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Kalos Procedure-01

**Operations Manual: Part B** 



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LEGEND:





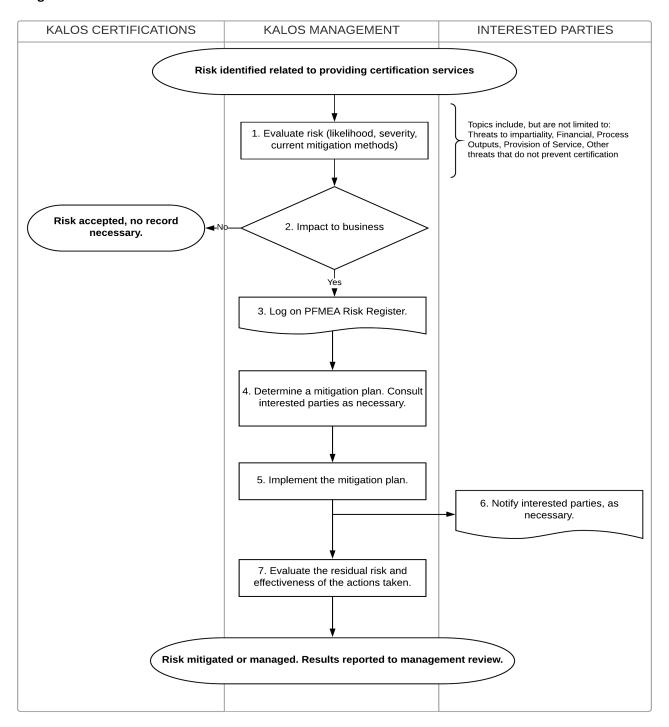








## 1. Risk Management

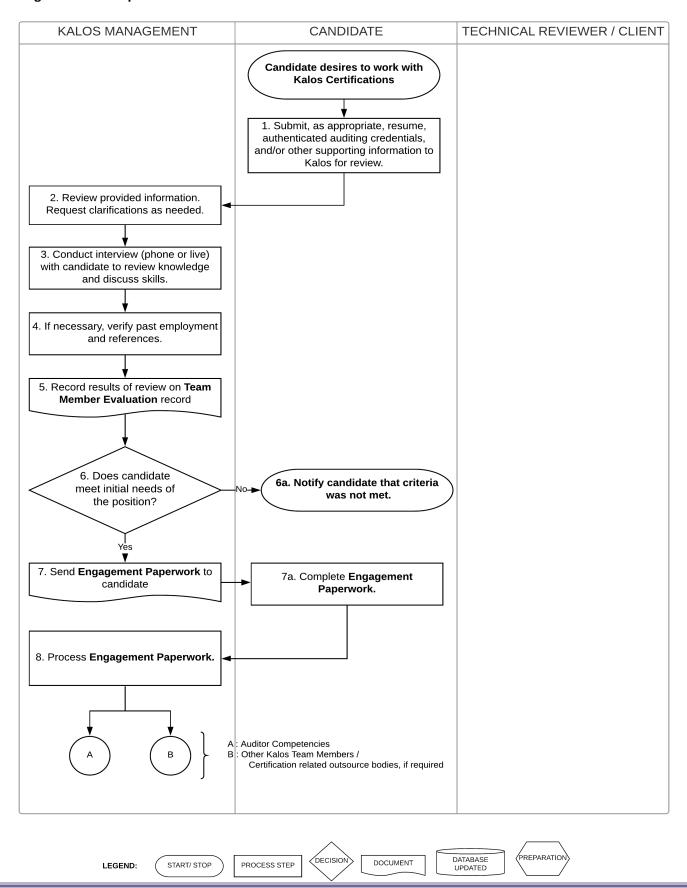


- **1.1** Kalos' management maintains an PFMEA style risk register (FM-01-06 Risk Management) to retain information about operational risks related to providing certification services. This documents the risk, related process/activity, mitigation actions, and risk priority number.
- 1.2 Risks are added and evaluated as they are identified and the risk register is reviewed, at a minimum, for effectiveness during Management Review (FM-01-09 Management Review Meeting Minutes).
- 1.3 When a relationship poses an unacceptable threat to impartiality or risk, then certification shall not be provided.

