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1 Purpose/Policy

The purpose of this document is to specify criteria that shall be used by recognized Auditing Organizations to determine the audit time necessary to conduct an audit of a medical device manufacturer for regulatory purposes according to the Medical Device Single Audit Program (MDSAP).

2 Scope

This document applies to MDSAP recognized Auditing Organizations conducting audits of a medical device manufacturer for regulatory purposes. Adherence to this document and its requirements will help mitigate the risk of inconsistent audit times being calculated by different Auditing Organizations performing similar audit activities within the medical device single audit program.

3 Definitions/Acronyms

Audit: A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. (ISO 9000:2015 clause 3.9.1)

Audit Time: Time needed to plan and accomplish a complete and effective audit of the client organization's management system. (ISO/IEC 17021-1:2015 clause 3.6)

***Auditing Organization (AO)*:** An organization that audits a medical device manufacturer for conformity with quality management system requirements. Auditing Organizations may be an independent commercial organization or a Regulatory Authority which perform regulatory audits. (IMDRF/ MDSAP WG/N5)

Auditor: A person with the demonstrated personal attributes and competence to conduct an audit. (ISO 9000:2015 clause 3.9.9)

***Auditor Day*:** Eight (8) hours excluding breaks, meals, and travel.

***Duration of Audit*:** Part of *audit time* spent conducting audit activities from the opening meeting to the closing meeting, inclusive. (ISO/IEC 17021-1:2015 clause 3.17)

Regulatory Authority: A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (GHTF/SG1/N78:2012)

4 Responsibilities

The Auditing Organization shall comply with this procedure as well as all applicable clauses of ISO/IEC 17021-1:2015 (e.g. clause 9.1.4) when calculating the duration of audit and determining audit time.

It is the responsibility of the Auditing Organization to maintain documented evidence of the calculations (and other justifications) that were used to determine the audit time necessary to conduct an audit of each medical device manufacturing facility for regulatory purposes.

Note 1: It is recognized that Auditing Organizations may be subjected to further requirements of other accredited certification schemes. This may influence the calculated audit time.

5 Procedures

5.1 Off-site Audit Time Determination

Off-site audit time (e.g. preparation, report writing, etc.) is to be determined by an Auditing Organization's policies and procedures.

5.2 Duration of Audit Calculation

The MDSAP audit model defines the MDSAP Audit Cycle including the scope, criteria and activities for different types of audits, Initial Certification (Stage 1 and 2), Surveillance, Re-audits (a.k.a. Recertification Audits), and Special Audits.
The appropriate scope and criteria defined within the MDSAP Audit Cycle for each type

of audit must be used when calculating audit duration. Consequently, the duration of audit will vary for each audit in the cycle. The planned duration of an initial audit should be confirmed during the Stage 1 audit. The planned duration for any subsequent audit may take into account the outcome of previous audit activities (surveillance, re-audit or special audits) or any requests from a Regulatory Authority.

The MDSAP audit model contains the purpose and anticipated outcomes when auditing seven (7) specific quality management system processes. The mechanism for auditing these quality management system processes, and achieving the anticipated outcomes, is the accomplishment of specific audit “tasks”. There are varying numbers of audit tasks depending on the process being audited. Although the order in which the audit of MDSAP processes is prescribed, the order in which tasks within each process are used for an audit is not prescribed. The order of tasks should not increase the calculated duration. In some cases efficiencies may be possible to shorten audit duration. The number of audit tasks accomplished during the audit of a medical device manufacturer will vary depending on the type of audit performed and the specific activities performed by the organization.

For example, if the organization does not manufacture sterile medical devices (or medical devices subject to sterilization by the user) and the devices do not require installation, or servicing, Production and Service Controls tasks 9, 26, and 27 will not be applicable and should not be considered in the duration of audit calculations. Conversely, if more than one design, or more than one manufacturing process, is selected for audit, the addition of duplicate audit tasks may need to be considered when making duration of audit calculations since the same tasks will be applied during multiple audit activities.

The calculation of the duration of audit is primarily based on the number of applicable audit tasks associated with the type of audit to be conducted (as defined in the MDSAP Audit Cycle) and the specific activities of the organization to be audited.

The table below summarizes the process for determining the duration of audit calculations. Wherever possible, the time required to accomplish the individual audit tasks has been based on empirical data generated from the validation of a similar “task-based” audit model.

