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| **SCS 9001:2021** |
| **MINIMUM ON-SITE AUDIT DAYS TABLE** |

Purpose: This audit days document describes how the minimum SCS 9001 Audit Time is calculated using the required SCS 9001 Audit Duration Calculation Tool.

**Core and Support Personnel Definitions:**

1. The total population of employees within scope must first be separated into Core and Support categorization as per the following definitions:
   * CORE Personnel: Personnel with key roles and responsibilities for achieving the expected outcome/performance of the SCS management system including those responsible for planning, implementation, design, management, internal auditing, and providing input to the SCS process design for the SCS Architecture; AND CORE PERSONNEL ALSO INCLUDES individuals that plan, define requirements, design, test , implement manufacturing controls and manage security processes for the product AND SERVICE.
   * Support Personnel: Those personnel required to follow the SCS processes and controls. (Remaining people in the organization that are not SCS Core Personnel).

**Process:**

1. Audit time is calculated by determining the headcount for Core and Support personnel. Enter the Core and Support headcount in the required SCS 9001 Audit Duration Time Calculation Tool based on the Audit Days Table per Headcount shown below.

Note: The separation of Core personnel and Support personnel is primarily for the purpose of calculating total audit time. Actual audit activities should be planned as-needed with the required personnel.

**Audit Days Table per Headcount**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | |  | | |  |  | | |  | | |  |
| **STEP 1** | | | | |  | **STEP 2** | | | | |  | **TOTAL** | | | |
| **SCS Core Personnel** | | |  | |  | **SCS Support Personnel** | | |  | |  | **Initial Audit Duration (Days)** | | | |
| 1-10 | | | 6 | |  | 1-10 | | | .5 | |  | **SUM of**  **STEP 1 + STEP 2**  (Total will vary by organization) | | | |
| 11-15 | | | 7 | |  | 11-15 | | | .5 | |  |
| 16-25 | | | 7 | |  | 16-25 | | | 1 | |  |
| 26-45 | | | 10 | |  | 26-45 | | | 1 | |  |
| 46-65 | | | 12 | |  | 46-65 | | | 1 | |  |
| 66-85 | | | 13 | |  | 66-85 | | | 1 | |  |
| 86-125 | | | 14.5 | |  | 86-125 | | | 1 | |  |
| 126-175 | | | 15.5 | |  | 126-175 | | | 2 | |  |
| 176-275 | | | 17 | |  | 176-275 | | | 2 | |  |
| 276-425 | | | 18 | |  | 276-425 | | | 2 | |  |
| 426-625 | | | 20 | |  | 426-625 | | | 2 | |  |
| 626-875 | | | 21 | |  | 626-875 | | | 2.5 | |  |
| 876-1175 | | | 22 | |  | 876-1175 | | | 2.5 | |  |
| 1176-1550 | | | 23.5 | |  | 1176-1550 | | | 2.5 | |  |
| 1551-2025 | | | 25 | |  | 1551-2025 | | | 2.5 | |  |
| 2026-2675 | | | 26.5 | |  | 2026-2675 | | | 2.5 | |  |
| 2676-3450 | | | 27.5 | |  | 2676-3450 | | | 3 | |  |
| 3451-4350 | | | 29 | |  | 3451-4350 | | | 3 | |  |
| 4351-5450 | | | 30 | |  | 4351-5450 | | | 3 | |  |
| 5451-6800 | | | 31 | |  | 5451-6800 | | | 3 | |  |
| 6801-8500 | | | 32.5 | |  | 6801-8500 | | | 3 | |  |
| 8501-10700 | | | 33.5 | |  | 8501-10700 | | | 3.5 | |  |
|  |  |  | |  | | | |  | | | | | | |

1. **Applied Table Factors:** The SCS 9001 Audit Duration Time Calculation Tool applies the factors in tables 1-3 below.

