Chapter 21

ISO9000 QMS

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21.1 What It Is

It is basically a rule-based Compliance systems , or Quality Assurance System.

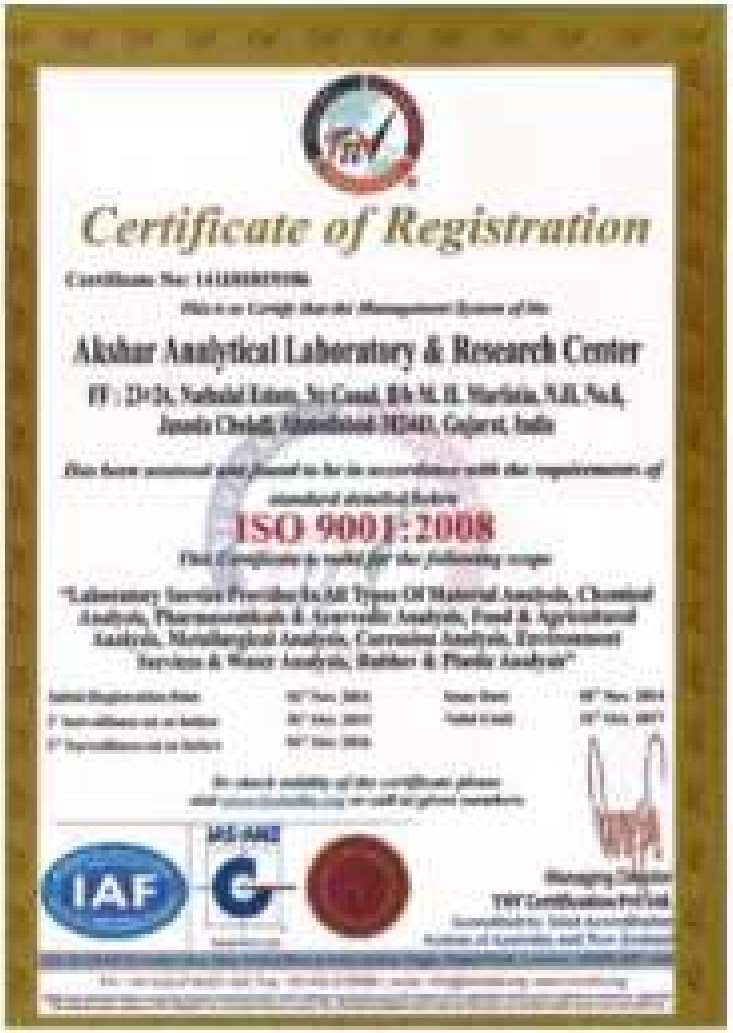
Some Quality Assurance Systems are:

1. ISO9000 Quality Management System (QMS)
2. Good Manufacturing Practice (GMP)
3. Hazard Analysis and Critical Control Point (HACCP)
4. Product/Industry Specific systems, such as – TL9000 (Quality system for telecommunication industry), QS9000 – (Quality system for automobile industry)
5. Etc.

However, it is not directly technical or product quality; it is Management Quality, which ultimately ensures product quality.

ISO9000 QMS provides a documented set of guidelines as to how the management of an organization should work to ensure quality.

It requires certification through external third-party audit.



Certificate of Registration

Akshar Analytical Laboratory & Research Center

ISO 9001:2008

"Laboratory Service Provider In All Types Of Material Analysis, Chemical Analysis, Pharmaceuticals & Ayurvedic Analysis, Food & Agricultural Analysis, Metallurgical Analysis, Corrosion Analysis, Environment Services & Water Analysis, Rubber & Plastic Analysis"

IAF

কিংবোয়াশ অ্যাকল্স্ লিঃ এর

HACCP সার্টিফিকেট অর্জন

21.2 Application base

- Any kind of production industry,
- Healthcare organizations, including hospital, clinic, diagnostic centers
- University, training houses/centers (including computer training institutes)
- R&D organization,
- Construction, consulting and project management organization,
- Airways, and other transportation/logistical companies,
- Food companies, including airways catering service,
- Etc.

