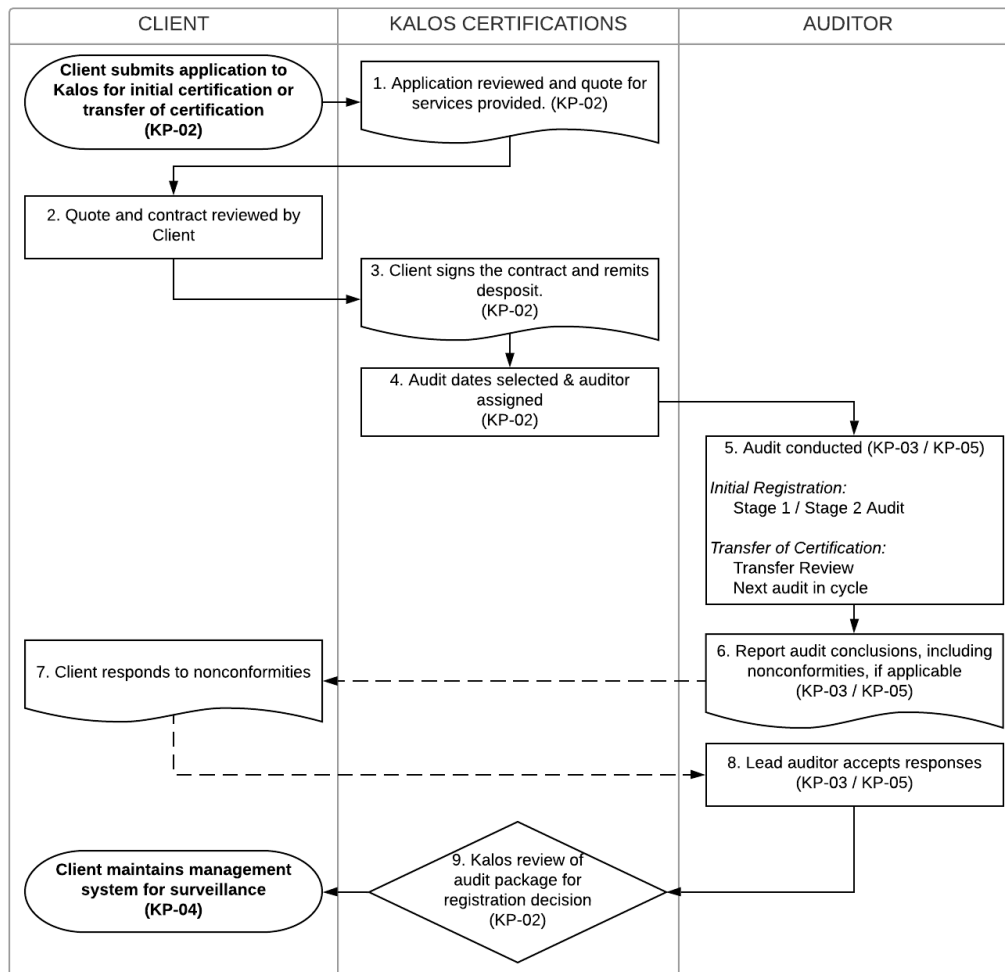


We know achieving ISO 9001 certification can be confusing at first, so we've compiled some frequently asked questions based on our initial conversations with clients. We'd love to discuss all of this further with your team, but we know some reference material can be helpful!

1. What is ISO 9001? And what can I expect from it?

ISO 9001 sets out the criteria for a quality management system and is the only standard in the family that can be certified to (although this is not a requirement). It can be used by any organization, large or small, regardless of its field of activity. This standard is based on several quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement

2. What are the steps to get certified?



Supporting Documents:
 KP-01 Operations Manual (Part A / B)
 KP-02 Client Processes
 KP-03 Planning & Conducting ISO 9001 Audits
 KP-04 Client Bill of Rights & Responsibilities
 KP-05 Planning & Conducting AS9100 Audits

3. How much time is required between Stage 1 and Stage 2?

All new clients must complete a Stage 1 and Stage 2 audit. Kalos may conduct the Stage 1 and Stage 2 back-to-back. Most clients choose to put 2-4 weeks in between the Stage 1 and Stage 2 audits.

The purpose of Stage 1 is to assess your organization's readiness for ISO 9001: 2015 certification.

