



# KALOS

## CERTIFICATIONS

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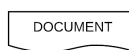
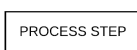
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Kalos Procedure-05  
**Planning & Conducting**  
**AS9100/AS9120 Audits**

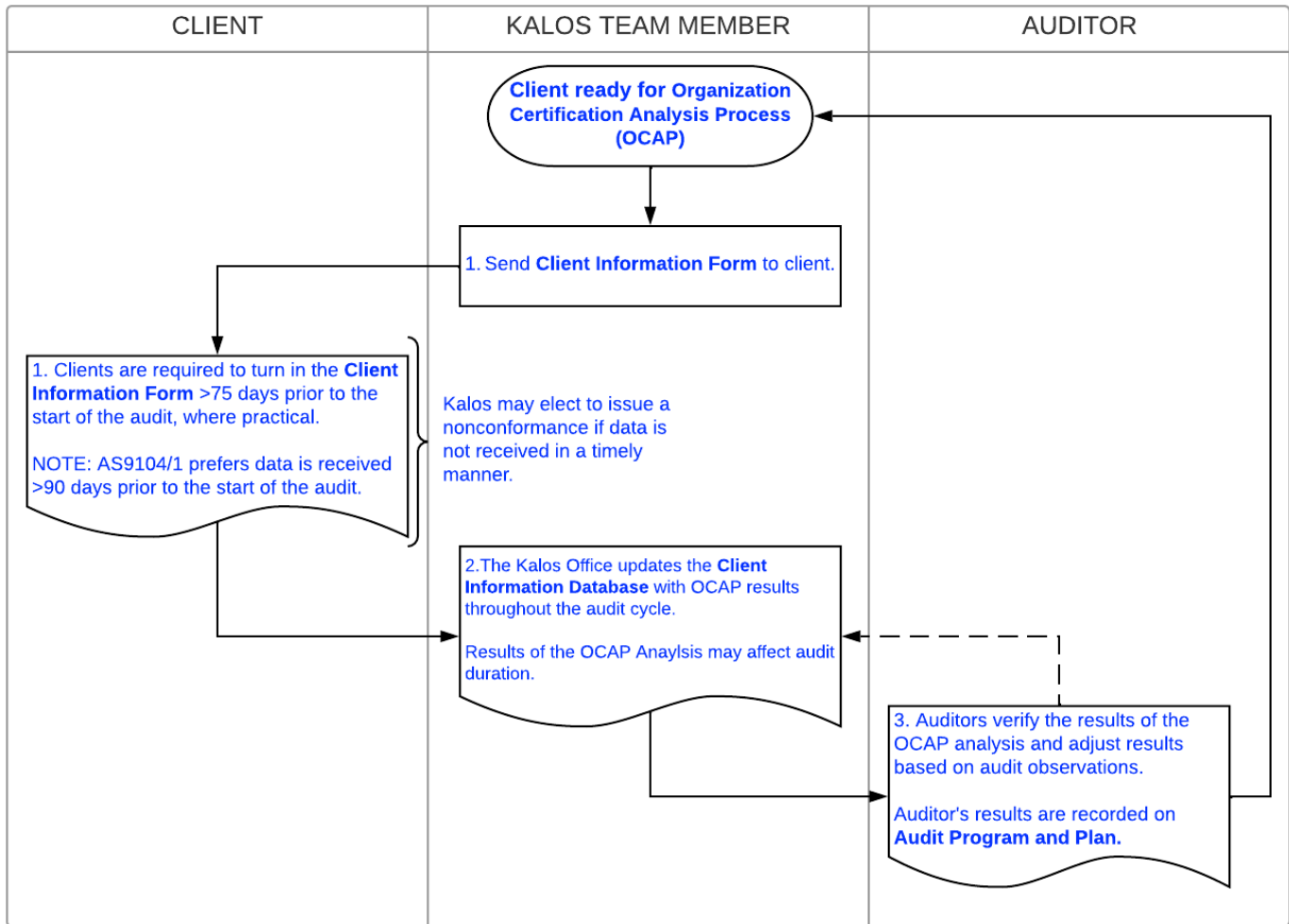
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**1. Organization Certification Analysis Process (OCAP) and Performance Data Collection**



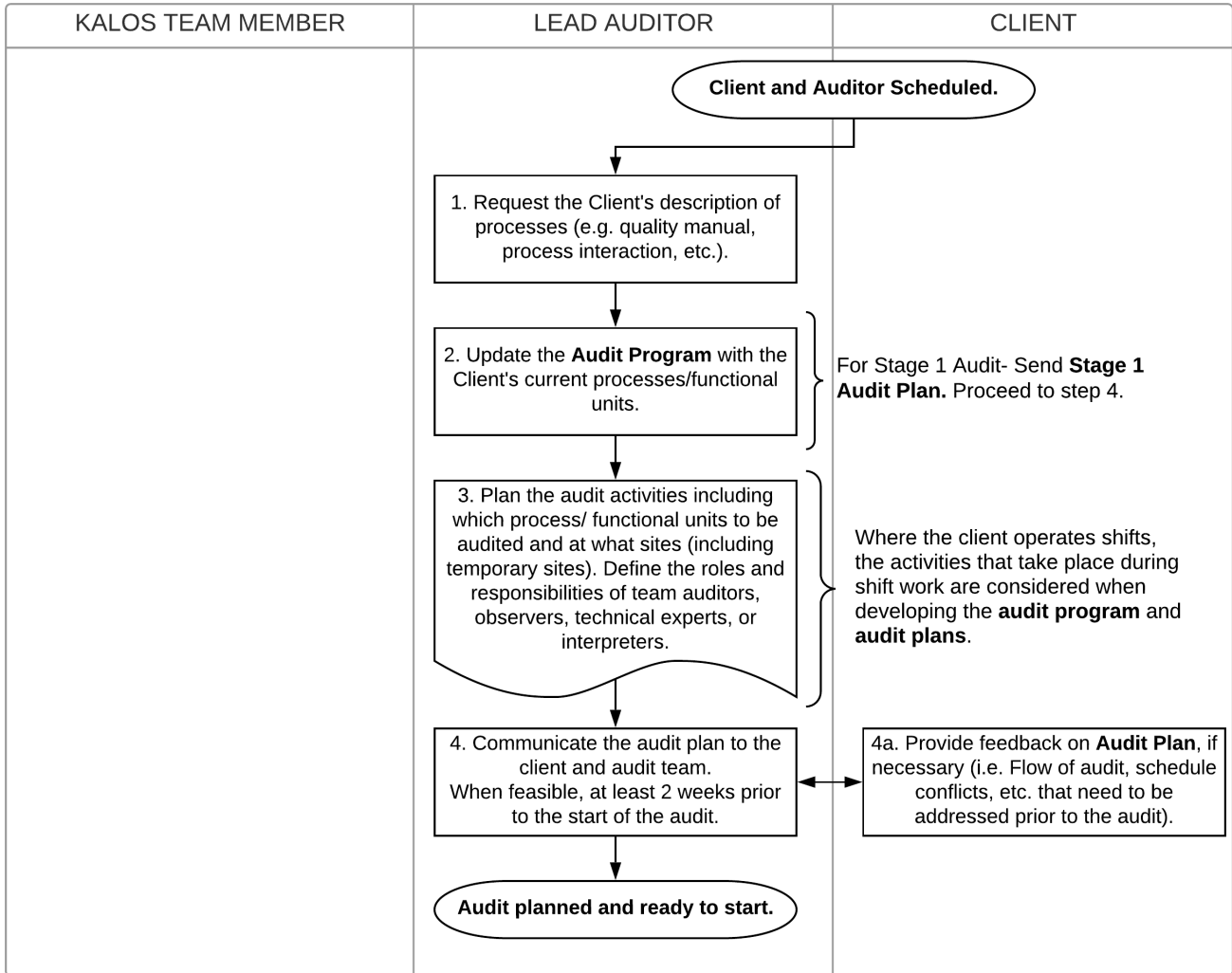
**1.1 Kalos in conjunction with clients performs a comprehensive analysis of the organization’s QMS scope, site structure, certification audit program, and risk assessment. The results and supporting information shall be documented and retained (see AS9104/1 Figure 1).**

- The analysis is:
  - Conducted prior to initial certification and updated for each surveillance or recertification audit;
  - Verified and the verification documented by the CB’s audit team; and
  - Updated by the audit team and adjustments made to the audit plan or program, as applicable.

