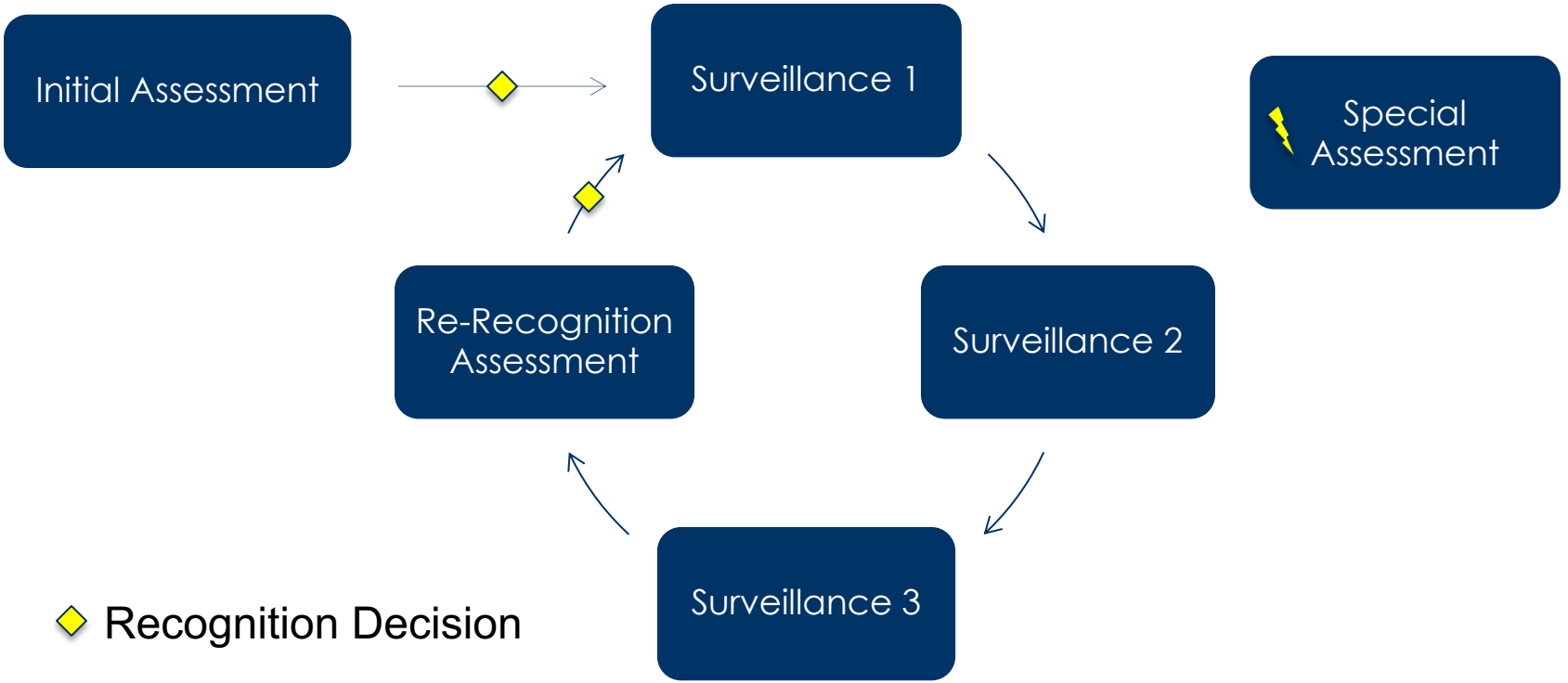
MDSAP Assessment Program

What Are We Talking About?

- Assessment Cycle
- Assessment Criteria
- Decision Points
- Assessment Activities
- Assessment Model

Assessment Cycle



Assessment Cycle

Initial

- Application review
- Stage 1 assessment (including doc. review)
- Stage 2 on-site assessment (Head Office)
- 3 witnessed audits
- On-site assessment of critical location (as applicable)

Surveillance

- Surveillance on-site assessment (Head Office)
- Witnessed audit
- On-site assessment of critical location (as applicable and necessary)

Re-Recognition

- Stage 1 assessment (including doc. review)
- Re-recognition on-site assessment (Head Office)
- Witnessed audit
- On-site assessment of critical location (as applicable and necessary)

Assessment Cycle

- The assessment cycle is tailored to each Auditing Organization (AO), through their assessment program, considering:
  - The specificities of the AO (size, geographic coverage, technical areas,…)
  - Past performance
  - Changes
    - to the AO
    - to MDSAP
  - Signals identified by Regulatory Authorities (RA)
    - About the AO (complaints, allegations …)
    - About certified manufacturers (application for marketing authorization, adverse events, whistleblowers …)

