

 Responsible Office/Division	Document No.: MDSAP AS P0017.001	Page: 1 of 14
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Title: Technical Review and Recognition Decision Procedure		Project Manager: Robert G. Ruff, USFDA

Table of Contents

1. Purpose/Policy
 2. Scope
 3. Definitions/Acronyms
 4. Authorities/Responsibilities
 5. Procedures
 6. Forms
 7. Reference Documents
 8. Document History
- Approval Sign-Off Sheet

1. Purpose

The purpose of this procedure is to describe the tasks and responsibilities relative to the review of information gathered during the assessment activities and the follow-up of the nonconformities to support the decision making process relative to the recognition of Auditing Organization (AO) under the Medical Device Single Audit Program (MDSAP). The procedure also includes policies relative on making the recognition decisions.

2. Scope

This procedure applies after each complete annual assessment of the AO (Initial, Surveillance, Re-recognition) or when the escalation of nonconformities is deemed necessary per AO nonconformity procedure.

3. Definitions/Acronyms

Recognition Decision

Decision on the conformity of the Auditing Organization to the applicable requirements for recognition under the Medical Device Single Audit Program (MDSAP), including, where appropriate, the decision to recognize, to withhold, refuse, suspend, reinstate, restrict, extend, or revoke the recognition, including if necessary preconditions to the implementation of the decision, conditions to meet after implementation of the decision, and updates to the Assessment Program of the considered Auditing Organization

AO: Auditing Organization

APM: Assessment Program Manager

RAC: Regulatory Authority Council

Technical Review and Recognition Decision Making Procedure	Document No.: MDSAP AS P0017.001	Page 2 of 14
---	-------------------------------------	--------------

TRRC: Technical Review and Recognition Committee

4. Authorities/Responsibilities

Assessment Program Manager (APM)

- Prepares the assessment file for review by the Technical Review and Recognition Committee (TRRC)
- Verify that the assessment file is clear and meets the applicable requirements (Quality Controls)
- Liaises with the AO or the Assessment Team Leader (ATL) to clarify ambiguities of the assessment file
- Presents the file during the TRRC meeting and make recommendations, taking into account the ATL's recommendation, but may not be one of the RA representatives of the Committee
- Prepares the recognition decision notification letter and have it signed by the RAC Chairperson
- Ensures the implementation and follow-up of the recognition decision, including the update of the Assessment Program as applicable

Assessment Team Leader (ATL)

- Clarifies the assessment file if requested by the APM

Technical Review and Recognition Committee (TRRC)

- Reviews the assessment file and crafts the recognition decision (decision to recognize, withhold, restrict, suspend or revoke recognition, including associated preconditions or modalities of implementation)

TRRC Chairperson

- Leads the assessment file review and the decision-making process through consensus building or, as necessary, by vote
- Ensures the consistency of the decision with precedence
- Liaises with the RAC, as necessary, to explain the proposed recognition decision

Regulatory Authority Council

- Makes the final recognition decision
- (RAC Chairperson) signs the recognition decision notification letter

5. Procedures

The flowchart MDSAP AS F0017.1 illustrates the process detailed in this procedure. The appendix 1 of this procedure explains the principles supporting the requirements of this procedure and the Regulatory Authorities' recognition decision

Preparation of the Assessment file for review by the Technical Review and Recognition Committee

Upon receipt of an assessment file from the assessment team, including

Technical Review and Recognition Decision Making Procedure	Document No.: MDSAP AS P0017.001	Page 3 of 14
---	-------------------------------------	--------------

assessment reports, nonconformity reports and the assessment team recommendations, the APM performs the quality control checks to verify the completeness of the assessment file. The APM updates the form MDSAP AS F0005.2 Assessment Program Management File.

APM prepares the assessment file for review by the TRRC. The APM includes his/her recommendation and corresponding rationale using the document. Should the APM need clarification to understand the content of the assessment and the nonconformity reports, in order to support the recommendation and to present the file to the TRRC, he/she may request confirmatory information from the assessment team or the AO, as relevant.

The file presented to the TRRC includes the reports of all assessment activities included in the annual assessment (i.e. Stage 1 Assessment, On-Site Assessment at the head office and critical locations, Witnessed Audits).