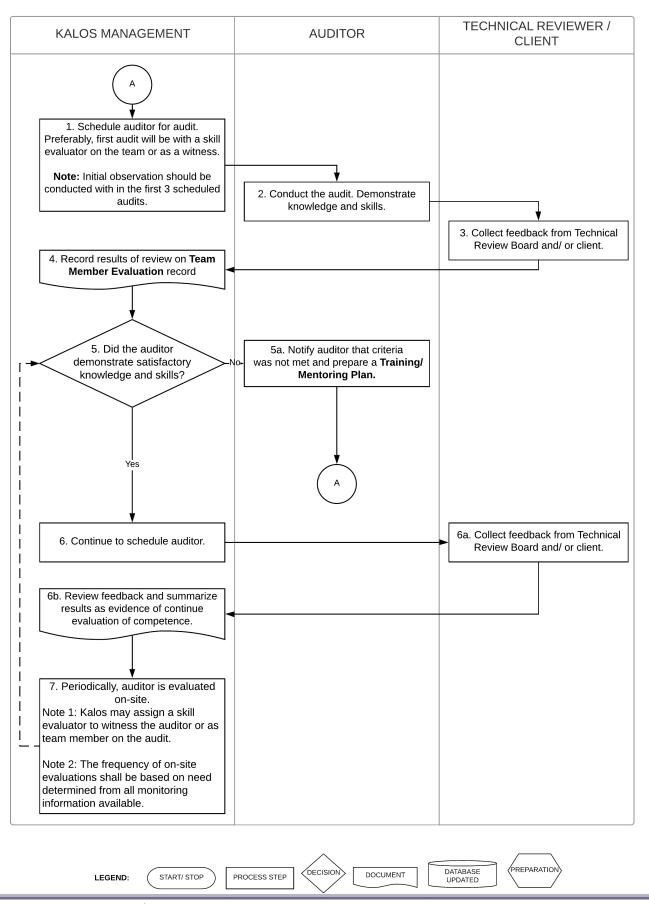




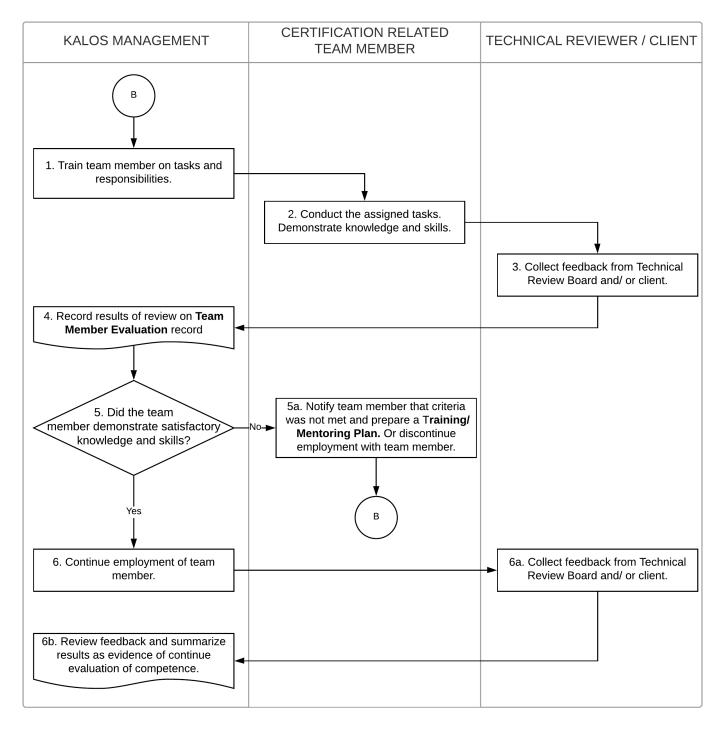
## 2. Management of Competencies







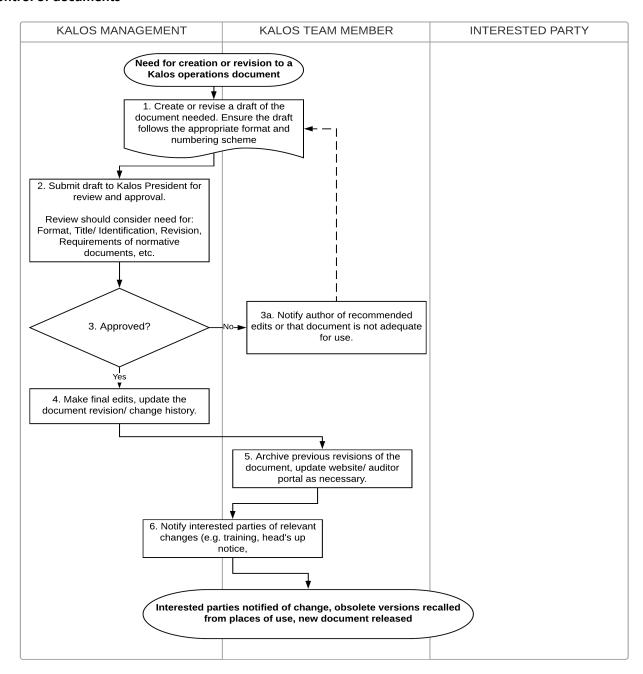




- **2.1** Criteria for competence are documented on the FM-01-03 Competency Matrix.
- **2.2** At least annually, auditors and office team member feedback are summarized in to a performance review.
- 2.3 As appropriate, Kalos shares auditor performance information with the responsible auditor authentication body (AAB) when there are issues with competency or witness assessments.
- 2.4 Kalos uses AQMS auditors listed in OASIS who are both competent and authenticated in accordance with requirements for AS9100 audits.



#### 3. Control of documents



- **3.1** Where feasible, process maps with swim lanes are used to communicate process inputs, activities, and expected outputs. In addition to legends included at the bottom of the page, Figure 2 shows a guide for reading the process maps.
- **3.2** Documents considered "logs" are working documents and may have their content updated continually. If the structure of the log needs to change, the document approval flow will be followed.
- 3.3 Documents of external original needed for operations at Kalos are identified and their distribution is controlled.
- 3.4 The ICOP resolutions logs and associated documents are obtained, reviewed and changes implemented. Heads Up notices may be used to communicate the changes to certified clients.
- 3.5 Master copies of documents are maintained electronically.





Figure 1: Document Levels

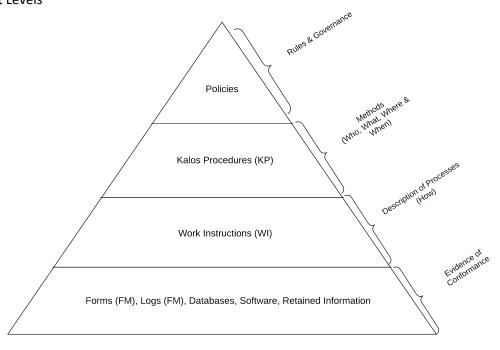
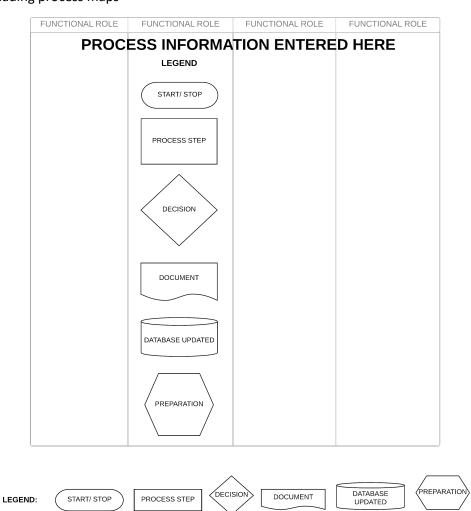


Figure 2: Guide for reading process maps







#### 4. Control of Records<sub>1</sub>

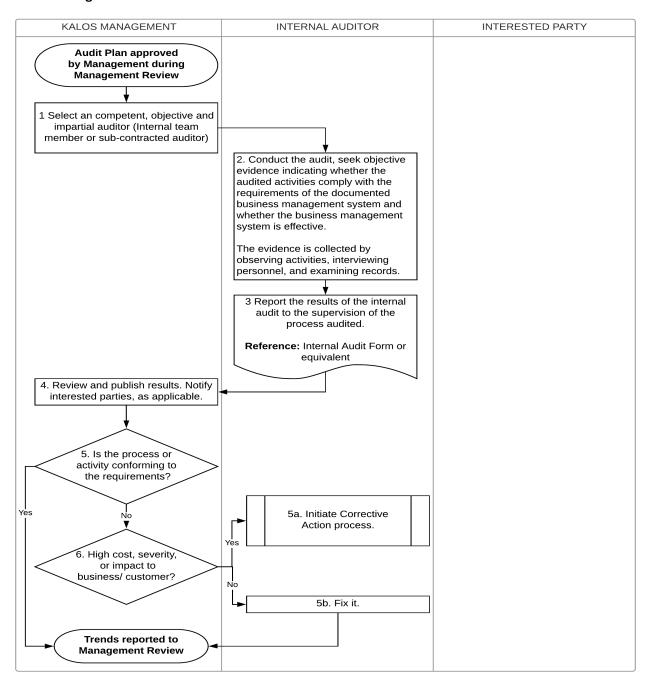
- **4.1** Kalos uses an ISO 27001 certified cloud server provider with HIPPA compliance. Our records are backed up daily.
- **4.2** In the event physical records are retained, locked filing cabinets are used.
- **4.3** In the event of a crash or accidental deletion of a record, Kalos President is able to retrieve up to 30 days of history.
- **4.4** Kalos President administratively assigns access to records and ability to delete records based on functional role in the organization. This access is periodically audited and revised, as needed.
- **4.5** Records are retained in accordance with the following table unless otherwise stated in regulatory or contractual obligations.

Record Type	Retention <sub>2</sub>	Disposal Method
Client Record	6 years after end of contract	Delete or Shred
Financial Record	7 years	Delete or Shred
Operations Record	6 years	Delete or Shred
Personnel Record	6 years after end of contract	Delete or Shred

**NOTE** 1: Control of Documents and Records may also be referred to as Control of Documented Information **NOTE** 2: Retention indicated is a minimum. Electronic records may be saved longer be virtue of process.



## 5. Internal Auditing



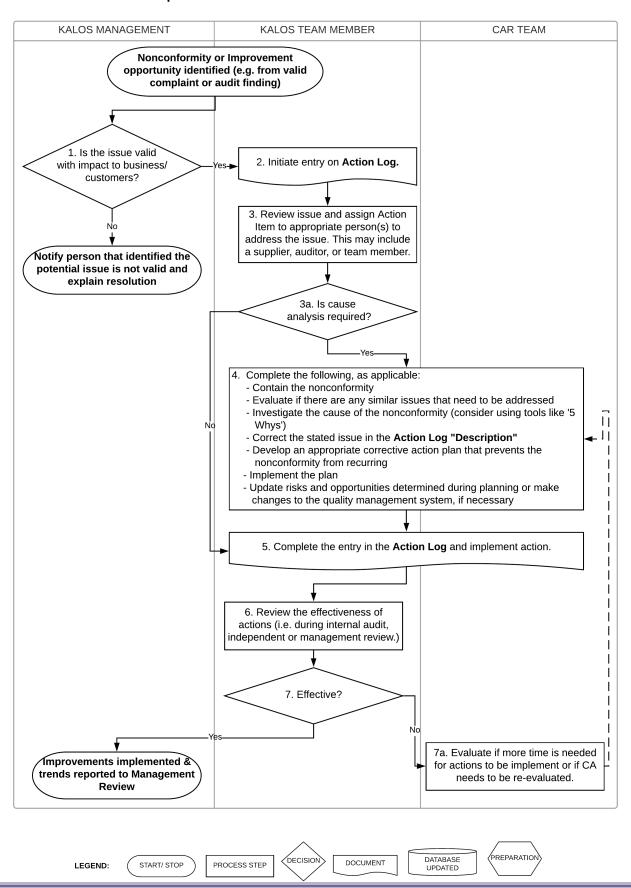
### **5.1** Kalos ensures that:

- if Kalos chooses an internal auditor outside the contracted auditor pool, formal engagement paperwork is not required.
- internal audits are conducted by competent personnel knowledgeable in certification and auditing;
- auditors do not audit their own work;
- personnel responsible for the area audited are informed of the outcome of the audit;
- any actions resulting from internal audits are taken in a timely and appropriate manner;
- any opportunities for improvement are identified.



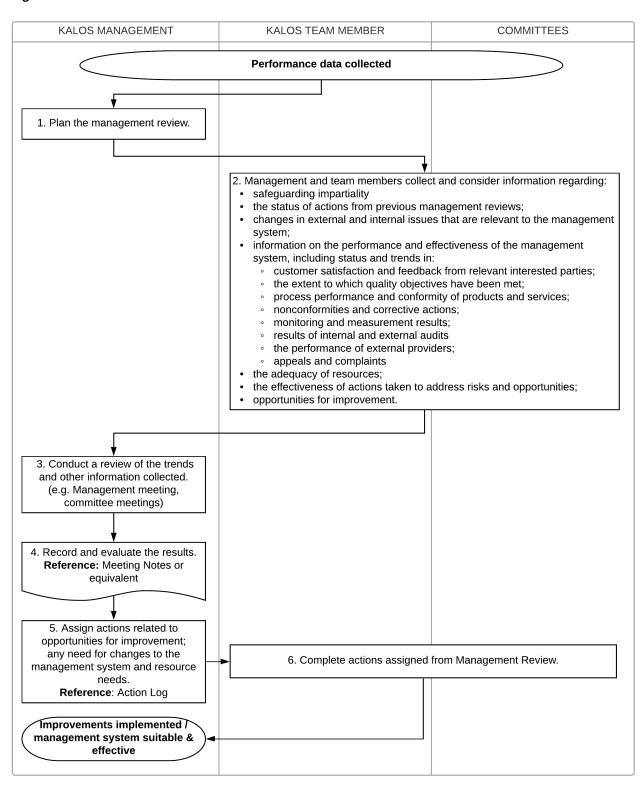


## 6. Internal Corrective Actions & Improvements





## 7. Management Review



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Revision History  DRAFT		Date	
		12/22/2018	
RELEASE	Michaela Scarla	1/19/2019	
Revised per ANAB Document Review comments listed in FA-5000 and CL-5313.  Section 1.2 –  Maintaining this scope of service prohibits the following: Providing management consultancy to our certified clients.  Section 3.2 -  Added "Kalos provides awareness training and requires all certification personnel to disclose conflicts of interest and act impartially."  Added "Where a client has received management systems consultancy from a body that has a relationship with Kalos Certifications, then Kalos shall not certify the management systems for a minimum of two years following the end of the consultancy."  Revised to "Kalos Schedulers are aware of the threats to impartiality and assign auditors, other accompanying persons, and technical reviewers appropriately."  Revised to "Kalos FM-01-04 Auditor Engagement Agreement, FM-01-15 Board Member Engagement Agreement, and FM-01-16 Observer Agreement includes impartiality and conflict of interest clauses."  Section 4.2 -  Their key responsibility is to review the audit package, ensure reports comply to applicable requirements including Kalos Procedures, ISO 17021-1, Mandatory Documents, ANAB accreditation rules. Based on the review TRB makes a certification recommendation.  Kalos President assigns competent team members that employed or under contract with Kalos (auditor or board member) to the Technical Review Board.  Rules for Assignment:  Must have lead auditing experience.  Must understand standard and certification requirements and have demonstrated competence to evaluate the outcomes of audit processes.  Must not make decisions for client where the Technical Reviewer was a participant of the audit or provided management consultancy with in the past two years.  Section 9-  Process Map A revised to include step 7 "Periodically, auditor is evaluated on-site. Note 1: Kalos may assign a skill evaluator to witness the auditor or as team member on the audit. Note 2: The frequency of on-site evaluations shall be based on need determined from all monitoring information avail	Michaela Scarla  Michaela Scarla	3/2/2019	
	Michaela Scarla	5/3/2019	
Revised per internal audit findings listed in Action Log.  Section 1 – Risk Management  Added "Other threats that do not prevent certification" to the process map notes.  Section 2 – Management of Competency  Clarified "A" and "B" on first process map.  Section 5 – Internal Audit  Added "If Kalos chooses an internal auditor outside the contracted auditor pool, formal engagement paperwork is not required."  Section 6 – Improvement & CA  Update flowchart "Nonconformity or Improvement opportunity identified (e.g. from valid complaint or audit finding)"  Update flowchart "3. Review issue and assign Action Item to appropriate person(s) to address the issue. This may include a supplier, auditor, or team member." (removed "client")  Section 7 – Management Review  Removed "annually"	Michaela Scarla	7/15/2019	
Revised per 2019 ANAB Audit and 2020 Internal Audit Section 2 – Updated process map (Action Log KA-2020-51) Section 4 – Added "NOTE 2: Retention indicated is a minimum. Electronic records may be saved longer be virtue of process." (Action Log # KA-2019-33)	Michaela Scarla	3/10/2020	
Revised per AS9104 and AS9101 requirements.  o Added bold, italics for AS9101/ AS9104 gaps  Minor corrections to spelling, grammar, numbering of process maps.	Michaela Scarla	9/14/2020	
Revised per ANAB Document Review and Board Review	Michaela Scarla	11/10/2020	
Revised per ANAB Office Audit OFI's:	Michaela Scarla	3/30/2021	
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LEGEND: START/STOP PROCESS STEP DECISION DOCUMENT DATABASE UPDATED PREPARATION