



# KALOS

## CERTIFICATIONS

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### Kalos Procedure-02

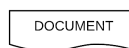
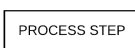
## ISO 9001/AS9100 Client Process

Maintained in accordance with ISO 17021, **AS9101**, **AS9104**, and supporting IAF Mandatory Documents  
*Items formatted in bold, italics are Aerospace specific requirements.*  
Items highlighted blue are Medical specific requirements.

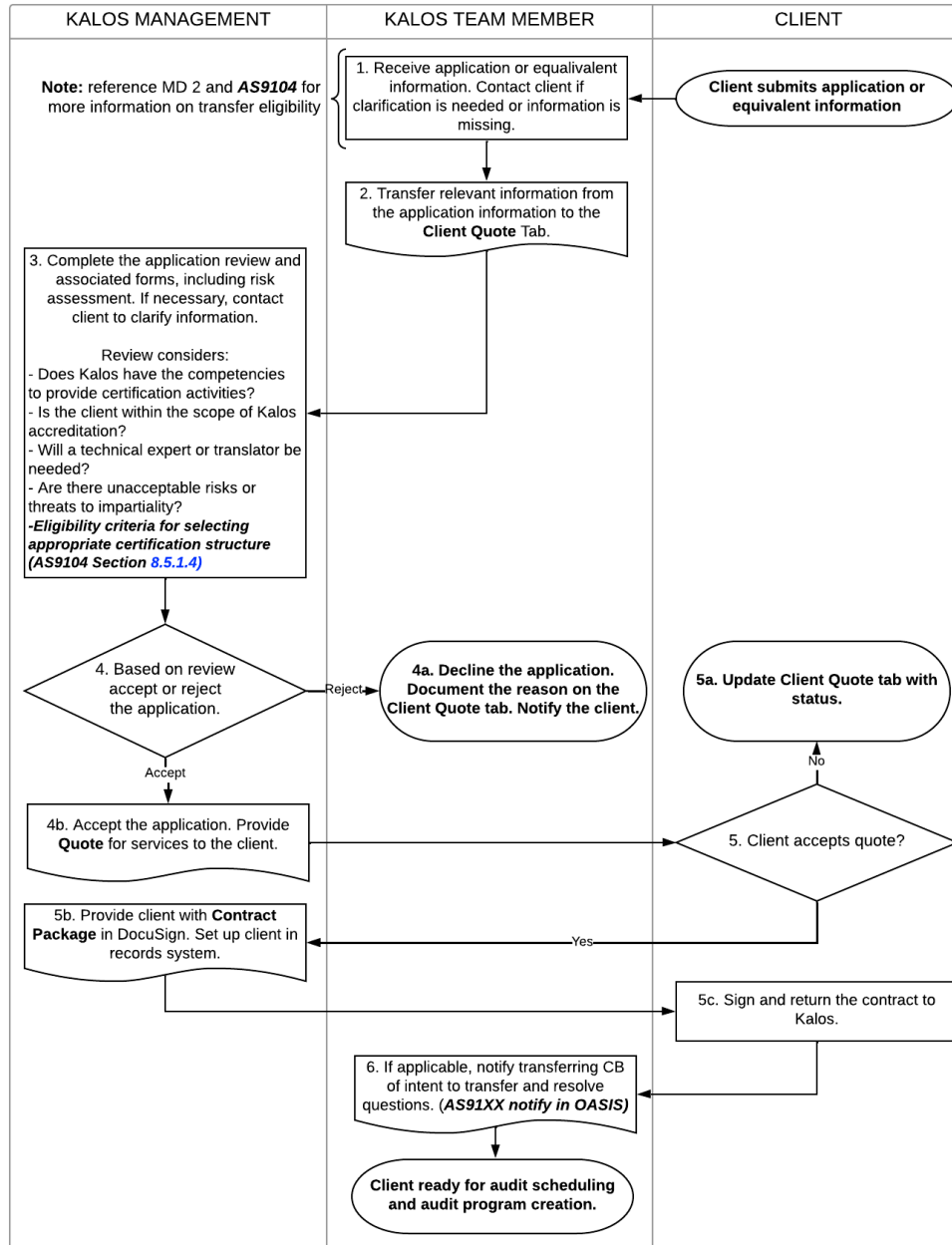
## Table of Contents

1. Application & Review .....	3
2. Audit Team Selection .....	4
3. Determining Audit Time & Scheduling .....	5
4. Multi-site Sampling .....	6
5. Types of Audits.....	6
6. Certification Decisions .....	10
7. Observers, Technical Experts, & Guides.....	12
8. Head's Up Notices .....	14
9. Use of Information and Communication Technology (ICT) .....	15

**LEGEND:**



## 1. Application & Review



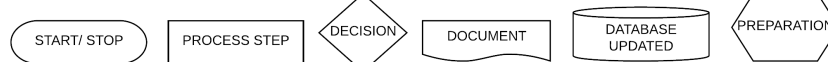
### 1.1 Information Gathering

- For over the phone quotes, complete the application with the client and ensure ICT preferences are recorded.
- **Kalos uses the application or equivalent information to initially define the context of the organization and proposed scope of certification. Context and scope may be adjusted during Stage 1 + 2 as appropriate.**
- **The AQMS standard(s) (i.e., 9100 or 9120) utilized for certification shall be selected based on the organization's scope of certification.**
- **When a Kalos client with an existing ISO 9001 certificate wishes to upgrade to an AQMS standard, a full initial audit (Stage 1 and Stage 2) of all requirements for the applicable AQMS standard (e.g. AS9100) is required.**

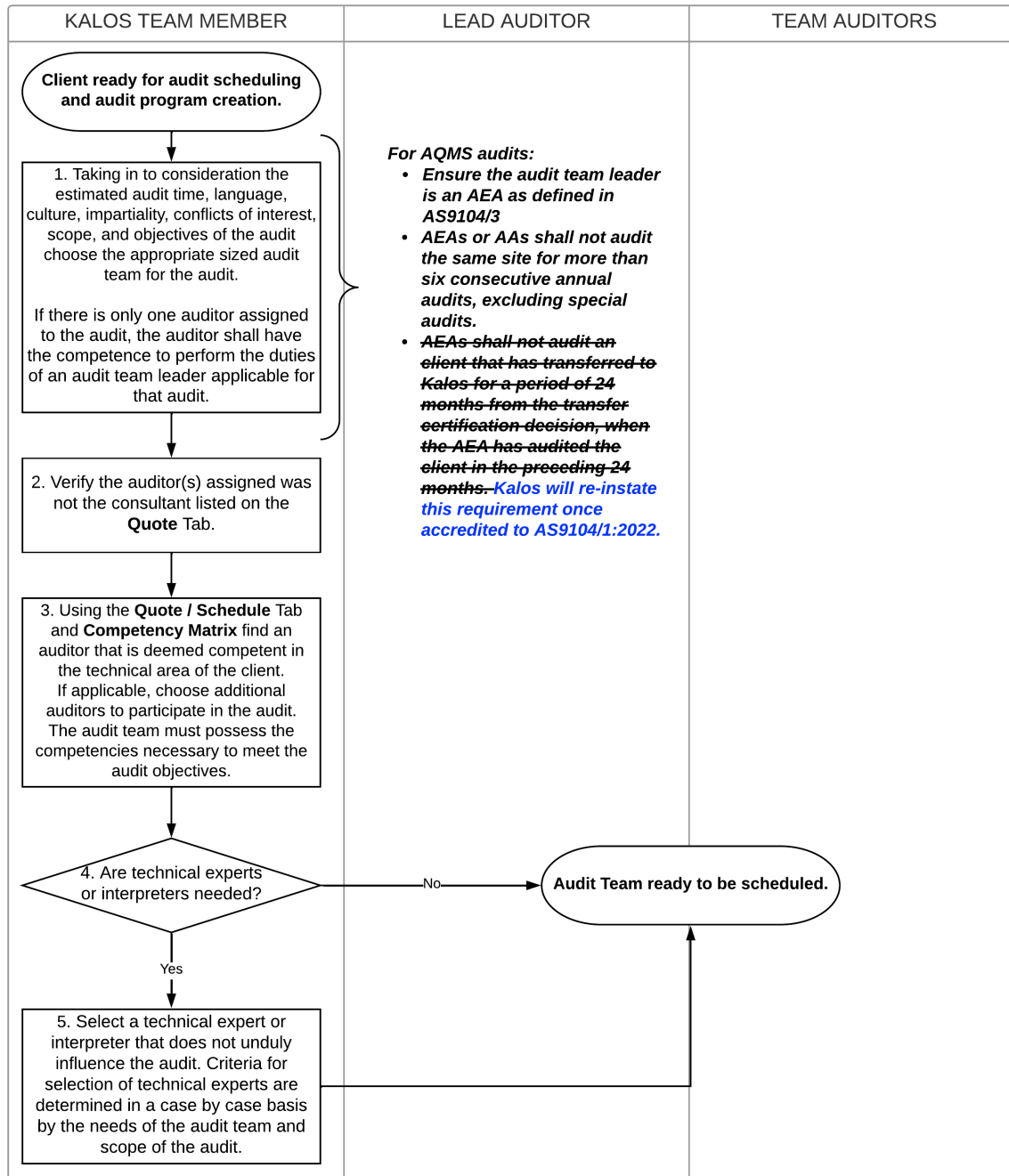
### 1.2 [Intentionally left blank]

### 1.3 Information that was clarified/corrected from the client application is updated in the client quote. Application is not adjusted.

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## 2. Audit Team Selection

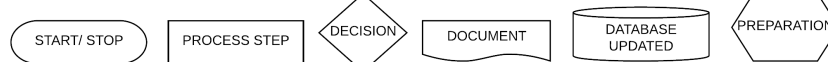


**2.1** The audit team leader, in consultation with the audit team, shall assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities.

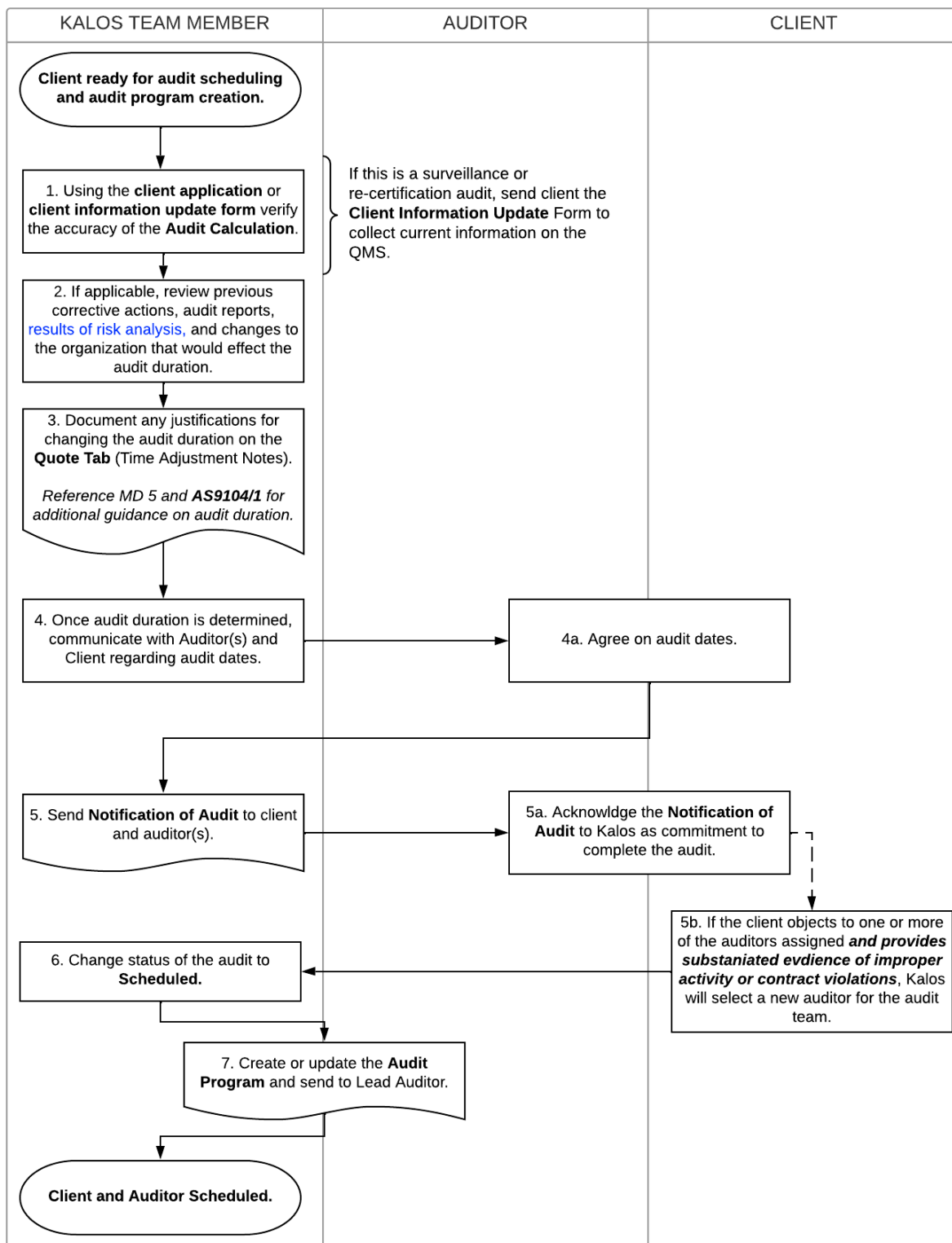
- Such assignments consider the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts.
- Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives.

**2.2** Auditors-in-training may participate in ISO 9001 audits, provided a lead auditor is appointed as an evaluator. The evaluator shall be competent to take over the duties and have final responsibility for the activities and findings of the auditor-in-training. Reference **WI-02-01 Auditor Mentoring Program** for more information.

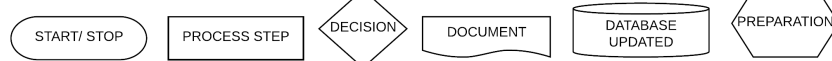
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### 3. Determining Audit Time & Scheduling



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**3.1** One audit day is normally 8 hours of auditing activities.

**Note:** This does not include breaks or travel.

**Note:** The number of audit days shall not be reduced by increasing the number of hours worked per a day.

**Note:** NCR verification time may be conducted outside of the normal 8 hour work day, if feasible for client.

**3.2** Audit activities include:

- conducting the opening meeting
- performing document review while conducting the audit
- communicating during the audit
- assigning roles and responsibilities of guides and observers
- collecting and verifying information
- generating audit findings
- preparing audit conclusions
- conducting the closing meeting

**3.3** For AS91XX audits, Kalos uses the audit duration baseline defined in AS9104/1 Table 8.

**4. Multi-site Sampling**

**4.1** Where multi-site sampling is used for the audit of a client's management system covering the same activity in various geographical locations, the client's **FM-02-09 Multi-Site Calculation** and **FM-03-04M Audit Program** is updated to reflect the frequency of auditing each site and time calculations.

**4.2** The rationale for the sampling plan shall be documented for each client on the **FM-02-09 Multi-Site Calculation**.

**4.3** Where there are multiple sites not covering the same activity, sampling is not appropriate.

**4.4** Site sampling is not appropriate for AS91XX clients.

**5. Types of Audits**

**5.1** Initial – Stage 1

- The initial certification audit of a management system is conducted in two stages: stage 1 and stage 2.
- The purpose of the stage 1 activity is to determine readiness for certification.
- The **FM-03-02 Stage 1 Audit Report** or **AS9101 forms** documents the conclusions with regards to readiness for Stage 2 and any areas of concern that could be classified as a nonconformity during stage 2.
- At the time of quoting an interval between stage 1 and stage 2 will be selected and scheduled. If upon the auditor's and/or client's decision the interval should need to change, the Kalos Scheduling team should be contacted to revise the arrangement for stage 2 as soon as possible.
- For ISO 9001 only, Kalos and client may agree to utilize remote auditing to complete the Stage 1 activity, if feasible.
- **For AS91XX clients, initial Stage 1 audits include on-site evaluation of the client's site-specific conditions.**
- If there are significant changes that impact the client's management system, Kalos may repeat all or part of stage 1 activity.
- **For multi-site organizations, the Stage 1 audit includes an evaluation of the identified central function. In addition, a relevant number of sites representative of different technologies and dissimilar activities are included in the Stage 1 audit.**

**5.2** Initial - Stage 2

- The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's management system. The stage 2 shall take place at the site(s) of the client.

LEGEND:

START/ STOP

PROCESS STEP

DECISION

DOCUMENT

DATABASE  
UPDATED

PREPARATION

- The **FM-03-05 Audit Report** or **AS9101 forms** document the conclusions and considers the required topics of ISO 17021.

### 5.3 Surveillance

- The purpose of the surveillance audits is to give Kalos Certifications confidence that the client's certified management system continues to fulfill requirements between recertification audits.
- Surveillance audits are on-site audits, but are not necessarily full system audits, and are planned together with the other surveillance activities.
- Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.
- The **FM-03-05 Audit Report** or **AS9101 forms** documents the conclusions and considers the required topics of ISO 17021-1.

### 5.4 Recertification

- The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification.
- Recertification audits are full systems, on-site audits and are planned together with the other recertification activities. If there are significant changes to the management system or context, a stage 1 activity may be included.
- Kalos aims to conduct recertifications audits 45-60 days prior to expirations to allow ample time to complete the audit package and perform an effective Technical Review prior to expiration.
- A **FM-02-04/05 Recertification Review** is conducted by the Kalos Office to evaluate the performance of the management system over of the course of the audit cycle.
- Prior to a certification decision being made, all major nonconformities are corrected and corrective action implemented and verified.
- In the event the corrective actions cannot be verified prior to the expiration date, the suspension process will be initiated.
- Following expiration of certification, Kalos can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted.
- Restored certifications will fall in line with the previous certification cycle.

### 5.5 Special Audit– General

- Client's may request a scope expansion via **FM-02-03 Client Change Request** or equivalent record.
- After a review of the application for change and if determined necessary, Kalos will schedule a special audit to verify the change and integrity of the client's management system.
- **For AS91XX – a request to expand existing certification scope, revise certification structure, increase the number of site(s), and/or change in site location(s) requires a special audit per AS9104/1.**
- Scope expansion audit may also be conducted in conjunction with a surveillance or recertification audit.

### 5.6 Special Audit – Short Notice

- It may be necessary for Kalos to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients. **For AQMS clients, the audit must be completed within 30 calendar days from the receipt of the complaint.**
- This may become necessary if a certified client is:
  - Unresponsive to scheduling request for recertification or following up on major nonconformities;
  - The need to investigate severe complaints from users;
  - Client's advertising indicates a change to the scope that impacts the validity of the certification.

LEGEND:

START/ STOP

PROCESS STEP

DECISION

DOCUMENT

DATABASE  
UPDATED

PREPARATION

- Kalos will make attempts to communicate with the client, however ultimately the dates selected for the short notice audit will proceed.
- Kalos exercises additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

### 5.7 Special Audit -Transfer Audits

- **Only valid certifications from a CB with an AQMS accreditation from an ICOP scheme approved AB shall be eligible for transfer.**
- **Kalos generates a new OCAP (or equivalent) and performs a special audit as part of the pre-transfer review.**
  - **When the OCAP risk analysis is high risk or an outstanding major nonconformance (reference 9101) exists, then a special audit is performed on-site.**
- **For organizations with PBS/RP, Kalos assures conformance to the requirements as defined in AS9104/1 Appendix D, Table D.1, prior to transfer.**
- **Kalos does not issue certification to the transferring client unless:**
  - **All nonconformities have corrections, corrective action, and verification accepted by the current CB; or**
  - **The accepting CB assures that nonconformities are accepted and associated corrective actions are effective; and**
  - **The client's AQMS shall be returned to conformity, prior to the certification decision.**
- **The accepting CB shall not use the initial certification process to avoid resolving outstanding nonconformities.**

**NOTE: Kalos may request and obtain the relevant OASIS database information necessary to assure nonconformity closure.**
- **The current CB shall cooperate with Kalos to facilitate the transfer. Kalos uses the OASIS database feedback process to create documented evidence of communication with the current CB.**
- **The current CB shall not use notification of a transfer as justification for suspension or withdrawal of the existing certificate before the transfer process to Kalos is completed.**

### 5.8 AQMS Combined and Integrated Audits

- **Audits of an Integrated Management System (IMS) are conducted in accordance with the requirements of IAF MD 11, AS9104/1 and the following:**
  - **During the OCAP risk analysis, the level of integration of the management system is established;**
  - **For an IMS with fully integrated AQMS standards, Kalos calculates the audit duration for each standard individually; then, takes the standard with the highest amount of audit duration and add 50% of the audit duration for each additional standard (i.e., Total Audit Duration = 9100 + 50% of 9110 calculation + 50% of 9120 calculation); and**
  - **For all other IMS audits, including organizations comprising of an ISO 9001 QMS and an AQMS with different scopes, Kalos complies with IAF MD 11 requirements and the audit duration time for the AQMS standard(s) is not reduced.**
  - **Certification documents issued as a result of a combined audit is issued as separate certificates for each AQMS standard.**

**NOTE: In situations where withdrawal of certification is restricted to a specific AQMS standard only, the affected certificate is revised.**

LEGEND:

START/ STOP

PROCESS STEP

DECISION

DOCUMENT

DATABASE  
UPDATED

PREPARATION



## 5.9 Client Business Continuity and Disaster Recovery

- In the event, a client is experiencing natural disaster or other situation affecting business continuity, Kalos evaluates what activities can be conducted safely to ensure the continuity of service and certification.
- Evaluation may occur via email or phone call with the objective of evaluating the following topics:
  - When will the facility/organization be able to function?
  - When will the facility/organization be able to ship products or perform the service defined within the current scope of certification?
  - Will the facility/organization need to use alternative manufacturing and/or distribution sites? If so, are these currently covered under the current certification, or will they need to be evaluated?
  - Does existing inventory still meet customer specifications or will clients need to be contacted regarding possible concessions?
  - If the client is certified to a management system standard that requires a disaster recovery plan or emergency response plan, has the client implemented the plan and was it effective?
  - Will some of the processes and/or services performed or products shipped be subcontracted to other organizations? If so, how will the other organizations' activities be controlled by the certified organization?
  - To what extent has operation of the management system been affected?
- Once an action plan is determined, the appropriate planning documentation is updated and the audit activities are scheduled.

LEGEND:

START/ STOP

PROCESS STEP

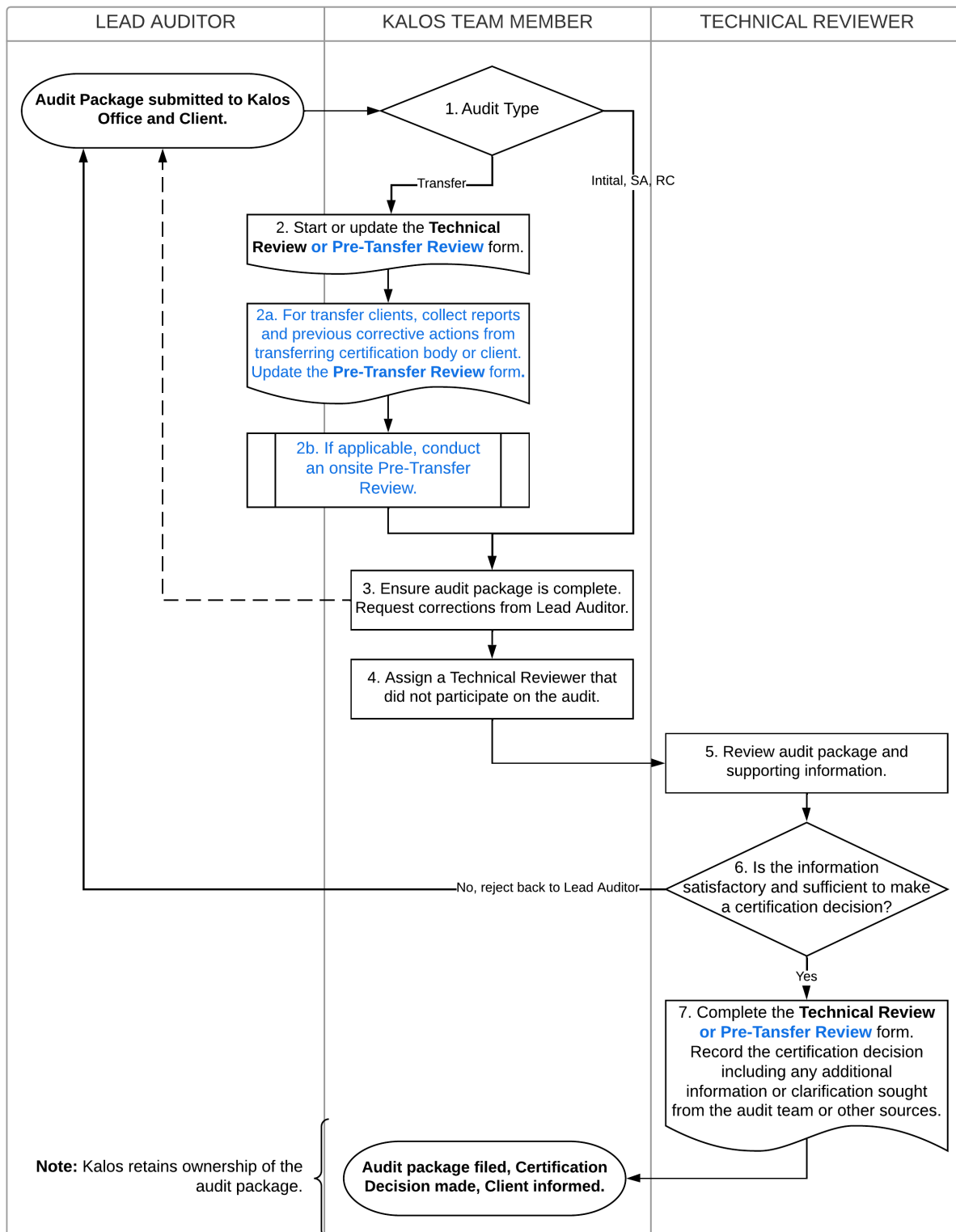
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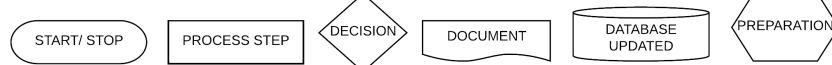
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PREPARATION

## 6. Certification Decisions



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### 6.1 Granting Certification

- Granting initial certification is based on a review of the audit report including lead auditor's recommendations, confirmation of the information on the application, confirmation of the audit objectives being achieved, and closure of corrective action requests.

### 6.2 Refusing

- Threats to impartiality, lack of Kalos team competencies, or other risk factors will result in a refusal of certification. This will be indicated at the client application process.

### 6.3 Maintaining

- Client must have a surveillance audit and demonstrate their continued commitment to the management system to maintain certification.
- Kalos performs technical reviews on surveillance audit.

### 6.4 Renewing Certification

- Kalos makes decisions on renewing certification based on the results of the recertification audit and the **Recertification Review** activity.
- When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the recertification decision.
- ***No certificate may be issued until all major and minor NCRs have been contained and satisfactorily corrected with root cause analysis, and corrective action is implemented, reviewed, accepted, and verified.***

### 6.5 Suspending Certification

- Kalos shall suspend certification in cases when, for example:
  - The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.
  - The certified client does not allow surveillance or recertification audits to be conducted at the required frequencies.
  - The client fails to implement corrective actions issued from a recertification audit prior to the expiration date of the certificate.
  - The certified client has voluntarily requested a suspension.
  - The client fails to pay for services according to terms of contract.
  - The client intentionally misrepresents their certification.
  - ***The client fails to re-establish conformance within 90 days from the date the nonconformance was issued; or***
  - ***An ethical complaint (e.g., code of conduct) or ethical related nonconformity has been substantiated with supporting objective evidence.***
- Under suspension, the client's management system certification is temporarily invalid.
- Kalos will restore the suspended certification if the issue that has resulted in the suspension has been resolved.
- Failure to resolve the issues that have resulted in the suspension in a time established by the Kalos shall result in withdrawal or reduction of the scope of certification.
- In most cases, the suspension would not exceed 6 months.
- When certification is restored, the expiry date of the new certification will be based on the expiry date of the previous certification. The issue date on a new certificate shall be on or after the recertification decision.
- ***When a client's AQMS certificate is suspended, the OASIS database shall be updated within 14 days.***

LEGEND:

START/ STOP

PROCESS STEP

DECISION

DOCUMENT

DATABASE  
UPDATED

PREPARATION

## 6.6 Withdrawing Certification

- If the client fails to meet the requirements of re-instatement of certification, Kalos will withdraw the certification and request all certificates be removed from use or destroyed.
- ***When a client's AQMS certificate is withdrawn, the OASIS database shall be updated within 14 days.***

## 6.7 Reducing the Scope of Certification

- Due to process-based standards being used, Kalos reduction to the scope of certification is limited to reducing the sites within the scope or changing of non-applicable requirements. If during the certification cycle some standard requirement become non-applicable, a special audit may be performed to verify the effectiveness of the change to the management system (e.g. design of products).
- Failure to meet requirements of the standard will result in nonconformities being issued and addressed during audits.

## 7. Observers, Technical Experts, & Guides

### 7.1 Observers

- The presence and justification of observers during an audit activity is agreed to by Kalos and the client prior to the start of the audit.
- The audit team ensures that observers do not unduly influence or interfere in the audit process or outcome of the audit.

**NOTE:** Observers can be members of the client's organization, consultants, witnessing accreditation body personnel, regulators or other justified persons.

### 7.2 Guides

- Each auditor shall be accompanied by a guide, unless otherwise agreed to by the audit team leader and the client.
- Guide(s) are assigned to the audit team to facilitate the audit.
- The audit team shall ensure that guides do not influence or interfere in the audit process or outcome of the audit.

LEGEND:

START/ STOP

PROCESS STEP

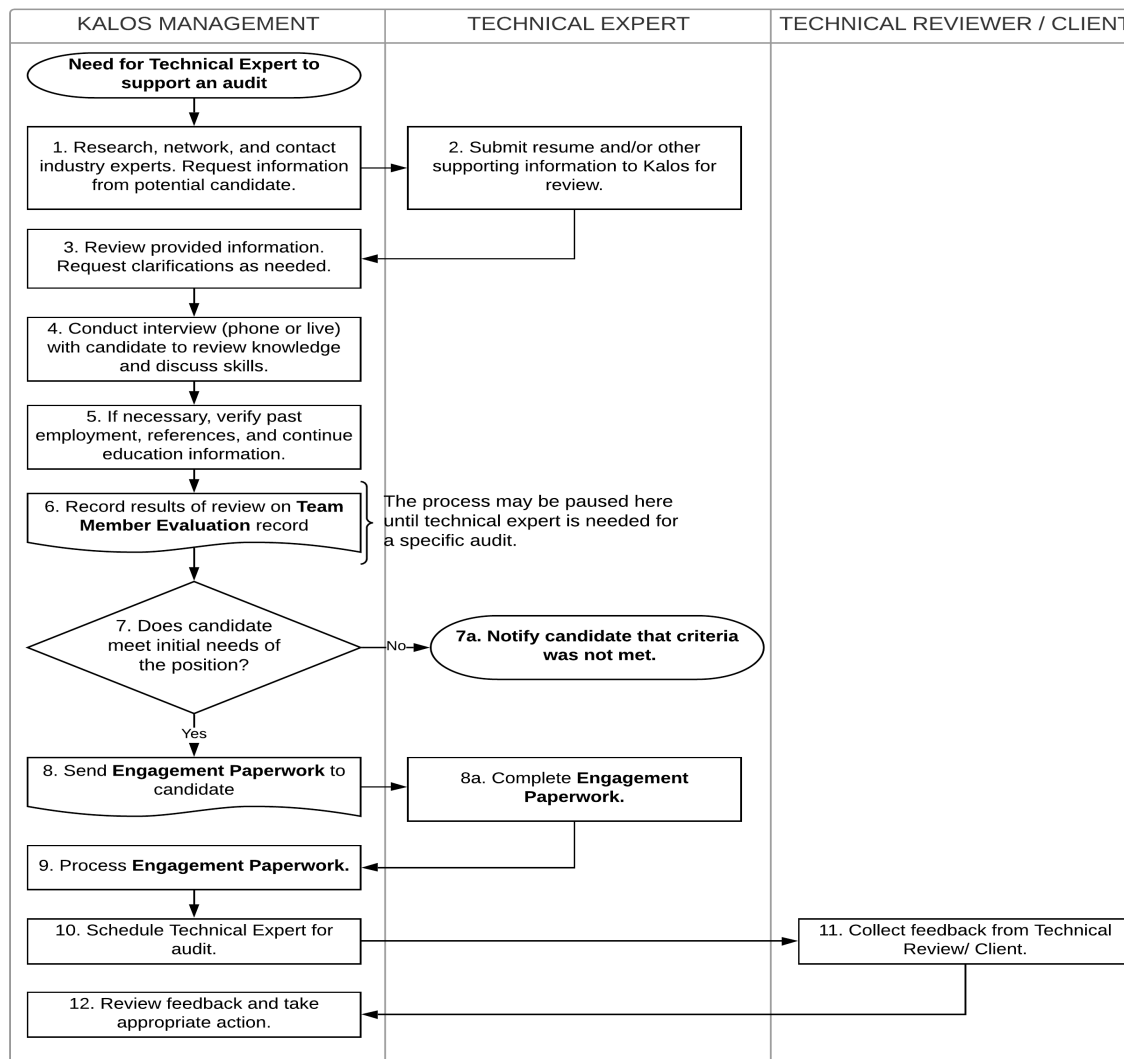
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DOCUMENT

DATABASE  
UPDATED

PREPARATION

### 7.3 Technical Experts

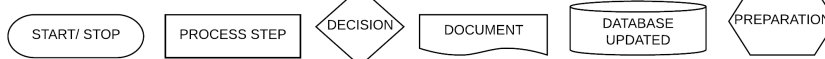


- The role of technical experts during an audit activity is agreed to by Kalos Certifications and the client prior to the start of the audit.
- A technical expert shall not act as an auditor in the audit team.
- The technical experts shall be accompanied by an auditor.

**NOTE:** The technical experts can provide advice to the audit team for the preparation, planning or audit.

**NOTE:** *If Kalos uses a subject matter or technical expert, the competency records include details of how the expert is selected and how their technical knowledge is assured on a continuing basis.*

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#### 7.4 ANAB Witness Audits

- Kalos Office along with ANAB Assessor select the witness audits.
  - Create a Kalos Folder here: Kalos Operations - Documents/06 Operations Records/External Audit
- ANAB sends the **FM 5310, Witness Assessment Criteria Form (WACF)** to the Kalos six months prior to the proposed start month of the witness assessment (as indicated on the form).
- The Accreditation Manager shall complete the **FM 5310, Witness Assessment Criteria Form (WACF)** with the necessary detail needed to confirm the audit with ANAB and return it to the ANAB coordinator at least 120 days prior to the month in which the audit is scheduled to start.
- Once the audit is loaded to EQM (<https://anab.jadian.com>), collect and submit the Pre-Audit information >30 days prior to the start of the audit.
  - Completed Client Profile, FM 5301
  - Client Records, including:
    - current certification documents (certificate)
    - audit report/s from the past year
    - audit program
    - document review, if applicable
  - Audit Information, including:
    - Audit Plan
    - Audit Day Calculation and Justification.
  - Uncontrolled copy of procedures for conducting this type of audit
  - Evidence of audit team's competence
  - Evidence of formal auditor credentials (e.g. auditor certification) if applicable
- Respond to RFI's and NCR's per **KP-01 Operations Manual Part B**.
- Submit the Kalos Audit Report package to EQM <30 days after the close of the audit.

#### 7.5 IAQG Witness Audits

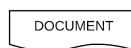
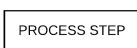
- Kalos receives an OASIS Feedback Ticket.
  - Accreditation Manager responds via Feedback Ticket and email to the assessor.
  - Provide a list of eligible audits and target dates.
- Kalos Office along with IAQG Assessor select the witness audits.
  - Create a Kalos Folder here: Kalos Operations - Documents/06 Operations Records/External Audit
- Accreditation Manager responds to email requests from IAQG Assessors.
- Respond to RFI's and NCR's per **KP-01 Operations Manual Part B**.

### 8. Head's Up Notices

**8.1** Periodically Kalos uses **Head's Up Notices** to communicate changes to our requirements for certification.

**8.2** Through other defined means or at the next regularly scheduled audit Kalos will verify that each certified client complies with the new requirements.

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## 9. Use of Information and Communication Technology (ICT)

- 9.1 Significant risks and opportunities associated with the use of ICT during the audit process are captured on the **FM-01-06 Operations Log- Risk tab** and in the tables of **WI-01-04 Remote Auditing**.
- 9.2 When clients indicate they would be interested using ICT on the **application, Client Information Update** form, or **other method**, Kalos will review that client and Kalos have the infrastructure to support the objective.
- 9.3 Utilization and Extent
- Conference calls or web meetings may be used by auditors during audits to verify the activities of off-site or traveling employees.
  - If the review of the client application indicates Stage 1 audit objectives can be met utilizing remote auditing – **combined**, the **NOA, audit plan** and **report** will indicate the extent to which ICT has been used.
- 9.4 The **Competency Matrix** will indicate if auditors are deemed competent to utilize ICT to achieve audit objectives.
- 9.5 If virtual sites are included within the scope, the certification documentation shall note that virtual sites are included, and the activities performed at the virtual sites shall be identified.

LEGEND:

START/ STOP

PROCESS STEP

DECISION

DOCUMENT

DATABASE  
UPDATED

PREPARATION

Revision History	Approved By	Date
<i>Revised due to form name change.</i> Section 1 – Application Review – updated flow chart to say “quote” instead of “program”	Michaela Scarla	8/14/2019
<i>Revised per ANAB and 2020 internal audit recommendations.</i> <ul style="list-style-type: none"> <li>Section 1 – added “Note: reference MD 2 for more information on transfer eligibility” to process map.</li> <li>Section 2 – updated process map based on current Log names and Action Log KA-2020-52.</li> </ul>	Michaela Scarla	3/10/2020
<i>Revised per AS9104 implementation</i> <ul style="list-style-type: none"> <li>Changed title</li> <li>Added <b>bold, italics</b> for AS9101/ AS9104 gaps</li> <li>Minor corrections to spelling, grammar, numbering of process maps.</li> </ul>	Michaela Scarla	9/9/2020
<i>Revised per ANAB Document Review and Board Review</i>	Michaela Scarla	10/8/2020
<i>Revised per 2021 Kalos Internal Audit:</i> <ul style="list-style-type: none"> <li>Section 1.2 added “Information that was clarified/corrected from the client application is updated in the client quote. Application is not adjusted.” KA-2021-69.</li> <li>Process Map 3 Step 3 updated “3. Document any justifications for changing the audit duration on the Quote Tab (Time Adjustment Notes).”</li> </ul>	Michaela Scarla	3/26/2021
<i>Multi Site Forms - FM-02-09 Multi-Site Calculation references added</i>	Michaela Scarla	12/26/21
<i>Revised per 2022 Internal Audit:</i> <ul style="list-style-type: none"> <li>Revised Section 1 and 3 Process Map per KA-2022-112 and KA-2022-103.</li> <li>Revised Section 6 Process Map per KA-2022-111</li> </ul>	Michaela Scarla	3/28/2022
<i>Updated per AS9104/1:2022 Transition:</i> <ul style="list-style-type: none"> <li>Revised section 1.1 for 8.5.1.3</li> <li>Revised Process Map 1 Step 3 for 8.5.1.4</li> <li>Revised section 5.5 for 8.5.10</li> <li>Revised section 5.7 for 8.5.9</li> <li>Revised section 5.8 for 8.5.2</li> <li>Revised section 6 for AS9104/1 8.5.11</li> </ul>	Michaela Scarla	10/3/2022
<i>Updated per AS9104/1:2022 Transition Feedback Round 1:</i> <ul style="list-style-type: none"> <li>Site sampling AS9100 changed to AS91XX.</li> <li>Update process map 2</li> </ul>	Michaela Scarla	11/15/2022
<i>Updated per Kalos 2025 Internal Audit:</i> <ul style="list-style-type: none"> <li>Added “Note: NCR verification time may be conducted outside of the normal 8-hour work day, if feasible for client.”</li> <li>Added Section 5.9 Client Business Continuity and Disaster Recovery</li> <li>Added Section 7.4 External Witness Audits</li> <li>Added Section 7.5 IAGQ Witness Audits</li> <li>Minor updates to Section 10. Use of Information and Communication Technology (ICT)</li> </ul> <p><b>9.6</b> Significant risks and opportunities associated with the use of ICT during the audit process are captured on the <b>FM-01-06 Operations Log- Risk tab and in the tables of WI-01-04 Remote Auditing.</b></p> <p><b>9.7</b> When clients indicate they would be interested using ICT on the <b>application, Client Information Update</b> form, <b>or other method</b>, Kalos will review that client and Kalos have the infrastructure to support the objective.</p> <p><b>9.8</b> Utilization and Extent</p> <ul style="list-style-type: none"> <li>If the review of the client application indicates Stage 1 audit objectives can be met utilizing remote auditing – <b>combined</b>, the <b>NOA, audit plan and report</b> will indicate the extent to which ICT has been used.</li> </ul>	Michaela Scarla	3/24/2025

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