Chapter 15. Monitoring and Measurement Resources Related

Contents:

0) Introduction

There are several applicable clauses in this chapter. The focus is on monitoring and measuring, measurement equipment, and laboratory controls. Some new requirements e.g. calibration labs, need explanation to understand IATF's intent. There have been many NCs written on this area.

1) 7.1.5 , 7.1.5.1 Monitoring and measuring resources (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine and provide reliable monitoring and measuring resources to ensure products and services conforms to requirements. The organization shall ensure that the resources provided: (a) are suitable for the specific type of monitoring and measurement activities being undertaken; (b) are maintained to ensure their continuing fitness for their purpose. Appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources shall be retained

(Highlights of the clause)

- (Ref to old Standards) There has been a similar clause 7.6. Control of monitoring and measuring equipment, in the old version of ISO9001, which was lengthy and complicated.
- The new clause only takes the first portion of the older clause. Additionally, it is also simplified. It states the organization shall provide resources (a) suitable for the specific type of monitoring and measurement activities being undertaken; (b) maintain the resources to ensure continued fitness for their purpose.
- The requirement becomes more readable. One subtle change is from 'equipment' to 'resource', but there is no real significance in terms of controls. You can continue to use the word 'equipment' without penalty.
- There is another Clause 7.1.5.2 Measurement Traceability, that deals with the traceability matter (2nd portion of the old clause). And there is also a third related clause 7.1.5.2.1 that deals with Calibration/Verification records.
- Documented information shall be retained as evidence.

(Compliance Best Practice)

7.1.5 , 7.1.5.1 Monitoring and measuring resources

1. *To ensure suitable equipment has been selected, an organization should be able to explain how equipment are decided. For example, why a calliper is used instead of a height gauge.*
2. *There is generally no need for documented evidence, but convincing answers should be ready.*
3. *IATF Auditor will certainly ask to see a master list of Monitoring and Measurement equipment, and you should have this ready. The list shall include all measuring equipment: lab and field equipment, measuring jigs and fixtures. See* ***Exhibit 15-1.***

2) 7.1.5.2 Measurement Traceability (ISO9001)

(Clause Description-Paraphrase)

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: (a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; (b) identified in order to determine their status; (c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary

NOTE A number or another identifier traceable to the device calibration record meets the intent of the requirements in ISO 9001 :2015.

(Highlights of the clause)

- This is the second part of the Clause 7.6 of the previous ISO9001:2008 standard. Essentially nothing has changed but wordings are not the same. It becomes more readable.
- Measurement traceability is not mandatory for ISO9001. Its provision shall be based on customer or internal requirement. However, for IATF, traceability is required.
- Refer to clause content a) to c). Actions shall be taken if an equipment is found to be unfit for use.

(Compliance best practice)

7.1.5.2 Measurement Traceability

- *Measurement traceability means traceable to international standards, or the national equivalent. In practice, this means accreditation to ISO/IEC 17025, or to the national equivalent.*
- *Accreditation certificate of the calibration lab shall be ready for verification*

3) 7.1.5.2.1 Calibration/Verification records (IATF16949)

(Clause Description-Paraphrase)

A documented process is needed to manage calibration/verification records. Records of the calibration/verification activity for all gauges and measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to internal, legal, and customer requirements shall be retained. Calibration/verification activities and records shall include the following details: (a)

revisions due to engineering changes; (b) incidents of out-of-calibration readings; (c) assessment of the risk caused by the out-of-calibration condition; (d), records previous measurement results obtained with this piece of test equipment, last calibration date and the next due dates; (e) notification to the customer if suspect product or material has been shipped; (f) statements of conformity to specification after calibration/verification; (g) verification that the software version used for product and process control is as specified; (h) records of the calibration and maintenance activities for all gauging); (i) production-related software verification used for product and process control

(Interpretation & Comments)

- (Ref to old Standards). There had been a similar Clause, 7.6.2 of the same title, in the previous ISO/TS 16949. The content has been much expanded.
- A documented process is now needed for managing records and calibration/verification activities and records.
- All employee-owned, customer-owned, and onsite-supplier owned equipment are subjected to this control, as before.
- .Records shall include information of (a) to (i) of the requirements.
- A few new things being added as requirement: software versions used for product and process control required for calibration; and notification records to customer in the event that product conformities are affected by out of specs equipment.

(Compliance best practice)

7.1.5.2.1 Calibration/Verification records

- *An organization shall have an master list of monitoring and measuring equipment, showing all the equipment, equipment reference code, type of calibration, frequency of calibration, calibration date and next due date. See **Exhibit 15-1** for a specimen. Note that the listing shall also include software for product and process control.*
- *The master list is further cascaded down to individual equipment. See **Exhibit 15-2.***
- *And when an equipment fails between calibrations, there is a great risk of non-conforming parts flowing out to customers. You need to respond and check on many things in mitigation: notifications to customers, actions taken for out-of-calibration are recorded and reported. This is best recorded in another form,* as *evidence for compliance. See **Exhibit 15-3.***
- *Calibration certificate of an equipment must have the accreditation body's logo and Lab's membership number (normally the national accreditation body's) on the certificate. If there is no logo printed on the certificate, it means the lab is not accredited for the particular test. It is not wrong use of stationery as the labs might claim.*
- *Also note that calibration and verification reports shall be approved by a responsible authority internally and indicated on the reports. A phrase "approved for use" and signed, or affix a personalized stamp is sufficient to satisfy item (g) of the requirement.*

4) 7.1.5.3.1 Internal laboratory (IATF16949)

(Clause Description-Paraphrase)

An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test, or calibration services. This laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement, as a minimum, requirements for: (a) adequacy of the laboratory technical procedures; (b) competency of the laboratory personnel; (c) testing of the product; (d) capability to perform these services correctly,

traceable to the relevant process standard; when no national or international standard(s) is available, a methodology shall be defined to verify measurement system capability; (e) customer requirements, if any; (f) review of the related records.
NOTE says accreditation to ISO17025 is not necessary.

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(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 7.6.3.2.1 of the same title, in the old version of ISO/TS16949. It is almost a word-for-word reproduction of the old clause.
- The only exception is point (e), customer requirement is now a point of consideration.
- Should spell out the capability relevant info (a) to (f)

(Compliance best practice)

7.1.5.3.1 Internal laboratory

- *Compliance of this clause requires the organization to list down all the testing capabilities (can be by category e.g. dimension, force, mass etc.). See **Exhibit 15-4** for a specimen.*
- *Next, you can infer competency by listing down the tests, test methods/work instructions, customer requirement, competency requirement, technicians/operators etc. See **Exhibit 15-4.***
- *IATF Auditor may sample from the list for competency. Example: if you indicate technician competency is trained on calibration by an external lab, then certificates should be available as evidence.*

5) 7.1.5.3.2 External laboratory (IATF16949)

(Clause Description-Paraphrase)

External/commercial/independent laboratory facilities used for inspection, test or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration, either (a) accredited to ISO/IEC 17025 or national equivalent (e.g., CNAS-CL01 in China, see SI-10), (b) evidence that the external laboratory is acceptable to the customer

NOTE 1 gives allows second party audit using customer-approved method

NOTE 2 Calibration by the equipment manufacturer is still allowed, but organization should ensure that the lab meets the requirements listed in 7.1.5.3.1

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 7.6.3.2 of the same title. There had been no change from the previous requirement.
- The external lab performing calibration will be checked on their accreditation as well as their scope of services.
- When calibration services are performed by equipment manufacturers, it is still allowed with conditions. In the past, this was generally taken lightly, but now it is under control.
- Second party audit of calibration, lab is also allowed, but customer approved needed and method shall be used is approved by customer.

(Compliance best practice)

7.1.5.3.2 External laboratory

- *The calibration lab used must provide evidence of accreditation and the scope authorized.*
- *For using labs not accredited to ISO/IEC17025, organization needs to obtain waiver from relevant customers.*
- *Some equipment can only be calibrated by the OEM. They are still permitted to do so, with conditions., as below:*
  - *obtain customer waiver for their use. This can be just a letter from all customers affected. This is the best option.*
  - *provide evidence of the OEM's compliance to 7.1.5.3.1. See* ***Exhibit 15-5.***
  - *2nd Party audit of the calibration lab is also allowed with customer approval.*
- *2nd Party audit of the calibration lab is not preferred as the lab auditing is a specialized skill that needs special training*

6) SIs & FAQs

SI Nbr	IATF Clause	Description
10 ***revised***	**7.1.5.3.2. External laboratory**	External/commercial/independent laboratory facilities used for inspection, test, or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and either: — the laboratory shall be accredited to ISO/IEC 17025 **or its national equivalent (e.g., CNAS-CL01 in China) by an accreditation body (Signatory) of the ILAC MRA (International Laboratory Accreditation Forum Mutual Recognition Arrangement – www.ilac.org)** ~~or national equivalent~~ and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report shall include the mark of a national accreditation body; or — there shall be evidence that the external laboratory is acceptable to the customer. ***Rationale for change:*** *Some organizations found the lab accreditation requirements for external/commercial/independent laboratory facilities used for inspection, test, or calibration services confusing and needed clarification. Clarified lab accreditation requirements and expectations.*

