CMD 各管理体系和/或服务认证方案对外管理要求

CMD External Management Requirements for Management Systems and/or Service Certification Schemes

1、目的 Purpose

为规范 **CMD** 各管理体系和/或服务认证,公开 **CMD** 开展各管理体系和/或服务认证的实施依据,现将各管理体系和/或服务认证的认证方案名录发布,并明确获取渠道,便于各相关方获取和使用。

To standardize CMD's management systems and/or service certification, disclose the implementation basis for CMD's management systems and/or service certification, publish the directory of certification schemes for each management system and/or service certification, and specify the acquisition channels to facilitate access and use by Interested parties.

2、范围 Scope

本文件适用于 **CMD** 所开展的各管理体系和/或服务认证,明确各管理体系和/或服务认证的认证方案获取路径。

This document applies to all management systems and/or service certifications conducted by CMD and specifies the acquisition methods for the certification schemes of each management system and/or service certification.

3、目录清单 Directory List

| 序号 Serial No. | 文件编号 Doc. NO. | 文件名称 Doc. Title |
|---------------------|------------------|---|
| 1 | CMD-WG-054 | 管理体系认证实施方案 Management System Certification Implementation Scheme |

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| 2 | CMD-WG-065 | 医疗器械质量管理体系认证实施方案 Medical Device Quality Management System Certification Implementation Scheme |
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| 3 | CMD-WG-064 | 建筑工程质量管理体系认证实施方案 Construction Project Quality Management System Certification Implementation Scheme |
| 4 | CMD-WG-066 | 信息安全管理体系认证实施方案 Information Security Management System Certification Implementation Scheme |
| 5 | CMD-WG-055 | 医疗器械风险管理评价认证方案 Certification Scheme for Medical Device Risk Management Evaluation |
| 6 | CMD-WG-063 | 医疗器械上市后风险管理体系认证方案 Certification Scheme for Post-Market Risk Management System of Medical Devices |
| 7 | CMD-WG-056 | 批发零售服务认证实施规则 Implementation Rules for Wholesale and Retail Service Certification |
| 8 | CMD-WG-057 | 售后服务认证实施规则 Implementation Rules for After-Sales Service Certification |
| 9 | CMD-WG-058 | 维修服务认证实施规则 |

| | | Implementation Rules for Maintenance Service Certification |
|----|------------|--|
| 10 | CMD-WG-059 | 仓储服务认证实施规则 Implementation Rules for Warehousing Service Certification |

4、获取路径 Acquisition Path

4.1 各相关方,如初次或扩大申请管理体系和/或服务认证组织、已获证管理体系和/或服务认证组织、需要时管理体系和/或服务认证的采信方、监管部门等,可根据使用情况向 **CMD** 申请获取所需的认证方案原文,也可随时向项目管理人员申请获取相关认证方案。

Interested parties, including clients applying for initial or expanded management system and/or service certification, clients already certified for management system and/or service certification, the admitting parties of management system and/or service certification, regulatory authorities, and others, when needed, may apply to CMD to obtain the original texts of the required certification schemes according to their usage needs, or may request the relevant certification schemes from the project manager at any time.

4.1.1 对于初次或变更(如扩大、缩小等)申请管理体系和/或服务认证的组织需向 **CMD** 提交管理体系和/或服务认证的申请资料并与 **CMD** 签订了管理体系和/或服务认证合同且生效后可提供认证方案原文,由初次受理的人员与项目管理人员沟通协调获取最新有效的认证方案,向受审核方提供。

Organizations applying for initial or change (such as expansion, reduction, etc.) management system and/or service certification shall submit application materials to CMD and enter into a management system and/or service certification contract with CMD, which shall take effect. The original certification scheme may then be provided. The personnel initially accepting the application shall communicate and coordinate with the Project Manager to obtain the latest valid certification scheme and provide it to the auditee.

4.1.2 机构对管理体系和/或服务认证方案进行维护,发生变更时同时更新目录清单,各相关方需要时,需与项目管理人员沟通获取。若由于获证组织的原因,丢失相关认证方案等发生时,可主动向组织指定的项目管理人员索取,该项目管理人员调取最新有效的认证方案,向获证组织提供。

The certification body shall maintain the management system and/or service certification schemes and update the directory list simultaneously when changes occur. Interested parties shall communicate with the Project Manager to obtain the updated information as needed. If the certified organization loses relevant certification schemes due to its own reasons, it may proactively request them from the designated Project Manager. The Project Manager shall retrieve the latest valid certification scheme and provide it to the certified organization.

4.1.3 需要时,管理体系和/或服务认证的采信方、监管部门等需提供官方的申请文件,明确申请的原因、所需的认证方案、用途等信息并加盖公章,由相关项目管理人员提交 **CMD** 主管副总,经批准后才可向需求方提供认证方案的原文。

When necessary, the admitting parties of management system and/or service certification, regulatory authorities, etc. are required to provide official application documents, clearly stating the reason for the application, the required certification scheme, intended use, and other pertinent information, duly stamped with the official seal. These documents shall be submitted by the relevant project manager to the CMD Deputy General Manager in charge, and only upon approval may the original certification scheme be provided to the requesting party.

4.2 管理体系和/或服务认证管理人员, 联 系 人: 孙帅 联系电话: 010-64237550

Management personnel for management system and/or service certification, Contact Person: Sun Shuai; Contact Number: 010-64237550