

Calculating MDSAP Audit Times

Note: This article does not include the audit time changes announced by Health Canada on October 31, 2017. (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/international/single-audit-program-reduction-audit-times.html>)

MDSAP

The Medical Device Single Audit Program, MDSAP, uses an audit model accepted by regulators in Australia, Brazil, Canada, Japan, and the United States. MDSAP doesn't add additional requirements, but instead, provides a common method for an Auditing Organization, AO, to verify compliance with the existing regulations.

MDSAP Audit Types

The MDSAP model has provision for four audit types: Initial Certification (Stage 1 and Stage 2), Surveillance, Recertification, and Special. In addition, the audit model identifies seven process, each of which is further divided into tasks. Each task has a predetermined time for the audit.

Duration Tools

To help determine the audit duration, MDSAP has provided two tools – a procedure to determine the audit time (MDSAP AU P0008.005: Audit Time Determination Procedure) and an Excel workbook to perform the calculations (MDSAP AU F0008.2.002 Audit Duration Calculation Form (Audit Model 2017)). Both tools are available from <https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377580.htm>

The audit calculations does not include off-site time such as preparation and report writing.

For each audit type, the AO determines the processes and tasks included. Each task has an established time as shown in the table.

MDSAP Process	Tasks per Process	Minutes per Task (Planning Document)	Minutes per Task (Workbook)
Management	11	28.8	36
Device Marketing authorization and Facility Registration Process	3	28.0	35
Measurement, analysis, and Improvement Process	16	30.4	38
Medical Device Adverse Events and Advisory Notices Reporting Process	2	30.4	38
Design and Development Process	17	16.8	21
Process and Service Controls Process	29	35.2	44
Purchasing	12	12	15

Notice that the time per task in the planning document are not the same as the time per task in workbook.

Duration Calculation

For each audit type the AO determines the processes and tasks to include.

The workbook provides two methods to do the calculation, but expects the user to employ only one of them. In Method #1, list the number of tasks to perform for each process. In Method #2, there is a table that lists each task. Enter 0 if the task is not applicable to the audit and 1 if it is applicable. If the audit requires the task to be accomplished more than once, *i.e.*, an increase in the sampling rate, then enter the appropriate digit (2, 3, 4, ...).

In an Initial Certification audit, assume the AO performs each task one time. The worksheet for Method #2 says that such an audit takes 49 hours and 58 minutes – 50 hours. Assuming 8 hours for each audit day, this is 6 days and 2 hours in auditor days. If some audit tasks are conducted at the same time by multiple auditors, this could reduce the number of calendar days.

Adjustments

The Planning Document has provisions for adjustments of the audit duration. For example, if the organization doesn't "engage in design and development activities" the audit of the Design and Development can be limited to Task # and Task #16.

Task #1: Verify that those devices that are, by regulation, subject to design and development procedures have been identified.

Task #16: Determine if the design was correctly transferred to production.

The Planning Document, 5.3.3, says that if the audit requires assessment of a correction or corrective action from a previously cited nonconformity, then each nonconformity is an additional task under Measurement, Analysis, and Improvement. These tasks have a standard time of 38 minutes in the workbook.

The Planning Document, 5.3.6, allows adjustments based on the number of employees. The total audit duration may be reduced by up-to 10% for 16 to 45 employees and up-to 20% for 15 or fewer employees.

Health Canada Notice

The notice from Health Canada announces a reduction in audit times. Notice that the MDSAP audit time calculation does not depend on the company size, only the audit tasks to perform. However, there could be an adjustment for the number of employees. Other audit duration models include the number of employees and the number of shifts in the audit time calculation.

The notice says that the MDSAP Consortium has implemented the following changes:

- Streamlined the MDSAP audit approach in the revised version of the audit model. This has reduced the total number of tasks to be accomplished and reduced the overall audit time
- Introduced a 10% reduction in audit time for manufacturers with 45 or fewer employees

- Introduced a 20% reduction in audit time for manufacturers with 15 or fewer employees
- Introduced a 20% reduction in the duration of surveillance and re-certification audits for all manufacturers
- Clarified the expectations for annual surveillance audits with the goal of reducing the audit time.