



# KALOS

## CERTIFICATIONS

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### Kalos Procedure-01

## Operations Manual: Part A

Maintained in accordance with ISO 17021, **AS9101**, **AS9104**, and supporting IAF Mandatory Documents

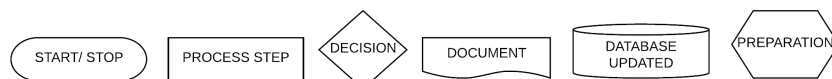
*Items formatted in bold, italics are Aerospace specific requirements.*

Items highlighted blue are Medical specific requirements.

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## 1. Scope of Kalos Certifications LLC

- 1.1 Kalos Certifications LLC ("Kalos") is a member managed limited liability corporation established in the State of Arizona.
- 1.2 We provide the following services:
- Accredited ISO 9001/ AS9100 /AS9120 certification services
  - [Unaccredited 13100 Gap Assessments](#)
  - [Pending - ISO 13485 Medical Accreditation](#)
- 1.3 Maintaining this scope of service prohibits the following:
- Certifying another certification body's management system.
  - Providing management consultancy.
  - Providing internal auditing services to our certified clients.
  - Outsourcing audits to a management system consultancy organization.
  - Marketing our services as linked to a management system consultancy organization.
- 1.4 At this time, Kalos does not have branch offices, agents, or franchises. Operational control and authorities are managed at the central site 22601 N. 17<sup>th</sup> Ave. Suite 120 Phoenix AZ, 85027.

## 2. Quality Policy

- 2.1 Kalos Certifications LLC is committed to providing objective and impartial certification services to our clients. We use management of competencies, risk analysis, and key performance indicators to evaluate and continually improve our operations while complying with internal, standard, and regulatory requirements.

## 3. Impartiality & Conflict of Interest Policy

- 3.1 Kalos and its management is committed to the principles of impartiality embodied within the ISO 17021-1 standard and supporting IAF Mandatory Documents. Kalos manages conflicts of interest related to providing certification services through risk analysis and the maintenance of our processes.
- 3.2 Key practices include, but are not limited to:
- Kalos provides awareness training and requires all certification personnel to disclose conflicts of interest and act impartially.
  - Kalos does not allow commercial, financial or other pressures to influence impartiality.
  - Kalos **FM-01-04 Auditor Engagement Agreement, FM-01-15 Board Member Engagement Agreement, FM-01-16 Observer Agreement, or similar document** includes impartiality and conflict of interest clauses.
  - Kalos **Notification of Audit** includes an impartiality and conflict of interest clause that is communicated prior to each audit.
  - Kalos Schedulers are aware of the threats to impartiality and assign auditors, other accompanying persons, and technical reviewers appropriately.
  - 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 system for a minimum of two years following the end of the consultancy.
  - Kalos auditors that have provided management consultancy to a client shall not audit the client for a minimum of 2 years after the service is provided.
  - Kalos clients have a right to refuse an auditor based on conflict of interest.

## 4. Responsibilities

- 4.1 Kalos retains authority for decisions relating to certification, including granting, refusing, maintaining, expanding or reducing the scope of, renewing, suspending, restoring following suspension, or withdrawing of certification.
- 4.2 Technical Review Board (TRB)
- Their key responsibility is to review the audit package, ensure reports comply with applicable requirements including Kalos Procedures, ISO 17021-1, **AS9101, AS9104**, Mandatory Documents, and ANAB accreditation rules. Based on the review TRB makes a certification recommendation.
  - Based on TRB recommendation, [the Accreditation Manager or designee](#) makes final certification decision.