**NOTE: Data from Stage 1 activities can be used to document the analysis of the organization.**



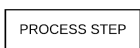
## 2. Audit Program & Planning



### 2.1 AQMS Audit Teams

- *The Team Leader, in consultation with Kalos Scheduler, plans the audit considering auditor competence, background knowledge in Standards and technological/industrial sectors.*
- *The audit plan demonstrates that the lead auditor has assigned auditors to effectively audit the client sites.*
- *Audit team leader must ensure that an AEA is on-site and actively involved at each site during the entire audit.*
- *The background knowledge of the audit team may be supplemented by an organization briefing, specific training, or the assignment of experts (e.g., subject matter or technical experts from industry or professional institutions).*

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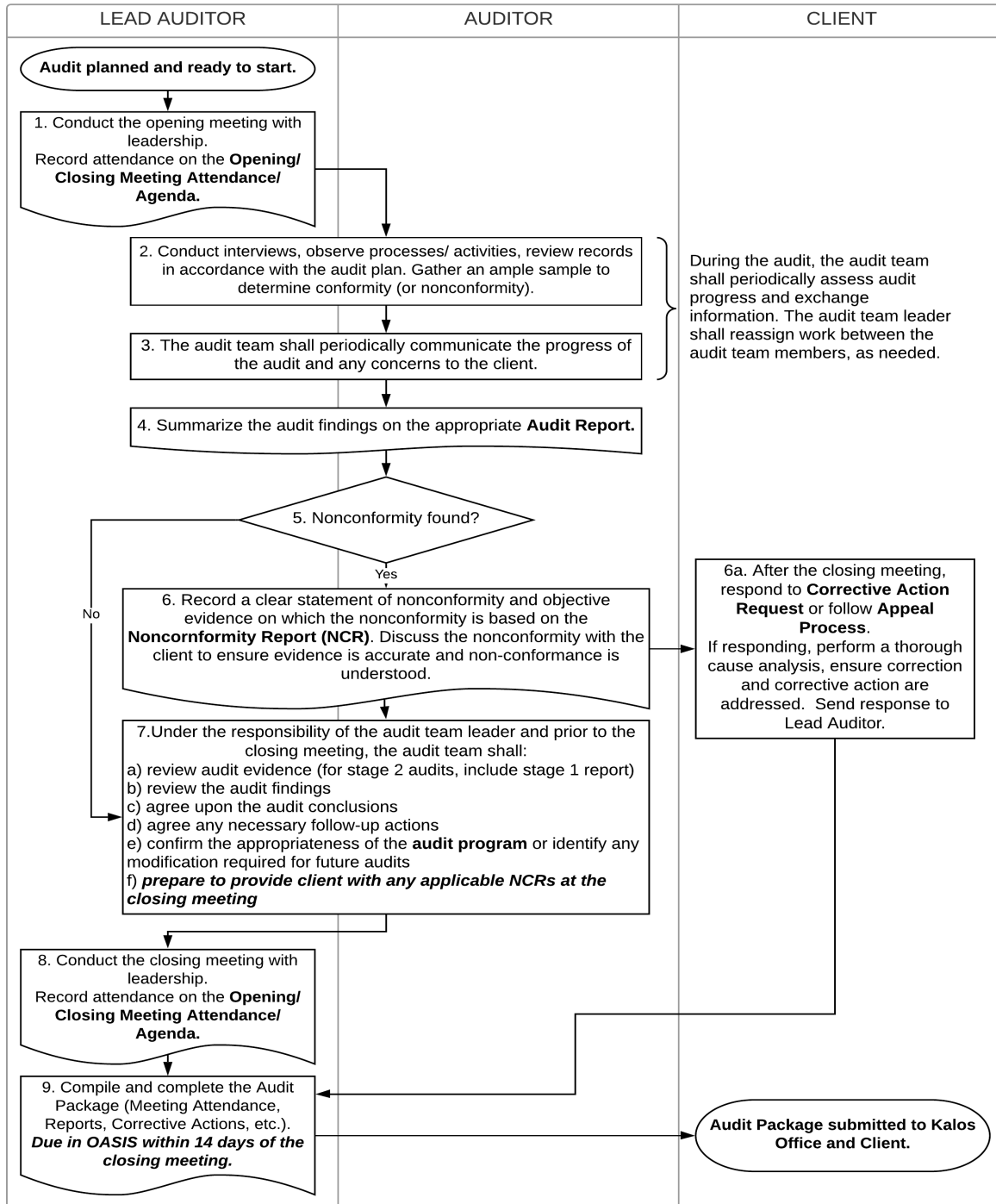


