WG6 – Quality System Audit & Assessment

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Cebu : November 21st -25th , 2016

AHWP

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

WG06 Progress Update

ASIAN HARMONIZATION WORKING PARTY

Work Item		Deliverables	Timeline	Status
1	Reviewing IMDRF final document N8	Guidance document	Q2, 2017	
2	Finalizing Importer & Distributor Guidance doc.	Guidance document	Q3, 2015	Done
3	Conducting training session during annual meeting on I/D adopted guidance documents	Workshop	Q4, 2015	Done
4	Aligning WG6 documents with WG7 documents		Q1, 2016	In Progress
5	Reviewing IMDRF final document N11 &N22	Guidance document	Q1, 2016	Done
6	Reviewing IMDRF final document N3 &N4	Guidance document	Q3,2016	Done
7	Reviewing IMDRF final document N5 &N6	Guidance document	Q1, 2017	
8	Submit the IMDRF documents for comments as draft proposed documents for AHWP ME	Draft documents	Q2, 2017	
9	Final documents to be submitted for comments	Final documents	Q3, 2017	
10	Endorsement on the adopted documents during annual meeting	Final adopted document	Q4, 2017	

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Aligning the definition of WG6 documents with WG7 document

- Manufacturer
- Importer
- Distributor
- Authorized Representative

IMDRF Final Documents

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- N3:

Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition.

- N4:

Competence and Training Requirements for Auditing Organizations.

- N5:

Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations.

- N6:

Regulatory Authority Assessor Competence and Training Requirements

- N8:

Guidance for Regulatory Authority Assessors on the Method of Assessment for MD SAP Auditing Organizations

- N11:

MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

- N22:

MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes.

IMDRF MDSAP WG N3

"to allow ISO/IEC 17021:2011 to act as the generic base requirements and then utilize this IMDRF MDSAP document to add prescriptive requirements for medical device Auditing Organization and to negate or eliminate certain of these generic base requirements, which were meant for commercial entities"

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IMDRF MDSAP WG N4

Specification of

Pre-requisite
Education,
Experience, and
Competencies

to be demonstrated and maintained by personnel involved in audits and decision making functions.

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IMDRF MDSAP WG N11

" To explain the assessment process and outcomes, including the method to "grade and manage" nonconformities resulting from a recognizing Regulatory Authority(ies)'s assessment of an Auditing Organization; and, to document the decision process for recognizing an Auditing Organization or cessation of recognition. "

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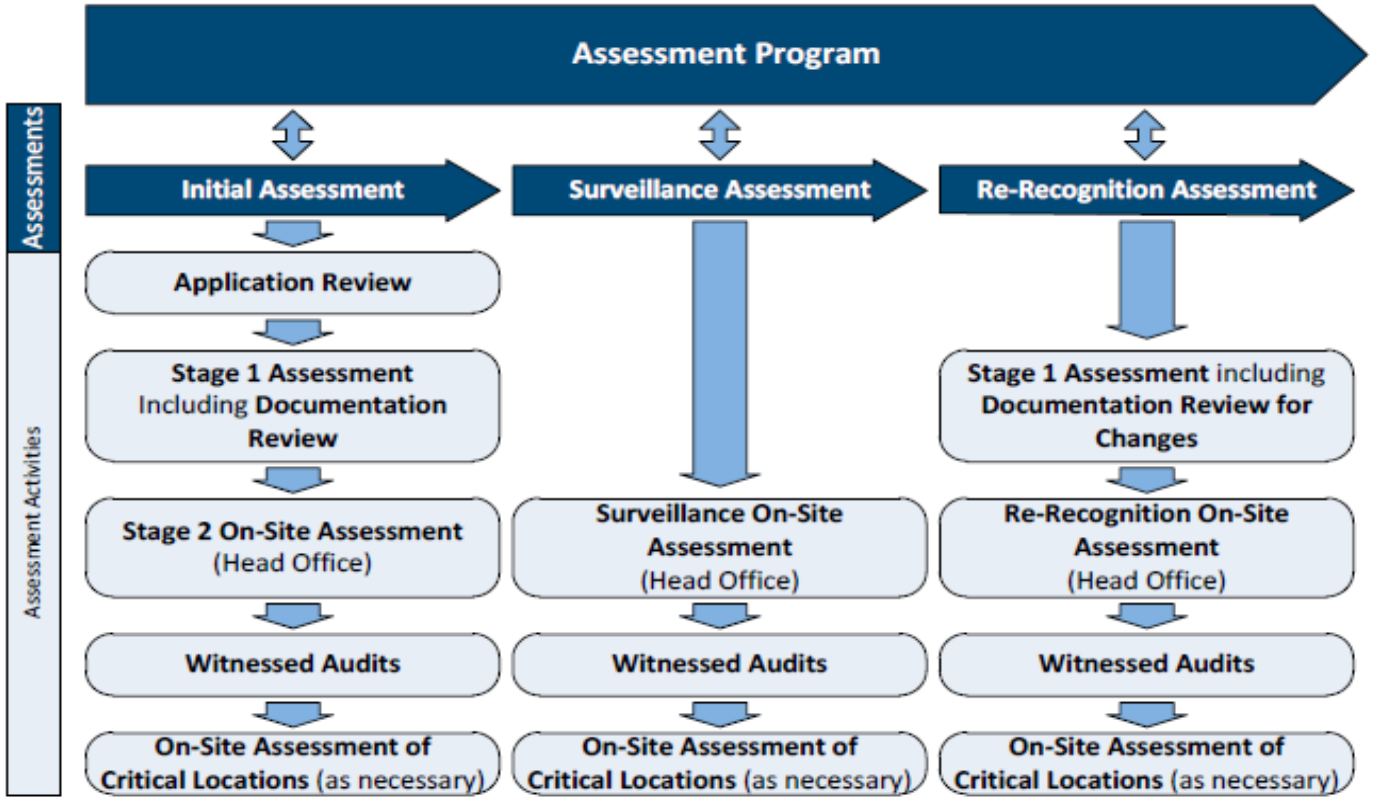
IMDRF MDSAP WG N11



