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GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED FINAL DOCUMENT

Title: **A Guide to Understanding Presently Available Audit Duration Determination Systems**

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Acknowledgements

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1. Preface

The document herein was produced by the Global Harmonization Working Party (GHWP), a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices and has been subject to consultation throughout its development process.

2. Introduction

Presently 2 systems serve as internationally recognized practices for facilitating QMS audit planning by providing the basis for audit time duration – a critical factor in ensuring that optimum resources such as auditors can be effectively utilized to achieve the audit objectives.

3. Purpose

This guidance document serves to summarize the current best practices on audit duration determination with the aim of eventually developing an audit duration guidance for regulators for the purpose of auditing medical device distributors.

4. Scope

The scope of this guidance document encompasses quality management system auditing processes to be established and implemented by Regulatory authorities and/or the conformity assessment bodies appointed by them under prevailing legislature.

5. References

MDSAP procedure MDSAP AU P0008.007 Version e: 2018-10-16

IAF MD 5:2015 International Accreditation Forum, Inc. Issued: 09 June 2015 IAF Mandatory Document DETERMINATION OF AUDIT TIME OF QUALITY AND ENVIRONMENTAL MANAGEMENT SYSTEMS

6. Discussion

In the following sections, the reader is guided to presently available established practices for determination of audit time.

- **What systems are available for the determination of audit time?**

Presently 2 systems are widely used.

The International Accreditation Forum has published a series of documents to guide Certification Bodies in determination of audit time.

Alternatively, the regulators who presently participate in the MDSAP scheme have developed a determination scheme. This method of determination can be presently found at the following location:

- **Why do we need to understand these 2 systems?**

An understanding of these 2 systems is vital for medical device regulators at large who require Conformity Assessment bodies to perform audits on medical device manufacturers and/or distributors. Regulators who intend to perform audits on their own will also find the adaptable guidance documents invaluable.

A comprehensive understanding of these 2 approaches will enable a regulator to decide if it wants to adopt a either of these systems or adapt the approaches therein.

- **Why is it important to have a systematic approach to auditing?**

In order for an audit to be effective, audit duration must be determined based on technical rationale. An audit where the duration is arbitrarily selected will very unlikely not be sufficient or be overestimated. An audit with insufficient man days will result in audit objectives whereas one where the duration is unnecessarily high will bind resources (primarily auditors) which can otherwise be utilized at other audits.

As such, it is important that regulators are able to have a technical basis to determine the duration of an audit it is planning.

- **How do IAF Mandatory documents specify the method of determining audit time?**

Two IAF Documents collectively provide the method of determining audit duration for a medical device manufacturing plant. Of these, the document, IAF MD9: 2017 represents *the parent document* in respect of auditing medical device organizations. This document specifies audit duration within a table which links the audit duration read the effective number of personnel. While a comparable table is set forth in the document IAF MD5:2019, the document MD9 categorically states that in the case of medical device organizations, table D. 1 of its Annex DnX shall be used instead. This being the case, any person determining audit duration for a medical device organization should take care not to utilize the table QMS1 of IAF MD5:2019 and instead resort to table D. 1 NXD as given in IAF MD 9: 2017

Essentially, a person intending to determine audit duration shell refer to table D of IAF MD 9 by looking up the duration which corresponds with the hit count of the company which will be audited.

Worked Examples

Example 1:

In the following example the audit duration is determined for a medical device manufacturing company with an effective head count of 235. In order to match the audit duration with the head count, it is necessary to select the heat count range of 176- 275 because this is the range which encompasses the head count of 235. As can be seen below, the audit time that should be considered is 12.

Table D.1 as given in Annex D of IAF MD 9:2017	
Effective Number of Personnel	Audit Time Stage 1 + stage 2 (days)
126-175	**12**
176-275	**12**
276-425	**13**

The range 176-275 is selected because 235 lies within the limits of this range.

Example 2: Wrong example

Interesting, had the audit duration been erroneously determined from table MD5, duration would be inadvertently lesser.

Table QMS 1 of Annex A of IAF MD 5:2015	
Effective Number of Personnel	Audit Time Stage 1 + stage 2 (days)
126-175	**8**
176-275	**9**
276-425	**10**

WRONG APPROACH

Table QMS 1 of IAF MD 5 SHOULD NOT BE USED FOR DETERMINATION

Table D .1 of MD9 also specifies factors which may increase or reduced audit duration. In the case where the certification scope is limited to distribution or transportation, reduction maybe up to 50% in total from table D .1.

- **How does the MDSAP algorithm work?**

The MDSAP system for determination of audit duration involves assigning a score to a series of processes for each of the following MDSAP subsystems of chapters, i.e:

- Management
- Device Marketing authorization and Facility Registration
- Measurement, analysis and Improvement
- Medical Device Adverse Events and Advisory Notices Reporting
- Design and Development
- Production and Service Provision
- Purchasing

Documented requirements for audit time determination is specified in an MDSAP procedure maintained at the FDA website i.e. MDSAP AU 0008.007 and the accompanying duration calculation Excel program (otherwise known as the P0008 algorithm) MDSAP AU F0008.2.002 These documents (and other MDSAP audit procedures and forms) may be downloaded from the link [MDSAP Audit Procedures and Forms | FDA]

The MDSAP algorithm is initiated by determination of the number of audit tasks which an auditing organization performs. Basing on these quantitative inputs, the algorithm provides the total audit time.

In the case of devices regarded as *low risk*, the empty set procedure allows for reduction of audit of the audit duration by a certain percentage if the effective headcount of the company is 100 or less. In order to qualify for such reductions, requirements specified in the procedure MDSAP AUP0008.007 must be met

Example :

In the following example, a user has entered the required tasks for each of the subsystem for a company whose headcount is reported to be 95.

Note that:

- Only 16 (out of a total 17) tasks has been entered for Chapter 5 Design and Development. This is because the user has excluded Task12 Software Design and Development as the medical device to be audited is a non-active medical device and thus is not incoporated with a software.

- There are 27 tasks i.e. 2 less than the total of 29. The user has purposefully omitted Tasks i.e. Installation (Chapter 6 Task 27) and Servicing (Chapter 6 Task 28) the medical device that is manufactured does not require installation or servicing hence thee 2 requirements need not be audited.

- No reduction percentage has been applied even though the headcount is 100 or less. This is because the criteria for low risk deices have not been met. As such, a factor of 100% is entered by the user of the algorithm.

MDSAP Process	Number of Tasks per Process	Number of Applicable Tasks to be Audited	Time per Process (hh:mm)
Management	11	11	6:36
DMA&FR	3	3	1:45
MA&I	16	16	10:08
MDAE&ANR	2	2	1:16
D&D	17	16	5:36
P&SC	29	27	19:48
Purchasing	12	12	3:00
Sub-Total	90	87	48:09
Additional time, as deemed necessary by the Auditing Organization, including for Stage 1 if applicable (hh:mm)			
Adjustment (%)		**100%**	48:09
Total (hh:mm)			96:18
Duration of Audit (mandays)			**12 days and 0 hours**

Audit time calculated by the P0008 algorithm

Audit days is calculated

The user of the algorithm should take note that the above calculation does not include the stage one audit time. To this, the procedure requires an additional 25% of audit days to be added to the tabulated figure determine from the algorithm.

In respect of surveillance audits the algorithm above can be used by selecting tasks which shall be audited for that particular audit.

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