THE JAPANSE STATUS OF LABORATORY ACCREDITATION BASED ON FASTENER QUALITY ACT.

Tutomu Aoyagi
JAB (The Japan Accreditation Board for Conformity Assessment)
Tokyo, Japan
and
O Yoshio Imai
Consulting Engineer
Tokyo, Japan

Abstract

Since 1997, JAB (The Japan Accreditation Board for Conformity Assessment) had started the activity of accreditation for the laboratory based on U. S. PL101-592: the Fastener Quality Act that was signed by President Bush on 1990.

The number of accredit laboratories are 69 in Japan, 21 in Taiwan, 2 in Korea and 189 in U. S. A, as of 09/10/1998.

The JAB accreditation encompasses the requirements of the ISO/IEC Guide 25, and the relevant requirements of ISO 9002.
The purpose of ISO/IEC Guide 25, also had been harmonized as JIS Z 9325 "General requirements for the competence of calibration and testing laboratories " mainly facilitates and promotes acceptance of calibration and test results between countries to avoid barriers to trade through as "one stop testing".
The features and differences between Guide 25 and ISO 9000 will be clarify in this report.

1. Introduction

Status of Accredit Laboratories in the world based on FQA (Fastener Quality Act)

In Japan, FQA became a trigger that made running the laboratory accreditation system in the field of fastener industry exporting fasteners to USA.

As the result, there are 69 Accredit Mechanical/Chemical Laboratories as of 09/10/1998.

Status of another country's Laboratories numbers including Japan, Korea and Taiwan is shown in Table 1.

Table 1 FQA Accredit Laboratory in The World

Country:		Laboratory Accreditation Body				
		A2LA	NVLAP	NADCAP	JAB	other
USA	189	107	49	33		
JAPAN	69		21		48	
TAIWAN	21	17	4			
CANADA	11	3	2			6
U.K	5					5
GERMANY	4	1				3
KOREA	2	1	1			
BRAZIL	2		2			
INDIA	2		2			
ITALY	2	2				
FINLAND	1			1		
MEXICO	1		1			
NETHERLAN	1	1				
TOTAL	310	132	82	34	48	14

A2LA:American Association for Laboratory Accreditation
NVLAP:The National Voluntary Laboratory Accreditation Program
NADCAP:National Aerospace and Defense Contractors Accreditation Program
JAB:Japan Accreditation Board of Conformity Assessment

The purpose of the Fastener Quality Act (FQA) is to protect the public safety by:

(1) Requiring that certain fasteners sold in commerce conform to the specifications to which they are represented to be manufactured,

(2) Providing for accreditation of laboratories engaged in fastener testing, and

(3) Requiring inspection, testing and certification in accordance with standardized methods.

The Act has elements which will enhance traceability, accountability, and responsibility from the manufacturer's plant throughout distribution and finally to the end user.

Quantities of fasteners that export to USA by country are shown in Table 2 to compare Laboratory number (Table 1) and export quantities of fasteners to USA,

Table 2 Fastener Export to USA

TAIWAN	517,131	618,566	730,209	727,864	739,737
JAPAN	337,438	412,840	441,729	418,695	408,927
CHINA	32,527	43,083	56,353	53,057	62,934
KOREA	48,745	53,297	54,102	42,291	44,021
	1993	1994	1995	1996	1997

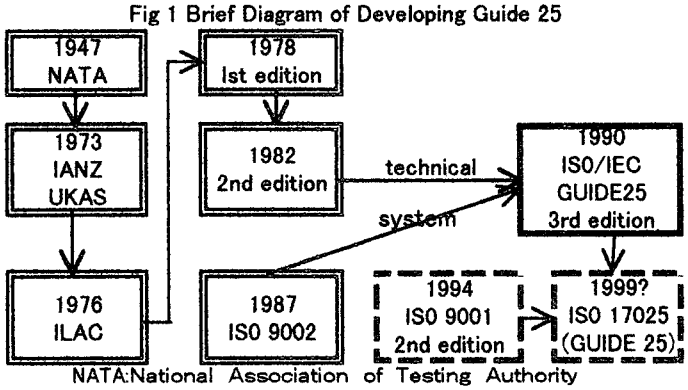
(US$1,000)

2. Concept of ISO/IEC Guide 25

Basically FQA is formed by concept of ISO/IEC Guide 25 "General requirements for the competence of calibration and testing laboratories".

Origin of Guide 25 is able to trace back to 1947.
In Fig 1 you can see the brief diagram of developing ISO/IEC Guide 25, and also that will be revised as ISO 17025 in near future.

Fig 1 Brief Diagram of Developing Guide 25



NATA:National Association of Testing Authority
IANZ:International AccreditationNew Zealand
UKAS:United Kingdom Accreditation Service
ILAC:International Laboratory Accreditation Conference

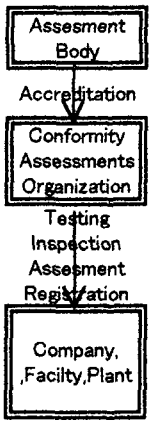
In ISO/IEC Guide 25(adopted as JISZ9325), an authoritative accreditation body conforming to ISO/IEC Guide 58 (adopted as JISZ9358) assesses competence of a laboratory to conduct tests in a specific field.
In case of FQA these fields are Chemical (Chemical analyses and detection including instrumental and automated methods) and Mechanical (Tests, measurements, and evaluation of physical properties of materials, components, and assemblies.), then the body accredits laboratories if laboratories meet requirements of Guide 25.

ISO/IEC prescribes through the guides about requirements to be met and procedures to be done for each organization that carried out inspection, product certification, testing and calibration and management system registration.

Those relations to ISO/IEC Guide are prescribed Fig 2.

Items to be assessed by accreditation body are the following items such as quality system, personnel, facilities, equipment, environmental conditions, measurement traceability, control of testing methods, etc.

Fig 2 Relation between ISO／IEC Guide and Conformity Evaluation



Calibration and Testing	Inspection	Product Certifcation	Sysytem Certification
The Japan Accreditation Board for Conformity Assessment			
Guide 58	ISO17010 (Draft)	Guide 61	
Calibration and Testing Laboratories	Inspection Organization	Product Assesment Organization	Registrar Organization
Guide 25	ISO17020 (Draft)	Guide 65	Guide 62
			ISO9000 Series ISO14000 Series

3. Differences between ISO9000 and Guide 25

Assessing items are very similar to the items of ISO9000 management series. Because of similarities are some kinds of confusions about identification between Guide25 and ISO9000 there.

The following quotation about Q & A from A2LA bulletin (A2LA NEWS No63) shows an example of confusion.

It states as follows;

Question: Will ISO 9000 registered/certified calibration services be accepted?

Ans. : No, there are important differences between laboratory accreditation using ISO/IEC Guide 25 and quality system certification using the ISO 9000 series of standards.

The key difference can be summarized by the fact that the essence of ISO/IEC, Guide 25 is to ensure the validity of calibration data, while technical credibility is not, addressed in the 9000 series.

Accredited calibration laboratories must maintain a Scope of Accreditation which identifies the specific parameters, ranges, best measurement capabilities, and techniques for which accreditation has been granted.

ISO 9000 certified laboratories do not have a defined scope of capabilities.

There are several significant differences between laboratory accreditation using Guide 25 and quality system certification, but the key difference can be summarized

by the fact that the essence of Guide 25 is to ensure the validity of test data, while technical competence is not addressed in ISO 9002 .

One of the methods to ensure the validity of test data is "Proficiency Testing." Proficiency testing (PT) is a type of external quality control, such as inter laboratory comparisons and round robins.
The purpose of PT is to verify the performance of each test site (laboratory) is in line with others performing the same analysis.
The lab staff runs testing the artifacts, whose expected values are unknown to the subscribers. Then they return their results to the PT provider. The results are reviewed to determine whether each participant passes or fails established performance levels.

The reporting format of the result is next method to ensure the validity of test data.
The traceability with uncertainty is very important.
Following is quoting from Guide 25 about "Reporting the results"

> The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.
> The results shall normally be reported in a test report (sometimes called test certificate) or a calibration certificate and should include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used.

The final product of a laboratory is test data

Functions of the test report are prescribed Fig 3.

Fig 3 What are Functions of the Test Report?

- ◆The final product of a laboratory
- ◆Describe analytical information.
- ◆Offer the character of commodity.
- ◆Clarify level of the achievement to the regulation
- ◆Acceptable the report internationally between mutual recognized country.
- ◆Not necessary re-testing when receive items.

4. Conclusion

With globalization of economy, nationally or internationally a time will come true, in which the commodities such as material, parts, facilities, plant and information could be move so smoothly and economically with the test date of accredited laboratory.

Users of test data, therefore, should concern themselves with both the potential for performing a quality job (quality system) and technical competence (ability to achieve a technical result). The best available method of achieving these two objectives is through laboratory accreditation bodies, operating themselves to best international practice, requiring laboratories to adopt best practices and by engaging assessors who are expert in the specific tests in which the customer is interested.
Acceptance of test data, nationally or internationally, should therefore be based on the application of Guide 25 to assure the necessary confidence in the data's validity.

References

1. Tutomu Aoyagi, "Laboratory Accreditation System-Supporting Reliability of Analytical Date" Sep. 4, 1998. 2nd Analytical Chemistry Symposium in Tokyo
2. Shinsaku Onodera. "Certification-Certification and Conformity Evaluation in Standardization" CORONA PUB. 1995,
3. Peter S. Unger. "ISO9000 and Guide25" Bulletin. A2LA. 1996.
4. ISO/IEC Guide 25 "General requirements for the competence of calibration and testing laboratories".
5. ISO/IEC Guide 58 "Calibration and testing laboratory accreditation systems-General requirement for operation and recognition"
6. ISO9000 "Quality management and quality assurance standard."
7. Bulletin. A2LA. May 1997, No 63
8. Bulletin. The Fastener Institute of Japan, Sept. 1998 No. 5
9. http://users.aol.com/a2la/a2la.htm
10. http://www.jab.or.jp/
11. http://www.proficiency.org/
12. http://www.nist.gov/fqa/