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实施方案



Certification during Prevention and Control of COVID-19 新冠疫情防控期间的认证工作实施方案



TÜV SÜD Certification and Testing (China) Co., Ltd. 南德认证检测(中国)有限公司 Revision Effective Date 版本号 生效日期 02 2020-06-01 Doc. No. Page 文件编号 页码 GCN_CCB_W_2 2/11 0.01CS

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Establishment and History of Changes 文件生效及修改记录

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Rev. No. 版本 号	Clauses Affected 修改章节	Effective Date 生效日期	Reasons / Contents 原因 / 内容	Prepared By 编制	Reviewed By 审核	Approved By 批准
00		2020-03- 11	Establishment of Document文 件生效	Zhang He	Zhang Wenqi, Andreas Horn	Andreas Horn
01	4.3,4.4	2020-03- 18	Added measures for recertification, clarified the situations for remote audit, added application situation for remote ICT 增加了再认证的措施,澄清了远程审核的情况,补充了远程操作ICT的应用	Zhang He	Zhang Wenqi, Andreas Horn	Andreas Horn
02	4.3.2	2020-06- 01	Separated follow-up audit for low risk region and high& medium region. 细化了低风险和中高风险地区的监督审核要求。	Zhang He	Zhou Jianfang	Andreas Horn

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1. Purpose 目的

This work instruction is developed according to the relevant requirements of the State Administration for Market Regulation(CNCA) and CNAS accreditation requirements, combined with own actual situation. The purpose is to protect the personnel of TÜV SÜD Certification Testing (China) Co., Ltd. (hereinafter as TÜV SÜD (China)) and the audited factories so as to control the CORONA (COVID-19) virus epidemic situation, and in the meantime, to ensure the effectiveness of certification and continuity of certification business and also ensure the certification activities is under-controlled, consistently and effectively managed.

为保护南德认证检测(中国)有限公司(以下简称南德(中国))和受审核方人员安全,有效控制2019新型冠状病毒疫情,同时为确保认证有效性和认证业务的连续性,规范疫情防控期间认证工作的实施,根据市场监管总局(认监委)有关要求和CNAS认可要求,结合自身实际情况特制定本作业指导书。

2.Scope 范围

This work instruction applies to voluntary product certification activities in TÜV SÜD (China) 本作业指导书适用于南德(中国)自愿性产品认证活动。

3. Responsibilities 职责

The head of the regional/company HSE is responsible for the preparation of the TÜV SÜD (China) operation emergency response measures and the arrangement of the implementation. 区域/公司HSE负责人负责编制南德(中国)运行应急管理方案并安排实施。

CRT-CHN coordinate with HSE and HR department for emergency response management of relevant certification personnel and activities during epidemic period within TÜV SÜD (China). CRT-CHN is also responsible to formulate a work program for prevention and control other than emergency management within the institution, and to guide business units to organize and carry out various certification work during epidemic period.

认证部门负责在疫情防控期间配合HSE部门和HR部门做好机构内认证相关人员和活动的应急 管理。制定除机构内应急管理以外的防控工作方案,指导业务部门组织开展疫情防控期间各项 认证工作。

Technical Certifiers are responsible to arrange communication with customers during this period, plan the evaluation and follow-up measures after the COVID-19, if applicable.

授权技术签字人负责在疫情防控期间安排与客户进行信息沟通和交流,并策划认证审核方案和 疫情结束后的后续跟进措施(如果适用)。

Factory inspectors are responsible for communicating information related to the on-site inspection. Other divisions of responsibilities are detailed in chapter 4.

工厂检查员负责与现场检查有关的信息沟通。其他职责划分,详见第4章节。

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4.Work Instruction 作业指导

4.1 Emergency Response Measures within the institution 疫情防控期间机构内运行应急管理 Please refer to GCN procedure "Emergency Response Measures" (GCN_ HSE_P_03CS). 请参见大中华区程序《突发事件应急预案》(GCN_HSE_P_03CS)。

4.2 Communication 信息沟通与交流

4.2.1 Communication with the Administrative authorities 与疫情有关的属地行政沟通

During this epidemic period, the head of the regional/company HSE is responsible for communicating actively with the territorial government and it's representative departments on the measures and requirements for epidemic prevention and control, to deal with them in a timely manner, and to inform all employees of the specific measures to be implemented if necessary. In accordance with the requirements of epidemic prevention and control, the head of the regional/company HSE may establish the employee information reporting system and initiate the implementation.