2.2 Table 1:

The following table explains the reports required for each type of audit conducted.	Stage 1	Stage 2	Surveillance	Recertification	Transfer @ Surveillance	Transfer @ Recertification	Corrective Action Revisit	Special
<b>Legend</b> Required   If Applicable   Optional   Not Required								
FM-02-02 Client Information Update Request <i>(includes OCAP, Specification Matrix, and PBS/RS data from client)</i>			X	X	X	X		
FM 05-01 B - Notification of Audit (Printable) <i>(includes OCAP, Specification Matrix, and PBS/RS data from office)</i>	X	X	X	X	X	X	X	X
FM 05-01 C - ADC & Recertification Review (Printable) <i>(includes OCAP, Specification Matrix, and PBS/RS data from office)</i>	X	X	X	X	X	X	X	X
FM-05-02 AS Opening- Closing Meeting Agenda and Attendance	X	X	X	X	X	X	X	X
FM-05-03 AS Stage 1 Audit Plan	X					X		
FM-05-04 AS Audit Program and Plan <i>(includes OCAP, Specification Matrix, and PBS/RS data from auditor)</i> o <i>If possible, please send a draft to the client prior to Stage 1 audit.</i>	X	X	X	X	X	X	X	X
AS9101 Form 1 Stage 1 Report	X			X		X <sub>1</sub>		
AS9101 Form 2 QMS Matrix		X	X	X				
AS9101 Form 3 Process Effectiveness Assessment Report (PEAR)		X	X	X				
AS9101 Form 4 Nonconformity Report o <u>Surveillance Audit</u> – Acceptable plan submitted within 30 days, correction verified at current audit, corrective action verified at next audit. o <u>Recertification Audit</u> – Acceptable plan submitted within 30 days, corrective action implemented and verified within 60 days or prior to expiry date.		X	X	X	X	X		X
AS9101 Form 5 Audit Report		X	X	X	X	X	X	X
AS9101 Form 6 Supplemental Audit Report							X	X
FM-05-05 AS Pre-transfer Visit Plan					X	X		
FM-05-06 AS Pre-Transfer Review					X	X		
1. Transfer audits conducted within 12 months of the client’s expiration require <i>(until AS9104/1:2022 transition is complete)</i> : a. A stage 1 on-site audit which includes validation of the adequacy and validity of the existing certification as described in ISO/IEC 17021 and ISO 17021-1 which allows the new CB to gain an understanding of the transferring client’s management system and site operations. b. A special on-site audit described in 9104-001 clause 8.8.c) as a ‘stage 2 audit’ which is used to validate the implementation, including effectiveness, of the management system including the items listed in 9101 clause 4.2.1 as well as any areas of concern highlighted the pre-transfer review and the on-site stage 1 audit.								



### 3. Conducting the Audit



**3.1** In the event an audit is unable to be completed or audit objectives are not met, the lead auditor is to communicate this with the client and contact the Kalos office immediately. The office will determine the appropriate action to be taken on a case by case basis (e.g. rescheduling, adding time to subsequent surveillance, exchanging an auditor, etc.)

