



มาตรฐานผลิตภัณฑ์อุตสาหกรรม

THAI INDUSTRIAL STANDARD

มอก. 5068—2549

ISO/IEC GUIDE 68 : 2002

การตกลงสำหรับการยอมรับและการยอมรับ ผลการตรวจสอบและรับรองไปใช้

ARRANGEMENTS FOR THE RECOGNITION AND ACCEPTANCE OF
CONFORMITY ASSESSMENT RESULTS

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

กระทรวงอุตสาหกรรม

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กระทรวงอุตสาหกรรม ถนนพระรามที่ 6 กรุงเทพฯ 10400
โทรศัพท์ 0 2202 3300

ประกาศในราชกิจจานุเบกษา ฉบับประกาศและงานทั่วไป เล่ม 124 ตอนพิเศษ 156ง
วันที่ 17 ตุลาคม พุทธศักราช 2550

วัตถุประสงค์ลำดับแรกของการตรวจสอบและรับรองคือการสร้างความเชื่อมั่นให้กับผู้ใช้ว่าผลิตภัณฑ์ การบริการ และระบบนั้นเป็นไปตามข้อกำหนดซึ่งความเชื่อมั่นนั้นนำไปสู่การยอมรับผลิตภัณฑ์ การบริการ และระบบของตลาด (ซึ่งอาจรวมถึงความสอดคล้องด้านกฎระเบียบด้วย)

หนึ่งในเหตุผลของการถูกตรวจสอบและรับรองซ้ำของการค้าสินค้าและบริการระหว่างประเทศก็คือการขาดความเชื่อมั่นของผู้ใช้ในประเทศหนึ่งที่มีต่อความสามารถของหน่วยงานที่ดำเนินกิจกรรมด้านการตรวจสอบและรับรองของอีกประเทศหนึ่ง ดังนั้นความเชื่อมั่นในการทำงานของหน่วยตรวจสอบและรับรอง และหน่วยรับรองระบบงานจึงจำเป็นต่อผู้ซื้อทั้งภาคเอกชนและผู้ซื้อทั่วไป ผู้ออกกฎระเบียบ และผู้ใช้อื่น ๆ

การสร้างความเชื่อมั่นดังกล่าวสามารถทำให้บรรลุผลผ่านความร่วมมือระหว่างหน่วยตรวจสอบและรับรอง และ/หรือหน่วยรับรองระบบงานต่าง ๆ ให้เกิดการยอมรับร่วมกันและส่งเสริมงานของผู้เข้าร่วมแต่ละหน่วยงาน

องค์ประกอบและขั้นตอนการดำเนินงานต่าง ๆ เท่าที่เคยใช้มาและพบว่าใช้งานได้จริงสำหรับการจัดทำและคงไว้ซึ่งความร่วมมือต่าง ๆ ได้น่ามากกล่าวไว้ในเอกสารนี้

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ กำหนดขึ้นโดยรับ ISO/IEC GUIDE 68 : 2002 Arrangements for the recognition and acceptance of conformity assessment results มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO/IEC GUIDE ฉบับภาษาอังกฤษเป็นหลัก

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดขึ้นเพื่อให้ทันกับความต้องการของผู้ใช้และจักได้แปลเป็นภาษาไทยในโอกาสอันสมควร หากมีข้อสงสัยโปรดติดต่อสอบถามที่สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

คณะกรรมการมาตรฐานผลิตภัณฑ์อุตสาหกรรมได้พิจารณามาตรฐานนี้แล้ว เห็นสมควรเสนอรัฐมนตรีประกาศตาม มาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511



ประกาศกระทรวงอุตสาหกรรม

ฉบับที่ 3758 (พ.ศ. 2550)

ออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม

พ.ศ. 2511

เรื่อง กำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม

การตกลงสำหรับการยอมรับและการยอมรับผลการตรวจสอบและรับรองไปใช้

อาศัยอำนาจตามความในมาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511 รัฐมนตรีว่าการกระทรวงอุตสาหกรรมออกประกาศกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม การตกลงสำหรับการยอมรับและการยอมรับผลการตรวจสอบและรับรองไปใช้ มาตรฐานเลขที่ มอก. 5068-2549 ไว้ดังมีรายละเอียดต่อท้ายประกาศนี้

ประกาศ ณ วันที่ 10 สิงหาคม พ.ศ. 2550

โสมิต ปันเปี่ยมรัชฎ์

รัฐมนตรีว่าการกระทรวงอุตสาหกรรม

มาตรฐานผลิตภัณฑ์อุตสาหกรรม

การตกลงสำหรับการยอมรับและ

การยอมรับผลการตรวจสอบและรับรองไปใช้

0. บทนำ

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ กำหนดขึ้นโดยรับ ISO/IEC GUIDE 68 : 2002 Arrangements for the recognition and acceptance of conformity assessment results มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO/IEC GUIDE ฉบับภาษาอังกฤษเป็นหลัก

1. ขอบข่าย

มาตรฐานนี้ได้ให้คำแนะนำในการจัดทำ การประกาศและการปฏิบัติในการจัดทำข้อตกลงสำหรับการยอมรับและการยอมรับผลการดำเนินงานโดยหน่วยงานที่ทำหน้าที่ตรวจสอบและรับรอง และกิจกรรมอื่นๆ ที่เกี่ยวข้องไปใช้กิจกรรมที่มาตรฐานนี้มุ่งเน้นให้นำไปใช้เป็นเรื่องของธุรกิจการค้าระหว่างประเทศที่ไม่มีกฎข้อบังคับมาเกี่ยวข้องขณะที่ความตกลงของบรรดาภาครัฐที่กระทำกันจะเป็นการทำธุรกิจการค้าของสินค้าและบริการภาคบังคับ อย่างไรก็ตาม มาตรฐานนี้เป็นเพียงข้อเสนอแนะและเรื่องทั่วไปที่ไม่ได้กล่าวถึงข้อกำหนดใดเป็นพิเศษตั้งข้อตกลงของภาครัฐ

ในบางประเทศอาจมีข้อจำกัดด้านบุคลากรและหน่วยงานที่จำเป็นเกี่ยวข้องกับโครงสร้างพื้นฐานด้านการตรวจสอบและรับรองของสถาบันจึงไม่สามารถเข้าร่วมในข้อตกลง ข้อเสนอแนะสำหรับการจัดหาและพัฒนาหน่วยงานดังกล่าวไม่จัดอยู่ในขอบข่ายของเอกสารนี้

รายละเอียดให้เป็นไปตาม ISO/IEC Guide 68 : 2002 ข้อ 1

2. เอกสารอ้างอิง

รายละเอียดให้เป็นไปตาม ISO/IEC GUIDE 68 : 2002 ข้อ 2

3. คำศัพท์และบทนิยาม

ความหมายของคำศัพท์และบทนิยามที่ใช้ในมาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้ ให้เป็นไปตาม มอก.5002-2549
รายละเอียดให้เป็นไปตาม ISO/IEC GUIDE 68 : 2002 ข้อ 3

4. องค์ประกอบของข้อตกลง

รายละเอียดให้เป็นไปตาม ISO/IEC Guide 68 : 2002 ข้อ 4

5. การจัดตั้งกลุ่มข้อตกลง

รายละเอียดให้เป็นไปตาม ISO/IEC Guide 68 : 2002 ข้อ 5

6. ภาคผนวก ก. (ให้ไว้เป็นข้อแนะนำ) ตัวอย่างสำหรับการจัดทำข้อตกลง

รายละเอียดให้เป็นไปตาม ISO/IEC Guide 68 : 2002 Annex A

Introduction

The primary objective of conformity assessment is to provide confidence for users that requirements applicable to products, services and systems have been met. Such confidence, in turn, directly contributes to the market acceptance (which may include regulatory compliance) of those products, services and systems.

One of the reasons why internationally traded goods and services are subject to repetitive conformity assessments is a lack of confidence by users of conformity assessment in one country regarding the competence of bodies carrying out conformity assessment activities in other countries. Confidence in the work of conformity assessment bodies and accreditation bodies is therefore essential to private and public purchasers, regulators and other users.

Such user confidence can be achieved through cooperation among conformity assessment bodies and/or accreditation bodies, resulting in mutual recognition and promotion across borders of each participant's work.

The elements and procedures used so far and found practical for establishing and maintaining such cooperations are described in this Guide.

Arrangements for the recognition and acceptance of conformity assessment results

1 Scope

This Guide provides an introduction to the development, issuance and operation of arrangements for the recognition and acceptance of results produced by bodies undertaking similar conformity assessment and related activities. The activities to which this guidance is intended to apply are those related to the conduct of unregulated marketplace transactions extending across borders from one country to another. While agreements among governments pertaining to transactions of regulated goods and services can take into account the agreements addressed by this Guide, the guidance provided here is introductory and general in nature and does not specifically address any special requirements that governmental agreements might generate.

Some countries may be concerned about having the necessary human and institutional resources with respect to conformity assessment infrastructures which would permit them to participate in such arrangements. Guidance on the acquisition and development of the resources required is beyond the scope of this Guide.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 2 and the following apply.

NOTE Clauses 12 to 17 of ISO/IEC Guide 2:1996 (on conformity assessment) are under revision as ISO/IEC 17000.

3.1

recognition arrangement

arrangement whereby participating bodies acknowledge to others that the conformity assessment results of the other participating bodies have been produced by competently performed, equivalent procedures

3.2

acceptance arrangement

arrangement whereby participating bodies use conformity assessment results of other participating bodies when these are acknowledged as having been produced by competently performed, equivalent procedures

3.3

agreement group

bodies that are signatories to the agreement on which an arrangement is based

3.4 peer assessment

evaluation of a body, against specified requirements, by representatives from other bodies in, or candidates for, an agreement group

NOTE In this Guide the term “agreement” refers to the document signed by the participants of an agreement group.

4 Elements of an agreement

4.1 General

A comprehensive list of elements contained in agreements related to conformity assessment results is given in 4.2 to 4.12. In general, most of the elements are addressed in an agreement.

4.2 Title

The term “mutual recognition agreement” is sometimes used when the agreement has a legally binding nature, such as a mutual recognition agreement in regulatory fields among government authorities from different countries. Consequently, in order to distinguish voluntary applications from government agreements, “mutual recognition arrangement” or “multilateral recognition arrangement” is commonly used in voluntary applications, such as accreditation and certification/registration systems.

4.3 Introduction

Generally an introduction or preamble is provided, which briefly describes the reason for the agreement, the history behind its establishment, and details of the needs which it is intended to address (for example, facilitation of trade or reduction of multiple assessment activities).

4.4 Signatories

The organizations or types of organization forming the agreement group are specified including, when appropriate, details of their legal status and geographical or other eligibility conditions.

4.5 Scope

This subclause normally clearly specifies the category of product and/or sector and conformity assessment activity covered by the agreement.

4.6 Conditions for eligibility

Agreements generally specify the conditions for eligibility to enter into an agreement group. These conditions are generally document-based (see the Bibliography) and include satisfactory demonstration of the following:

- a) conformity to the requirements of the relevant documents applicable to the eligible bodies;
- b) procedures that result in competently performed assessments within the scope of the agreement;
- c) availability of resources to sustain commitment and the ability to continue to meet the obligations to the agreement group.

4.7 Individual obligations of signatories

A significant part of the agreement is the statement of what the signatories agree to undertake, or other requirements to which they commit themselves. Typical items of commitment included in existing agreements are as follows:

- a) recognition of the equivalence of the conduct of activities within the scope of the agreement by its signatories;
- b) acceptance of results produced by other signatories as applicable within the scope of the agreement;
- c) promotion of public awareness of the equivalence of the performance and, where applicable, the results produced by signatories to the agreement;
- d) maintenance of the confidentiality of information so designated with respect to other signatories;
- e) acceptance of legal and liability responsibilities, as well as responsibility for notifying other signatories of significant changes in status.

NOTE Agreements vary in the extent to which they call for the acceptance of results by the signatories. Some agreements are without a requirement for acceptance of any results, while others require one signatory to use in their entirety the results produced by other signatories, thus avoiding redundant work by a signatory in the decision-making process.

4.8 Collective obligations of signatories

Another significant part of the agreement is the statement of what the signatories agree to undertake collectively. Items of collective responsibility often appearing in agreements elaborate on conditions for the following:

- a) evaluation and resolution of complaints relative to the operation of the agreement;
- b) maintenance and operation of an ongoing system of surveillance and/or re-assessment on a periodic basis;
- c) processing and resolution of disputes occurring within the group within the scope of the agreement;
- d) use of a common logo and/or document by the signatories, if so agreed.

NOTE Before accepting the use of a common logo, signatories may initially limit the scope of the arrangement until they develop confidence among themselves.

4.9 Relationships with other agreement groups

Some international agreements provide for relationships with other agreement groups. The typical relationship is with regional groupings of similar scope. To effect these relationships, an agreement will probably have conditions for entry and continuing membership of the regional grouping, which ensure adherence by regional group signatories to the conditions given in 4.7.

4.10 Duration of the agreement

The commencement date of the agreement will be indicated and possibly also the period of validity of the agreement and the conditions under which participation by one or more of the signatories may be suspended or withdrawn, or the agreement as a whole may be terminated.

4.11 Points of contact

Most agreements include identification of the signatory contact personnel who are responsible for updating and exchanging information, publishing details of the arrangement in their respective territories, and identifying when a signatory is unable to fulfil its obligations under the arrangement.

4.12 Official signatures

The text of an agreement normally contains the signatures and titles of personnel of appropriate authority representing each body which is a signatory to the agreement. The date of each signature is also recorded.

