether it can be expended. The audit activity with respect to expanding certification scope can be conducted alone, and can also be with surveillance audit of certified organization or recertification. The expanded certification scope shall be auditted in complete element and process.

Audit team shall notice that when preparing audit plan, all-element audit shall be conducted of products and services involved in the proposed expanded scope. When making audit conclusion, it shall specify whether to recommend the proposed expanded scope.

6.9.3.2 提前较短时间通知的审核 Short-notice audits

对于为了调查投诉、对变更进行评审、对暂停的组织进行追踪、或对获证组织的体系运行有效性进行确认，必要时，经评审，可以考虑在提前较短时间（1~2天）通知组织对上述情况进

行现场验证。由于在这种情况下，组织没有机会对审核组的派遣表示反对，因此，派遣审核组时，应特别要考虑公正性的问题。

调查组织投诉的纠正措施时，应要求组织提供有关投诉的记录及其纠正措施的记录，纠正措施应包括：1.法规要求时，通知有关部门；2.尽快恢复符合性；3. 防止再发生；4.评价并减少任何质量管理体系的不利方面及相关影响；5.确保与管理体系其它部分的充分协调；6.评审已经采取的纠正措施的有效性。只有纠正措施的有效性得到证实并对程序、文件和记录格式进行了必要的更改后，才能认为纠正措施的实施已经完成。

For the purpose of investigating the complaints, reviewing the change, following-up the suspended organization, or confirming the effectiveness of certification holder's system operation, when necessary, it can be considered to inform organization about the on-site verification against the above matter in a short notice (1~2 days). In this case, the organization does not have the opportunity to express opposition; therefore, the impartiality issue shall be especially considered when assigning audit team.

When investigating correction actions of organization complaints, organization shall be asked to provide records of complaints and corrective action, corrective actions shall include: 1. requirements of regulation, inform related department; 2. recover conformity as soon as possible; 3. prevent occurring again; 4. evaluate and reduce harmful and impact of QMS; 5. ensure coordination with other management system; 6. review validity of the corrective actions. Only having confirmed the effectiveness of corrective actions and madethe necessary changes of procedures, documentation and records, it can be thought that the implementation of corrective actions have been completed.

6.9.3.3 认证信息的变更

当组织申请对其公司名称、办公地址、认证范围涉及的人数、认证范围等关键信息进行变更时，合同评审人员应安排文件评审，确认组织的管理体系文件中的相关信息均已进行了变更。一般情况下，文件审核结合现场审核进行；由审核员经现场文件审核后确认是否给予推荐变更认证信息。

When the organization applies to change the key information such as its company name, address, the number of people involved in the scope of the certification, the scope of certification, and other key information, the contract assessor shall arrange the document review to confirm that the relevant information in the organization's management system documents has been changed. Generally, the document audit is combined with the on-site audit. After verification by the on-site auditor, the auditor confirms whether the recommended change certification information is available.

6.9.3.4 如果ICAS发现获证组织发生了与OHS有关的严重事件，如严重事故或严重违法，实施独立于监管机构的特殊审核是必要的，以便调查管理体系是否存在严重问题以及是否有效发挥作用。ICAS应记录调查的结果。

Independently from the involvement of the competent regulatory authority, a special audit may be necessary in the event that ICAS becomes aware that there has been a serious incident related to occupational health and safety,for example, a serious accident, or a serious breach of regulation, in order to investigate if the management system has not been compromised and did function effectively. ICAS shall document the outcome of its investigation.

6.9.4 暂停、撤销认证或缩小认证范围 Suspending, withdrawing certification, or reducing scope of

certification

6.9.4.1 发生以下情况(但不限于)时, ICAS应暂停获证组织的QMS和(或) EMS和(或) OHSMS认证资格:

a) 客户的获证管理体系持续地或严重地不满足认证要求（包括有效性）。
b) 监督审核发现不符合项（含严重不符合项），且未在规定时限内进行提交整改措施计划或予以有效整改;
c) 获证产品持续地或严重地不满足认证要求（包括有效性）。
d) 认证证书所涉及的产品质量监督抽查发现重大不合格的;
e) 在没有正当理由的情况下，监督审核推迟 30 天以上;
f) 未按规定使用认证证书和认证标志,且在规定的时间内未进行有效整改;
g) 发生影响质量、环境、职业健康安全、信息安全及能源管理体系的重大事故的;
h) 发生重大质量、环境污染、职业健康安全投诉，但未造成严重后果者;
i) 不承担、履行认证合同约定的责任和义务的。如未按期交纳认证费用且经指出后仍未交纳的;
j) 被有关执法监管部门责令停业整顿的。
k) 持有的与质量管理体系范围有关的行政许可证明、资质证书、强制性认证证书等过期失效，重新提交的申请已被受理但尚未换证的。
l) 获证客户主动请求暂停;
m) 由获证客户提供的或在特殊审核期间，审核组直接收集的有关导致监管机构参与（调查）的事件信息，如严重事故或严重违法（行为），一旦证明体系严重地不能满足 OHSMS 认证要求的。

ICAS shall suspend the QMS and (or) EMS and(or) OHSMS certification qualification when the following (but not limited to) happens:

a) The client's certified management system has persistently or seriously failed to meet certification requirements; (including effectiveness).

b) nonconformity (including Major nonconformity) is found in surveillance audit , and corrective action plan or effective corrections are not adopted within require time scale;

c) Certified product has persistently or seriously failed to meet certification requirements; (including effectiveness);

d) Major nonconformity has been found in quality surveillance spot check for product covered in the certification certificate;

e）Surveillance audit has been postponed more than 30 days without justification;

f) Fail to use certification certificate and mark in a properly way as required, and effective corrections are not taken within required time scale;

g) Major accidents occurred which will affect quality, environmental, occupational health and safety, information security and energy management system;

h) Major complaints for quality, environmental, occupational health and safety and energy management system, but no major consequence has caused by it;

i) Not undertaking, fulfilling responsibilities and obligations agreed in the certification agreement. For example, failing to pay certification fees on schedule even after being reminded;

j) Relevant law enforcement and supervision department has ordered business suspension.

k) Administrative license, quality certificate, mandatory certification certificate etc. that are related to scope of quality management system has expired, and new application has been accepted but certificate is not renewed.

l) Certified client has voluntarily requested a suspension;

m) Information on incidents such as a serious accident, or a serious breach of regulation necessitating the involvement of the competent regulatory authority, provided by the certified client or directly gathered by the audit team during the special audit, including a suspension or withdrawal of the certification, in cases where it can be demonstrated that the system seriously failed to meet the OH&S certification requirements.

6.9.4.2 一般情况下,认证资格暂停期为3至6个月,应在该期限内采取措施消除引起暂停的原因;如果获证组织未能在规定的时限内解决造成暂停的问题，ICAS将撤销或缩小其认证范围。

Under normal circumstances, the suspension period of certification qualification is 3 to 6 months, and measures should be taken to eliminate the causes of suspension within the period; ICAS will revoke or reduce the scope of its accreditation if the organization fails to resolve the suspension within the prescribed time frame.

6.9.4.3 在暂停认证期间，获证组织的管理体系认证证书暂时无效。ICAS应做出具有强制实施力的安排，以确保暂停认证期间避免获证组织继续宣传其认证资格。ICAS应使认证证书的暂停信息可公开获取，并采取其认为适当的任何其他措施。

During the suspension, the certification certificate of the certified organization’s management system is temporarily invalid. ICAS shall make arrangements with compulsory enforcement to ensure the certified organization could not promote its certification qualification. ICAS shall make information for suspending certificate publicly accessible and take any other actions it regards as appropriate.