The forms MDSAP AU F0008.1 and MDSAP AU F0008.2 described below contain instructions and an Excel spreadsheet for automatically calculating the duration of audit based on the number of tasks, and the time for each task, as summarized in the table below.

MDSAP Process	MDSAP Tasks per Process		Number of Applicable Tasks to be Audited	Minutes per Audit Task	Total Number of Minutes per Process	Audit Hours per Process	MDSAP On-site Auditor Days
			A	**B**	A x B	A X B ÷ 60	A × B ÷ 60 ÷ 8
Management	11			**28.8**			
DMA&FR	3			**28.0**			
MA&I	16			**30.4**			
MDAE&ANR	2			**30.4**			
D&D	17			**16.8**			
P&SC	29			**35.2**			
Purchasing	16	12*		**12.0**			
Total	94	90*					

* To be used with MDSAP AU P0002 Audit Model (reflecting ISO 13485:2016)

Management = Management Process
DMA&FR = Device Marketing Authorization and Facility Registration Process
MAI = Measurement, Analysis and Improvement Process
MDAE&ANR = Medical Device Adverse Events and Advisory Notices Reporting Process
D&D = Design and Development Process
P&SC = Process and Service Controls Process
Purchasing = Purchasing Process

5.2.1 Calculating Duration of Audit – for audits **excluding** *Stage 1:*

- Apply MDSAP duration of audit adjustments *(5.3)* as applicable.
- Use MDSAP P0008 algorithm contained within the table above to calculate the total time necessary to accomplish all applicable audit tasks.

5.2.2 Calculating Duration of Audit – for ***initial*** *certification audits (Stage 1, Stage 2)*:*

- Apply MDSAP duration of audit adjustments *(5.3)* as applicable.
- Use MDSAP P0008 algorithm contained within the table above to calculate the total time necessary to accomplish all applicable audit tasks.
- From the calculated time necessary to accomplish all applicable audit tasks, add 25%. The result will reflect the total time to achieve applicable audit tasks, including the duration of audit and a provision for Stage 1 audit activities that are conducted off-site.

  Note: When using Forms MDSAP AU F0008.1 and MDSAP AU F0008.2 to calculate duration of audit for initial certification audits, the embedded algorithm automatically applies the cited additional 25%.

5.2.3 Calculating Duration of Audit – for ***non-initial*** *certification audits that* ***include***

Stage 1:*

- Apply MDSAP duration of audit adjustments *(5.3)* as applicable.
- Use MDSAP P0008 algorithm contained within the table above to calculate the total time necessary to accomplish all applicable audit tasks.
- From the calculated time necessary to accomplish all applicable audit tasks, add additional time (if necessary) as deemed appropriate by the auditing organization to accomplish audit objectives. The result will reflect the total time to achieve applicable audit tasks, including the duration of audit and a provision for Stage 1 audit activities that are conducted off-site.

5.2.4 Calculating Duration of Audit – for surveillance audits:

- Identify applicable audit tasks in accordance with the guidance in Appendix 1.
- Apply MDSAP duration of audit adjustments (5.3) as applicable.
- Use MDSAP P0008 algorithm contained within the table above to calculate the total time necessary to accomplish all applicable audit tasks.
- From the calculated time necessary to accomplish all applicable audit tasks, add additional time (if necessary) as deemed appropriate by the Auditing Organization to accomplish audit objectives.

* The Auditing Organization shall determine how best to accomplish tasks of Stage 1 and Stage 2 with regards to off-site record review and on-site verifications. The Auditing Organization may combine elements of Stage 1 and Stage 2 to allow for a single on-site visit to the manufacturer. (IMDRF N3 9.3.1)

5.3 Duration of Audit Adjustments

The Duration of Audit can be adjusted when certain additional conditions are encountered.

5.3.1 Adjustments specific to Design and Development (when applicable)

5.3.1.1 If the organization to be audited does not engage in design and development activities, the audit of Design and Development can be limited to tasks 1 and 16.

5.3.1.2 If the organization to be audited manufactures medical devices that were designed prior to regulatory design and development requirements and does not actively design new devices, the audit of Design and Development can be limited to tasks 1 and 4 (Design Change Procedures) and 13 through 16.

5.3.1.3 For medical devices containing software, applicable design and development activities specific to the software may result in the duplication of design and development tasks.