Assessment Criteria

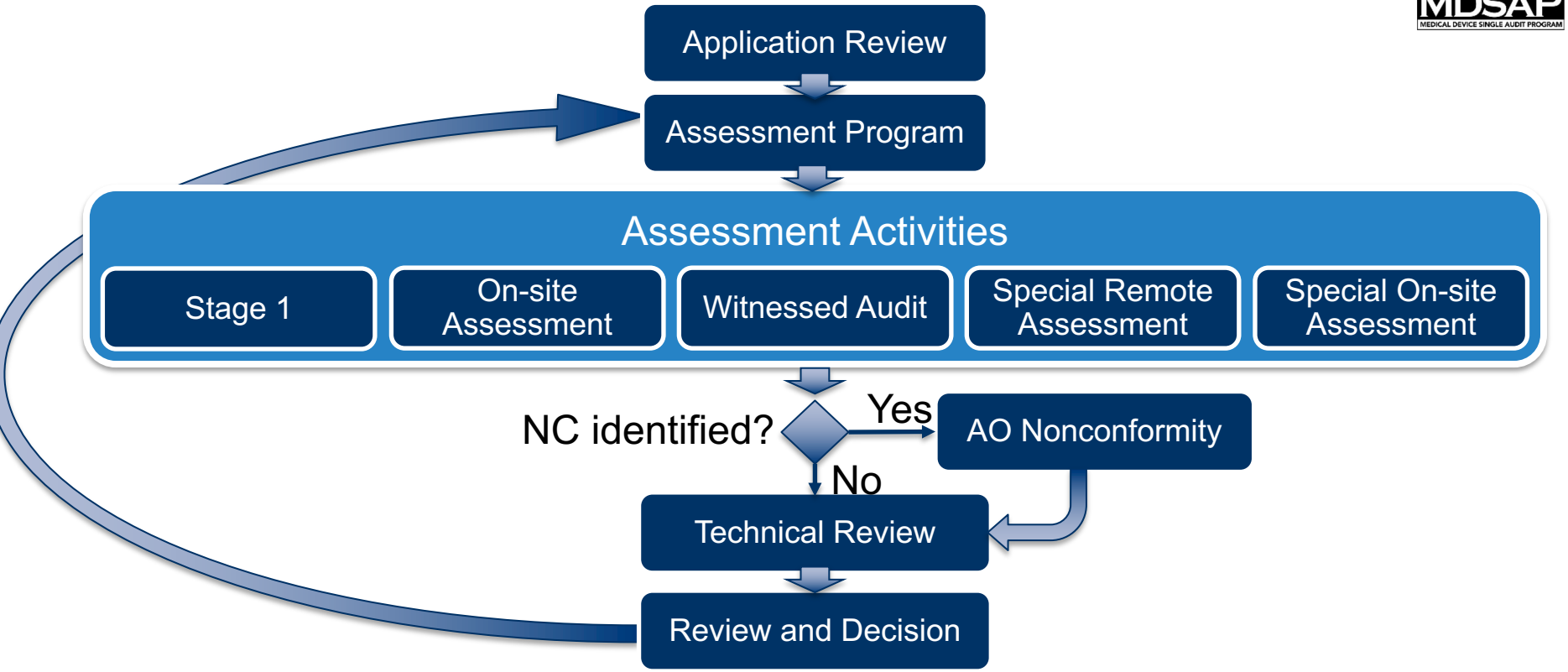
Main references

- IMDRF/MDSAP WG/N3 FINAL:2016 (Edition 2) – *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition*
- IMDRF/MDSAP WG/N4 FINAL:2013 – *Competence and Training Requirements for Auditing Organizations*
- ISO/IEC 17021-1:2015 – Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

Other references

- MDSAP AU series of documents covering:
  - P0026 – Threat to impartiality
  - WI0006 – Auditor training
  - P0029 – Notification of an organization's participation
  - P0002 – Audit model
  - P0008 – Audit time determination
  - P0019 – Content of audit reports
  - P0026 – Certification documents
  - P0027 – Post audit activities and timeline

Assessment Processes



Assessment Processes

- **General**
  - Assessments are pre-announced and information is exchanged between the assessment team and the AO to enable their effectiveness.
    - Only exception: unannounced special on-site assessment (i.e. for cause)

Assessment Processes

- **Application Review**
  - Objectives
    - Ensure that the information about the Auditing Organization and its management system is sufficient for the conduct of the assessment
    - Consider the assessment resources available
    - Consider the profile and potential of the applicant towards the program
    - Make a decision whether to accept the application

Assessment Processes

- **Stage 1**
  - Objectives
    - Evaluate the compliance of the AO's management system documentation to the assessment criteria
    - Evaluate the AO's understanding of the assessment criteria
    - Identify the AO's locations and site-specific conditions
    - Evaluate the preparedness of the AO for Stage 2, including whether they have planned or performed internal audits and management review
    - Understand the AO's structure, operations, and management system to define their Assessment Program
    - Review the need for specific resources during Stage 2