疫情防控期间,区域/公司HSE负责人负责与属地政府及主管部门就有关疫情防控的措施、要求积极沟通,及时处理,必要时告知所有员工具体实施措施。应根据疫情防控要求,建立员工信息报告制度并实施。

- 4.2.2 Administrative communication related to certification 与认证工作有关的行政沟通
- a) TÜV SÜD (China) will promptly announce to the community the implementation of the certification work during the epidemic peroid, and inform local market regulators when needed;
- a) 南德(中国)将疫情防控期间的认证工作实施方案及时向社会公布,并在需要时通报地方市场监管部门:
- b) CRT-CHN actively obtains the relevant requirements from the State Administration for Market Regulation (CNCA) and promptly reports the relevant factory inspection information and the extension of validity and suspension status of the relevant certificates to CNCA;
- b) 认证部门积极获取市场监管总局(认监委)的相关要求,及时上报相关工厂检查信息和相关认证证书有效期顺延或暂停情况;
- c) CRT-CHN tries every means to maintain a good communication with accreditation body CNAS, to understand it's accreditation requirements, and timely report the implementation of the certification work during this period to the CNAS, if needed;
- c) 认证部门与认可机构CNAS保持沟通,了解认可要求,必要时及时将疫情防控期间的认证工作实施方案报送认可机构;
- d) CRT-CHN actively obtains the relevant requirements of the accreditation authority, and reports the relevant factory inspection information and the extension of validity and suspension status of the relevant certificates, if needed;
- d) 认证部门积极获取认可机构的相关要求,必要时向认可机构通报因疫情影响的获证组织工厂检查、证书有效期顺延或暂停等情况。

4.2.3 Communication with customer 与客户的信息沟通

During the epidemic period, all relevant personnel involved in the certification activities shall adopt a variety of ways to maintain smooth communication with clients, identify and inform customers of the certification plans during this time, and ensure that customers are aware of the impact of the COVID-19 on certification activities and obtain appropriate solutions, including but not limited to the following:

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疫情防控期间,所有参与认证活动的相关人员,应采取多种方式与客户保持通畅的信息沟通, 识别、确定并向客户通报疫情期间的认证活动安排、确保客户知悉疫情对认证活动的影响并获 得适宜的解决方案,包括但不限于以下内容:

- a) TÜV SÜD (China)'s emergency response measures during COVID-19 outbreak period, see 4.1;
- a) 疫情防控期间南德(中国)的应急管理措施, 见4.1;
- b) Seek to personalized measures to ensure the validity of the certificate owned by the customers, on the condition to meet this work instruction;
- b) 在符合本作业指导书的前提下, 保证客户已获证书有效性的个性化措施;
- c) The response measures to the projects which cannot be completed as scheduled due to the impact of the outbreak;
- c) 受疫情影响不能及时完成项目的应对措施;
- d) Responses measures to factory inspections during the outbreak.
- d) 在疫情期间涉及工厂检查的应对措施。

TÜV SÜD (China) takes special care of the customers whose products are beneficial to the people's livelihood and the epidemic prevention and control during this period. The relevant personnel should communicate with these customers and try as far as possible to meet their certification needs on the condition that national regulations and internal procedures are fulfilled. Head of CRT-CHN shall be contacted so as to find a suitable solution and to report such situation to CNCA and CNAS, if necessary.

南德(中国)特别关注疫情防控期间涉及国计民生和疫情防控的相关客户,相关人员与其沟通 并在符合国家规定和机构内部规定的前提下,应尽可能满足其认证需求。必要时,需及时联系 认证部门负责人,以商定合适的解决方案并及时上报认监委和CNAS。

4.2.4 Communication related to factory inspection 与工厂检查有关的信息沟通

If a factory inspection is to implement during the epidemic, the factory inspector should communicate with the factory's representative, including but not limited to below information:

若在疫情期间需开展工厂监督检查,工厂检查员应与工厂代表沟通信息,包括但不限于:

- a) Local epidemic situation and administrative control requirements in the factory location;
- a) 工厂所在地疫情信息及行政管控要求:
- b) When the certified products have been put back on production;
- b) 恢复在线生产获证产品的时间;
- c) When to deliver the certified products:
- c) 交付当前认证范围内产品的时间:
- d) Whether the existing inventory products still meet the customer's requirements and whether there are concessions to be released;
- d) 现有库存产品是否仍符合客户要求, 以及是否存在让步放行的情况;
- e) Whether an alternative production site is applied for the certified products, and whether the whole or part of production process is subcontracted to other organizations, if applicable, the controls measures of the alternative production sites and/or subcontracting organizations shall be shared;
- e) 获证产品是否使用替代的生产场所,过程是否分包给其他组织,以及替代的生产场所或分 包组织的相关活动的控制措施;
- f) Information from the certificate holder that can help to prove the certification validity, including but not limited to relevant manuals, procedures, records, etc., a questionnaire or a self-assessment report might be necessary, if needed;