Note: Some audit tasks may be accomplished concurrently during the accomplishment of a separate audit task. In this case, reference should be made in the audit report that multiple audit tasks were accomplished concurrently. The report should clearly reference where the findings of each audit task are discussed.

5.3.2 Adjustments specific to Production & Service Control (when applicable)

5.3.2.1 If the manufacturing process selected to be audited during a surveillance audit was comprehensively audited during a previous audit in the current MDSAP audit cycle and there have been no significant changes to the process or indicators of potential concerns, the time estimated for auditing this process may be reduced. The time allocated shall be commensurate with the need to establish on-going conformity and operational control, but shall not be reduced by more than 30% of the calculated time.

5.3.3 Adjustments specific to assessment of previously cited nonconformities

5.3.3.1 If the audit requires the assessment of corrections and/or corrective actions from previously cited nonconformities, these nonconformities should each be considered a separate task under Measurement, Analysis and Improvement (MA&I) with the appropriate additional time allocated. The estimated additional time for the Stage 1 audit (where applicable) shall not include additional time specifically for the review of previously identified nonconformities.

5.3.4 Adjustments specific to assessment of critical suppliers

5.3.4.1 Additional time should be added based on the number of critical suppliers, where necessary, as determined by the AO.

5.3.5 Adjustments based on Multiple Site Audits

5.3.5.1 When multiple site audits are conducted, the duration of audit for each individual site should be calculated separately. The total duration of audit is the cumulative duration of audit necessary to audit each individual site. Multiple site audits may require the duplication of audit tasks at multiple sites. Conversely, multiple sites may not have the same responsibilities and processes. The duration of audit for each site should be calculated based on the specific responsibilities and processes of that site. While a particular site may not be responsible for certain activities, consideration should be given to including audit time to verify the interfaces between various sites where responsibilities are distributed. Sampling of design and manufacturing sites is not permitted.

5.3.6 Adjustments based on organization size

The duration of audits may be adjusted based on the number of employees involved in the design and/or manufacturing of medical devices within the scope of the audit under certain circumstances.

In order to apply the audit duration adjustments in this section, the following three criteria must all be met:

- the organization must design and/or manufacture only lower risk medical devices (e.g. considering the duration of use, non-active, non-implantable, does not have special characteristics);
- the organization must implement only simple designs (e.g. few components using commonly used materials) and/or manufacturing processes (e.g. few process steps where wide tolerances are acceptable); and,
- The organization must have a history of medical device regulatory audits showing a good standing QMS (e.g. nonconformities not exceeding grade 3), without obstacles to the fulfilment of the audit objectives.

In cases where an organization does not meet the basic criteria above, the AO may still apply a smaller adjustment based on justification and the history / past compliance / knowledge of the organization.

These adjustments based on organization size are not applicable to the design and/or manufacturing of high risk products or the use of complex design and/or manufacturing processes.

The following devices and activities are not eligible for audit duration adjustments under this section:

- Life-supporting or life-sustaining devices;
- Implantable devices;
- Devices that come into contact with the central cardiovascular system* or the central nervous system†;
- Devices that emit ionizing radiation and devices and software intended to monitor or control such devices;
- Devices that incorporate a drug or biologic constituent;
- Devices that incorporate human or animal tissues or their derivatives
- IVDs for the detection of cancer, infectious agents, or transfusion-transmitted diseases;
- IVDs for the detection of congenital disorders of the fetus;

- IVDs for blood grouping or tissue typing to ensure immunological compatibility;
- IVDs for near patient testing (point of care or self-test), excluding pregnancy and fertility tests
- Sterilization processes that do not follow an established international standard;
- Aseptic processing; and,
- Sterilization processes performed in-house.

* The central cardiovascular system means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta (including ascending, arch, descending, thoracic and abdominal), inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries.

† The central nervous system means the brain, meninges, spinal cord and cerebrospinal fluid.

To apply the adjustments based on the size of the organization, the audit duration calculated using the P0008 algorithm, and adjusted in accordance with section 5.3 above, is multiplied by the appropriate factor in the table below:

Employees	***Adjustment Factor***
1 to 5	-42%
6 to 10	-39%
11 to 15	-35%
16 to 25	-28%
26 to 45	-18%
46 to 65	-14%
66 to 85	-10%
86 to 100	-5%

Note: All considerations affecting audit time calculations, including considerations not referenced within this document (e.g. as specified in ISO/IEC 17021-1:2015, clause 9.1.4) should be described in the recorded justification supporting the audit time determination.