Assessment Processes

- **Stage 1**
  - Identified areas of concern that could be classified as a nonconformity during the Stage 2 On-Site Assessment are documented and communicated to the AO

Assessment Processes

- **Stage 2**
  - Objectives:
    - Confirm the compliance of the AO's management system documentation to the assessment criteria
    - Evaluate the AO's implementation and monitoring of their management system
    - Evaluate the operational controls of the AO's processes, including when implemented by external resources
    - Confirm that the AO conducted internal audits and management reviews
    - Evaluate the competence of the AO and the resources available to fulfill their obligations

Assessment Processes

- **Witnessed Audit**
  - Objective: Observe an audit team performing an audit at a medical device manufacturer to verify
    - The conformity of auditing practices
    - The ability to determine the conformity of the manufacturer to applicable requirements
    - The ability to reliably report on the audit findings, including nonconformities
    - The ability of the AO to assign an audit team with the necessary competence

Assessment Processes

- **Witnessed Audit**
  - When selecting an audit to observe, the RA consider:
    - The classification of the devices manufactured
    - The type of audit being conducted, preferably initial or re-certification audit
    - Geographical location of the audit
    - The identity of the auditors assigned
    - Manufacturing processes and technology being used
    - Known problems with the manufacturer being audited or their devices that have been identified from adverse events, post-market surveillance data, etc.
  - Assessors refrain from interfering and influencing the conduct and conclusion of the audit
  - The process includes the review of the audit report and the nonconformities issued to the manufacturer

Assessment Processes

- **Assessment at Critical Locations**
  - RA decide on whether to assess the applicant at locations other than the Head Office that perform any of critical functions:
    - Development and approval of the management system policies, processes, and procedures relevant to MDSAP
    - Review and acceptance of applications from manufacturers and the issuance of contracts, including the determination of the scope and duration of the audit
    - Assignment of audit teams
    - Final review of audit reports
    - Competence management activities that apply to auditors, technical experts, and final reviewers
    - Management, monitoring, and oversight of the AO's MDSAP certification scheme

Assessment Processes

- **Assessment at Critical Locations**
  - Objectives
    - Review the relationship and arrangements between the Head Office and the Critical Location
    - Evaluate the management system applicable at the Critical Location
    - Evaluate the conformity of the activities undertaken by the Critical Location on the AO's behalf to the assessment criteria and the AO's requirements
    - Evaluate the controls in place at the Critical Location that enable the AO to monitor the activities at that location

Assessment Processes

- **Surveillance On-Site Assessment**
  - Objectives
    - Annually review the continued implementation, conformity and effectiveness of the AO's management system though
      - Review of internal audits and management review
      - Review of competence management activities
      - Review of actions taken on nonconformities identified during the previous audit;
      - Treatment of complaints and appeals
      - Evaluate records relative to the audit and certification of manufacturers
      - Evaluate continuing operational control
      - Review any changes
    - Review a sample of audit reports submitted to the RA by the AO

Assessment Processes

- **Re-Recognition On-Site Assessment**
  - Objectives
    - Evaluate the effectiveness of the AO's management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of recognition
    - Confirm the continued conformity of the AO's management system to the audit criteria
    - Confirm the AO's commitment to maintain the effectiveness of the management system

Assessment Processes

- **Special Assessments**
  - In addition to other assessment activities defined in the typical assessment cycle
  - May be triggered by
    - The AO requesting a change of the scope of recognition or following a notice of change potentially affecting the result of prior assessments
    - The recognizing RA based on signals indicating concerns with regards to the AO's activities
    - The results of previous regulatory assessment activities
  - Objectives focused on the trigger and its potential impact on the AO to meet applicable requirements

On-site Assessment Method

On-site Assessment Method

Process: Management
Legal entity, legal responsibility liability, financing & eligibility
Quality Management System documents
Quality policy, quality objectives and quality planning
Organizational structure, responsibility, authority
Adequacy of auditing resources
Management of impartiality
Management review

On-site Assessment Method

Process: Use of external resources
Extent of use and controls of external resources
Contractual arrangements with external resources
Internal competence to review the outcome of outsourced activities

On-site Assessment Method

Process: Measurement, Analysis & Improvement	
Procedures relative to measurement, analysis and improvement	Management of nonconforming audit reports or certification documents after their sharing and publication
Sources of quality data	Internal audits
Investigation, corrections, corrective actions and preventive actions to address nonconformities and potential nonconformities	Complaint handling and management
Reporting of corrective actions impacting the recognition	Communication with external resources having contributed to a nonconformity or complaint
Decision on conformity to regulatory requirements supported by nonconforming audit or audit reports	Outputs of these activities as inputs into the management review