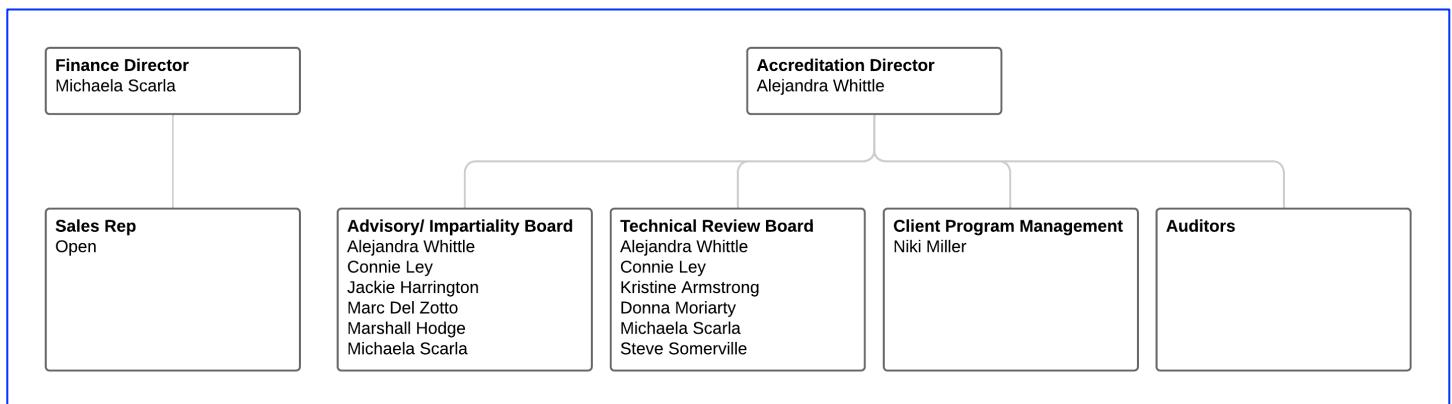
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- Kalos **Finance Officer** assigns competent team members that are employed or under contract with Kalos to the Technical Review Board.
- **While the lead auditor is responsible for accurate data entry, TRB will verify audit data entered in OASIS database.**
- Rules for Assignment:
  - Must understand standard and certification requirements and have demonstrated competence to evaluate the outcomes of audit processes.
  - Must be knowledgeable of Kalos Procedures, ISO 17021-1, Mandatory Documents, ANAB accreditation rules.
  - 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.

#### 4.3 Advisory/ Impartiality Board

- The board's key responsibility is to advise Kalos Management on any threats to impartiality or conflict of interest that pose a risk to the certification program. Should Kalos Management or the AIB identify any threat to impartiality, Kalos will take appropriate action to eliminate and mitigate the threat.
- Kalos **Owners** request participation on the Advisory/ Impartiality Board.
- Rules for participation are outlined in **WI-01-01 Advisory/ Impartiality Board Charter**.



## 5. Confidentiality Practices

- 5.1 Confidentiality plays a key role in building a business partnership with our clients. Often audits gain privileged access to information needed determine conformity of the client's management system.
- 5.2 Key practices include, but are not limited to:
  - Educating Kalos personnel and auditors on the importance of confidentiality.
  - Including confidentiality clauses in our legally enforceable **FM-01-04 Auditor Engagement Agreement, FM-01-15 Board Member Engagement Agreement, FM-01-16 Observer Agreement, or similar document.**
  - Assigning access to Kalos electronic information based on functional role and taking appropriate action when roles change.

## 6. Outsourcing

- 6.1 Kalos does not outsource certification services to other certification bodies or organizations.
- 6.2 Kalos does not outsource decisions for granting, refusing, maintaining, expanding or reducing the scope of, renewing, suspending or restoring, or withdrawing of certification.
- 6.3 Kalos maintains legally enforceable agreements covering the arrangements, including confidentiality and conflicts of interests with each outsourced body.

## 7. Use of marks

- 7.1 Kalos is under agreement with the ANAB for the use of their mark in association with the Kalos Certifications LLC mark. Kalos maintains legally enforceable arrangements that require our certified clients to conform to the requirements of the



certification body when referring to its certification status in communication media such as the internet, brochures or advertising, or other documents.