The exceptions to this rule are:

- Special assessments performed in addition to the annual assessment
- Assessment activities identifying a situation representing an immediate public health threat and requiring a decision before the completion of the remaining assessment activities planned
- Escalated nonconformities

Planning for the Technical Review and Recognition Committee meeting

The TRRC meeting is planned by the MDSAP SME Lead Project Manager or his/her delegate in order to assure the availability of all members. The TRRC includes at a minimum:

- One TRRC Chairperson to; lead the meeting, ensure that discussions are moving forward towards consensus, and, when consensus cannot be reached, to decide on an alternative decision-making method (see details in section ***Endorsement and Issuance of the Decision*** below). The chairperson should be knowledgeable of recognition decision precedents.
- The MDSAP Assessment Program Manager (APM) to; present the file and address questions from the TRRC.
- One Representative of each Regulatory Authority, among the subject matter experts for the MDSAP. The committee must be independent from the assessment file being reviewed; therefore committee members cannot have participated in any assessment activities being reviewed by the committee. In exceptional circumstances (e.g. due to scarce resources), a minimum of two (2) of the representatives must not have been involved. In such situations, representatives who were involved in the activities will abstain from discussing the activities in which they participated, and the documented rationale for the

TRRC decision shall declare the representatives' involvement.

Prior to the TRRC meeting, the members of the TRRC must have access to the assessment reports and should examine all related information available including the outcome of the APM's technical review and recommendation.

Scoring System for the Degree of Confidence in the Auditing Organization

The scoring of the degree of confidence follows three (3) steps:

1. Initial grade based on the review of the reports by individual TRRC members

When an assessment file includes several assessment reports, the relative significance of the findings from on-site assessments compared to witnessed audits is in the order of 1:2. This means that

Each RA Representative assigns a confidence grade on a scale from 0 to 5 taking into account the table below:

Grade	Meaning of the Initial Grade for the Degree of Confidence in the AO
5	There is solid evidence of compliance with the recognition criteria allowing for insignificant nonconformities (in grade and number). The principles supporting the MDSAP audit activities for regulatory purposes are well understood and respected.
4	Nonconformities have been identified however they were not significant (i.e. grade between 1 and 3, number not representing an overall threat to the reliability of the audit reports and certificates, no obvious linkage between the identified nonconformities and more significant concerns) and the proposed action plan is appropriate. The principles supporting the MDSAP audit activities for regulatory purpose are well understood and generally appropriately addressed.
3	There are significant nonconformities identified <u>either</u> individually (i.e. grade 4 to 6) <u>or</u> collectively (i.e. considering their number and linkage). Nevertheless the major key principles of impartiality and competence are not significantly affected by these nonconformities and the action plan is appropriate.
2	There are very significant nonconformities identified <u>both</u> individually (i.e. grade 5 to 6) <u>and</u> collectively (i.e. considering their number and linkage), affecting major key principles of impartiality and/or competence, there is limited objective evidence of unreliable reports or misleading certificates and the action plans proposed by the AO are appropriate.

1	There is objective evidence of multiple unreliable audit reports or misleading certificates, or organized malpractices in direct conflict with the principles of impartiality, competence, responsibility, openness, confidentiality or responsiveness to complaints
0	There is evidence of conscious fraudulent practices, such as falsifying auditing activities or documents necessary to the confidence in the reliability of the audit reports

2. Application of correction factors for the determination of a corrected grade

Each RA Representative may apply a correction factor to the initial grade, as follows:

Plus 0.5 bonus point - is applied when there is evidence of a commitment to systematically improve the robustness of the AO's management system beyond the strict treatment of the identified nonconformities.

Minus 0.5 penalty point - is applied when there is a repeated pattern of inappropriate or ineffective action plans being proposed by the AO or when the AO repeatedly does not meet the timeline to implement effective action plans.

3. Consolidation into a single TRRC Confidence Score

The TRRC chairperson collates the corrected grades determined by the participating RA Representatives. The confidence score is the average of all individual corrected grades.

If there are individual grades that deviate from the confidence score by more than 1 point, the TRRC chairperson is to initiate a discussion in order to understand and possibly resolve the divergence of grades. As a result of this discussion, the TRRC chairperson should invite the participating RA Representatives to reconsider their individual corrected grade and subsequently recalculate the final confidence score.