6 Reference Documents

ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 1: Requirements

ISO 9000:2015 Quality management systems – Fundamentals and vocabulary

MDSAP AU P0002 Audit Model

MDSAP AU G0002 Companion Document

MDSAP AU F0008.1 Duration of Audit Calculation Spreadsheets and Instructions (To be used when calculating audits against ISO13485:2003 using MDSAP AU P0002)

MDSAP AU F0008.2 Duration of Audit Calculation Spreadsheets and Instructions (To be used when calculating audits against ISO 13485:2016 using MDSAP AU P0002)

7 Document History

VERSION No.	VERSION date	Description of Change	Author Name/Project Manager
001	2013-12-13	Initial Release	Robert Ruff, FDA
002	2016-08-15	Document was revised to meet the new ISO/IEC 17021-1:2015 Requirements. Only minor changes were made.	Liliane Brown, FDA
003	2017-01-24	Following revisions were made: 1. reflect new terms contained in ISO/IEC 17021-1:2015 (e.g. duration of audit, audit time); 2. reflect revised specified requirements regarding the calculation of off-site audit time (preparation, report writing, etc.); 3. add "Duration of Audit Calculations" for audits including and excluding Stage 1 (S1); 4. reflect allowed adjustments are relative to duration of audit. QMS Manager: to request an expedited review and approval by the RAC. This is a deliverable promised during the December Ottawa forum. After RAC approval and posting to the web, please prepare and send	Robert Ruff, FDA

		a transmittal notifying AOs and RAs of the revised document's availability. The new procedure should be implemented when calculating times reflecting the use of MDSAP AU P0002.004 (revised audit model generated to reflect ISO/IEC 13485:2016). 5. created a new form (MDSAP AU P0008.2) to reflect the new Spreadsheet that was created to display the new audit time calculation algorithm based on the new audit model. 6. Title change from “Audit Time Calculation to Audit Time Determination”.	
004	2017-02-15	Following revisions were made: 1. Chart revised to consider reduction in audit tasks in Purchasing Process when using MDSAP AU P0002.004 Audit Model used to reflect ISO 13485:2016; 2. A note was added to clarify automatic calculations performed by attached forms; 3. Attached forms corrected error on tab #1 of each form on either the number of tasks relative the purchasing process or the total number of tasks; and, 4. The instruction tab of each form now clarifies that: “Two (2) options are available to determine an audit duration. When using this form, Auditing Organizations are expected to use one tab, not both.” Note: those were minor changes and would not need to be re-approved and/or reviewed.	Robert Ruff, FDA
005	2017-08-23	The following revisions were made: 1. Note 2 under section 4 was deleted 2. Clarification was provided for sections 5.3.2.1; 5.3.3.1; 5.3.4.1; and 5.3.5.1 Reductions in duration of audit based on the size of the organization were introduced in section 5.3.6.1 for organizations up to 45 employees.	Frédéric Hamelin, Health Canada

006	2018-04-24	The following revisions were made: 1. Audit duration adjustments based on the size of the organization were revised for organizations of up to 100 employees. 2. Added guidance on surveillance audits Added appendix 1 – Surveillance Audits	Frédéric Hamelin, Health Canada
007	2018-10-16	Adjusted formatting throughout the document	Keith M Smith, TGA Hiromi Kumada, PMDA

Version 007

Approval

Approved: **Signature on File** Date: October 16, 2018

MDSAP Lead Project Manager for RAC Chair

Appendix 1 – Surveillance Audits

A Surveillance Audit shall be conducted in accordance with Clause 9.6.2.2 of ISO/IEC 17021-1:2015 and clause 9.6.2 of IMDRF/MDSAP WG/N3:2016 and using applicable MDSAP Audit Process tasks.

The purpose of a series of surveillance audits is to assure that all applicable requirements of ISO 13485:2016 and the relevant regulatory requirements from participating regulatory authorities are audited during the cycle of a three year audit program for the manufacturer. Surveillance audit objectives during the audit cycle shall specifically include evaluation of:

- the effectiveness of the manufacturer's QMS incorporating the applicable regulatory requirements; including the effectiveness of corrections and corrective actions for nonconformities previously identified by the AO.
- the manufacturer's ability to comply with these requirements; and
- new or changed product/process related technologies; and,
- new or amended product technical documentation in relation to relevant regulatory requirements.

In addition, surveillance audits shall include a review of issues related to medical device safety and effectiveness since the last audit such as complaints, problem reports, vigilance reports, and recalls/field corrections/advisory notices.

These objectives allow the MDSAP recognized auditing organization to maintain confidence that the QMS continues to meet requirements between re-audits (re-certification audits) and the confidence that the QMS has the ability to effectively implement corrections and corrective actions to prevent the recurrence of previously identified nonconformity. The auditor should again expect that the documentation and records are maintained to demonstrate continued compliance with regulatory requirements during the post-market phase of the device life-cycle.

Surveillance audits do not require a Stage 1 audit unless significant changes have occurred since the last audit. For example, where there are QMS changes associated with new legislation, or legislative changes, or if otherwise deemed necessary by the auditing organization.

Each *individual* surveillance audit in the cycle need not cover all MDSAP requirements. However, as a minimum, each surveillance audit must address the following (as applicable):

i) A review of changes to the manufacturer, their QMS, or their products, since the previous audit
   - *Note: changes may necessitate regulatory submissions*

ii) The MDSAP Audit Process tasks as listed in the tables below:

- *Note: Where there are indicators of existing or potential nonconformities in the data, or other information observed during a surveillance audit that suggest that such nonconformities have not been adequately addressed by the manufacturer's QMS, an audit of the Design and Development Process and/or the Production and Service Controls Process should focus on those indicators of existing or potential nonconformities.*

- *Note: If the first surveillance audit includes the Design and Development Process, the second surveillance should include the Production and Service Controls Process (or vice-versa) unless further indicators of existing or potential nonconformities dictate otherwise.*

iii) Confirmation that the manufacturer has arrangements in place to maintain the currency of the technical documentation for all devices (see Audit Model Annex 1).

Guidance on the selection of samples of data for the audit of the processes in i) and ii) above is provided within the relevant tasks of those MDSAP Audit Processes. The selection should be limited to the data that is germane to those processes.

The following table should be used as a reference regarding the suggested frequency of auditing tasks for each process during the three-year audit cycle. For tasks that are identified in the table as "Audit 1 of 2 Surveillances", Auditing Organizations have flexibility as to the selection of which tasks are covered in either surveillance audit #1 or surveillance audit #2, provided that the tasks are covered in either surveillance audit.

The Auditing Organization should include the determination of the audit tasks to complete during each surveillance assessment in the audit program of their client (see ISO/IEC 17021-1:2015 clause 9.1.3)

Process: Management Task #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
1			X
2			X
3			X
4			X
5	X		
6		X	
7			X
8			X
9	X		
10	X		
11	X		

Process: Device Marketing Authorization and Facility RegistrationTask #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
1			X
2	X		
3	X		

Process: Measurement, Analysis and Improvement Task #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
1			X
2		X	
3	X		
4	X		
5		X	
6		X	
7		X	
8		X	
9		X	
10	X		
11			X
12	X		
13	X		
14	X		
15	X		
16	X		

Process: Medical Device Adverse Events and Advisory Notices Reporting Task #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
1	X		
2	X		

Process: Design and Development Task #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
1	X		
2		X	
3		X	
4		X	
5		X	
6		X	
7		X	
8		X	
9		X	
10		X	
11		X	
12		X	
13	X		
14		X	
15	X		
16		X	
17		X	

Process: Production and Service Controls Task #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
1			X
2	X		
3		X	
4		X	
5			X
6		X	
7		X	
8		X	
9		X	
10		X	
11	X		

Process: Production and Service Controls Task #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
12		X	
13		X	
14		X	
15			X
16	X		
17	X		
18		X	
19			X
20			X
21		X	
22		X	
23		X	
24			X
25	X		
26			X
27		X	
28			X
29		X	

Process: Purchasing Task #	Audit Every Surveillance	Audit 1 of 2 Surveillances	Not Typically Necessary to Audit During Surveillance
1		X	
2		X	
3		X	
4		X	
5			X
6	X		
7			X
8		X	
9		X	
10		X	
11	X		
12		X	