FAQ I	ATF Clause	Questions and Answers
7	**7.1.5.3.2 External laboratory**	**QUESTION 1:** **When can the equipment manufacturer be used to calibrate inspection and test equipment?** **If an accredited laboratory exists but is very remote and/or expensive and the inspection or test equipment manufacturer is nearby and available can they be used (even if they are not accredited to ISO/IEC 17025)?** **ANSWER 1:** The inspection or test equipment manufacturer developed the methodology to maintain and adjust the equipment to meet calibration requirements as part of the design and manufacture of the inspection or test equipment. Therefore, the original equipment manufacturer of the inspection and test equipment is qualified to calibrate the equipment they designed and manufactured. The organization shall obtain customer approval before using any original equipment manufacturer for calibration services. **QUESTION 2:** **If the organization has inspection, measuring and test equipment in the final assembly and test area, is it considered an internal laboratory?** **ANSWER 2:** No. In-line measurement and test equipment used in any part of the manufacturing process or assembly process is not considered to be an internal laboratory.

14	**7.1.5.3.2 External laboratory**	**QUESTION:** **Is it required that the calibration certificate or (test) report of an external laboratory bears the mark (or logo or symbol) of the relevant national accreditation body that accredited the laboratory to ISO/IEC 17025?** **ANSWER:** Yes, only certificates of calibration or test reports including the mark of a national accreditation body are acceptable. The accreditation mark (often also called "accreditation logo" or "accreditation symbol") of a national accreditation body provides documented evidence that the provided inspection, test, or calibration services were performed according to the accreditation scope and that they comply with the requirements of ISO/IEC 17025, and are subject to supervision of a national accreditation body.

7) Supplementary Notes

Legend: HOC= Highlights of Clause, CBP= Compliance Best Practice, S&Q= SIs & FAQ, EXH= Exhibits

Clause	Section	Clarification Subjects
7.1.5, 7.1.5.1	CBP	**SN15-1. On basis of choice for measurement equipment, where can we get some guidelines?**
7.1.5, 7.1.5.1	CBP	**SN15-2. Will IATF auditor really check on equipment suitability stated in the above question?**
7.1.5.3.2	CBP	**SN15-3. Why do we ask for the accreditation certification of calibration lab? Isn't a company number given by the national standard adequate?**
7.1.5.3.2	CBP	**SN15-4. What are the common equipment that needs equipment manufacturers to calibrate.**
71521	CBP	**SN15-5. What is software for product and process control? How is this calibrated?**

SN15-1. On basis of choice for measurement equipment, where can we get some guidelines?
This is a section in AIAG MSA reference manual, discussing on this subject. Please refer.

SN15-2. Will IATF auditor really check on equipment suitability stated in the above question?
An auditor may only ask this kind of questions when an equipment chosen seems inappropriate. Example, the control plan says a dimension is to be measured by callipers, but a height gauge is used in the production line. The IATF auditor will naturally ask which is the correct method, and what is the basis of the decision.

SN15-3. Why do we ask for the accreditation certification of calibration lab? Isn't a company number given by the national standard adequate?
Although the membership is given by the accredited lab, the scope does matter. The scope is stated on the certificate or attached as an addendum. Not all members are accredited to do all sorts of tests and permitted to calibrate all kinds of measuring equipment. Additionally, there is also an expiry date of the accreditation cert. An expired accreditation certificate is not an admissible evidence of validity.

SN15-4. What are the common equipment that needs equipment manufacturers to calibrate.
Common equipment are CMM, torque wrench, machine operating software, colour meter, some process control software etc.

SN15-5. What is software for product and process control? How is this calibrated?
Software for operations control generally has the capability to judge, calculate etc, and controlled by the settings. These settings may deviate with usage and time, and calibration is needed. Examples are

robotic welders, automatic load cells for chemical mixing etc. In the lab, there are also measurement software on plating or paint thickness. They are either calibrated with another software or another method for comparison. If the outcome is not obtained, the software is out of order and need adjustments.

8) Exhibits

Exhibit 15-1. Equipment Master List

Measuring Equipment Master List

Description	Model/Serial No.	Acceptance Criteria	Equipment No.