6.9.4.5 如果获证组织未能在ICAS规定的时限内解决造成暂停认证的问题，或有下列情形之一的，ICAS应撤销其认证或缩小其相应的认证范围。

a) 客户主动提出申请(注销);
b) 客户被注销或撤销法律地位证明文件;
c) 客户被国家质量监督检验检疫总局列入质量信用严重失信组织名单;
d) 拒绝配合认证监管部门实施的监督检查，或者对有关事项的询问和调查提供了虚假材料或信息;
e) 拒绝接受国家产品质量监督抽查的;
f) 出现重大的产品和服务等质量安全事故，经执法监管部门确认是获证组织违规造成的;
g) 暂停期限内未能对引起暂停的原因采取有效的纠正措施;
h) 暂停认证证书的期限已满但导致暂停的问题未得到解决或纠正的（包括持有的与质量管理体系范围有关的行政许可证明、资质证书、强制性认证证书等已经过期失效但申请未获批准）;
i) 不按相关规定正确引用和宣传获得的认证信息，造成严重影响或后果，或者认证机构已要求其纠正但超过 2 个月仍未纠正的;
j) 严重违反法律法规;
k) 管理体系发生重大变更且在暂停期间未能采取有效纠正措施,经评审其管理体系不符合要

求;

If certified organization fails to solve the problem that has caused suspension within the time limited by ICAS, or, in the case one of the following happens, ICAS shall withdraw its certification or reduce relative certification scope.

a) The client actively submits application (for withdrawal);

b) Evidence document for client's legal status has been withdrawn;

c) client has been listed into the list of quality dishonesty auditees by AQSIQ

d) Avoid cope with surveillance examination undertaken by certification supervision department, or provide false materials or information in regards of questioning and investigation of relevant issues

e) Refuse accept national product quality surveillance spot check

f) Major quality safety accidents have happened towards products and services, and law enforcement and supervision department has confirmed it was due to the violation of laws by the certified organization.

g) No effective corrective actions have been adopted against cause for the nonconformity within the suspension period

h) The certificate suspension has expired but problem has not been solved or corrected (including administrative proof evidence, qualification certificate, mandatory certification certificate that are related to the scope of QMS have expired but application is not approved).

i) Quote and promote received certification information without proper compliance with relevant regulations and causes major influence or consequence. Or, CB has asked it to correct but it fails to take actions for more than two months.

j) Major violation of laws and regulations.

k) Major changes has occurred to management system during suspension period, but no effective actions has been taken. Its management system is not compliance with requirements as a result of assessment;

6.9.4.6 如果获证组织在认证范围的某些部分持续地或严重地不满足认证要求,ICAS应缩小其体系认证范围，以排除不满足要求的部分。认证范围的缩小应与认证标准的要求一致。

If part of the certification scope of the certified organization continuously or seriously fails to meet the certification requirements, ICAS shall reduce its certification scope of system in order to eliminate the unqualified part. The reduction of certification scope shall be consistent with the certification standard.

6.9.4.7 ICAS应与获证组织就撤销体系认证时的要求做出具有强制实施力的安排，以确保获证组织接到撤销认证的通知时，立即停止使用任何引用认证资格的广告材料。

ICAS shall make arrangements with compulsory enforcement to ensure certified organization immediately stops using any advertising materials quoting certification qualification upon receiving the notice of certification suspension.

6.9.4.8 在任何组织提出请求时，ICAS应正确说明获证组织的体系认证被暂停、撤销或缩小的情况。

ICAS shall specify the situation of the suspending, withdrawing or reducing of the certified organization's system certification if any organization requests.

6.9.5 扩大范围+年度监督审核（或再认证审核） Scope expanding+annual surveillance audit (or recertification audit)

6.9.5.1 审核策划 Audit planning

当一次审核要完成“扩大范围+年度监督审核（或再认证审核）”任务时，审核策划时应充分考虑：

1）除须完成于认证范围涉及的相应产品/服务有关的过程、区域和部门的审核外，扩大范围部分还应对文审、内审、管理评审、管理目标制定及完成情况、资源配置、风险管理等主要要素的审核；审核方案制定及审核计划制定时应予以体现；《审核方案》中应明确体现特殊认证（如扩大范围、缩小范围等）的类型；

2）审核派遣时，应将所有审核类型、审核依据及审核目的予以体现；

3）审核人天策划时应考虑审核工作内容及强度、距离等多种因素，策划的内容在《审核方案》中体现；

4）审核计划的编制应考虑几个审核目的的特点及现场实施的可操作性

If ’ scope expanding+annual surveillance audit (or recertification audit)’ is required to be completed in stage 1 audit, the following shall be taken into consideration when planning for audit:
1) Apart from completing audit of process, areas and departments of products/services involved in certification scope, for expanded scope, it shall also conduct audit of document review, internal review, management review, planning and completion of management objective, resource allocation, risk management and other key factors. It shall be shown in the planning of audit programme and audit plan. ‘audit programme’ shall show types of special audit(such as scope expanding, scope reducing etc.);
2) When planning audit assignments, it shall consider all audit types, audit basis and audit objectives;
3) When planning audit man day, it shall consider working content and intensity and distance of the audit, planning is detailed in the ‘audit programme’;
4) The preparation of audit plan shall consider features of several audit objectives and operability of on-site implementation

6.9.5.2 审核Audit

审核时应依据审核计划进行。尤其是扩大认证范围的部分，基本上和初次认证审核相同，要覆盖拟扩大范围的产品和服务所涉及的所有条款、部门和区域。

审核报告中，要分别体现出对几个审核目的评价和审核结果总结；尽量不要和例行年度监督的评价混在一起；且推荐结论应该单独体现；

Audit shall be carried out according to audit plan. Especially for expanded scope, it shall be the same as initial certification audit and cover all clauses, departments and areas involved in products and services of proposed expanded scope.

In the audit report, it shall detail evaluation on several audit objectives and conclusion of audit results; it shall not be mixed up with evaluation on routine annual surveillance; conclusion for recommendation shall be detailed separately;

6.9.5.3 认证决定 Certification decision

认证决定人员应特别关注扩大认证范围的审核内容和审核组推荐结论；并结合推荐结论，最终做出对该项目的认证决定意见；这个认证决定意见应与本次审核目的相对应，如审核目的有三个，认证决定意见也应该有三项。认证决定的最终结论为该组织的认证证书上的最终认证范围。

Certification decision makers shall pay special attention to audit content with respect to scope expanding and conclusion of recommendation by the audit team. They shall make the final decision on this project by combing conclusion of recommendation, and the final decision shall correspond to the audit objectives, if there are three audit objectives, there shall be three certification decisions. The final conclusion of certification decision is the final scope of certification on the certificate.

6.9.6 补充审核 Supplementary audit

当本次审核的档案资料经注册部评定最终确认无法达到审核目的，需要进行全面或部分内容的补充审核，经评定还需要通过现场审核收集证据以验证纠正和纠正措施的有效性时，由注册部认证决定人员发出补充审核通知书，该通知书应交给审核部，同时抄送市场部，由市场部客服人员通知受审核方并进行沟通以确保补充审核的有效实施。

If the audit file confirmed by the Registration Department that can not be achieved need to full or partial audits supplement. If evidence is needed to form to verify the formation of correction and corrective actions, the Register Department issued a supplementary notice to the audit department and with a copy to the marketing department. client service staff from market department inform the auditee and communicate with it effectively to ensure the effective implementation of the supplementary audit.

7 审核档案及组织记录 Audit file and organizational records

7.1 审核组成员必须将审核形成记录，在审核结束时交审核组长；

The audit team members must generate records of audit and submit it to audit team leader at the end of the audit.

7.2 审核组长负责检查所有审核记录的完整性，妥善保管于审核档案中，并应在不符合项整改有效性经验证后的2个工作日内提交机构档案管理人员；审核报告的提交最迟不能超过审核结束后30天。

The audit team leader is responsible for checking the integrity of all audit records and safe kept in the audit file. The audit record shall be delivered to records management personnel after the end of the two working days, audit report shall be submitted within no longer than 30 days after the end of the audit.

7.3 获证组织记录应包括：

- 申请资料及初次认证、监督和再认证的审核报告；
- 认证协议；
- 抽样方法的理由；
- 确定审核时间的理由；

- 纠正与纠正措施的验证；
- 投诉和申诉及任何后续纠正或纠正措施的记录；
- 适用时，委员会的审议和决定；
- 认证决定的文件；
- 认证文件，包括与产品（包括服务）、过程相关的认证范围，管理绩效统计情况，适用时，包括每个场所相应的认证范围；
- 建立认证的可信度所需的相关记录，如审核员和技术专家能力的证据；
- 审核方案。

Records on certified clients shall include the following:

a) application information and initial surveillance and recertification audit report ;
b) certification agreement;
c) justification of the methodology used for sampling;
d) justification for auditor time determination;
e) verification of correction and corrective actions;
f) records of complaints and appeals, and any subsequent correction or corrective actions;
g) committee deliberations and decisions, if applicable;
h) documentation of the certification decisions;
i) certification documents, including client name, scope of certification and geographic position, scope of certification with respect to products(including services) and process, including relevant scope of certification of each site as applicable;
j) related records necessary to establish the credibility of the certification, such as evidence of the competence of auditors and technical experts.
k) audit programme.

7.4 认证协议由市场部负责保管，认证可信度所需的相关记录由技术资源管理部负责保管，其余的组织记录由注册部负责保管并扫描成电子档放置公司服务器上。

Certification protocol is kept by marketing department. Records of certification credibility are kept by technology resource management department and other organization records are kept by registration department and put on company's server in electronic copy.

7.5 档案管理人员根据程序《记录控制程序》（ICASP05）对记录进行控制。

File management personnel shall control the records according to *Record Control Procedure* (ICASP05).

8 相关程序 Relevant Procedures

《认证授予、拒绝、保持、变更、暂停、恢复、撤销程序》（ICASP11）

《记录控制程序》（ICASP05）

《申诉、投诉、争议处理程序》（ICASP06）

Procedure for Granting, Refusing, Maintaining, Changing, Suspending, Restoring and Withdrawing of Certification (ICASP11)

Record Control Procedure (ICASP05)

Appeal, Complaint and Dispute Handling Procedure (ICASP06)

9 相关记录 Relevant Records

a) 申请表（MFP0388）

b) 报价单（MFP0306）

c) 管理体系认证合同书（MAP0312）

d) 审核方案（MFP0394）

e) 审核组派遣通知书（MFP0308）

f) 审核计划（MFP0311）

g) 签到表（MFP0312）

h) 开始会议查检表（MFP0313）

i) 不符合项报告（MFP0314）

j) 管理体系一阶段审核检查表及报告（MFP0373）

k) 管理体系审核报告（MFP0315）

l) 结束会议查检表（MFP0316）

m) 客户信息确认表（MFP0318）

n) 审核查检表（MFP0309）

o) 《QMS认证审核人天表及收费标准》（MAP0315）

p) 《环境管理体系认证审核人天表及收费标准》（MAP0380）

q) 《职业健康安全管理体系审核人天表及收费标准报价》（MAP0381）

r) 《医疗器械质量管理体系审核人天表及收费标准》（MAP0379）

a)Application Form（MFP0388）

b)Quotation（MFP0306）

c)Management System Certification Contract（MAP0312）

d)Audit Programme（MFP0394）

e)Notice of Assignments of Audit Team（FP0308）

f)Audit Plan（FP0311）

g)Attendance Form （FP0312）

h)Opening meeting Checklist（FP0313）

i)Non-conformance Report（FP0314）

j)Management System First-stage Audit Checklist and Report（FP0373）

k)Management System Audit Report（FP0315）

l)Closing Meeting Checklist（FP0316）

m)Organization Information Conformation Form（MFP0318）

n)Audit Checklist（FP0309）

o)QMS Audit Man day and Charge Standard（MAP0315）

p)Environment Management System Audit Man day and Charge Standard（MAP0380）

q)Occupation Health Safety Management System Audit Man day and Quotation of Charge Standard（MAP0381）

r)Medical Device Quality Management System Audit Man day and Charge Standard（MAP0379）