ISO Guide 34, 17025, and 9001 Explained

By Christopher Gaines

We've entered an age when quality has become imperative in the arena of high tech industry. The International Organization for Standardization (ISO) has provided a level playing field for all manufacturers to *officially* state the quality of their products and business practices.

ISO 9001, ISO 17025, and ISO Guide 34 are the three most valuable credentials for standard manufacturers. What do these credentials really mean?

1st Level - ISO 9001

- Certifies that a company has official written procedures and training documentation in the areas of customer service, product design, manufacturing, analysis, change management, certification, packaging, shipping, and purchasing.
- This standard is very customer service oriented. Every complaint is documented and corrective and preventive measures must be put into place.

ISO 9001 QSR-1034 BY QSR

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Three levels of ISO accreditation

Bottom Line

As long as a company is consistent in its documented actions, it can remain ISO 9001 certified.

2nd Level - ISO 17025

- Certifies that quality-oriented tests are performed correctly. These tests establish that the product is indeed a
 quality product.
- All aspects of quotations and contracts, the Research and Design operation, and Manufacturing and Quality
 Control activities are examined by this standard. The qualification, education, and training of all associates are
 scrutinized against their job responsibilities. Even the qualifications of vendors and collaborators are checked, as
 well as every Quality Critical specification and purity requirement.

Bottom Line:

To be ISO 17025 accredited, a company must not only be consistent, but must also be proficient in testing the quality of their products.

3rd Level - ISO Guide 34

- This accreditation deals directly with Certified Reference Material (CRM) manufacturers.
- CRMs can only be manufactured by a Guide 34 accredited producer.
- All methods that the manufacturer uses to certify their standards must be validated and proven to be accurate.
- Requires that an "uncertainty", which includes all of the sources of error involved in certifying the standard, be reported on the Certificate of Analysis. Furthermore, the Certificate of Analysis itself must observe stricter requirements imposed by the ISO committee.

Bottom Line:

Guide 34 provides the highest level of quality assurance, confidently stating that the manufacturer's standards are produced correctly and competently.

Inorganic Ventures is accredited to *all three* of the above certifications. We encourage you to review our <u>scope and certificates</u> and <u>contact us</u> should you have any questions.