|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document intended for the certification body and the lead auditor / 供認證機構和首席審核員使用的文件** | | | | |
| The name and surname of the auditor | |  | | |
| 審核員姓名 | |
| Issue date | |  | | |
| 簽發日期 | |
| Signature of auditor is not required. The certification body accepts this document in word format. | | | | 不需要審核員簽名。 認證機構接受此文檔的 word 格式。 |
|  | | | | |
| No. | ISO 9001 requirements | | Documents confirming the implementation of requirement/Comment from assessment | |
| 不。 | ISO 9001 要求 | | 確認實施要求/評估意見的文件 | |
| **4.** | **Context of the organization** | | **组织的背景** | |
| 4.1 | Understanding the needs and expectations of interested parties | |  | |
| 了解相關方的需求和期望 | |
| 4.2 | Understanding the needs and expectations of interested parties | |  | |
| 了解相關方的需求和期望 | |
| 4.3 | Definition of the scope of the quality management system | |  | |
| 質量管理體系範圍的定義 | |
| 4.4 | Definition of the scope of the quality management system | |  | |
| 質量管理體系範圍的定義 | |
|  | | | | |
| **5.** | **Leading** | | **领导** | |
| 5.2 | Leadership and commitment | |  | |
| 領導力和承諾 | |
| 5.2 | Quality policy | |  | |
| 質量方針 | |
|  | Roles, responsibilities and permissions in the organization | |  | |
| 組織中的角色、職責和權限 | |
|  | | | | |
| **6.** | **Planning** | | **策划** | |
| 6.1 | Actions relating to risks and opportunities | |  | |
| 與風險和機遇相關的行動 | |
| 6.2 | Quality goals and planning to achieve them | |  | |
| 質量目標和實現這些目標的計劃 | |
| 6.3 | Planning changes | |  | |
| 規劃變更 | |
|  | | | | |
| **7.** | **Assistance** | | **支持** | |
| 7.1 | Resources | |  | |
| 資源 | |
| 7.2 | Competence | |  | |
| 權限 | |
| 7.3 | Awareness | |  | |
| 意識 | |
| 7.4 | Communication | |  | |
| 溝通 | |
| 7.5 | Documented information | |  | |
| 文件化信息 | |
|  | | | | |
| **8.** | **Organization** | | **运行** | |
| 8.1 | Planning and supervision of operational activities | |  | |
| 業務活動的規劃和監督 | |
| 8.2 | Product and service requirements | |  | |
| 產品和服務要求 | |
| 8.3 | Design and development of products and services | |  | |
| 產品和服務的設計和開發 | |
| 8.4 | Supervision of processes, products and services provided from outside | |  | |
| 對外部提供的過程、產品和服務的監督 | |
| 8.5 | Production and service delivery | |  | |
| 生產和服務交付 | |
| 8.6 | Product and service release | |  | |
| 產品和服務發布 | |
| 8.7 | Supervision of non-compliant outputs | |  | |
| 監督不合規輸出 | |
|  |  | |  | |
| **9.** | **Evaluation of Performance** | | **绩效评价** | |
| 9.1 | Monitoring, measurement, analysis and evaluation | |  | |
| 監測、測量、分析和評價 | |
| 9.2 | Internal audit | |  | |
| 內部審計 | |
| 9.3 | Management review | |  | |
| 管理評審 | |
|  | | | | |
| **10.** | **Improvements** | | **改进** | |
| 10.1 | Identifying and selecting opportunities for improvement and implementing necessary actions to meet requirements and increase customer satisfaction | |  | |
| 識別和選擇改進機會並實施必要的措施以滿足要求並提高客戶滿意度 | |
| 10.2 | Nonconformities and corrective actions | |  | |
| 不符合項和糾正措施 | |
| 10.3 | Continuous improvement of the suitability, adequacy and effectiveness of the quality management system | |  | |
| 持續改進質量管理體系的適宜性、充分性和有效性 | |