Range of Recognition Decisions

The range of possible recognition decisions is dependent on the type of assessment as described below.

The confidence score determined by the TRRC assists with determining a recognition decision as described in the following guidelines. The TRRC may deviate from the guidelines however a rationale for any such deviation must be documented.

1. Recognition Decision Following an Initial Assessment

For an initial assessment, there are essentially three (3) potential recognition decisions:

- **Recognition:** the applicant is recognized as an Auditing Organization for a four (4) year period for the scope of recognition requested by the AO in its applications and may undertake audit activities within the framework of the MDSAP.
- **Preconditioned Recognition:** the applicant is not yet granted recognition as an Auditing Organization. The conditions that must be satisfied before granting recognition are specified, (including the timeline for demonstrating that these conditions are satisfied) as part of the recognition decision. The AO may not start auditing under MDSAP until:
 - It has provided objective evidence to show that the specified conditions have been satisfied within the specified timeline; and
 - The Assessment Program Manager (APM) has confirmed that the conditions have been satisfied; and
 - The AO is formally notified that the recognition decision is active

The APM has the discretion to extend the timeline to allow the AO to satisfy the specified conditions if deemed justified taking into account the information provided by the AO prior to the initial deadline, including a request for extension of the timeline with the rationale supporting the request and a detailed plan for completing the actions necessary to satisfy the conditions.

If the AO is unable to satisfy the conditions within the specified timeline, the decision is converted to a “Refusal” decision unless a new superseding decision is made taking into account additional information made available after the initial decision.

- **Refusal:** the applicant is not to be recognized as an Auditing Organization and may not audit under the MDSAP. A new application from the same AO is required if the applicant is to be reconsidered. Such applications will not be accepted within 12 months of a previous recognition decision.

The table below specifies the recommended type of recognition decision, based on the TRRC confidence score (CCS):

Committee Confidence Score(CCS)	Decision making guidelines
3.5≤CCS≤5	Recognition
3.0≤CCS<3.5	Preconditioned recognition
0≤CCS<3.0	Refusal

Technical Review and Recognition Decision Making Procedure	Document No.: MDSAP AS P0017.001	Page 7 of 14
---	-------------------------------------	--------------

The recognition decision may include additional **comments** or **requests**.

A Comment is information for the AO to consider but does not require any follow-up by the Regulatory Authorities before the next assessment. Comments should be taken into account by RA Assessors as input to the next assessment.

A Request is information derived from an assessment activity and is subject to follow-up by the Regulatory Authorities prior to the next annual assessment. The timeline for the AO to provide the necessary information for review/assessment must be included in the decision. Requests typically relate to the evidence of implementation and/or the effectiveness of corrective actions for significant nonconformities.

The APM has the discretion to extend the timeline to allow the AO to satisfy the specified request, if deemed justified, taking into account the information provided by the AO prior to the initial deadline, including a solicitation for extension of the timeline with the rationale supporting the solicitation for extension and a detailed plan for completing the actions necessary to satisfy the request. An extension may not exceed the date of the next routine assessment.

Restricted Scope, an alternative to preconditioned recognition: if the TRRC has concerns in relation to the AO's level of compliance with MDSAP requirements for only some specific elements of the scope of recognition applied for, the TRRC may decide to grant a restricted scope of recognition.

2. Recognition Decision Following a Surveillance Assessment or Re-Recognition Assessment

For a surveillance assessment or a re-recognition assessment, there are essentially four (4) potential decisions:

- **Continuation of Prior Recognition or Re-Recognition:** the recognition remains valid for the current scope of recognition or is extended for four (4) years. The AO may continue undertaking audit activities within the framework of the MDSAP.
- **Conditional Recognition:** the recognition remains valid but the recognition decision is associated with conditions that must be satisfied in a specified timeline. At the end of the specified timeline, the AO may continue auditing activities under MDSAP only if:
 - It has provided objective evidence within the specified timeline to show that the specified conditions have been satisfied; and either
 - The review of the provided information is still pending, or
 - The Assessment Program Manager (APM) has confirmed that the conditions have been satisfied; and the AO is formally notified that the recognition decision is active

The APM has the discretion to extend the timeline to allow the AO to satisfy the

Technical Review and Recognition Decision Making Procedure	Document No.: MDSAP AS P0017.001	Page 8 of 14
---	-------------------------------------	--------------

specified conditions, if deemed justified, taking into account the information provided by the AO prior to the initial deadline, including a solicitation for extension of the timeline with the rationale supporting the solicitation and a detailed plan for completing the actions necessary to satisfy the conditions. An extension may not exceed the date of the next routine assessment.