The basic objectives will be:

- to review your management system documented information (i.e., quality manual or equivalent, quality policy, scope, objectives, process interactions, etc.)
- processes and equipment used
- evaluate the site-specific conditions / discuss preparedness for stage 2
- review your understanding regarding the requirements of the standard with respect to identification of key performance indicators
- evaluate if the internal audits and management reviews are being planned and performed
- assess the level of implementation of your Quality Management System (QMS)
- Identify areas of concern that may lead to nonconformance in Stage 2

There are risks and benefits to completing your stage 1 and stage 2 back-to-back.

- Risks
 - The Stage 1 report will identify any "areas of concern" the auditor has related to your QMS. If areas of concerns are identified, your team may not have time to complete the necessary corrective actions before the Stage 2 audit. These concerns may turn into nonconformances at stage 2.
 - If your site is not prepared for certification, your Stage 2 will be rescheduled for a later date. Your organization is responsible for expenses incurred for travel, etc. per the Kalos Contract.
- Benefits
 - Your organization may save money on auditor travel cost.

4. Does nonconformance prohibit my organization from getting certified?

No. You may have nonconformances and still achieve certification. All nonconformances must be closed and verified before a certificate is issued.

5. Do I have to be audited every year?

Yes. Kalos must conduct an audit each calendar year for your organization to maintain its certification.

6. What is the difference between a Kalos pre-assessment and consultant internal audit?

A **Kalos Pre-Assessment** is an option available to new clients. A Kalos auditor will visit your facility and assess a sample of your processes, like a surveillance audit. They will provide an FM-03-05 Audit Report with any opportunities for improvement or nonconformances identified in Section 6 of the report. The responses to pre-assessment findings are not required to be submitted to Kalos.

- The auditor may not offer any consulting or solutions for the issues found.
- The pre-assessment visit does not fulfill the requirements of ISO 9001:2015 section 9.2 or a stage 1 audit.
- The organization must still complete an internal audit through their preferred method (incumbent team members or consultant).
- The organization must also complete a full stage 1 and stage 2 activity to achieve certification.

A **Consultant Internal Audit** is an option available to all clients. Below is a list of consultants that have helped clients achieve their certification goals. The use of any consultant does not mean that the certification process will be simpler, easier, faster or less expensive. Kalos' process does not change based on the use of any consultant.

- The deliverables of a consultant internal audit are determined by the client and consultant.
- Consultants may offer suggested solutions to issues found during the internal audit.
- The consultant internal audit may be used to fulfill the requirements of ISO 9001: 2015 section 9.2.
- The organization must also complete a full stage 1 and stage 2 activity to achieve certification.



Please contact consultants directly for more information. We can't wait to see the results of all your work!

QMS Consultants

Alex Audits, LLC

Alejandra Whittle

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<https://www.linkedin.com/in/alex-whittle-19419410/>

Service Area: Arizona

KSY Auditing and Consulting Services LLC

Karey Yates

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Service Area: Arizona

J P J Consulting, LLC

Jeff Poshka

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Service Area: Arizona

Forkel Quality Consulting

Ruth Forkel

512-914-7561

ruthforkel@aol.com

<https://www.linkedin.com/in/ruth-forkel-17a69311/>

Service Area: Texas

Gladhill Associates International (Auditor Training)

Burt Gold

623-939-4412

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<http://www.gladhillassociates.com>

Service Area: Virtual

Business Management Systems Consulting

Bretta Kelly

(602) 445-9400

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Service Area: National

H2H Consulting, LLC

Debbie Hart

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debbie@h2hconsult.net

<https://www.linkedin.com/in/debbie-hart-b297b2178/>

Service Area: National

Process Improvement Excellence Consulting, LLC

Rebeca Salo

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Service Area: Arizona

Meyer QMS

Lea Kinney

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www.MeyerQMS.com

Service Area: National

My Quality Plus

Fran Francis

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Service Area: Southwest USA

NIST/ DFARs Cybersecurity Consultants

Cyber Security Business Services

Belle Sandlin

480-980-9507

belle.sandlin@cysecbiz.com

<https://www.cysecbiz.com>

Onsite Technical Services

Jim Hunton

602-892-3551

JimHunton@onsite-tech.com

<http://www.onsite-tech.com/>

Other Arizona Resources

Arizona Manufacturing Extension Partnership

Rodney Nelson

Rodneyn@AZcommerce.com

<https://www.azcommerce.com/programs/arizona-mep>

General Business Consulting (marketing, website)

Alexandra Jobe

Alex@AlexandraJobe.com

<https://alexandrajobe.com>

7. Is Lead Auditor Training required?

No. The expectation for clients is that they understand the requirements of the standard and apply them effectively. This could be accomplished in several ways based on the learning style and experience of the client.

