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**CERTIFICATION AND ACCREDITATION INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

RB/T 180-2017

**Guidelines for process based quality management systems
audit
(English Translation)**

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard is proposed and managed by the National Certification and Accreditation Administration.

This standard was drafted. China National Accreditation Center for Conformity Assessment, Huaxin Technology Inspection Co., Ltd., Hangzhou Dekai Wantai Certification Co., Ltd.

Division, Tianjin Huacheng Certification Center, China Quality Certification Center, Guangzhou Saibao Certification Center Service Co., Ltd., Fangyuan Logo Certification Group Co., Ltd.

Division, Beijing Zhongda Huayuan Certification Center.

Introduction

The focus on the effectiveness and performance of the quality management system reflects a core purpose of the ISO 9001:2015 standard, namely "quality management" the expected result of the system. As a method of evaluating the effectiveness of the quality management system, the audit should always be based on this core purpose.

Reflects the demands of all parties involved in the quality management system certification to provide an effective and efficient review.

In order to obtain a good quality management system audit effectiveness and performance, we should provide consistent products and services that meet customer requirements.

And put customer satisfaction in the important matters of audit attention. In terms of achieving organizational goals and providing products and services that meet the requirements, Focus on the evaluation of the effectiveness of the quality management

system. Through the evaluation of the actual operation process of the organization, the organization of the quality management system process and even Improvements in the overall system help to achieve a higher level of quality management system performance. Quality management system audit should reflect this A recognition and pursuit.

The quality management system consists of interrelated processes, and a coordinated process system helps the organization to effectively achieve its desired results.

Conduct audits based on the organization's process systems and their associated relationships, and based on the actual operational results of each process and their performance Obtaining the effectiveness of the implementation of the quality management system will help achieve the intended purpose of the audit.

The process-based quality management system audit method proposed in this standard reflects the following audit ideas, that is, the organization has determined Cheng is based on the following considerations.

- Whether the process is determined and properly defined;
- Whether the risk factors that cause the process to deviate from the outcome are determined and effectively addressed;
- Process objectives and key performance indicators;
- Resources and information required for the process;
- The operational requirements of the process are consistent with the direction of the organization's development;
- Measurement and measurement methods for the process;
- the effectiveness of the process in achieving the desired results;
- The impact of process performance on the performance of the organization's management system.

The above review method provides a feasible way and means to improve the effectiveness and performance of the audit, and is the best audit practice.

Summary.

The benefits of implementing a process-based quality management system audit are.

- Focusing on the effectiveness and efficiency of the organizational process, improving the organizational process and its ability to improve

Note and provide organizations with information that can improve their performance;

- Provide customers and their stakeholders with confidence in the stability of organizational performance;

- reflects the common concern of the organization and its related parties;
- Reduced audit risk;
- Conducive to the ability of auditors;
- The value-added effect of the audit is significant.

Implement a process-based audit approach that avoids previous audits.

- Pay too much attention to documented procedures and ignore the concerns about the results of the organization's quality management system;
- Disconnected from the actual operation of the organization and separated from the process in which the organization operates;
- Focusing on the examination of the standard requirements one by one, hindering the evidence of effective connection between the organizational process and its processes Collection.

Successful implementation of a process-based quality management system audit requires the establishment of a process-based approach and a process-based approach and risk-based the thinking comes to support and manage the quality management system to support it.

This standard promotes a risk-based approach to audit management practices to consider the risks associated with the audit process. This risk includes the adoption the method of review, the availability of information and communication technologies, the sampling used in the audit process, the operating environment of the audited organization, and the Risks and legal issues, etc. Effective risk management should be integrated into the planning of audits, resources, selection of audit teams, audit implementation, etc.

In various activities.

This standard does not state requirements, and those related to management system certification should comply with the requirements of GB/T 27021.1.

This standard has the following relationship with GB/T 19011-2013.

GB/T 19011 provides a general guide for management system audit and is a necessary basis for the implementation of this standard.

There are a variety of audit methods that can be used in the audit. This standard provides a process-based quality management system audit method.

guide.

Process-based quality management system audit guide

1 Scope

This standard gives the basic ideas and methods for process-based quality management system audit, and implements a process-based quality management system.

The review provides guidance.

This standard applies to all organizations that implement external and internal audits of the quality management system.

This standard can also be used as a reference for the implementation of other management system audits, see Appendix E.

Note 1: External audits include what is commonly referred to as "second party audits" and "third party audits". The second party audit is related by the relevant parties of the organization or by other personnel.

In the name of the party. Third-party audits are conducted by an external, independent review organization.

Note 2: Internal audit, also known as first party audit, is carried out by the organization itself or in the name of the organization and can be used as the basis for the organization's self-qualification statement.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 19000-2016 Quality Management System Foundation and Terminology GB/T 19001 quality management system requirements GB/T 19011-2013 Management System Audit Guide GB/T 27021.1 Conformity assessment management system auditing certification body requirements Part 1. Requirements

3 Terms and definitions

The following terms and definitions defined in GB/T 19000-2016 and GB/T 19011-2013 apply to this document.

Process-based quality management system audit
processbasedqualitymanagementsystemsaudit Evaluate the organization's quality management system in accordance with the interrelationships between the processes and processes identified by the organization to determine that they meet the audit criteria A systematic, independent, documented process of degree.