If the AO is unable to satisfy the conditions within the specified timeline, the TRRC will convert the decision into a “Temporary Suspension” decision unless the TRRC makes a new superseding decision to take into account additional information made available after the initial decision.

- **Temporary Suspension:** This situation applies when a previously recognized AO no longer satisfies the requirements for recognition for its current scope of recognition. The conditions for re-instating the recognition must be included in the decision, including a date by which the AO must demonstrate that the specified conditions have been satisfied, as well as the impact of the suspension on audited and certified manufacturers in each jurisdiction. The recommended suspension time is 90 days but the TRRC may decide a different duration. A new recognition decision is necessary to re-instate the recognition or to extend the period of suspension.

If the AO is unable to satisfy the specified conditions by the specified date, the recognition decision is converted to a “Revocation” decision unless a new superseding decision is made taking into account additional information made available after the initial decision.

While the recognition is suspended, the AO may not:

- Perform an initial audit for any manufacturer within the framework of the MDSAP
- Accept applications from manufacturers to transfer MDSAP audit services;
- Extend the scope of MDSAP audit activities
- Issue a certificate renewing an expiring certificate (The AO may perform the renewal audit but must wait until the suspension is lifted to issue the certificate).

MDSAP Regulatory Authorities shall publish the decision to temporarily suspend the recognition of an AO. The Regulatory Authorities should further scrutinize audit reports from the temporarily suspended Auditing Organization, before accepting the reports as a basis for marketing authorization.

- **Revocation:** This situation applies when a previously recognized AO no longer satisfies the requirements for recognition for its current scope of recognition and which represents an unacceptable risk to public health, or the AO has not met the conditions for reinstating a suspended recognition. The recognition of the AO is discontinued. The AO may not undertake audit activities within the framework of the MDSAP or issue new or revised ISO 13485 certificates. A new application from the same AO is required if the applicant is to be reconsidered. MDSAP will not accept such applications within the 12 month period following a previous recognition decision.

MDSAP Regulatory Authorities shall publish the decision to revoke recognition of an AO. All audit reports and ISO 13485 certificates issued after the previous AO assessment may warrant further scrutiny. The Regulatory Authorities should consider the impact of the circumstances resulting in revoking recognition when making new marketing authorization decisions based on audit reports or ISO 13485 certificates issued by the AO. Manufacturers previously audited by the AO within the framework of the MDSAP must be notified of the need to make necessary arrangements to provide a valid audit report and, where required, a new ISO 13485 certificate, within 18 months of any audit conducted by the AO prior to the previous successful MDSAP assessment of the AO. The AO is to determine the relevant reference date and provide to the manufacturer in the notice.

The table below specifies the recommended type of recognition decision, based on the TRRC confidence score:

Committee Confidence Score (CCS)	Decision making guidelines
$3.5 \leq \text{CCS} \leq 5$	Continued Recognition or Re-Recognition
$3.0 \leq \text{CCS} < 3.5$	Conditional Recognition or Conditional Re-Recognition
$2.5 \leq \text{CCS} < 3.0$	Temporary suspension of Recognition
$0 \leq \text{CCS} < 2.5$	Revoke Recognition

The final decision may in addition include **comments** or **requests** as defined above.

Restricted scope, an alternative to temporary suspension or revocation; - if the TRRC has concerns in relation to the AO's level of compliance with MDSAP requirements only for some specific elements of the scope of recognition applied for, the TRRC may decide to grant recognition for a restricted scope of recognition.