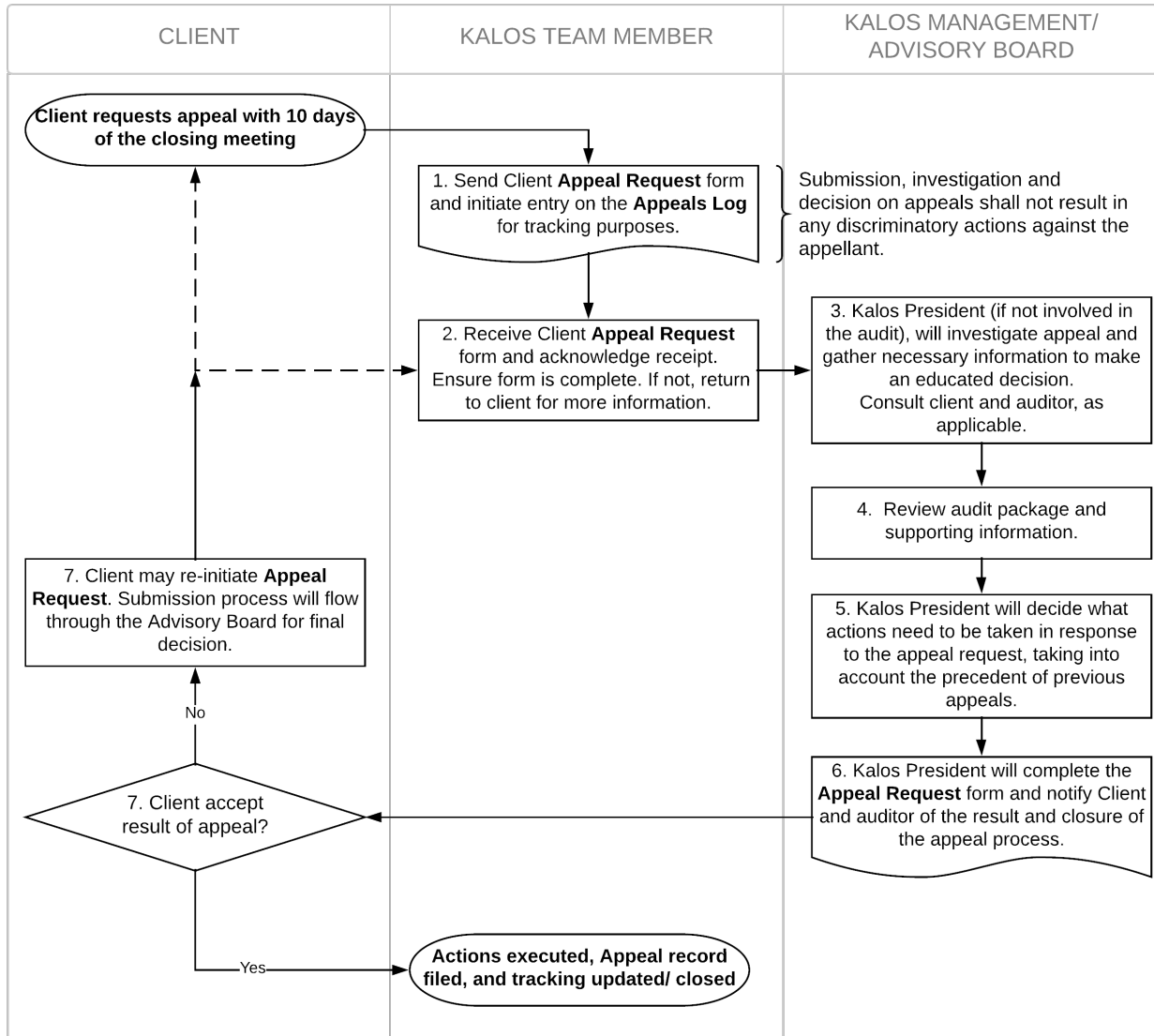


**3.2 Nonconformity Management**

- *Kalos initiates the client certification suspension process (KP-02), when an organization fails to demonstrate that conformance to the applicable standard has been re-established within 90 days from the issuance of a Nonconformity Report (NCR).*

