The ideal state of reliability control within corporations —Response to ISO 9000S:2000 and uncertainty—

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The International System of Units (SI) has been adopted for international commercial transactions under the GATT/ TBT agreement. The system of weights and measures has been completely in effect since January 2000, resulting in brisk international transactions. As a result, data reliability using these common terms has become very important, and international recognition has been forthcoming. Furthermore, ISO 9001:2000 was enacted in December 2000, and has proven to be a revision better adapted to the current situation than the previous standard of ISO 9001:1994. (I will leave the details of this matter to other documents.) Also, ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories" was enacted in January 2000, strengthening the requirements for establishing traceability systems set forth in standards such as QS 9000 and the 1994 and 2000 versions of ISO 9001. With top international priority on mutual approval for maintaining data reliability and "uncertainty," the system of third party accredited businesses (testing labs and calibration agencies) has resulted in such organizations as JNLA/JCSS (the Japan National Laboratory Accreditation System/the Japan Calibration Service System) and JAB (The Japan Accreditation Board for Conformity Assessment) being established in Japan. Today, a considerable number of testing labs and calibration agencies have been accredited. This has made one stop service possible, a system in which results tested in one site are accepted equally everywhere in the world.

In the future, corporations will find it increasingly important to establish in-house traceability systems and to have a reliability specialist capable of handling reliability maintenance for measuring and traceability. This article will discuss these issues.

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1. Introduction

Quality reliability in the broadest sense is currently a topic of international concern, evidenced by such examples as quality management systems, environmental management systems, product liability (PL), and testing lab accreditation. All of these examples are directly or indirectly concerned with the reliability of "measuring" and the capacity to assure such measuring reliability.

Calibration technology for measuring equipment can be cited as an example of technology fundamental to the manufacturing worksite. To assure the continuous manufacture of uniform product quality on the production line, measuring equipment must constantly be supervised as tools for measuring product quality. The immediate provision of higher level standards to calibrate those tools is essential in a wide range of fields.

The ISO/IEC 17025 standard set down conditions for testing labs and calibration agencies as well as technology standards required for accreditation. This standard contains all items required in ISO 9001:1994, and Table 1 shows a comparison of these two standards. (See next page.)

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2. Traceability

Creating traceability systems requires an approach with special emphasis on the following standpoints. (Note: Traceability means the guarantee that measuring equipment in a worksite has been calibrated at uninterrupted regular intervals according to domestic or international standards.)

(1) Creating international measurement standards based on international rules

(2) Clarifying internationally the structure of traceability systems, and establishing technology standards and operating methods for those systems

(3) Working to maintain international conformity (mutually recognized)

Traceability for measuring equipment is essential to certification for quality management systems. Quality management systems are used in traceability control, and so quality management and traceability management systems are considered to have a complementary relationship. Table 2 shows a summary of the requirements of each standard for traceability systems stipulated by the Japanese Measurement Law and the "uncertainty" requirements in those standards. (See p. 19.) Fig. 1 also shows an outline of traceability systems. (See p. 20.)

In Japan, when general users and corporations receive calibration according to specific secondary standards, they are able to then receive a written guarantee of calibration with the logo of the Japan Calibration Service System (JCSS) clearly stating the connection between those secondary standards and national measurement standards.

Table 1 A comparison of ISO/IEC 17025 and ISO 9001:1994

ISO/IEC 17025 ⇒ ISO9001:1994		ISO9001:1994 ⇒ ISO/IEC 17025	
Requirement No.	**Related item No.**	**Requirement No.**	**Related item No.**
4. Management requirements			
4.1 Organization	4.1	4.1 Management responsibility	4.1, 4.2, 4.9, 4.10, 4.14, 5.2, 5.5
4.2 Quality system	4.1, 4.2	4.2 Quality system	4.2, 4.14
4.3 Document control	4.5	4.3 Contract review	4.4
4.4 Review of requests, tenders and contracts	4.3	4.4 Design system	5.4
4.5 Subcontracting of tests and calibrations	4.6, 4.10	4.5 Document and data control	4.3, 5.4, 5.5
4.6 Purchasing services and supplies	4.6, 4.10	4.6 Purchasing	4.5, 4.6, 4.7, 5.5, 5.6
4.7 Service to the client	4.6	4.7 Control of customer-supplied product	5.8, 5.10
4.8 Complaints	――――	4.8 Product identification and traceability	5.5, 5.8
4.9 Control of nonconforming testing and/or calibration work	4.1, 4.13	4.9 Process control	4.12, 5.3, 5.4, 5.5, 5.8, 5.9
4.10 Corrective action	4.1, 4.14, 4.17	4.10 Inspection and testing	4.5, 4.6, 4.9, 4.12, 5.4, 5.5, 5.8, 5.9, 5.10
4.11 Preventive action	4.14	4.11 Control of inspection, measuring and test equipment	5.3, 5.4, 5.5, 5.6
4.12 Control of records	4.1, 4.10, 4.16, 4.17	4.12 Inspection and test status	5.5, 5.8, 5.9
4.13 Internal audits	4.17	4.13 Control of nonconforming product	4.9
4.14 Management reviews	4.1	4.14 Corrective and preventive action	4.10, 4.11
5. Technical requirements			
5.1 General	――――	4.15 Handling, storage, packaging, preservation and delivery	5.9
5.2 Personnel	4.1, 4.18, 4.19	4.16 Control of quality records	4.12
5.3 Accommodation and environmental conditions	4.9, 4.11	4.17 Internal quality records	4.10, 4.13, (4.12)
5.4 Test and calibration methods and method validation	4.4, 4.5, 4.9, 4.10, 4.11	4.18 Training	5.2, 5.5
5.5 Equipment	4.5, 4.6, 4.9, 4.10, 4.11, 4.12, 4.18	4.19 Servicing	4.7, 5.2, 5.10
5.6 Measurement traceability	4.6, 4.11	4.20 Statistical techniques	5.9
5.7 Sampling	――――	――――	――――
5.8 Handling of test and calibration results	4.7, 4.8, 4.9, 4.10, 4.12, 4.15	――――	――――
5.9 Assuring the quality of test and calibration results	4.2, 4.9, 4.10, 4.15, 4.20	――――	――――
5.10 Reporting the results	4.10, 4.19	――――	――――

* ISO 9001: 1994 does not cover most of the technical requirements found in item 5 of ISO/IEC 17025.

Table 2 Overview of uncertainty requirements from different standards

Standard	Contents of standard
ISO 9001:1994 Quality systems	4.11 Control of inspection, measuring and test equipment 4.11.1 General Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability. 4.11.2 Control procedure a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision; b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;
ISO 9001:2000 Quality management systems – Requirements	7.6 Control of monitoring and measuring devices Where necessary to ensure valid results, the items (a) through (e) must be fulfilled. e.g. a) be calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national measurements standards; where no such standards exists, the basis used for calibration or verification shall be recorded; • The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained. Within this text, ISO 10012-1/-2 is cited for reference.
ISO 9004:2000 Quality management systems – Guidelines for performance improvements	7.6 Control of measuring and monitoring devices In order to provide processes should include confirmation that the devices are fit for use and are maintained to suitable accuracy and accepted standards, as well as a means of identifying the status of the devices. • ISO 10012-1/-2 is described for reference.
ISO 10012-1:1992	4.6 Uncertainty of measurement Measurement uncertainty should be determined by the measurement process incorporated in the relevant system. The supplier should consider such factors as the following in uncertainty: the measuring equipment itself, the measurement sequence, specific or different operators, effects of influencing conditions (temperature, humidity, vibration, dust, and suspended particles), incomplete compensation applied to measurement results, measurement standards used, and measurement principles.
ISO 10012-2:1997	Uncertainty is described in such items as: 4. Recommendations 4.2 Documentation: The documentation should state an allocation of responsibilities and the action to be taken. The required performance of the measurement process should be documented. 4.3 Measurement processes: The performance characteristics required for the intended use of the measurement process should be characterized. 4.6 System for control of measurement processes 4.7 Data analysis for control of measurement processes
ISO/DIS 10012:2000 Measurement control systems	This new standard was made by combining ISO 10012-1:1992 and ISO 10012-2:1997, and so in all of Item 7 "Measurement control system realization," uncertainty is required, and particularly so in the following: 7.1.3 Equipment characteristics 7.1.5 Confirmation process records 7.2.2 Process realization 7.2.4 Records of control of measurement processes 7.3 Measurement realization 7.3.1 Measurement uncertainty: Measurement uncertainty shall be estimated for each measurement process covered by the measurement control system. Uncertainty estimations shall be recorded. The analysis of measurement uncertainties shall be completed before the confirmation of the measuring equipment, and the validation of the measurement process. 8. Measurement control system analysis and improvement 8.2.1 Analysis of the measurement processed 8.2.2 Corrective action for the measurement process
QS9000:1998	4.10 Inspection and Testing-Element 4.10.2.4 Incoming Product Quality: The supplier's incoming quality system shall use one or more of the methods: e.g. Part evaluation by accredited laboratories 4.10.6 Supplier Laboratory Requirements: The laboratory (supplier's testing facility-chemical, metallurgical, reliability, test validation, e.g. fastener labs) shall have a laboratory scope. The laboratory shall document all its policies, systems, programs, procedures, instructions and findings which enable the laboratory to assure the quality of the tests or calibration results it generates within the scope.

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QS9000:1998 (*continued*)	4.10.7 Accredited Laboratories: Commercial/independent laboratory facilities used by the supplier shall be accredited laboratory facilities. 4.11 Control of Inspection, Measuring and Test Equipment-Element 4.11.1 General: Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability. 4.11.2 Control Procedure: The supplier shall: a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision; b) Calibration Services: Calibration of inspection, measuring or test equipment shall be conducted by a qualified in-house laboratory, a qualified commercial/independent laboratory, or a customer-recognized government agency. Reference: Policies regarding measurement uncertainty are covered in ISO 10012-1.
ISO/IEC 17025	5.4.6 Estimation of uncertainty of measurement 5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations. 5.4.6.2 In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. 5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis. This is also described in 5.4.1, 5.4.2, 5.4.3, 5.4.5 and elsewhere.

The design of the logo used can differ depending on the designated calibration agency and the calibration accredited operator.

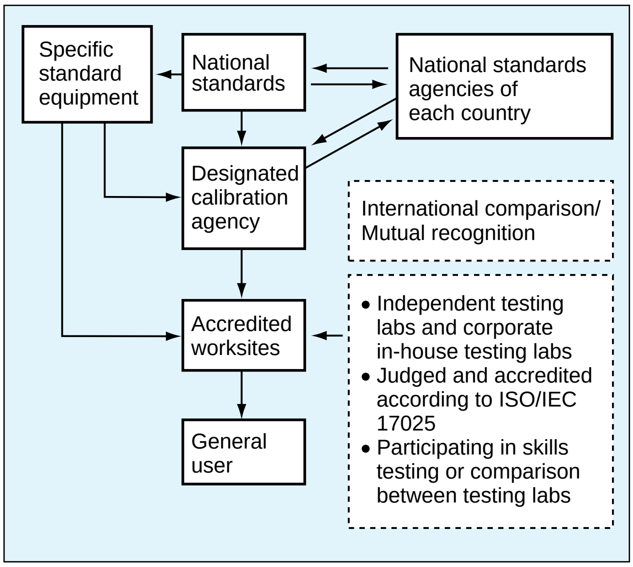

Fig. 1 Traceability systems

3. *Accredited testing labs and accredited calibration agencies*

3-1 Agencies certified according to ISO 9002:1994

Under ISO 9002:1994 certification, testing labs and calibration agencies are certified to have quality systems organizations, and are not certified based on technical requirements. However, ISO/IEC 17025 certification contains items for technical requirements. Table 3 shows this relationship. (See next page.)

3-2 Data reliability certification circle

Fig. 2 shows a relationship composition to maintain reliability of data.

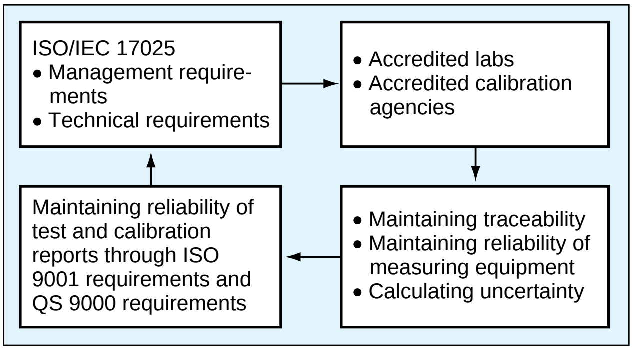

Fig. 2 Data reliability certification circle

3-3 Accreditation and certification

ISO 9001 and ISO 14001 agencies investigate whether systems conform to their requirements, whereas testing labs and calibration agencies accredited according to ISO/IEC 17025 take the stance of observing the quality of products from corporations and factories, and so both are positioned as investigative agencies. Acquiring ISO 9001 and ISO 14001 consists of acquiring "a document providing a written guarantee from a third party that the stipulated products, processes, or services conform to requirements of the standards," and this is called "certification." Acquiring ISO/IEC 17025 consists of acquiring "a document formally recognizing by an authoritative agency that an agency or individual has the capability to accomplish a specific function," and this is called "accreditation."

Table 3 ISO 9001:2000 and accredited testing labs in Japan

	ISO 9001:2000	JNLA	JCSS
Characteristics	• Quality Management Systems (QMS) • Examination of compatibility of QMS standards with optional certification from contracts with private agencies • Continually improving quality, customer satisfaction (CS), valuing customer trends, etc.	• Domestic Japan National Laboratory Accreditation System • Test operator accreditation system based on the Industrial Standardization Law • Accreditation of testing labs	• Domestic Japan Calibration Service System • Calibration operator accreditation system based on the Measurement Law • Accreditation of calibration agencies
Remarks 1	• Handles traceability according to JCSS. • Has a reliability certification system for measuring equipment control systems.	Because calibration and traceability are guaranteed when there is a JCSS mark for being within an applicable range, there is no need to review the ISO 9000:1994 edition requirements again because the ISO 9000:1994 edition requirement items are compounded in the ISO/IEC 17025 requirements. The same is true for sites such as testing labs and calibration agencies accredited by the Japan Accreditation Board for Conformity Assessment (JAB). (Refer to Table 1 and Fig. 1.)	
Remarks 2	• Includes ISO 10012 (Measurement Control Systems) for reference. • Has no technical requirements. • Requires person responsible for quality control. • Quality Management System (QMS) and reliability are questioned.	ISO/IEC 17025 • Management requirements, items 4.1 through 4.13 • Technical requirements, items 5.1 through 5.10 Comparisons between testing labs and participation in skills testing • Requires quality controller (person responsible for quality control) and technology controller (person responsible for technology control). • Requires reliability of testing and calibration methods, and testing and calibration data.	

3-4 Reliability of data and reports required by ISO/IEC 17025

(1) To maintain the reliability of items such as procedure sheets, when revising hand-written documents, clearly indicate places revised, and clearly write the date and name of the person revising the document.

(2) Concerning the competence of testing labs and calibration agencies, the competence of the organization must be grasped, and testing and calibration competence exceeding that necessary to maintain reliability is not judged.

(3) When errors are made in the record, the person rectifying the error must be specified, and the original data must be preserved.

(4) Regarding technical requirements, "the level that every factor contributes to uncertainty must be considered," and "personnel in testing labs and calibration agencies must receive adequate training and technical skills." Appropriate measures must be taken to avoid contamination or interference that could cause failure of work quality (reliability) in the testing environment from factors affecting uncertainty (temperature, humidity, dust, and so on).

4. Approach to uncertainty

4-1 Data reliability

Examples of uncertainty are given in Fig. 3, 4, and 5. In Fig. 3, there is a large degree of uncertainty in the measurement values, the values are overlapping, and there is no real variation. In Fig. 4, the data has the same average value as that in Fig. 3, but the degree of uncertainty is smaller, and there is clearly variation. In Fig. 5, (a) and (d) are within tolerance and pass, while (b) and (c) require further study or deliberation, and (e) is a non-conforming value.

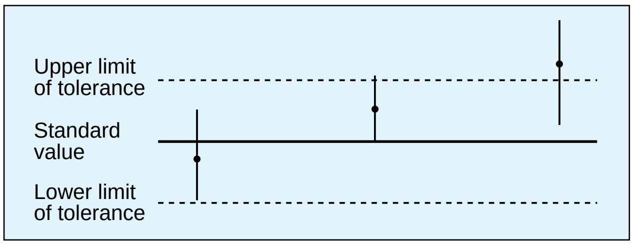

Fig. 3 Example of uncertainty in measurement values (1)

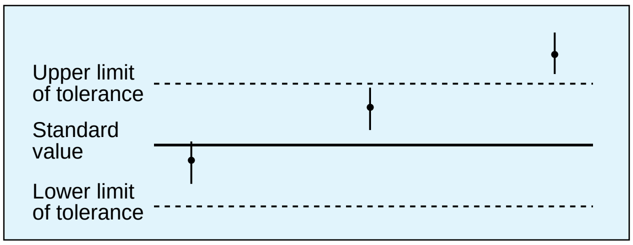

Fig. 4 Example of uncertainty in measurement values (2)

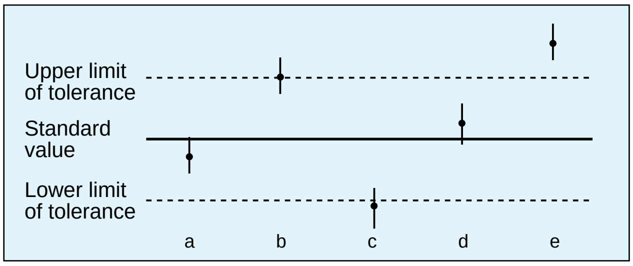

Fig. 5 Example of uncertainty in measurement values (3)

As you can see here, results will vary depending on the breadth of uncertainty (the reliability threshold). Therefore, uncertainty factors must be caught and examined for clarification.

4-2 Calculating uncertainty

Conventional wisdom has considered it adequate to simply calculate one digit further than the value required to determine tolerance. However, when dealing with measurements for comparison and measurements for certification, not only are average measurement results important, but also the range of dispersion, in other words, the uncertainty, is important as well. Therefore, to express measurement results, an approach is required that indicates the breadth of the reliability threshold with uncertainty considered. This approach has been internationally established and published as the "Guide to the Expression of Uncertainty in Measurement: GUM" by the ISO.

These guidelines divide uncertainty into type A uncertainty: u_A (uncertainty that can be handled statistically) and type B uncertainty: u_B (other types of uncertainty).

In addition to these types, the guidelines calculate compound uncertainty: u_C, and then calculate extended uncertainty: U by multiplying extended coefficient k times the compound uncertainty. (For lack of space, the details of the method for calculating uncertainty will be dealt with on another occasion.)

4-3 Factors in uncertainty

By reducing factors that generate uncertainty to a minimum, uncertainty can be minimized. In particular, worker error is a major factor that can be attributed to such causes as mood, health, carelessness, presumption, and overconfidence and lack of concentration due to becoming habituated. Another major factor is fluctuation over time in measuring equipment. (These errors are incorporated into the measurement values.)

Human error requires countermeasures such as education, training, accredited qualifications, procedure sheet, improved jigs, automatic measurement, and a properly equipped environment. Also, to make system defects apparent, the following items must be considered.

(1) Quality (E.g., ISO 9000) ⇒ Product defects
(2) Environment (E.g., ISO 14000) ⇒ Environmental pollution
(3) Occupational safety (OHSMS) ⇒ Occupational accidents

5. Conclusion

Measurement data and data written up in reports bears international requirements to display such factors as dispersion and error as "uncertainty."

More than ever in the field of reliability, persons participating in or responsible for handling data involving commercial transactions or persons concerned with quality assurance will find it absolutely essential to consider uncertainty, both in domestic and international matters. Considering these matters systematically and establishing an organized system will make it possible to maintain a higher degree of reliability. Standards such as QS 9000 require the presentation of measurement data from accredited testing labs.

[Bibliography]

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4) ISO 10012-2 Quality assurance for measuring equipment—Part 2: Guidelines for control of measurement processes
5) ISO/DIS 10012 Measurement control systems
6) QS 9000:98 Quality System Requirements
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