



# KALOS

## CERTIFICATIONS

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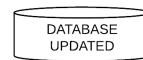
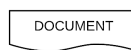
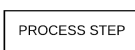
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Kalos Procedure-03  
**Planning & Conducting ISO 9001 Audits**

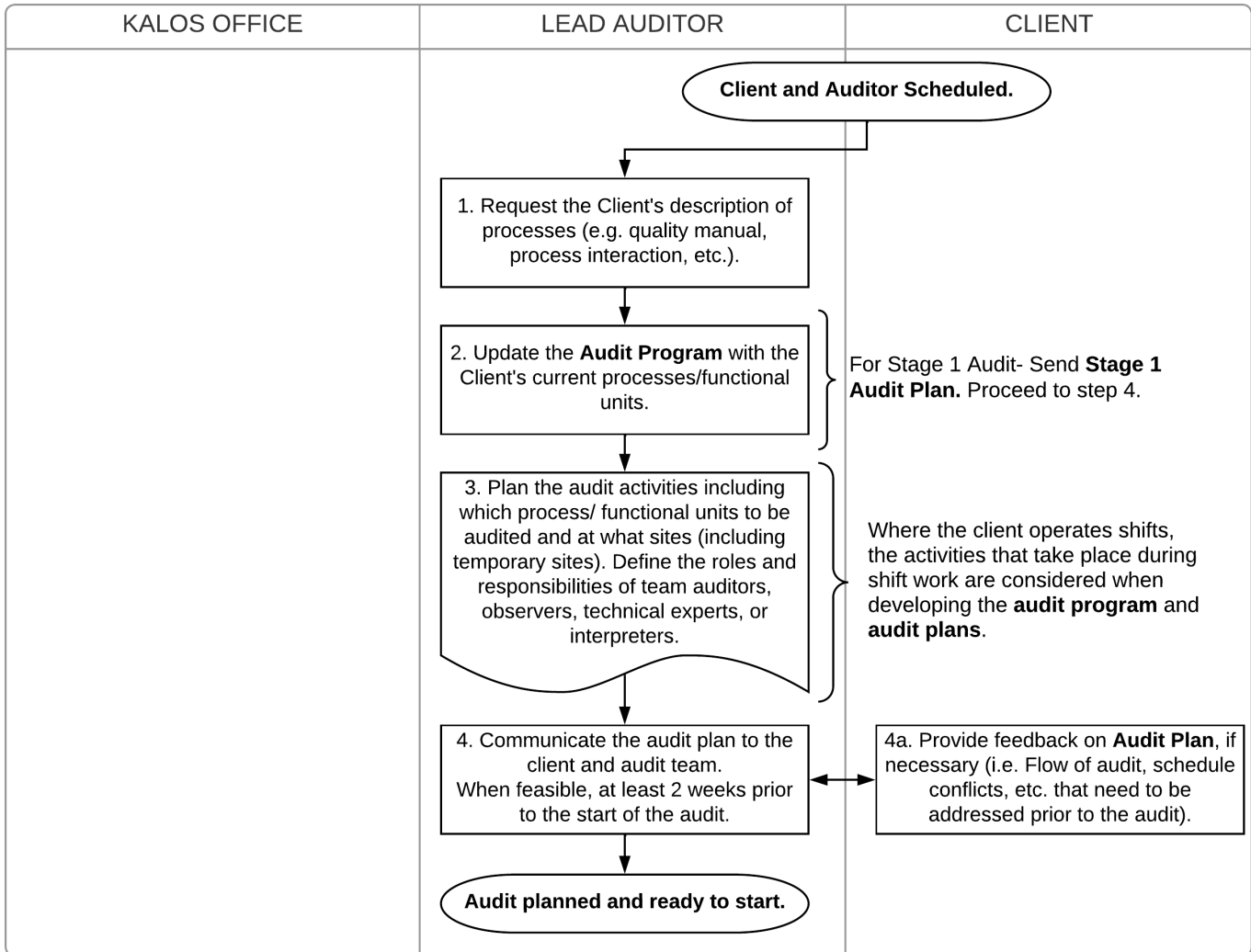
## Table of Contents

1. Audit Program & Planning.....	3
2. Conducting the Audit .....	4
3. Appeals.....	6

**LEGEND:**



**1. Audit Program & Planning**



1.1 [Intentionally Blank]

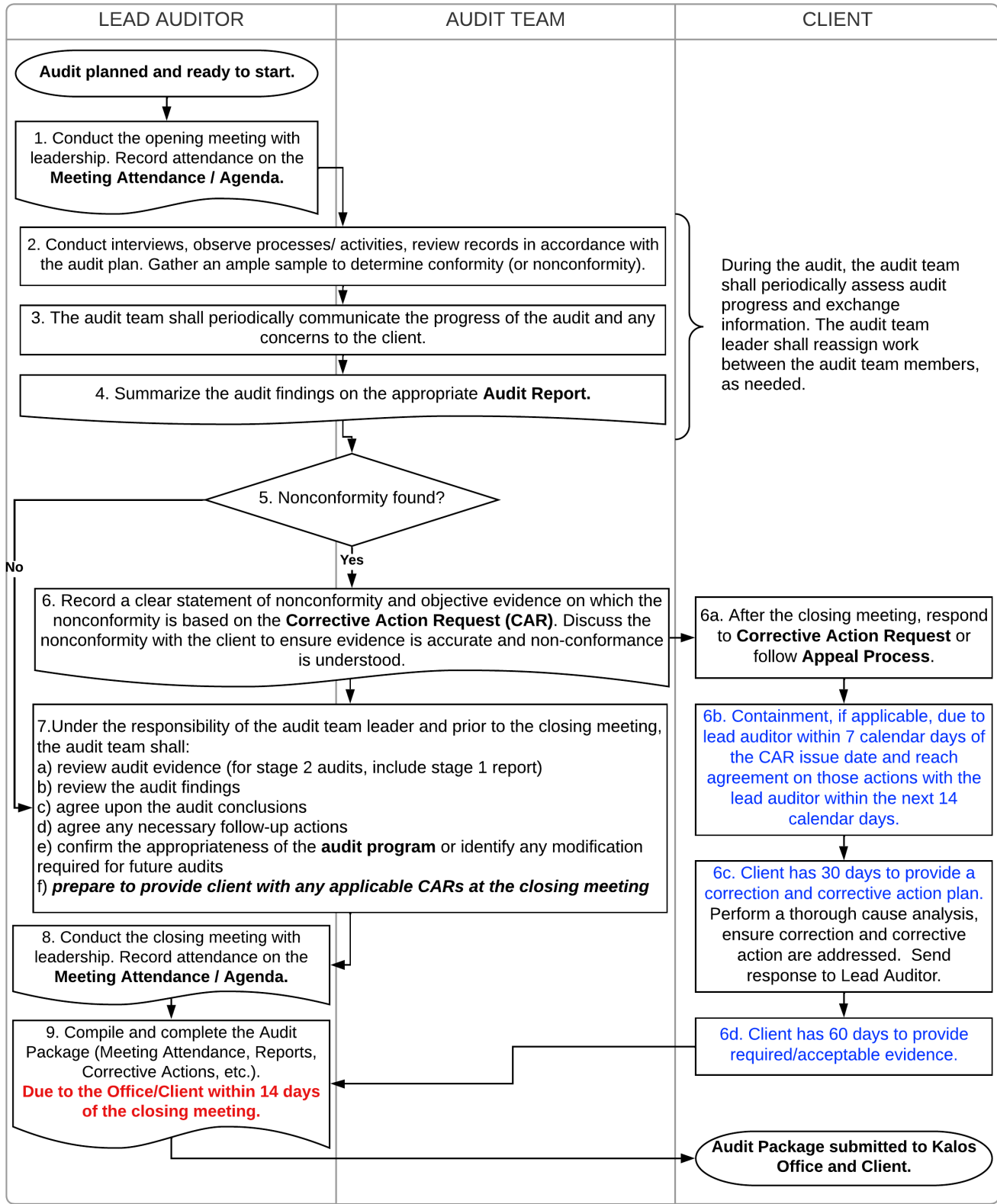
1.2 [Intentionally Blank]

**1.3 Shift Auditing**

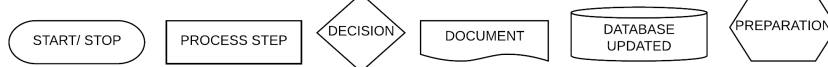
- For processes that occur on more than one shift, all shifts (including weekend shifts) shall be audited during the normal hours of work for the shift.
- The audit team shall audit the process activity, including interviews of personnel and observation of process activity and controls during the normal working hours of the shift.
- Auditing limited to only a review of a shift's outputs (e.g., documented information, product, etc.) is not considered to be adequate.
- Shift auditing, whereby a longer day is planned, cannot reduce required audit duration.



## 2. Conducting the Audit



LEGEND:



**2.1** 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.)

**2.2** 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

**2.3** [Intentionally Blank]

**2.4** [Intentionally Blank]

**2.5** [Intentionally Blank]

**2.6** Nonconformity Management

- Containment, if applicable, due to lead auditor within 7 calendar days of the CAR issue date and reach agreement on those actions with the lead auditor within the next 14 calendar days.
- Client has 30 days to provide a correction and corrective action plan.
- Client has 60 days to provide required/acceptable evidence.
- The Lead Auditor will reply with feedback/ status within 7 calendar days of Client submission.
- All audits require evidence of correction to be submitted.
- Initial/ Recertification audits require evidence of corrective action to be submitted.
- Failing to provide acceptable plans and evidence by the defined due dates, may result in the suspension process being initiated.

**2.7** [Intentionally Blank]

**2.8** [Intentionally Blank]

**2.9** Table: Report Package

The following table explains the documents required for each type of audit conducted.	Stage 1	Stage 2	Surveillance	Recertification	Transfer	Corrective Action Revisit	Special
<b>Legend</b> Required If Applicable Optional Not Required							
FM-02-02 ISO 9001 Client Information Update Request			X	X			
FM 03-00 B Notification of Audit (NOA), Audit Calculation, Risk, and Recertification Review (RR section completed for RC audits only)	X	X	X	X	X	X	X
FM-03-02 Stage 1 Audit Planning Package	X						
FM-03-03 Stage 1 Audit Report	X			X			
FM-03-18 ISO Audit Planning Package (Use FM-03-18M for Multisite Clients)		X	X	X	X	X <sub>1</sub>	X
FM-03-05 Audit Report (Due to client and Kalos 14 days after the closing meeting)		X	X	X			X
FM-03-17M Multi Site Process Audit Questionnaire (Use for Multisite Clients w/ Sampling)		X	X	X			
FM-03-07 Corrective Action Request (majors and minors) (Use FM-03-07M for Multisite Clients)		X	X	X	X		X
FM-03-08 Corrective Action Revisit Report						X	
FM-03-10 Pre-Transfer Planning Package					X		
FM-03-11 Pre-Transfer Review					X		
Process Audit Questionnaires		X	X	X			X

1. CAR Revisit Plan can be added to the original audit plan or attached as a separate audit plan.