**7.2** Clients of Kalos may use the marks in accordance with the following requirements:

- The client must maintain traceability back to Kalos Certifications LLC.
- There shall be no ambiguity, in the mark or accompanying text, as to what has been certified and by whom.
- The client may not make or permit any misleading statement regarding its certification.
- The client may not use or permit the use of a certification document or any part thereof in a misleading manner.
- The client upon withdrawal of certification, shall discontinue its use of all advertising matter that contains a reference to certification.
- The client agrees to amend all advertising matter when the scope of certification has been reduced.
- The client must not refer to its certification in a way that implies that Kalos certifies a product, service or process.
- The client must not imply that the certification applies to activities and sites that are outside the scope of certification.
- The client must not use its certification in such a manner that would harm the reputation of Kalos and lose public trust.

**7.3** Kalos does not permit its marks to be applied by certified clients to laboratory test, calibration or inspection reports or certificates.

**7.4** Use of Marks on Product Packaging

- Kalos mark shall not be used on a product nor product packaging nor in any other way that may be interpreted as denoting product conformity.

**NOTE:** Product packaging is considered bags, boxes, wrapping that can be removed without the product disintegrating or being damaged.

**NOTE:** Accompanying information is considered as separately available or easily detachable.

**NOTE:** Type labels or identification plates are considered as part of the product.

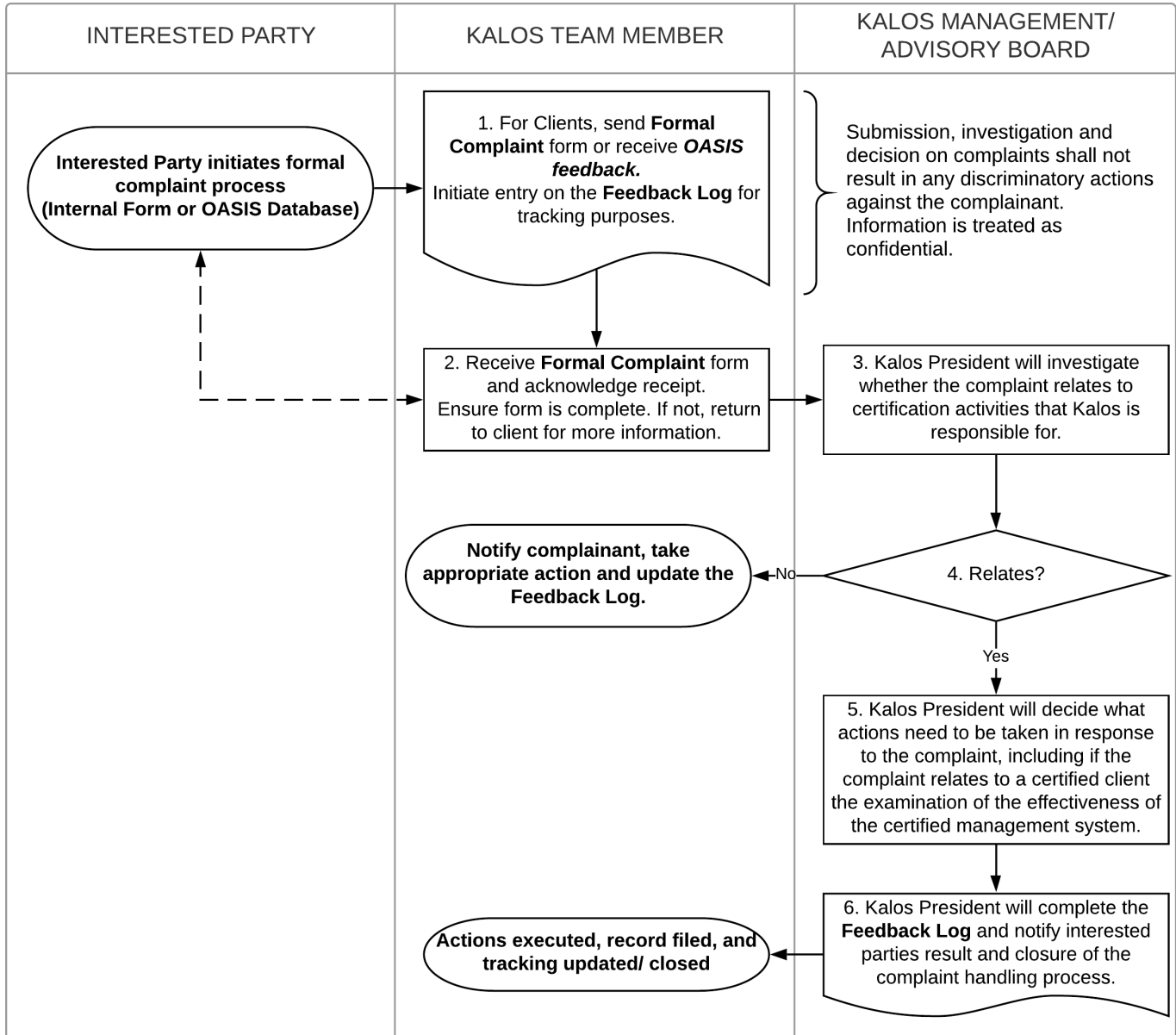
- Statements on product packaging or in accompanying information must denote that a certified management system is maintained.
- The statement shall in no way imply that the product, process or service is certified by this means.
- The statement shall include reference to:
  - identification (e.g. brand or name) of the certified client;
  - the type of management system (e.g. quality, environment) and the applicable standard;
  - the certification body issuing the certificate.