Table 1: Factors Related to Business and Organization (other than IT)

|  |  |
| --- | --- |
| Category | Grade |
| Type(s) of business and regulatory requirements | 1. Organization works in non-critical business sectors and non-regulated sectors 2. Organization has customers in critical business sectors\* 3. Organization works in critical business sectors\* |
| Process and tasks | 1. Standard processes and tools with standard and repetitive tasks; lots of persons doing work under the organization’s control carrying out the same tasks; few products or services. 2. Standard processes and tools but non-repetitive processes, with high # of products or services; 3. Complex processes, high # of products and services, many business units included in scope of certification (SCS system covers highly complex processes or relatively high # or unique activities) |
| Level of establishment of the Management System | 1. SCS system is already well established and/or other management systems are in place. 2. Some elements of other management system/s are implemented, others are not implemented. 3. No other management system implemented at all, the SCS system is new and/or not established. |

\*Critical business sectors are sectors that may affect critical public or private services that could cause risk to security, economy, image, and/or government ability to function or may have a large negative impact to the customers served by that sector.

Table 2: Factors Related to IT Environment

|  |  |
| --- | --- |
| Category | Factors Related to IT Environment |
| IT infrastructure Complexity | 1. Few or highly standardized IT platforms, servers, operating systems, dbases, networks, etc. 2. Several different IT platforms, servers, operating systems, dbases, networks. 3. Many different IT platforms, servers, operating systems, dbases, networks etc. |
| Dependency on outsourcing & suppliers, including cloud services | 1. Little or no dependency on outsourcing or suppliers. 2. Some dependency on outsourcing or suppliers, related to some but not all important business and/or product/service activities. 3. High dependency on outsourcing or suppliers, large impact on important business and/or product/service activities. |
| Information System, Product/Service Development | 1. None or very limited in-house system/app development. 2. Some in-house or outsourced system/app development for some important business and/or product/service purposes. 3. Extensive in-house or outsourced systems/application development for important business and/or product/service purposes. |

Table 3 – Impact of factors on audit time.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | IT Complexity | | |
| Low (3-4) | Medium (5-6) | High (7-9) |
| Business Complexity | High (7to9) | +5% to +20% | +10% to +50% | +20% to +100% |
| Medium (5-6) | 0% | 0% | +10% to +50% |
| Low (3-4) | 0% | 0% | +5% to +20% |

1. **General Requirements and Guidelines:**
2. Based on the Impact of factors on audit time, the CB determines whether an additional percentage of audit time is required and includes the justification for same in the SCS 9001 Audit Duration Time Calculation Tool.
3. Planning and audit report writing time is not included in the on-site audit-day calculation. Planning and audit reporting writing time is additional time. Recommendations: Additional planning time is typically 25%. Additional report writing time is typically 15%.
4. A SCS Management System scope may include a “virtual organization” resulting in non-applicability of IAF MD5:2019 Note 1, i.e., “(IAF MD5:2019 Note 1: A virtual site **cannot be considered** where the processes must be executed in a physical environment, e.g., warehousing, manufacturing, physical testing laboratories, installation or repairs to physical products.)”.   
   A “virtual organization” may be considered across multiple locations when the SCS management system utilizes common processes, controls, and tools in its implementation. Sites that have different processes, controls, and/or tools in its SCS management system implementation must be calculated separately.

SCS Audit Duration Time Calculation Tool Application to Calculate Audit Days Example for Virtual Organization:

* + A multi-site organization with 6 sites where common processes, controls and tools are used for **three** of the six sites will apply the SCS Audit Duration Time Calculation Tool for the Core and Support headcount for the three sites.
  + **Two** sites of the six sites have common processes, controls and tools. The Core and Support headcount will be combined to apply the SCS Audit Duration Time Calculation Tool.
  + **One** site has unique processes, controls and tools will use the SCS Audit Duration Time Calculation Tool for this one site separately.

1. Use the SCS 9001 Audit Duration Calculation Tool to determine audit days.

**Revisions History:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision** | **Date** | **Author** | **Changes** |
| **0.1** | **Sept 17, 2021** | **AB/CB** | **Initial Version for Pilot** |
| **0.2** | **October 2022** | **AB/CB** | **Removed references to underlying Management Systems.** |
| **0.3** | **Jan 13, 2023** | **AB/CB** | **Addressed decoupling from ISO 9001, enhanced definitions to Core personnel and Table 1, 2, and virtual organization** |