Date	Type/ Serial No	Internal/External , Frequency	Passed-Cert No/Report	Failed-Disposition	Location	Next Due Date

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- This master list is common. It is either a printed sheet, or stays on the computer. Recently I have also seen special software for controlling measurement equipment and calibration, which is interesting
- Both externally calibrated and internally verified equipment shall be on the list, irrespective if it owned by the organization, employee, or onsite supplier.
- Besides lab equipment, but measuring equipment fixed on shop floor, work stations, and measuring jigs shall also be included

Individual Measuring Equipment Calibration Record

Description	Equipment No	Model/Serial No.	Type: Internal/External	Frequency

Date	Type Int/Ext	Date First Use	Pass/Fail	Cert No/Report	Disposition (if fail)	Calib master (int Veri)	Next Due Date

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- This is a recording sheet for individual equipment, but getting less popular. The master list (Exhibit 15-1.) if well designed, will make this form redundant.
- However, this may be necessary for internally verified equipment to provide a running history, especially those with verifications more than once a year

Exhibit 15-3. Calibration Incident Records

Calibration Incident Record
(Equipment Out-of-Specs)

Date Failure	Equipment	Failure Description	Product Lots Affected	Flow out?	Customer Notification	Disposition

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- This recording is not mandatory. So this form is also not mandatory
- However IATF and customer auditors do ask around this area, to ensure calibration incident is well responded to
- If you have records, it should be easier to handle such queries. Such recording also create better awareness of the risk of calibration incidents

Exhibit 15-4 Internal lab capability

Internal lab capabilities

Type of Testing Capabilities

A. **Dimensions.** A1.Callipers, A2.Micrometers, A3.Feeler gauge, A4. Height gauge, A5. Smart scope, A6. Pin gauge, A7.Block gauge, A8. CMM
B. **Weight.** B1.Digital balance
C. **Force:** C1. Torque meter, C2.Torque wrench
D. **Temperature:** D1. Thermometer, D2. IR thermometer, D3.Thermal couple
E. **Visual:** E1. cracks, E2. Burr, E3.Wrinkles, E4. Waving

Competency

No	Name	Competent at	Testing	Verification	Int/Ext Trained
1	Zambri Ismail	A1, A2, A3, A4, A5, A6, A7, A8	x		Internal
		A1, A2, A3, A4, A5, A7		x	External
2	Zarith	A1, A2, A3, A4, A5, A6, A7	x		Internal
		A1, A2, A3, A4, A5, A7		x	External

Test Methods:

No	Test Method	Standard
1	Callipers	??
2	Weighing machines	??

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- There are many organizations just ignoring this clause and hoping that the auditors do not asked. If they ever, do, they will use their convincing talent to prove they are competent. Sometimes they are not so lucky.
- This requirement is here to stay. If auditors have not asked before, it does not mean they won't in the next round. You should start to prepare the evidence.
- This is a very simple way to show internal lab capabilities and no reasons why it cannot be done

Exhibit 15-5. Evidence by non-ISO17025 OEM-page 1

Common Document to Prove Conformance to 7.1.5.3.1 Internal Laboratory
By Equipment Manufacturers without ISO/IEC17025

1. Self Declaration as Equipment Manufacturer Evidence. Registration, patent, brochure etc.

2. If the calibration is performed by a agent, appointment letter to certify the appointment, as below:

HEXAGON

CERTIFICATE OF CONFORMITY

This is to certify that

DigiGate Technology (Thailand) Co., Ltd.
Portable Measuring Arms Service Center
72/50-51 Moo 3 Tambol Bangtalad
Ampur Pakkrad, Nonthaburi 11120
Thailand

has been assessed by the Factory;
conforms to requirements and
demonstrates competence in the area(s) of

Service of CIMCORE Absolute Arms (Level 3)
Calibration of CIMCORE Absolute Arms

ASC-DGTTHNTB-2018	2018-02-28 to 2019-02-28
Certificate	Validity
2018-03-28	
Issued	Certification Authority

3. Competency of Technician, attach evidence:

DigiGate

Ref No. 17/080

CERTIFICATE OF TRAINING

Hereby Awards this Certificate of Accomplishment to

[redacted]

Digigate (Thailand) Co., Ltd.