**7.5** When issues with the use of marks are discovered by Kalos representatives, Kalos will request correction, corrective action, or legal action, as necessary. Auditors may issue a corrective action request during onsite audits for these issues to be addressed.

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## 8. Complaint Handling (client, external)



- 8.1 Complaints from clients or external sources are investigated.
- **AQMS-related complaints, including those posted to the OASIS database, are reviewed, and responded to within 30 days of being received or posted.**
- 8.2 Kalos **Office Team** determines, together with the certified client and the complainant, whether and, if so to what extent, the subject of the complaint and its resolution shall be made public.
- 8.3 **Feedback gathered in the OASIS database shall be managed in accordance with AS9104/1 and OASIS requirements.**



Revision History	Approved By	Date
<i>See FM 01-06 G2 Operations Log - Document History for additional revision history</i>		
Revised per <b>AS9104 and AS9101</b> requirements. <ul style="list-style-type: none"> <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	9/14/2020
Revised per ANAB Document Review and Board Review	Michaela Scarla	11/10/2020
Revised per audit feedback: <ul style="list-style-type: none"> <li>Section 3.2 updated to “Kalos <b>FM-02-05 Notification of Audit</b> includes an impartiality and conflict of interest clause that is <b>acknowledged</b> prior to each audit.</li> </ul>	Michaela Scarla	3/5/2021
Revised per 2022 Internal Audit: <ul style="list-style-type: none"> <li>Corrections per KA-2022-92</li> </ul>	Michaela Scarla	3/28/2022
Updated per AS9104/1:2022 Transition: <ul style="list-style-type: none"> <li>Update 8.1 – 30-day response required</li> <li>Section 4 – Organization chart updated with names.</li> </ul>	Michaela Scarla	11/15/2022
Updated per KALOS-DR-2024-0842 RFI: <ul style="list-style-type: none"> <li>Updated 3.2 – remove form number FM 02-05 (typo s/b 02-04) to accommodate multiple standards. Update “acknowledged” to “communicated”.</li> </ul>	Michaela Scarla	2/8/2024
Updated per Kalos 2025 Internal Audit: <ul style="list-style-type: none"> <li>Updated the 1.1/1.2 to reflect current services.</li> <li>Updated “President” throughout document to other roles/groups as appropriate.</li> <li>Updated TBB Section “Based on TRB recommendation, the Accreditation Manager or designee makes final certification decision.”</li> <li>Updated the Org Chart.</li> </ul>	Michaela Scarla	3/24/2025

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