Examples of learning:

- knowledge gained from experience
- lessons learned from failures and successful project
- the results of improvements in processes, products, and services
- gathering knowledge from external providers – trainers or consultants

Kalos offers opportunities to gain knowledge of the standards and other relevant topics. We host **AZ Quality Network** meetings 2-3 times per year remotely. The topics range from current regulations, ISO standard topics, changes to standards/expectations, etc. This is a free, public seminar- so bring a colleague and share with friends! All persons open to learning are welcome.

It's also a great opportunity to meet other quality professionals, suppliers, auditors, and consultants.

Past topics can be viewed here: <https://kaloscertifications.com/az-quality-network>

We're always open to suggestions for topics or speakers!

Resources

ISO 9001 Auditing Practice Group

<https://committee.iso.org/sites/tc176sc2/home/page/iso-9001-auditing-practices-grou.html>

ISO 9001 Standard

<https://www.iso.org/standard/62085.html>

AS9100 Standard

<https://www.sae.org/standards/content/as9100d/>

IAQG OASIS Supply Chain Management Handbook (SCMH)

<https://iaqg.org/tools/scmh/>

8. What is the difference between IAF Technical Cluster and NACE Codes?

To best serve you and select an appropriate audit team, we assign an Accreditation Technical Cluster number to your organization. To maintain consistency, these technical clusters are based on the statistical nomenclature for economic activities NACE rev. 2 published by the Commission of European Communities (Official Journal L 393/1, 30.12.2006).

Often the financial department of your organization will have the NACE code established since most business tax forms require it. They can be very helpful in determining what NACE code and technical cluster best fit your organization.

More information on NACE codes here: <https://ec.europa.eu/eurostat/web/nace-rev2/correspondence-tables/publications>

A comparison of IAF Technical Clusters and NACE codes can be found in the table below.

QMS Accreditation Scope		
No	Description of economic sector / activity	NACE – Division / Group / Class (rev.2)
1	Agriculture, forestry and fishing	01, 02, 03
2	Mining and quarrying	05, 06, 07, 08, 09
3	Food products, beverages and tobacco	10, 11, 12
4	Textiles and textile products	13, 14
5	Leather and leather products	15
6	Wood and wood products	16
7	Pulp, paper and paper products	17
8	Publishing companies	58.1, 59.2
9	Printing companies	18
10	Manufacture of coke and refined petroleum products	19
11	Nuclear fuel	24.46
12	Chemicals, chemical products and fibres	20
13	Pharmaceuticals	21
14	Rubber and plastic products	22
15	Non-metallic mineral products	23, except 23.5 and 23.6
16	Concrete, cement, lime, plaster etc	23.5, 23.6
17	Basic metals and fabricated metal products	24 except 24.46, 25 except 25.4, 33.11
18	Machinery and equipment	25.4, 28, 30.4, 33.12, 33.2
19	Electrical and optical equipment	26, 27, 33.13, 33.14, 95.1
20	Shipbuilding	30.1, 33.15
21	Aerospace	30.3, 33.16
22	Other transport equipment	29, 30.2, 30.9, 33.17
23	Manufacturing not elsewhere classified	31, 32, 33.19
24	Recycling	38.3
25	Electricity supply	35.1
26	Gas supply	35.2
27	Water supply	35.3, 36
28	Construction	41, 42, 43
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	45, 46, 47, 95.2
30	Hotels and restaurants	55, 56
31	Transport, storage and communication	49, 50, 51, 52, 53, 61
32	Financial intermediation; real estate; renting	64, 65, 66, 68, 77
33	Information technology	58.2, 62, 63.1
34	Engineering services	71, 72, 74 except 74.2 and 74.3
35	Other services	69, 70, 73, 74.2, 74.3, 78, 80, 81, 82
36	Public administration	84
37	Education	85
38	Health and social work	75, 86, 87, 88
39	Other social services	37, 38.1, 38.2, 39, 59.1, 60, 63.9, 79, 90, 91, 92, 93, 94, 96

Excerpt from IAF ID 1: Informative Document for QMS and EMS Scopes of Accreditation