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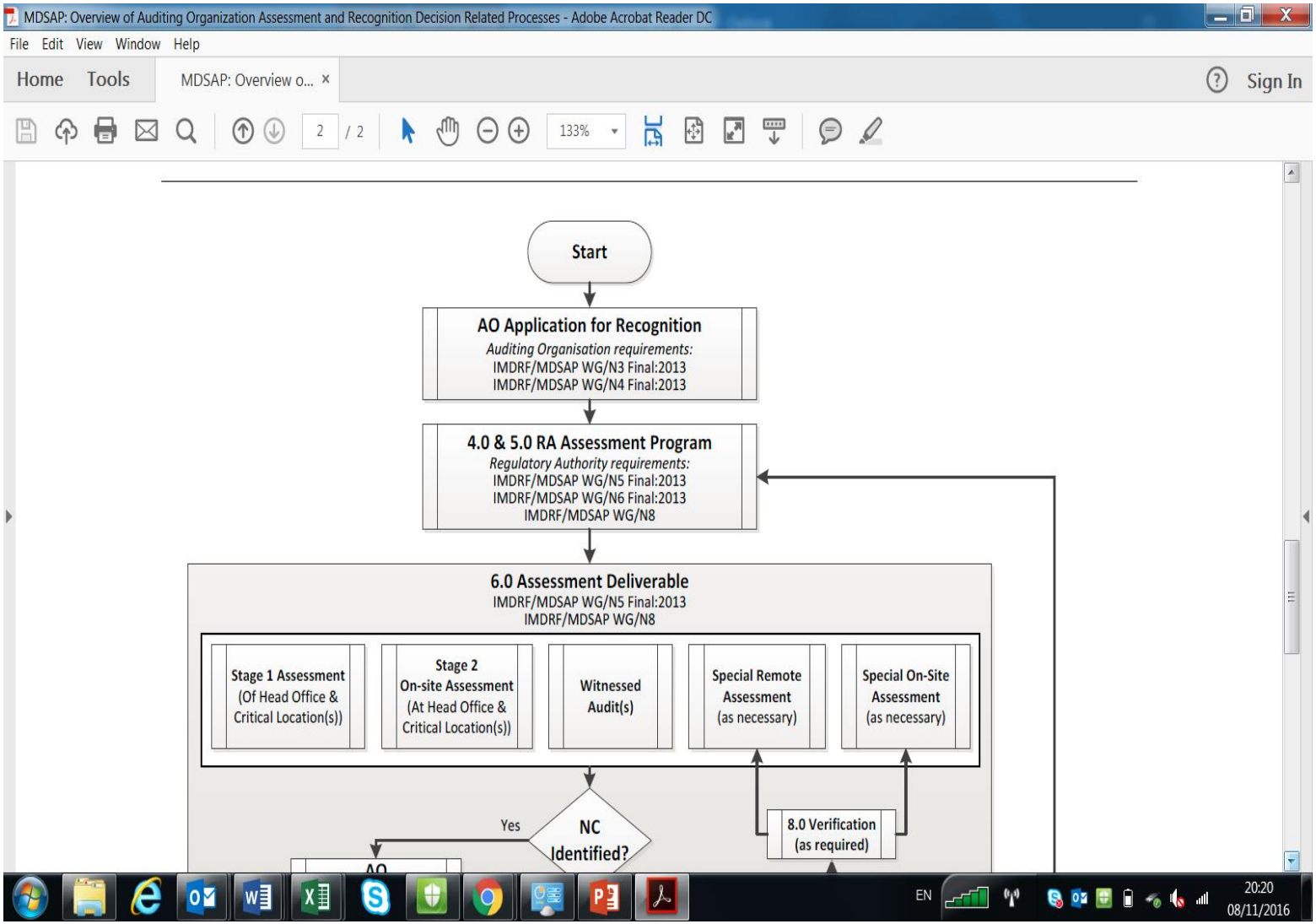
IMDRF MDSAP WG N22 Overview of Auditing Organization Assessment and Recognition Decision Related Processes

IMDRF MDSAP WG N22



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THANK YOU