21.3 Principles behind the system

It is based on eight principles, which are basically TQM principles, as given below –

1. Customer focus
2. Leadership
3. Involvement of people
4. Continual improvement
5. Process approach
6. System approach to management
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

21.4 Documentation system (2008 version)

It is basically a rule-based documentation system.

Rules are crated for all activities of the organizations.

Everybody must follow the rules, be right or wrong. Otherwise it is a "non-compliance".

Thus, often blamed as complex bureaucratic system.

This rigid structure was compulsory in 2008 version, but optional in 2015 version.

Looked after by Quality Management Representative (QMR) → from top management

Environment Management Representative (EMR) → MR

21.5 Audit and Certification

There are two kinds of audit :

1. Internal –to be conducted by the internal staff members
2. External – by an external third-party certification body.

The certification remains valid for three years, after which it can be renewed through another full-fledged 'Renewal audit' by the third-party.

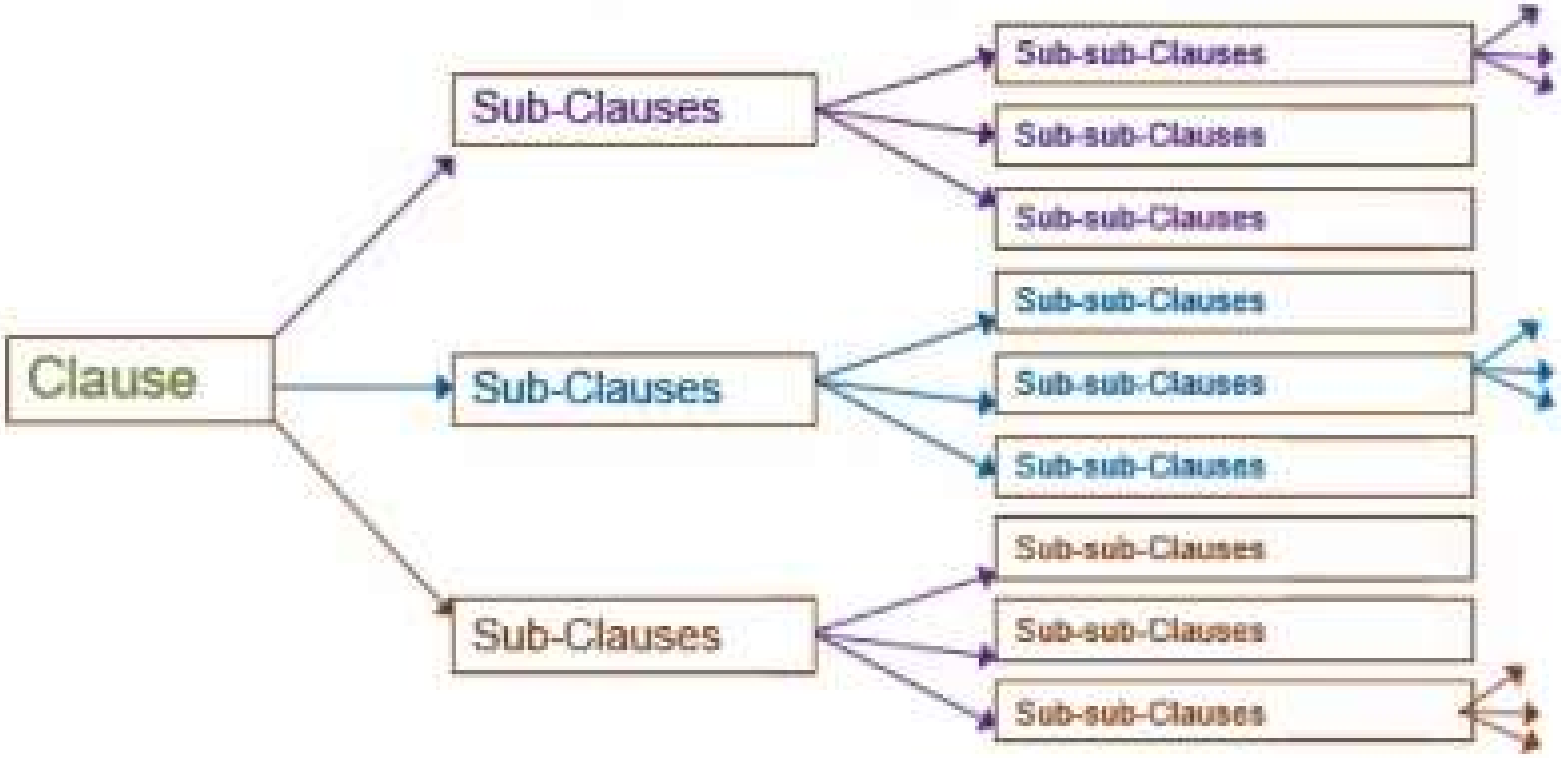
However, the organization has to go through half-yearly "Surveillance audit' by the third party to ensure that the QMS runs smoothly.