3. Recognition Decision Following an Extension of Scope of Recognition

For an assessment intended to extend the scope of recognition, there are essentially three (3) potential decisions:

- **Extension of Scope of Recognition:** the decision is to amend the scope of recognition. The expiry date of the initial or re-recognition decision is not changed. The AO may audit under the MDSAP for the extended scope of recognition. An AO may continue to audit under the MDSAP for the products, activities or locations falling within the requested extension of scope.
- **Preconditioned Extension of the Scope of Recognition:** the recognition decision remains valid for the current scope. The specified conditions that must be satisfied before granting recognition for the expanded scope, including the timeline for demonstrating that these conditions are satisfied, are part of the

recognition decision. The AO may not start auditing for the extended scope under MDSAP until:

- It has provided objective evidence to show that the specified conditions have been satisfied, within the specified timeline; and
- The APM has confirmed that the conditions have been satisfied; and
- The AO is formally notified that the recognition decision is active for the extended scope of recognition.

The APM has the discretion to extend the timeline to allow the AO to satisfy the specified conditions, if deemed justified, taking into account the information provided by the AO prior to the initial deadline, including a request for extension of the timeline with the rationale supporting the request and a detailed plan for completing the actions necessary to satisfy the conditions.

If the AO is unable to satisfy the conditions within the specified timeline, the TRRC is to convert the decision to a “Refusal” decision unless the TRRC, taking into account additional information made available after the initial decision, makes a new superseding decision.

- **Refusal to Extend the Scope of Recognition:** the recognition decision remains valid for its current scope. The AO may continue to audit under the MDSAP, not including products, activities or locations falling within the requested extension of scope. A new application from the same AO is required if the applicant is to be reconsidered. Such applications will not be accepted within 12 months of a previous recognition decision.

The table below specifies the recommended type of recognition decision, based on the TRRC confidence score:

Committee Confidence Score (CCS)	Decision making guidelines
$3.5 \leq \text{CCS} < 5$	Extension of the scope of Recognition
$3.0 \leq \text{CCS} < 3.5$	Preconditioned extension of the scope of recognition
$0 \leq \text{CCS} < 3.0$	Refusal to extend the scope of recognition

The final decision may in addition include **comments** or **requests** as defined above.

Endorsement and Issuance of the Recognition Decision

Once the TRRC has drafted the recognition decision, including a rationale, the TRRC chairperson presents the text and confirms that all TRRC members concur with and support the recognition decision as stated. If the TRRC has not reached consensus, the decision cannot be finalized. Any remaining concerns of TRRC

Technical Review and Recognition Decision Making Procedure	Document No.: MDSAP AS P0017.001	Page 11 of 14
---	-------------------------------------	---------------

members must be discussed and the draft decision updated as necessary until consensus is reached.

Where the divergence of opinion between the TRRC members is such that a consensus decision cannot be reached, the TRRC chairperson may either:

- Adjourn the deliberation and request the APM to re-perform the technical analysis, and specifically address the concerns of the TRRC members, or
- Decide to implement a vote on the decision that is most likely to obtain at least a 75% qualified majority among the participating RA Representatives.

If the TRRC chairperson adjourns the deliberations, a new TRRC meeting is scheduled preferably with the same TRRC members.

If a vote is required, the draft recognition decision proposal must record the divergence of opinion, the substance of the disagreement and the result of the vote.

The TRRC chairperson provides the drafted recognition decision and the supporting documents to all eight (8) MDSAP RAC members for review of the decision. RAC members may request additional information or clarifications to the TRRC chairperson.

The Regulatory Authority Council chairperson may endorse the recognition decision following the review and consensus of the RAC whenever possible.

The Assessment Program Manager (APM) communicates the agreed recognition decision to the AO. If the recognition decision is any of the following, the notification is to include a documented rationale:

- Preconditioned recognition or preconditioned extension of the scope of recognition
- Refusal to recognize or refusal to extend the scope of recognition
- Conditional recognition or conditional re-recognition
- Temporary suspension of recognition
- Revocation of recognition

The APM also ensures the publication and the dissemination of the recognition decision, as appropriate.

The RAC Chairperson signs the official notification of the Regulatory Authorities' recognition decision.

In case of refusal or recognition or revocation of recognition, the procedure MDSAP AS P0022 on Implementing Suspension or Revocation of Recognition applies.

If the decision includes changes to the assessment Program, the procedure MDSAP AS P0005 on Assessment Program applies.

Technical Review and Recognition Decision Making Procedure	Document No.: MDSAP AS P0017.001	Page 12 of 14
---	-------------------------------------	---------------

6. Forms

MDSAP AS F0017.1 – Technical Review and Recognition Decision Flowchart

MDSAP AS F0005.2 – Assessment Program Management File

MDSAP AS F0017.2 – Technical Review and Recognition Decision Making
Form

MDSAP AS F0017.3 – Committee Confidence Score Calculation Worksheet

MDSAP AS F0017.4 – Letter of Recognition Template

MDSAP AS F0017.6 – Assessment Team Recommendation Form

7. Reference Documents

MDSAP AS P0005 – Assessment Program Procedure

MDSAP AS P0016 – On-Site Assessment Procedure (Stage 2, Surveillance, Re-
recognition, Critical Locations)

MDSAP AS P0014 – Special Remote Assessment Procedure

MDSAP AS P0020 – Special On-Site Assessment Procedure

MDSAP AS P0015 – AO Nonconformities Procedure

MDSAP AS P0022 – Implementing Suspension or Revocation of Recognition

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-12-12	Initial Release	Robert G. Ruff/Marc- Henri Winter

Version
Approval

Approved: Chair, MDSAP RAC - Signature on file

Date: 2013/12/16

Technical Review and Recognition Decision Making Procedure	Document No.: MDSAP AS P0017.001	Page 13 of 14
---	-------------------------------------	---------------

Appendix 1

Principles supporting the decision making process under MDSAP

MDSAP will base fair recognition decision-making on the following principles:

- **Authority:** A committee of subject matter experts, the Technical Review and Recognition Committee (TRRC), including a committee Chairperson, appointed by the MDSAP Regulatory Authority Council (RAC) will draft recognition decisions **according to the policies and procedures developed to fulfil the Statement of Cooperation between the Regulatory Authorities participating in the Medical Device Single Audit Program. When consensus is reached, draft recognition decisions are to be proposed to the Regulatory Authority Council and if approved, endorsed by the RAC Chairperson.**
- **Consensus:** The TRRC members represent all regulatory authorities participating in the MDSAP. The TRRC members are to express their perspective to ensure final decisions take into account the view of all participating Regulatory Authorities. Consensus is reached when all TRRC members concur with, and support, the recognition decision.
- **Impartiality:** **The appointment of TRRC members is to ensure that they do not personally benefit from the outcome of a recognition decision. Recognition decisions made by the TRRC are by consensus to prevent an interested party from influencing the decision making process.**
- **Context:** The purpose of the regulatory Authorities' recognition decisions is to protect and promote public health whilst assuring timely and continued access to safe, effective, and high-quality medical devices.
- **Transparency:** The TRRC documents the recognition decisions as well as their rationale. The Regulatory Authorities provide the rationale to the AO with the recognition decision, if the recognition decision may adversely affect the Auditing Organization (AO).
- **Balance:** The Regulatory Authorities' recognition decisions take into account all relevant information, including assessment reports, any action plans developed by the AO, and any evidence available demonstrating implementation of corrections and/or corrective actions for identified nonconformities.

Technical Review and Recognition Decision Making Procedure	Document No.: MDSAP AS P0017.001	Page 14 of 14
---	-------------------------------------	---------------

- **Consistency:** The Regulatory Authorities' recognition decisions may rely on precedence to ensure similar decisions are made for similar situations.
- **Predictability:** Publicly available MDSAP Guidelines are to be used to support Regulatory Authorities' recognition decisions to allow stakeholders the opportunity to foresee the most probable outcome of the decision making process.
- **Proportionality:** The range of Regulatory Authorities' recognition decisions should include several options to address different levels of concern. The greater the concern, the more severe, or restrictive, the decision should be.
- **Process and Fact Basis:** **As a prerequisite to making the Regulatory Authorities' recognition decisions, the Assessment Program Manager and the Technical Review and Recognition Committee (TRRC) ensure that all prior activities are complete in accordance with the MDSAP Quality Management System and all corresponding records are on file. Assessment reports are to be supported by objective evidence.**
- **Appeal:** Auditing Organizations may appeal recognition decisions. The appeal decision may amend the prior recognition decision. Until the appeal decision is made, the prior recognition decision is to be implemented.