



## ISO 7101:2023 Self-Audit Tool Structure and Content

**Purpose:** The self-audit tool is designed to help healthcare organizations evaluate their conformity with the requirements of ISO 7101:2023. It aims to ensure the effectiveness of management systems for quality in healthcare, ultimately leading to improved patient care and organizational performance.

**Structure:** The self-audit tool is divided into sections that correspond to the main clauses of ISO 7101:2023. Each section includes a set of audit questions, criteria, and a scoring system to assess the organization's compliance and identify areas for improvement.

### Sections:

1. **Scope and Purpose**
2. **Leadership and Governance**
3. **Planning**
4. **Support**
5. **Operation**
6. **Performance Evaluation**
7. **Improvement**

### Scoring System:

- **0:** Not implemented
- **1:** Poorly implemented
- **2:** Partially implemented
- **3:** Fully implemented but not effective
- **4:** Fully implemented and partially effective
- **5:** Fully implemented and highly effective

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## Content

### 1. Scope and Purpose

#### 1.1 Understanding the Scope of the Management System

- **Audit Question:** Is the scope of the quality management system clearly defined and documented?



- **Criteria:** The scope includes all relevant services and processes within the healthcare organization.
- **Score:** [ ]

## 1.2 Purpose and Objectives

- **Audit Question:** Are the purpose and objectives of the quality management system aligned with the organization's mission and vision?
- **Criteria:** Objectives are measurable and linked to the strategic goals of the organization.
- **Score:** [ ]

## 2. Leadership and Governance

### 2.1 Leadership Commitment

- **Audit Question:** Does top management demonstrate commitment to the quality management system?
- **Criteria:** Evidence of leadership involvement in quality initiatives and resource allocation.
- **Score:** [ ]

### 2.2 Governance Structure

- **Audit Question:** Is there a defined governance structure that supports quality management?
- **Criteria:** Clear roles, responsibilities, and authorities for quality management are established.
- **Score:** [ ]

### 2.3 Quality Policy

- **Audit Question:** Is there a quality policy that is communicated and understood across the organization?
- **Criteria:** The quality policy is documented, accessible, and regularly reviewed.
- **Score:** [ ]



### 3. Planning

#### 3.1 Risk and Opportunity Management

- **Audit Question:** Are risks and opportunities related to quality management identified and managed?
- **Criteria:** There is a documented process for risk assessment and mitigation.
- **Score:** [ ]

#### 3.2 Quality Objectives and Planning to Achieve Them

- **Audit Question:** Are quality objectives established and plans to achieve them documented?
- **Criteria:** Objectives are specific, measurable, achievable, relevant, and time-bound (SMART).
- **Score:** [ ]

### 4. Support

#### 4.1 Resource Management

- **Audit Question:** Are resources (human, infrastructure, environment, and information) adequately managed to support the quality management system?
- **Criteria:** Resource needs are identified and met effectively.
- **Score:** [ ]

#### 4.2 Competence and Training

- **Audit Question:** Are personnel competent and provided with necessary training?
- **Criteria:** Training programs are in place and effectiveness is evaluated.
- **Score:** [ ]

#### 4.3 Communication

- **Audit Question:** Are communication processes effective in supporting the quality management system?
- **Criteria:** Communication channels are defined and utilized efficiently.
- **Score:** [ ]



#### 4.4 Documented Information

- **Audit Question:** Is documented information managed effectively to support the quality management system?
- **Criteria:** Documentation is controlled, accessible, and reviewed regularly.
- **Score:** [ ]

### 5. Operation

#### 5.1 Operational Planning and Control

- **Audit Question:** Are operational processes planned and controlled to meet quality requirements?
- **Criteria:** Procedures and controls are established for key processes.
- **Score:** [ ]

#### 5.2 Patient Care Processes

- **Audit Question:** Are patient care processes designed and managed to ensure quality and safety?
- **Criteria:** Care processes are evidence-based and patient-centered.
- **Score:** [ ]

#### 5.3 Emergency Preparedness

- **Audit Question:** Is there a system in place for emergency preparedness and response?
- **Criteria:** Emergency plans are documented, communicated, and regularly tested.
- **Score:** [ ]

### 6. Performance Evaluation

#### 6.1 Monitoring, Measurement, Analysis, and Evaluation

- **Audit Question:** Are processes for monitoring, measurement, analysis, and evaluation of quality performance established?
- **Criteria:** Performance data is collected, analyzed, and used for decision-making.
- **Score:** [ ]



## 6.2 Internal Audit

- **Audit Question:** Are internal audits conducted to evaluate the effectiveness of the quality management system?
- **Criteria:** Audit schedules, procedures, and follow-up actions are documented.
- **Score:** [ ]

## 6.3 Management Review

- **Audit Question:** Are management reviews conducted to ensure the quality management system's continuing suitability and effectiveness?
- **Criteria:** Reviews are documented and include assessment of objectives, performance, and opportunities for improvement.
- **Score:** [ ]

## 7. Improvement

### 7.1 Continual Improvement

- **Audit Question:** Is there a systematic approach to continual improvement in place?
- **Criteria:** Improvement initiatives are documented, tracked, and evaluated for effectiveness.
- **Score:** [ ]

### 7.2 Corrective Actions

- **Audit Question:** Are corrective actions taken to address nonconformities?
- **Criteria:** There is a documented process for identifying, documenting, and resolving nonconformities.
- **Score:** [ ]

### 7.3 Innovation and Best Practices

- **Audit Question:** Does the organization encourage innovation and the adoption of best practices?
- **Criteria:** Mechanisms for innovation and benchmarking are in place and utilized.
- **Score:** [ ]



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## Summary and Action Plan

### Overall Score:

- Sum of all scores: [ ]
- Average score per section: [ ]

### Strengths:

- Identified areas where the organization scores 4 or 5 consistently.

### Areas for Improvement:

- Identified areas where the organization scores below 3.

### Action Plan:

- Actions to address areas for improvement with responsible persons and timelines.

### Follow-up:

- Scheduled reviews to monitor the progress of the action plan.

This self-audit tool should be used regularly to ensure ongoing compliance with ISO 7101:2023 and to drive continual improvement in the organization's quality management system for healthcare.