Repeated or major noncompliance may lead to cancellation or postponement of certificate.

21.6 Clauses and Major Sub-clauses (2008 Ver.)

It is currently based on five clauses, which are:

Clause 4:	Quality Management System
Clause 5:	Management Responsibility
Clause 6:	Resource Management
Clause 7:	Product Realization
Clause 8:	Measurement, Analysis and Improvement



21.7 Historical Evolution

Supposed to be modified every 5 years, with suggestions from all member countries

First version in 1987 – ISO9001, ISO9002, ISO9003 certifications (No TQM)
2nd version in 1994 – ISO9001, ISO9002, ISO9003 certifications (No TQM)
3rd version in 2000 – ISO9001, along with strong emphasis on TQM
4th version in 2008 – ISO9001, along with strong emphasis on TQM
5th version in 2015 – ISO9001, along with strong emphasis on TQM

A similar Environmental Management System (EMS), or compliance system is ISO14000

21.8 New version ISO9001: 2015

- Older version (ISO9001:2008) will remain valid up to September 2018.
- It has been restructured in such a generic way that it can be combined or integrated easily with other management compliance systems, such as ISO14001:2015 (EMS), OHSAS18001, ISO45001 (Occupational Health and Safety Management Systems), SA8000 (Social Accountability, etc.
- They call this restructuring as **High Level Restructuring** (HLS).
- It strongly suggests employing the Plan-Do-Check-Act cycle at all levels in the organization.

21.9 Key elements of new version

- Risk analysis has been made explicit. Handling nonconformities and maintenance are part of risk analysis.
- It emphasizes on integration across the supply chain/value chain.
- Writing and maintaining Quality Manual and Procedures are no more compulsory.
- The terms "document" & "records" have been replaced with "documented information" (as evidence to conformance)

21.10 Clauses (Sections) of new version

Section 4 (Clause 4) : Context of the Organization

- Understanding the organization & its context, needs needs & expectations of interested parties

Section 5 (Clause 5) : Leadership

- Leadership & commitment
- Quality policy
- Organizational roles, responsibilities & authorities

Section 6 (Clause 6) : Planning

- Actions to address risks & opportunities

Section 7 (Clause 7) : Support

- Resources, Awareness of manpower, Communication
- Documented information

Section 8 (Clause 8) : Operation

- Operational planning & control
- Production of goods & services,
- Nonconforming goods & services

Section 9 (Clause 9) : Performance Evaluation

- Monitoring, measurement analysis & evaluation
- Internal Audit
- Management Review

Section 10 (Clause 10): Improvement

- Nonconformity & corrective action
- Improvement