In Recognition for attendance of Training in

"Calibration and Service Training"

On 26-28 July 2017

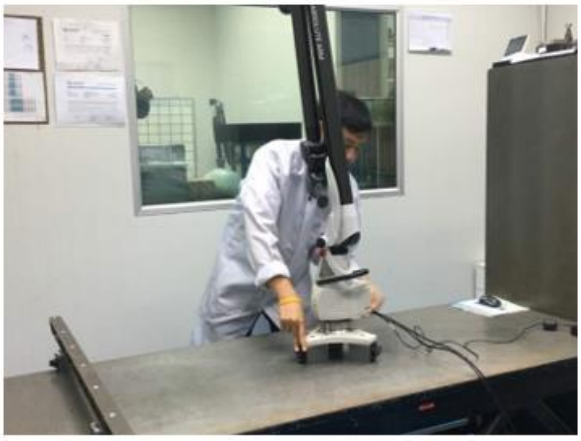
Yunood Salamad
DigiGate Technology (Thailand) Co., Ltd.

Chaiyod Kampradam
DigiGate Technology (Thailand) Co., Ltd.

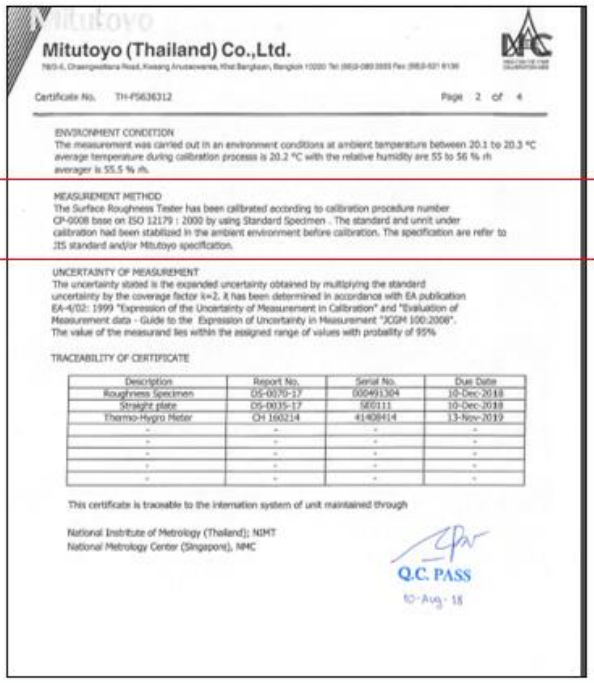
Please call + 66 0875981331 and ask for Technical Support if you have any questions.

Exhibit 15-5. Evidence by non-ISO17025 OEM-page 2

4. Lab Facilities: photo, calibration certs of equipment used for calibration. This can be exempted if calibration is done onsite, by calibration certs of equipment used are required.



5. Test Method (on the certificate of calibration



Mitutoyo (Thailand) Co.,Ltd.

Certificate No. TH-F5636312 Page 2 of 4

ENVIRONMENT CONDETION
The measurement was carried out in an environment conditions at ambient temperature between 20.1 to 20.3 °C average temperature during calibration process is 20.2 °C with the relative humidity are 55 to 56 % rh averager is 55.5 % rh.

MEASUREMENT METHOD
The Surface Roughness Tester has been calibrated according to calibration procedure number CP-0008 base on ISO 12179 : 2000 by using Standard Specimen . The standard and unnit under calibration had been stabilized in the ambient environment before calibration. The specification are refer to JIS standard and/or Mitutoyo specification.

UNCERTAINTY OF MEASUREMENT
The uncertainty stated is the expanded uncertainty obtained by multiplying the standard uncertainty by the coverage factor k=2, it has been determined in accordance with EA publication EA-4/02: 1999 "Expression of the Uncertainty of Measurement in Calibration" and "Evaluation of Measurement data - Guide to the Expression of Uncertainty in Measurement "JCGM 100:2008". The value of the measurand lies within the assigned range of values with probality of 95%

TRACEABILITY OF CERTIFICATE

Description	Report No.	Serial No.	Due Date
Roughness Specimen	05-0070-17	0004913304	10-Dec-2018
Straight plate	05-0035-17	520111	10-Dec-2018
Thermo-Hygro Meter	CH 160214	41408414	13-Nov-2019
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-

This certificate is traceable to the internation system of unit maintained through

National Institute of Metrology (Thailand); NIMT
National Metrology Center (Singapore), NMC

Q.C. PASS
10-Aug-18

Remarks given in this section explain on the Exhibit. Do not include them as part of the document

- If you are using equipment maker to calibrate your equipment , who is not certified to I7025, you should first try customer waiver
- If for some reasons, you cannot get the waiver, you can provide evidence of internal lab capability of the equipment maker. This is generally accepted as alternative compliance.

>> End of Chapter 15 <<