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f) 可以证明获证组织证书有效性的信息,包括但不限于相关的手册、程序、记录等,必要时可要求组织填写调查表或提供自评估报告;

All the above communication should be carried out in writing as far as possible. 所有沟通过程,应尽可能以书面形式进行。

- 4.3 Arrangements for certification projects 认证项目的安排
- 4.3.1 Initial factory inspection during COVID-19 疫情期间的首次工厂检查

During the COVID-19 prevention and control period, basically, TÜV SÜD (China) does not assign any staff to carry out on-site factory inspection in the affected areas and epidemic focus areas. In non-epidemic areas, a factory inspection can be performed, provided that below criteria are fulfilled:

在疫情防控期间,原则上南德(中国)不安排人员在疫区及疫情重点区域内执行首次工厂检查、监督检查、再认证工厂检查等现场活动。若在非疫区内实施首次工厂检查,需工厂具备以下条件:

- a) no hazards to health of factory inspector and other staff exists;
- a) 该现场活动不会对工厂检查员及其他相关人员造成身体危害;
- b) The acceptance of factory and inspector is given;
- b) 工厂和检查员书面接受现场检查实施;
- c) The factory has resumed production or resumed the online production of certified products;
- c) 工厂已恢复生产或恢复在线生产获证产品;
- d) There are no travel restrictions within the TÜV SÜD Group and within the administrative office of the plant location.
- d) 南德集团内部且工厂所在地行政机构已无出行限制规定。

TÜV SÜD (China) can reply on the factory inspection results carried out by other certification body within TÜV SÜD group, provided the product category is same and inspection date is not earlier than 12 months from initial certification decision date.

南德(中国)可采信TÜV SÜD 集团内部采用相同工厂检查标准的认证机构所实施的工厂检查结果,但产品类别需一致,且距首次认证认证决定日不超过12个月。

Considering internal risk control, basically, TÜV SÜD (China) doesn't consider remote audit for initial factory inspection activities. The initial factory inspection should be scheduled within 3 months after the outbreak is lifted.

考虑到内部风险控制,原则上,南德(中国)不考虑远程执行首次工厂检查活动。首次工厂检 查应安排在疫情解除后3个月内进行。

4.3.2 Follow-up surveillance during COVID-19 疫情期间的例行监督检查

Follow-up surveillance should be performed as scheduled in non-epidemic areas, provided that below criteria are fulfilled:

若在非疫区内实施监督检查,应尽量按计划进行,需工厂具备以下条件:

- a) no hazards to health of factory inspector and other staff exists;
- a) 该现场活动不会对工厂检查员及其他相关人员造成身体危害:
- b) The acceptance of factory and inspector is given;
- b) 工厂和检查员书面接受现场检查实施;
- c) The factory has resumed production or resumed the online production of certified products;

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c) 工厂已恢复生产或恢复在线生产获证产品;

- d) There are no travel restrictions within the TÜV SÜD Group and within the administrative office of the plant location.
- d) 南德集团内部且工厂所在地行政机构已无出行限制规定。

Otherwise, follow-up surveillance should be re-scheduled but not delayed more than 3 months from the original planned date for low risk region. Follow-up surveillance for high & medium risk region should be performed within 3 months after downgrading into low risk region.

否则应将例行监督检查时间重新策划,低风险地区不应能晚于原计划日期3个月。中高风险地区应在降级为低风险后3个月内实施监督审核。

According to the policy from the relevant authorities, remote surveillance audits are allowed, provided that the factory has resumed production or resumed the online production of certified products, details please refer to 4.4. Technical certifier and/or factory inspector shall notify CRT-CHN the remote audit plan and result, so as to report to CNCA and CNAS, if needed.

根据监管机构相关政策,远程监督检查亦是允许的,前提是工厂已恢复生产或恢复在线生产获证产品。具体实施方案详见4.4。该项目的授权技术签字人和/或工厂检查员需向认证部门报备检查计划和结果,以在需要时及时向CNCA和CNAS报备。

If none of above mentioned options could be achieved for follow-up surveillance, TÜV SÜD (China) may negotiate with the customers and suspend the corresponding certificate. The maximum time for suspension is from the date of suspension to the end of third month after the outbreak is lifted.

若上述方案都无法实现,南德(中国)可与持证方协商,对相应认证证书实施暂停处理。暂停处理的最长时限为暂停之日起至疫情解除后3个月内。

4.3.3 Surveillance for re-certification during COVID-19 疫情期间的再认证工厂检查

Measures for factory inspection in the purpose of re-certification is same as initial certification, that the factory inspection activity shall be completed with satisfactory results before certification decision. TÜV SÜD (China) can reply on the factory inspection results carried out by other certification bodies within the TÜV SÜD group, provided the product category is same and inspection date is not earlier than 12 months from certification decision date.

再认证的工厂检查实施方案与首次认证一致,即在再认证认证决定前,再认证工厂检查已完成且合格。南德(中国)可采信TÜV SÜD 集团内部采用相同工厂检查标准的认证机构已完成的工厂检查结果,但该工厂检查对应的产品类别需一致,且距再认证认证决定日不超过12个月。

Considering internal risk control, basically, TÜV SÜD (China) doesn't consider remote audit for recertification or extending the certification period.

考虑到内部风险控制,原则上,南德(中国)不考虑远程进行再认证工厂检查或将证书延期。

4.3.4 Other certification activities during COVID-19 疫情期间的其他认证活动

During the COVID-19 prevention and control period, for initial certification and recertification, the related certification activities such as certification application, contract review, evaluation planning, review and certification decision, etc. are carried out normally.

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疫情防控期间,初次认证和再认证涉及的其他认证活动,如认证申请、合同评审、审核方案策划、复核和认证决定等认证活动正常进行。

Evaluation activities such as testing and inspection are subject to the related labs and inspection bodies of corresponding business units and follow the corresponding prevention and control programs for implementing.

评价活动如测试、检验等,由其业务所在单元对应的合作机构依据其防控方案,统筹实施。

In the event that factory inspection activities are involved, 4.3.1~4.3.3 shall be followed. 涉及工厂检查活动的情况,按4.3.1~4.3.3方案执行。

4.4 The use of ICT during COVID-19 疫情期间ICT远程技术的应用

4.4.1 General 一般要求

TÜV SÜD (China) values the safety and convenience brought by information and communication technology (ICT) during COVID-19 period. On the condition that global IT procures "IT-Governance" (CLC-IT-001) and "IT Security and Compliance" are followed properly to guarantee information security and data confidentiality during this process, remote ICT application is highly recommended to internal staff during internal management and certification activities, including but not limited to: 在疫情期间,南德(中国)重视ICT应用带来的安全和便利性,在遵守集团IT程序《信息技术管理》(CLC-IT-001)和《信息技术安全与合规》(CLC-IT-002)以保证信息安全和数据保密的基础上,鼓励内部员工积极使用远程技术ICT于内部管理和认证活动等过程中,包括但不限于:

- a) Internal and external meetings for application review and evaluation planning;
- a) 与认证评审和策划相关的内外部信息沟通会议;
- b) Trainings for the development of certification personnel:
- b) 为认证人员能力提升所进行的培训;
- c) QMS activities to maintain internal quality system, such as internal audits, and management reviews;
- c) 为维护质量管理体系所进行的内外部质量管理活动, 例如: 内部审核、管理评审等;
- d) Follow-up surveillance, refer to 4.3.2;
- d) 例行监督检查, 见4.3.2

4.4.2 Remote follow-up surveillance 远程监督检查

During COVID-19 period, if remote follow-up surveillance is to be conducted, the factory inspector shall communicate with the factory representative and collect required documentation in consideration of the factory condition, product properties and requirements of CIG 023, etc. and then do risk assessment of the factory. If the risk is considered as controllable, technical certifier shall be contacted to update surveillance planning and create a specific surveillance plan. Factory inspectors shall review the collected documents and ask the factory's cooperation during remote ICT surveillance.

在疫情防控期间若安排远程实施例行监督检查,应由工厂检查员与工厂代表沟通,视工厂情况、产品属性和CIG 023要求等,向其收集所需资料,并进行风险评估。若风险可控,可与授权技术签字人协商修订检查策划方案,制定专项监督方案。工厂检查员依据该专属方案,对收集到的资料进行审查,并要求工厂配合使用ICT检查。

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Documents to be collected shall include but not limited to:

需收集的资料包括但不限于以下:

- a) Changes since last factory inspection;
- a) 自上次检查以来变化情况:
- b) The latest internal audit report and management review report;
- b) 最近一次内审及管理评审报告;
- c) Satisfactory test report and testing records of the relevant products;
- c) 相关产品合规性的检测报告和记录:
- d) Measures taken to ensure the certified products' conformity and the relevant records during COVID-19 period.
- d) 疫情防控期间, 客户为确保认证的产品符合规定要求所采取的措施及相关记录;
- e) Non-conformities and their relevant corrective measures during national and local monitoring;
- e) 国家及地方产品抽样检查中发现的问题及整改措施;
- f) Handling of appeals/complaints from the customers;
- f) 顾客的申/投诉处理情况:
- g) Documents required to maintain the effectiveness of quality management systems for the certified products;
- g)符合产品认证要求有效保持和运行产品保证体系所需的其他文件;
- h) Other documents or records required by CIG 023 and relevant certificate rule.
- h)参考CIG 023和相应认证实施规则的要求,所需的其他资料或记录。

4.4.3 Measures after COVID-19 疫情后的措施

During COVID-19 period, if some records would be missing by using remote ICT as alternative and these records would lead to critical impact on the certification accuracy, such certification application shall be politely turned down for further proceeding or not use alternative measures during planning. If the impact is not critical, such records shall be collected within 3 months after the outbreak is lifted. For the QMS activities, if some process couldn't be fulfilled by using remote ICT as alternative, CRT-CHN shall evaluate whether it will have a great effect on ISO 17065 quality system, if yes, relevant activities shall be supplemented within 3 months after the outbreak is lifted, otherwise, it could be considered in the next same activity. For other situations, similar principle applies.

在疫情期间, ICT远程方案的使用若导致某些记录缺失,会对认证准确性造成较大影响,应在申请评审时委婉拒绝受理该认证,或在方案策划时,拒绝采用相关替代措施。若影响较小,应在疫情结束后3个月内,进行补充。远程质量管理活动,若某些过程无法实现,认证部门应评估该缺失对有效运行ISO 17065质量管理体系的影响,若影响较大,应在疫情结束后3个月内补充。若较小,可在下一年度补充实施。其他远程替代活动,也应遵循相同的理念来执行。

5. Records 记录

The head of the regional/company HSE is responsible maintain the records related to emergency response measures and communication records with local government.

机构内应急管理和与疫情有关的属地行政沟通相关记录由区域/公司HSE相关负责人员记录并保存。

CRT-CHN is responsible to maintain the communication records with the authorities such as CNCA and CNAS.

与认证工作相关的行政沟通记录,由认证部门负责保存。

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Work Instruction 作业指导书

Certification during Prevention and Control of COVID-19 新冠疫情防控期间的认证工作

实施方案



China

The relevant records in relation to the factory inspection of a specific project are kept by the factory inspectors and shall be uploaded to the project documentation folder, if needed.

具体项目中涉及工厂检查的相关信息记录,由工厂检查员负责,若有需要。 需上传至项目文

The other records in relation to COVID-19 prevention and control are kept by the technical certifier and shall be uploaded to the project documentation folder, if needed.

具体项目中与疫情防控相关的其他记录,由授权技术签字人负责,若有需要,需上传至项目文 件。

6. Relevant Documents 相关文件

IAF ID3:2011 IAF **INFORMATIVE DOCUMENT** FOR **MANAGEMENT** OF

EXTRAORDINARY EVENTS OR CIRCUMSTANCES AFFECTING ABS. CABS AND CERTIFIED ORGANIZATIONS 《影响认可机构、合格评定机构

和获证组织的特殊事件或情况的管理》

"Guidelines for Certification Bodies to Respond to Outbreaks of New Coronary T/CCAA35-2020

Virus Pneumonia" 《认证机构应对新型冠状病毒肺炎疫情工作指南》

认可委(秘) "CNAS Notice on Accreditation Work Arrangements during the Prevention and

Control of the New Coronary Pneumonia Outbreak" 《CNAS关于在新冠肺炎 〔2020〕16号

疫情防控期间认可工作安排的通知》

GCN_ HSE_P_03CS Emergency Response Measures 突发事件应急预案

The use of information and communication technology (ICT) for auditing CNAS-CC14-2019

purpose《信息和通信技术(ICT)在审核中应用》

IT-Governance 信息技术管理 CLC-IT-001

CLC-IT-002 IT Security and Compliance 信息技术安全与合规