**3.3 AQMS Clients must provide copies of the audit report and associated documents/records to their customers and potential customers, upon request, unless justification can be provided (e.g., competitor confidentiality, conflict of interest). Client may provide access to this data through the OASIS database or by providing the audit report directly to the customer.**

**4. Appeals**



## 5. OASIS Data Management

5.1 Client and audit data are managed in OASIS in accordance with AS9104 and AS9101.

Description	Owner	Timeline	Cert Decision
AS9104 Appendix C required data	CB	30 days after cert issue	Yes
AS9104 Appendix C required data	CB	90 days after closing meeting	No
<ul style="list-style-type: none"> <li>○ organization name, address, and locations included on the certification (approval by the CB is required prior to revising this data);</li> <li>○ the name(s) and e-mail address(es) of the organization’s OASIS database administrator(s); and</li> <li>○ the organization’s contact person, phone, fax, e-mail address, and website, as applicable.</li> </ul>	Client OASIS Administrator	Initial, on Going	Either

## 6. Integrated Management Systems

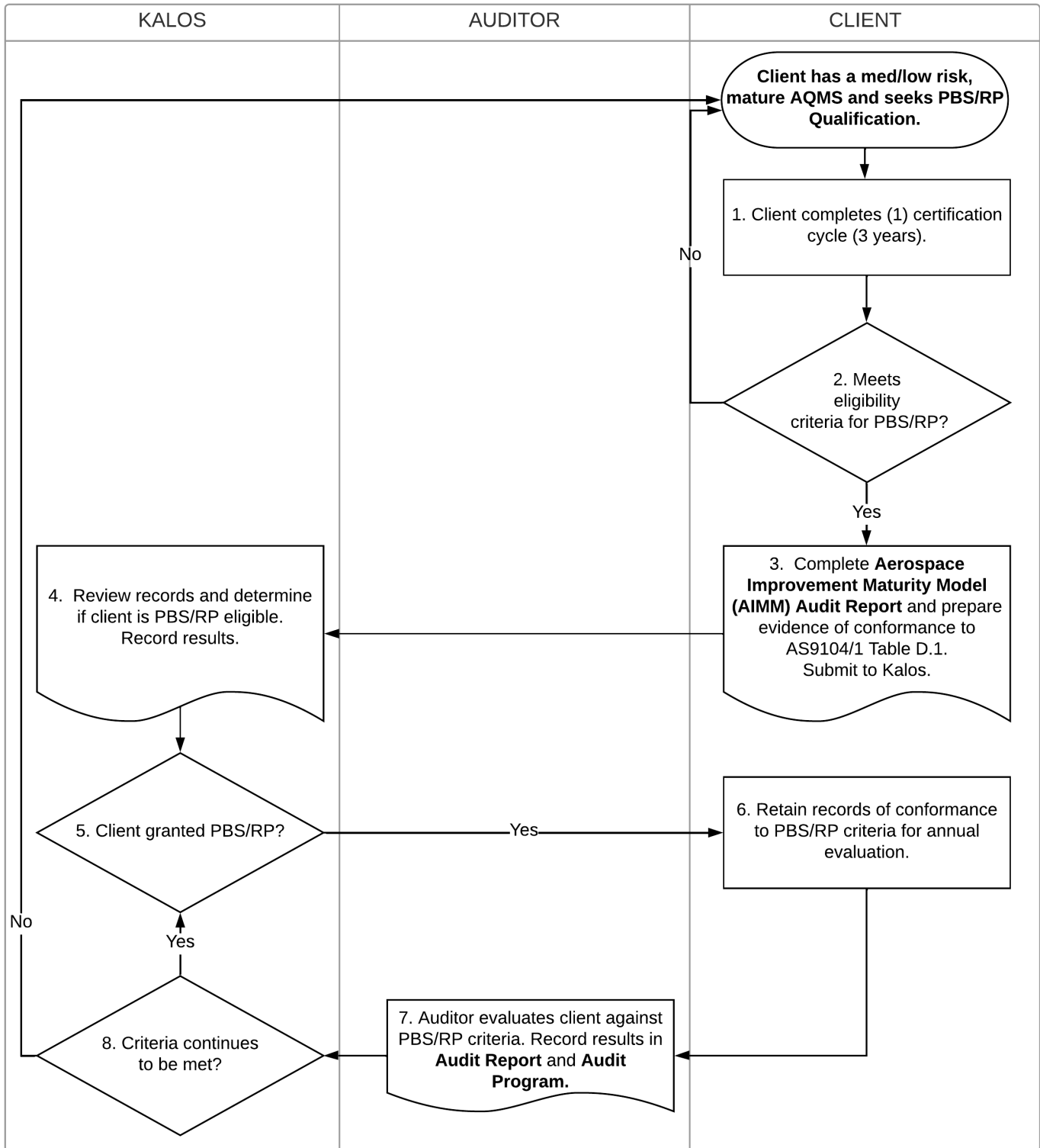
The audit plan shall ensure that:

- All areas and activities applicable to each AQMS standard covered by the scope of the visit are assessed by competent authenticated AQMS auditors.
- Sufficient time is allocated to accomplish a complete and effective audit of the client's management system(s) for the AQMS standards covered by the scope of the audit.
- The audit team, as a whole, satisfies the competence requirements for the relevant technical area(s) for each certification scheme covered by the scope of the combined audit. In cases where the audit team leader does not have the competence required to audit all AQMS standards covered by the combined audit, individual team members shall be appointed as the 'lead auditor' for each applicable standard and be responsible for any related recommendations that fall outside the competence of the audit team leader.
- All applicable elements of each AQMS standard relevant to the scope of the combined audit shall be adequately assessed. For example, when conducting a combined audit of an IMS covering 9100 and 9120, it would be unacceptable to verify the effectiveness of the system for “corrective action” by only auditing samples relevant to one of the standards (e.g., 9100).
- In some limited activities associated to the audit plan, it may be appropriate for AQMS auditors to audit aspects of an AQMS standard for which they are not formally qualified (e.g., 9100 AEA reviewing 9120 aspects):
  - areas where the requirements of the AQMS standards and the technical knowledge to undertake the audit is common (e.g., control of documents);
  - areas where the AQMS auditor verifies compliance with requirements which are administrative in nature; or
  - confirmation of evidence/close out of an audit trail.





**7. Performance Based Surveillance/Recertification Process Qualification**



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7.1 [Intentionally left blank]

7.2 General

- When a client applies for PBS/RP, the following table requirements apply:

PBS/RP QUALIFICATION REQUIREMENTS AND CRITERIA	
A. Completion of one AQMS certification cycle.	
B. The OCAP risk analysis from 8.5.1.5 results in a low/medium risk for each site, including the central function.	
C. Implementation of an Internal Audit Program in accordance with ISO 19011, including: <ul style="list-style-type: none"> <li>Annual audit of all applicable AQMS requirements; and</li> <li>Defined, structured, multiple event audit program that adjusts throughout the calendar year based upon:                             <ul style="list-style-type: none"> <li>performance;</li> <li>customer complaints;</li> <li>risk; and</li> <li>change management.</li> </ul> </li> </ul>	
D. Internal auditor competency that includes: <ul style="list-style-type: none"> <li>Auditor(s) that have completed a TPAB approved ASD Lead Auditor course (reference 9104/3).</li> </ul>	
	E. Organization has an ethics policy that includes communication and reporting processes.
	F. No externally identified major nonconformity (e.g., CB, customers, regulatory authorities), as defined in 9101, in the past 12 months related to internal audit, management review, or corrective action processes issued to either a single site or to the central function within a multi-site structure.
	G. No certificate suspension due to an AQMS nonconformance in the past six years.
	H. Meeting customer satisfaction metrics, based on customer provided data.