On-site Assessment Method

Process: Competence Management
Identification of necessary competence to operate as an AO
Procedure and criteria for competence evaluation of all personnel involved in audit and certification related activities
Identified personnel with demonstrated competence
Training to the audit process and certification requirements and access to corresponding current documents
Monitoring of personnel's competence and performance
Personnel's individual file
Effectiveness of the competence evaluation methods and the competence management process

On-site Assessment Method

Process: Audit & Decision	
Procedures for the control of the Audit & Decision Process	Final review of the audit file and decision making on the manufacturer's conformity to applicable requirements
Audit program establishment and update; audit time determination; planning of audits	Implementation and follow-up of the decision, including unannounced audits
Selection and assignment of competent audit team, and communication prior to the audit	Appeals
Audit performance and audit report	Audit and decision records
Review of correction and corrective action initiated in response to audit findings	Effectiveness of the Audit and Decision process

On-site Assessment Method

Process: Information Management
Control of documents and records
Public information on the AO's MDSAP Certification Scheme
Provision to the audited medical device manufacturers of detailed information on the audit and decision related processes
Contractual agreements with the audited medical device manufacturer
Sharing of information with Regulatory Authorities on auditing activities, decisions on regulatory compliance and certification status
Provision to the public of information on certification status or certifications granted, suspended or withdrawn
Control of confidential information

Assessments during COVID

- Assessments performed remotely
  - Head Office
  - Critical Location
  - Witnessed Audits

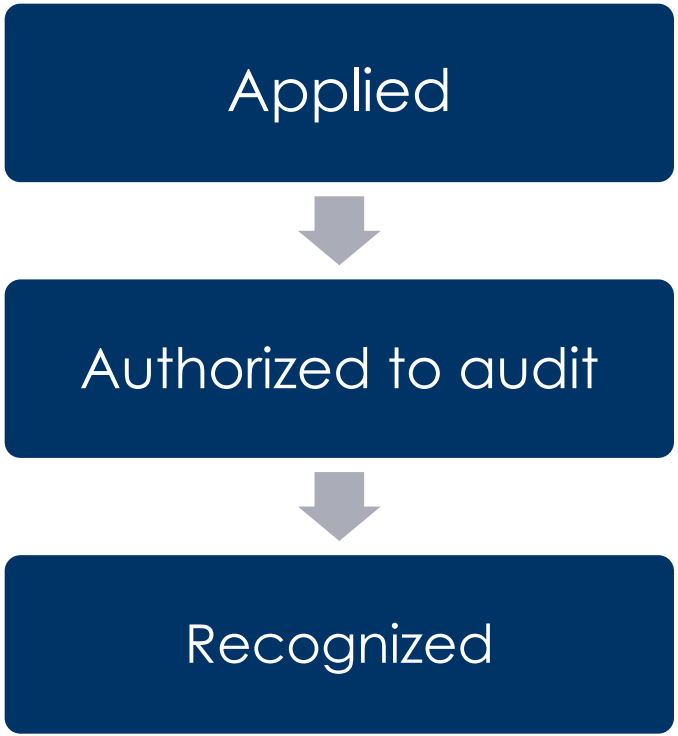
AO Nonconformity Process

- Assessors issue nonconformity (NG) report, specifying
  - Statement of NC
  - Applicable requirement that was not met by the AO
  - Grade of the NC, on a scale from 1 to 4 (low to high criticality)
- AO investigate the NC and propose a remediation plan
- Assessors review the remediation plan
- Closure of the NC depending on their grade
- Follow-up for review of implementation and verification of effectiveness

Recognition Decision

- May be any of the following:
  - Initial recognition with scope
  - Maintenance of recognition
  - Extension or restriction of scope
  - Re-recognition with scope maintained, restricted or extended
  - Cessation of recognition
  - No recognition (refusal)

Recognition Status



List of AO and their Recognition Status

- BSI Group America (R)
- DNV Product Assurance (/)
- DEKRA Certification (R)
- DQS Medizinprodukte (R)
- GMED (R)
- IMQ (/)
- Intertek Testing Services NA (R)
- MedCert (A)
- LRQA (A)
- NCC (A)
- NSAI (R)
- QMI-SAI Calada (A)
- SGS UK (R)
- TUV Rheinland NA (R)
- TUV SUD (R)
- TUV USA (R)
- UL LLC (R)

R: Recognized A: Authorized to audit /: Applied

Additional Information

- IMDRF website http://www.imdrf.org/documents/documents.asp
  - Assessment criteria: IMDRF documents N3, N4
  - Assessment program: IMDRF documents N5, N6, N11, and N8

- MDSAP Consortium webpages: https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-documents
  - MDSAP assessment processes and procedures

- International or National Standards Organizations
  - ISO/IEC 17021:2015


MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM