

 MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM Responsible Office/Division	Document No.: MDSAP AS P0017.003	Page: 1 of 16
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Title: Technical Review and Recognition Decision Procedure	Project Manager: Patricia Serpa, ANVISA	

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1. Purpose

The purpose of this procedure is to:

- describe the tasks and responsibilities relative to the review and verification of information gathered during assessment activities, and for the follow-up of nonconformities, that are used to support the decision making process relative to the recognition of Auditing Organization (AO) under the Medical Device Single Audit Program (MDSAP).
- describe the policies and procedures that relate to the making of recognition decisions.

2. Scope

This procedure applies to a **technical review process** that is to occur after each complete assessment of the AO (Initial, Surveillance, Re-recognition, Witnessed), when the escalation of nonconformities is deemed necessary in accordance with the AO nonconformity procedure, and prior to the imposition, removal or variation of a condition on a recognition decision.

This procedure also applies to a **review and decision process** that is to occur after initial recognition or re-recognition assessments, for an extension of scope, for a restriction of scope due to a safety issue, or, in cases of fraud due to misrepresentation or the falsification of evidence, due to the escalation of nonconformities, and for the imposition, removal or variation of a condition.

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3. Definitions/Acronyms

Authorization to perform audits under the MDSAP

A notification to a candidate AO, generated by the APM after completion of Stage 2 Assessment, authorizing the AO to schedule and perform three (3) consecutive witnessed audits under the MDSAP.

Recognition Decision

Decision on the conformity of the AO to the applicable requirements for recognition under the MDSAP, including, where appropriate, the decision to recognize with scope, maintain the recognition, extend or restrict the scope, re-recognize with scope maintained, restricted or extended, cease recognition or a refusal to recognize, including, if necessary, pre-conditions for the implementation of the decision, conditions to be met after implementation of the decision, and updates to the Assessment Program for the AO under consideration.

AO: Auditing Organization

APM: Assessment Program Manager

ATL: Assessment Team Leader

LPM: Lead Project Manager

RA: Regulatory Authority

RAC: Regulatory Authority Council

TRRC: Technical Review and Recognition Committee

4. Authorities/Responsibilities

Assessment Program Manager (APM)

- Undertakes the Technical Review;
- Prepares the assessment file for review and decision by the Technical Review and Recognition Committee (TRRC);
- Verifies that the assessment file is complete and contains all required documentation;
- 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 makes recommendations, taking into account the ATL's recommendation, but shall not be one of the RA representatives of the Committee;
- Determines if a candidate AO has successfully completed the requirements for a Stage 2 assessment and all identified non-conformities have been closed;
- Proposes decisions regarding the authorization of an AO to perform MDSAP witnessed audits;

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- Prepares the authorization letter and submits for signature by the RAC Chairperson;
- Prepares the recognition letter and submits for signature by the RAC Chairperson;
- Ensures the implementation and follow-up of the recognition decision, including the update of the Assessment Program as applicable;
- May propose the imposition, removal or variation of a condition;
- Update the “*List of AO Availability to Conduct MDSAP Audits*”, available in the MDSAP website.

Assessment Team Leader (ATL)

- Clarifies the assessment file if requested by the APM.

MDSAP SME Lead Project Manager (LPM)

- Plans the TRRC process and convenes the committee;
- Acts as TRRC chairperson or, particularly if he/she was part of the assessment team, designates a delegate.

Technical Review and Recognition Committee (TRRC)

- Reviews the assessment file and drafts the recognition decision;
- May propose the imposition, removal or variation of a condition.

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, including the imposition, removal or variation of conditions;
- (RAC Chairperson) signs the Authorization to perform witnessed audits under the MDSAP on behalf of RAC;
- (RAC Chairperson) signs the recognition decision letter on behalf of RAC.

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 (RAs’) recognition decision.

5.1 Initial Authorization to perform witnessed audits under the MDSAP

This section applies when the APM receives from the ATLs involved on the Stage 1

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Assessment, Stage 2 assessment and the assessment of Critical Locations as applicable:

- Audit reports and attachments;
- All nonconformity reports and attachments, after all are proposed for closure.

The APM reviews the documentation associated with these assessment stages, including those listed below to determine whether they are complete, prepared according to the specific procedures, and signed:

- AO Application for Recognition (MDSAP AS F0010.1) - AO Application Review Checklist (MDSAP AS F0010.3);
- Stage 1 Assessment Report (MDSAP AS F0013.2);
- On-Site Assessment-Audit Report for Head Office and, if applicable, Critical Location (MDSAP AS F0016.5);
- Non conformities report and attachments, if applicable (MDSAP AS F0015.2).

The APM liaises with the ATLS, or with the AO, to obtain clarification, if necessary, and determines whether the records are sufficient to indicate that the AO is in compliance with the assessment criteria and substantiate the closure of all nonconformities and hence would support a decision to authorize the AO to perform witnessed audits under MDSAP.

The APM confirms that all related documents are uploaded in the appropriate repository and informs the RAs of the availability of the information supporting the APM's recommendation to grant the authorization. The RAs may confirm or oppose the recommendation within one (1) week (7 calendar days). Upon confirmation by all RAs, or in the absence of any opposition within the week, the APM presents the authorization letter proposal to the RAC Chairperson for his or her signature.

In case a RA opposes the recommendation within a week, the APM provides all the elements to the LPM, who should initiate a discussion in order to understand and resolve the divergences. In cases where it is not possible to resolve the divergence, the LPM should convene a TRRC. If necessary, the APM informs the AO that some actions are required before the Authorization is granted.

The Authorization letter is prepared using the template MDSAP AS F0017.3. It indicates that the candidate AO can schedule and perform three (3) consecutive audits under the MDSAP. This notification specifies that MDSAP assessors must witness all three audits.

Note 1: The Authorization Letter will be valid for two (2) years. AOs that do not complete all necessary Witnessed Audits during the period of Authorization may be viewed as unable to meet the criteria for recognition.

Note 2: For the transition period between the MDSAP Pilot and MDSAP Operation Phase, the authorization process occurs as defined in the table below:

If, on 2016-12-31, a candidate AO has...	Then ...
Successfully met the <i>minimum criteria for Recognition</i> - Stage 1 and Stage 2 Assessments, and three Witnessed Audits.	The AO will be granted recognition in accordance with IMDRF/MDSAP WG/N11.
Successfully met the minimum criteria for Pilot Assessment - Stage 1 and Stage 2 Assessments, and one Witnessed Audit Note: In this scenario, the AO must have successfully completed at least one Witnessed Audit prior to the end of the pilot.	The AO will be automatically granted a new authorization to conduct the remaining MDSAP audit(s) necessary to complete the recognition criteria (all of which must be witnessed by RAs). This authorization is valid until 2018-07-31 .
Successfully met the criteria for Stage 1 and Stage 2 assessments and obtained authorization to conduct a first MDSAP audit.	The AO will be automatically granted a new authorization to conduct its three initial MDSAP audits (<i>all of which must be witnessed by RAs</i>). This authorization will be valid until 2018-12-31 .
Not applied during the MDSAP Pilot, or Not reached a point where the RAs could make a decision to grant authorization to conduct MDSAP Audits during the MDSAP Pilot,	The process for recognition may be pursued. After the completion of Stage 2 and all identified nonconformities are closed, the RAs will make a decision whether to authorize the AO to conduct an initial three Witnessed Audits (all of which must be witnessed by RAs). This authorization will be valid for 2 years from the date of decision.

Once the Authorization Letter is signed by the RAC Chair, the APM shall request the update of the “*List of AO Availability to Conduct MDSAP Audits*”, available in the MDSAP website, filling the column “*Authorized to Conduct MDSAP Audits*” with “Yes”.

5.2 Technical Review

The Technical Review is done by the APM and will take place after the completion of the initial assessment activities (Stage 1, Stage 2 and three witnessed audits), every year after the completion of surveillance activities (surveillance assessments and witnessed audits), after the completion of the re-recognition assessment activities (stage 1, re-recognition on-site assessments and at least one witnessed audit), when there is an escalation of nonconformities according to MDSAP AS P0015, or if a situation arises where a review of a recognition decision or the imposition / removal of conditions related to a recognition decision may be required by the TRRC or RAC.

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To perform the Technical Review, the APM shall fill MDSAP AS F0017.5 – Technical Review Form, that includes a quality control check to verify the completeness of the assessment file and:

- Verification that any written nonconformities comply with the requirements in clause 6.2 of IMDRF N11;
- Verification that the grading of nonconformity(s) complies with the requirements in clause 6.3 of IMDRF N11;
- Verification that the remediation plans for Grade 1 or Grade 2; nonconformity(s) complies with the requirements of clause 6.5 and 6.6 of IMDRF N11;
- Verification of implementation of remediation plans for Grade 3 and Grade 4 nonconformity(s) (where Grade 4 nonconformities are result of recurrence) and that they comply with the requirements of clause 6.5 and 6.6 of IMDRF N11;
- Any recommendation(s) where there is evidence of possible fraud, misrepresentation or falsification of evidence resulting in a Grade 4 nonconformity;
- Verification and evaluation of the Assessment Report(s);
- If applicable, the outcomes of any complaint or appeal from the AO on a particular nonconformity;
- Decision on closure of any nonconformity and any appropriate follow-up which may include Special Remote Assessment or Special On-site Assessment; and,
- If applicable, the verification of other information that could be used by the participating Regulatory Authorities, the TRRC or the RAC, to alter a recognition decision, or the conditions on that decision.

When after the technical review process a review and decision is not needed (see 5.2.1), the APM circulates by e-mail the filled MDSAP AS F0017.5 – Technical Review Form to the TRRC members for information and comments. The TRRC members have 7 calendar days for comments. If a major concern is observed by a member, a TRRC meeting may be scheduled.

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

For initial recognition, re-recognition, extension of scope, restriction of scope, safety issues, or in cases of fraud, misrepresentation or the falsification of evidence, or escalated nonconformities, or where other information is available that may impact a recognition decision or any conditions on the decision, the APM prepares the assessment file for review and decision by the TRRC. The APM includes his/her recommendation and corresponding rationale using the document MDSAP AS F0017.2 - Review and Recognition Decision Form. 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, the AO, or from the source of other information, as relevant.

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The file presented to the TRRC includes the reports of all prior assessment activities related to the decision that is to be made (i.e. Stage 1 Assessment, On-Site Assessment at the head office and critical locations, Witnessed Audits) and the MDSAP AS F0017.5 –Technical Review Form.

5.2.2 Planning for the Technical Review and Recognition Committee meeting

The LPM or his/her delegate coordinates the Review and Decision process assuring availability of members to comprise the committee. The TRRC includes at a minimum:

- A TRRC chairperson; to lead the committee, to ensure that discussions are moving forward towards consensus, and, when consensus cannot be reached, to decide on an alternative decision-making method. The chairperson should be knowledgeable of recognition decision precedents;
- The MDSAP APM to present the file and address questions from the TRRC; and
- One representative of each RA, chosen from among the subject matter experts for the MDSAP.

The committee members must be independent of the assessors and the APM that prepared the evidence for the assessment file being reviewed. Hence, committee members cannot have participated in any assessment activities being reviewed by the committee. In exceptional circumstances (e.g. due to a lack of 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.

TRRC members must have access to the assessment reports and all related information available, including the outcome of the APM's technical review and recommendation documented in the MDSAP AS F0017.2 Review and Recognition Decision Form.

The members of the TRRC should review all information available and document the recommended decision, rationale and comments in the appropriated field of the MDSAP AS F0017.2 Review and Recognition Decision Form and submit it to the TRRC chair.

The TRRC chairperson consolidates the information received from each TRRC member.

If there are divergent evaluations, the TRRC chairperson is to initiate a discussion in order to understand and possibly resolve the divergences. The TRRC chairperson should schedule a teleconference to discuss the divergent evaluation, if necessary. As a result of this discussion, the TRRC chairperson should invite the RA representatives to reconsider their individual decision.

Where the divergence of opinion between the TRRC members is such that a

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consensus decision cannot be reached, the TRRC chairperson may either:

- Adjourn the deliberation and request the APM to re-perform the technical review, 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 teleconference 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 drafts a recommended decision, representative of a qualified majority, including a rationale.

TRRC Chair presents the recommended decision and confirms that all TRRC members concur with and support the recognition decision as stated.

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

5.3 RAC decision and communication of decision

The TRRC chairperson provides the proposed decision and the supporting documents to the MDSAP RAC representatives for consideration.

The RAC members may request additional information or clarifications from the TRRC chairperson.

Following the review and consensus of the RAC, the RAC Chairperson documents the RAC decision on the appropriate field of the MDSAP AS F0017.2. Review and Recognition Decision Form. The APM notifies the AO of the decision made on their recognition status. A rationale will be included in the notification for adverse decision about the AO. The AO may appeal the decision through the Appeals Process (as per procedure MDSAP AS P0021).

If the decision is to recognize the AO, the recognition will be valid for 4 (four) years from the date of the RAC chair Recognition Letter signature.

Once the Recognition Letter is signed by the RAC Chair, the APM shall request the update of "*List of AO Availability to Conduct MDSAP Audits*", available in the MDSAP website, filling the column "*Recognition*" with "Yes". If there is any change in the Head-Office or Critical Location address, the column "*Location*" should also be updated.

When a previously recognized AO no longer satisfies the requirements for recognition, the notification of the decision will provide details for the cessation of recognition, including the date it becomes effective in the absence of an appeal, and

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will outline the Appeal provisions. Once the notice to cease recognition is received, the AO may not:

- Accept any new applications, including transfers from manufacturers from another AO;
- Perform an initial audit for any manufacturer whose application has already been accepted; or
- Extend the scope of a manufacturer's certification.

In cases where a public health issue is involved, the Appeals Process may be shortened to accommodate the perceived risk. Some recognizing RA(s) may impose other urgent actions in these cases. These actions would be detailed in a notification of cessation of recognition.

The cessation of recognition becomes effective either:

- In the absence of an appeal, on the date identified in the notification, OR
- Immediately after the appeals process confirms the decision to cease recognition.

When the cessation of recognition becomes effective, the AO shall cease all audits under the MDSAP.

After the decision to cease recognition is confirmed, the APM shall request the update of "*List of AO Availability to Conduct MDSAP Audits*", available in the MDSAP website, filling the columns "*Authorized to Conduct MDSAP Audits*" and "*Recognition*" with "No".

The AO is required to submit a new application if they wish to be reconsidered for recognition, after the decision to cease recognition is confirmed.

5.4 Range of Recognition Decisions

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

- 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
- Imposition or removal of conditions

5.4.1 Recognition Decision Following an Initial Assessment

For an initial assessment, there are essentially two (2) potential recognition decisions:

Recognition - The applicant is granted recognition for a specified scope when:

- The Review and Decision process found any non-conformities (Grade 1, 2, 3

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were brought to closure (see 6.7 of IMDRF N11) for all Initial Assessment Activities;

- The applicant is recognized as an AO for the duration of the assessment cycle and may:
 - o Undertake all audit activities within the scope of the application; or,
 - o Undertake audit activities within a restricted scope of the application.

The AO may request to vary the scope of their recognition application (extend or restrict) at any time. The MDSAP RAs may grant recognition for the new scope after it has performed relevant Assessment Activities in order to assess the new scope, and when any nonconformities (Grade 1, 2, or 3) are brought to closure (see clause 6.7 of IMDRF N11).

Refusal - The applicant is refused recognition when:

- The application process has been terminated by the assessment team(s) before completion of the Initial Assessment Activities due to the inability of the AO to satisfactorily comply with regulatory requirements;
- The Review and Decision process found the remediation plan(s) inadequate and unable to bring closure (see clause 6.7 of IMDRF N11) for any nonconformities (Grade 1, 2, 3 or 4) after the conclusion of the Assessment Process which included exchange(s) between the assessment team(s) and the AO; or,
- There is evidence of fraud, misrepresentation or falsification of evidence (Grade 4).

The applicant is not to be recognized as an AO and may not audit under the recognition program. A new application will not be accepted within 12 months of the previous recognition decision.

5.4.2 Recognition Decision Following an AO Request

Extension of Scope of Recognition - The AO has requested an extension of scope and the RAs have performed relevant Assessment Activities in order to assess the new scope. The Review and Decision process found any nonconformities (Grade 1, 2, or 3) were brought to closure (see clause 6.7 of IMDRF N11) for all relevant Assessment Activities. If the Review and Decision Process approves the amended scope, the expiry date of the initial or re-recognition decision is not changed.

Restricted Scope - The RAC may decide to restrict specific elements of the scope of recognition in response to a request from the AO.

5.4.3 Recognition Decision Following a Re-recognition Assessment

Re-Recognition - The recognition remains valid and is renewed for the duration of the next recognition cycle. The AO's recognition is renewed when the Review and Decision process found any nonconformities (Grade 1, 2, 3 or a Grade 4 issued due to recurrence) were brought to closure (see clause 6.7 of IMDRF N11) for all Re-

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recognition Assessment Activities.

The recognized AO may continue to undertake all audit activities within the scope of the application.

Re-recognition with Extension of Scope - The AO has requested an extension of scope and the RAs have performed all relevant Assessment Activities for the re-recognition and extension of scope. The Review and Decision process found any nonconformities (Grade 1, 2, or 3) were brought to closure (see clause 6.7 of IMDRF N11) for all relevant Assessment Activities.

Re-recognition with Restricted Scope - The RAC may decide to restrict specific elements of the scope of recognition, either:

- in response to a request from the AO; or
- after the Assessment Process has been exhausted and as an alternative to ceasing recognition, when the Review and Decision process concludes that the AO can no longer satisfy the requirements for recognition in relation to those specific elements.

Cease Recognition: The recognition is withdrawn when:

- the AO can no longer satisfy the requirements for recognition; or,
- There is evidence of fraud, misrepresentation or falsification of evidence (Grade 4).

An AO no longer satisfies the requirements for recognition when, after the Assessment Process has been exhausted, the Review and Decision process concludes that:

- The remediation plan of any repeat nonconformity graded 3 or 4 is inadequate; or
- The implementation of remediation for a first time nonconformity graded 2 or 3 proves to be ineffective and the AO is unable, or unwilling, to develop and implement effective remediation.

5.4.4 Recognition Decision following NC escalation

After an AO is recognized to perform audits under MDSAP, the Review and Decision process may be necessary if any nonconformity needs to be escalated (see MDSAP AS P0015). In this case, three (3) potential decisions are possible:

Maintenance of Recognition: the recognition remains valid for the current scope of recognition. The AO may continue undertaking audit activities within the framework of the MDSAP.

The decision to continue the Recognition may in addition include comments or conditions, as defined below (5.4.5).

If the maintenance of a Recognition is associated with conditions that must be satisfied in a specified timeline, the AO may continue auditing activities under

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MDSAP after the specified timeline, if, at the end of the specified timeline:

- The AO 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 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 end of the initially specified timeline. The information is to include a solicitation for an extension of the timeline, a rationale supporting the solicitation and a detailed plan for completing the actions necessary to satisfy the conditions.

An extension may not exceed the date that was planned for the next routine assessment.

If the AO is unable to satisfy the conditions within the specified timeline, the TRRC will make a new decision on whether to cease the recognition, or on whether to change the previous decision to take into account additional information made available after the initial decision.

Restricted Scope: The RAC may decide to restrict specific elements of the scope of recognition after the Assessment Process has been exhausted and, as an alternative to ceasing recognition, when the Review and Decision process concludes that the AO can no longer satisfy the requirements for recognition in relation to those specific elements.

Cease Recognition: The decision to cease the Recognition of an AO may be considered when:

- the MDSAP AO no longer satisfies the requirements for recognition;
- there is evidence of fraud, misrepresentation or falsification of evidence (Grade 4); or,
- at an AO request.

An MDSAP AO no longer satisfies the requirements for recognition when, after the Assessment Process has been exhausted, the Review and Decision process concludes that:

- The remediation plan of any repeat nonconformity graded 3 or 4 is inadequate; or
- The implementation of remediation for a first time nonconformity graded 2 or 3 proves to be ineffective and the AO is unable, or unwilling, to develop and implement effective remediation.

A decision to change the recognition status of an MDSAP AO, may affect manufacturers that have been audited by the AO. In this event, RAs may need to

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consider individual or collective transitional arrangements to ensure existing or potential public health risks are mitigated.

5.4.5 Comments and the Imposition or Removal of Conditions

Any recognition decision may include **Comments** or additional **Conditions** that are imposed, or removed, by the recognizing Regulatory Authority(s) by consensus.

A Comment is information for the AO to consider but does not require any follow-up by the RAs before the next assessment. Comments may be made by the APM, TRRC or RAC. Comments should be taken into account by RA Assessors as input to the next assessment.

A Condition may be imposed, removed or varied based on information derived from an assessment activity or at any time that new information becomes available, whether or not the information is derived from a planned assessment activity. Conditions may be imposed, removed or varied by the TRRC or the RAC.

Conditions may be enduring or are subject to follow-up prior to the next assessment. Where applicable, a timeline for the AO to provide information for review/assessment must be included in the decision. Conditions that are subject to follow-up 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 condition, 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 a rationale supporting the solicitation for extension, and a detailed plan for completing the actions necessary to satisfy the condition. In such cases, an extension may not exceed the date of the next routine assessment.

If any conditions are imposed, the maintenance of the recognition decision is subject to the Auditing Organization fulfilling all the requirements identified in the condition.

6. Forms

MDSAP AS F0005.2 - Assessment Program Management File
MDSAP AS F0017.1 - Technical Review and Recognition Decision Flowchart
MDSAP AS F0017.2 - Review and Recognition Decision Form
MDSAP AS F0017.3 - Letter of Authorization Template
MDSAP AS F0017.4 - Letter of Recognition Template
MDSAP AS F0017.5 - Technical Review 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

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
002	2016-09-26	Revision to adjust the procedure to IMDRF MDSAP N11 and to give instructions on the transition plan between MDSAP pilot and MDSAP operational phase	Patricia Serpa, ANVISA
003	2017-07-05	Inclusion of the " <i>List of AO Availability to Conduct MDSAP Audits</i> " in the procedure.	Fernanda Maia, ANVISA

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Approval

Approved: Signature on file Date: 2017-07-05
MDSAP RAC Chairperson

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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(RAs) participating in the Medical Device Single Audit Program(MDSAP). When consensus is reached, draft recognition decisions are to be proposed to the RAC and if approved, endorsed by the RAC Chairperson.**
- **Consensus:** The TRRC members represent all RAs participating in the MDSAP. The TRRC members are to express their perspective to ensure final decisions take into account the view of all participating RAs. 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 RAs' 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 RAs provide the rationale to the Auditing Organization (AO) with the recognition decision, if the recognition decision may adversely affect the AO.
- **Balance:** The RAs' 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.

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- **Consistency:** The RAs' 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 RAs' recognition decisions to allow stakeholders the opportunity to foresee the most probable outcome of the decision making process.
- **Proportionality:** The range of RAs' 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 RAs' recognition decisions, the Assessment Program Manager and the 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:** AOs 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.