- Multi-site organizations eligible for PBS/RP include the following auditing program requirements:
  - During annual surveillance, the central function and 33% of the sites, rounded up to the nearest whole number;
  - At recertification all remaining sites and the central function; and
  - Each site, process, and AQMS standard clause is audited at least once every 48 months.

7.3 [Intentionally left blank]

7.4 [Intentionally left blank]

7.5 When using PBS/RP, audit durations are calculated as follows:

- For a single site structure using PBS/RP, audit duration may be reduced up to 33% from the AS9104/1 Table 8 calculation. No more than 50% reduction allowed.
- For multi-site structures using PBS/RP, audit duration for each site shall be calculated using the “Recertification Audit Duration” requirements from AS9104/1 Table 8 for surveillance and recertification. This number may be reduced up to 33% per site. No more than 50% reduction allowed.  
 NOTE: This applies at initiation of PBS/RP and at any time during the certification cycle.
- For multi-site structures using PBS/RP for the central function, audit duration shall be calculated using the “Surveillance Audit Duration” requirements from Table 8 and may be reduced 33% for surveillance and recertification.

7.6 [Intentionally left blank]

7.7 [Intentionally left blank]

7.8 Annual Performance Based Surveillance/Recertification Process Adjustments

CERTIFICATE ISSUE	PBS/RP ADJUSTMENT		
A. Certificate suspension related to the QMS during the certification cycle	Not eligible for PBS/RP. Not eligible for the remainder of certification cycle plus one more certification cycle.		
B. OCAP results reflect overall high risk	Improvement plan shall be established; CB follow-up is required. No reduction in PBS/RP audit duration reduction for the central function per 8.5.3.5.c. Utilize the recertification criteria to calculate audit duration regardless of the audit type. If the high risk is not addressed by the next annual audit, then no sites are eligible for PBS/RP audit duration reductions, including the central function.	D. OCAP risk analysis is high for organization or site(s)	No PBS/RP audit duration reduction per 8.5.3.5 for the site(s). Include the site(s) in the annual audit plan.
C. Failure to re-affirm the PBS/RP qualification criteria are met	Establish an improvement plan and CB follow-up is required. No PBS/RP audit duration reduction per 8.5.3.5 for any sites, including the central function. If PBS/RP criteria is not met at recertification planning, then PBS/RP is not allowed.	E. Externally identified major AQMS nonconformity issued to a site(s)	No PBS/RP audit duration reduction per 8.5.3.5 for the site(s). Include the site(s) in the annual audit plan.
		F. Site(s) is not meeting or exceeding customer satisfaction metrics on the latest customer provided data	No PBS/RP audit duration reduction per 8.5.3.5 for the site(s). Include the site(s) in the annual audit plan.

NOTE: Site risk analysis should be performed when there is available site data to determine on-going effectiveness of PBS/RP.



Revision History	Approved By	Date
DRAFT	Michaela Scarla	9/1/2020
RELEASE – <i>successful ANAB document review completed 10/8/2020</i>	Michaela Scarla	11/10/2020
Update Audit Form matrix based to clarify transfer audit forms required.	Michaela Scarla	7/30/2021
Per 2022 Internal Audit: <ul style="list-style-type: none"> <li>Update form number to new AS form structure</li> </ul>	Michaela Scarla	3/28/2022
<i>Update per AS9120 application</i> <ul style="list-style-type: none"> <li>Section 5 – Integrated audits</li> </ul>	Michaela Scarla	5/11/2022
<i>Update per AS9104/1:2022 Transition:</i> <ul style="list-style-type: none"> <li>Section 1 added for OCAP</li> </ul>	Michaela Scarla	10/3/2022
<i>Update per PBS/RP requirements (pending submission and approval by ANAB – not in use):</i> <ul style="list-style-type: none"> <li>Add section 7</li> </ul>	Michaela Scarla	10/10/2022
<i>Updated per AS9104/1:2022 Transition Feedback Round 1:</i> <ul style="list-style-type: none"> <li>Section 3.2 - Change 60 to 90 days to align with KP-02</li> </ul>	Michaela Scarla	12/23/2022

**LEGEND:**