4.13 Conditions for amendment

The text of an agreement normally contains conditions with which (and the procedures by which) the terms of the agreement may be amended or otherwise altered.

NOTE Annex A lists some organizations that have agreements in place and gives uniform resource locations (URLs) for their websites that contain the texts of the agreements. These can be consulted to see how the elements documented here are actually represented in agreements.

5 Establishing the agreement group

5.1 Demonstrating conformity to internationally recognized requirements

5.1.1 In order to establish an agreement group, signatories need full confidence that potentially eligible bodies are all competent and work in an appropriately similar way. The process for building and maintaining confidence utilizes methods for demonstrating conformity with internationally recognized requirements for the bodies involved.

5.1.2 Several methods of demonstrating conformity to the requirements set out in the applicable documents are commonly used. Their choice is often negotiated according to the conformity assessment activities within the scope of the agreement. The methods are described in 5.2.1 and 5.2.2 and may be applied when two or more bodies are involved.

5.2 Methods for demonstrating conformity

5.2.1 Direct method

The direct method is chosen when confidence among the potential signatories can be created through direct contacts among them. Its technical basis is a peer assessment in which each of the potential signatories is evaluated by, or on behalf of, all the others. For practical reasons, the involved bodies often set up an assessment team that carries out the assessment of conformity on behalf of the others.

NOTE Peer assessment is the subject of ISO/IEC 17040, *General requirements for peer assessment of conformity assessment bodies* (under development); when completed, detailed information on the subject will be found there.

In addition to this assessment of conformity, the partners may cooperate operationally by arranging meetings, witnessing or discussing typical applications, or sharing training sessions. Where applicable, methods such as proficiency testing may be relied upon as a means of demonstrating equivalency of performance. Such cooperation builds confidence among the partners on an ongoing basis.

5.2.2 Indirect method

In the indirect method, confidence among the participants is based on the recognition of assessment results provided by external assessment systems. In particular, accreditation of the participants by accreditation bodies using equivalent procedures is a commonly relied upon method. These may include accreditation bodies that are themselves members of an agreement group. Thus, arrangements among accreditation bodies by which they recognize each other's work may support arrangements among conformity assessment bodies.

Alternatively, participants may be assessed by one or more bodies (e.g. certification bodies), often specified in the agreement. These bodies are selected for their competence but are not part of those conducting the

conformity assessment activities covered by the arrangement. Thus, this method does not directly involve the conformity assessment bodies interacting with one another in the confidence-building process.

5.2.3 Other methods

The direct and indirect methods described above are not necessarily mutually exclusive and may be combined for use for other purposes such as direct assessment of the signatory product certification bodies and indirect assessment of the testing laboratories they use. Another example is an international arrangement in which eligibility to become a signatory can be demonstrated directly (i.e. the body is assessed) or indirectly (i.e. by virtue of acceptance of participants from a regional grouping).

Regardless of the method, bodies that participate in such assessments should have similar competence and should operate in an equivalent manner. In any case, the principle of operational cooperation among them should apply.

5.3 Internationally recognized principles and requirements

Some key measures to facilitate the process of providing confidence in conformity assessment results may include the harmonization of

- procedures for ensuring transparency and document accessibility,
- the requirements for testing and inspection methods to be employed,
- the elements tested, inspected or assessed, which together make up the approval procedure,
- the methods of evaluation of measurement facilities and calibration of test equipment,
- the methods of control of environmental test conditions,
- the test, inspection or assessment report form,
- procedures for evaluation of the report, resulting in a decision on approval or not,
- the means used to communicate a positive or negative result of the approval procedure to involved parties (e.g. certificates, marks of approval),
- assessment and decision-making procedures,
- the application procedures followed by the testing, inspection and certification/registration bodies involved,
- the methods of evaluation of the competence of personnel, and
- the accreditation procedures.

Internationally recognized requirements for conformity assessment and accreditation bodies have been documented in ISO/IEC Guides and International Standards. The relevant documents are listed in the Bibliography.

Annex A (informative)

Examples of operational arrangements

A.1 General

Bilateral, regional and international arrangements have been implemented and have associated agreement groups of accreditation bodies and agreement groups of conformity assessment bodies. Below are examples of regional and international arrangements, and arrangements among accreditation bodies and among certification/registration bodies. All of the examples provided are bound by agreements comprised of the items introduced in Clause 4, and in their operation provide mechanisms for maintaining the arrangement in line with those used to establish them (see Clause 5).

A.2 Arrangements involving accreditation bodies

A.2.1 International

One example is the International Accreditation Forum, Inc. Multilateral Recognition Arrangement (IAF MLA). The IAF MLA is a recognition arrangement. This arrangement is based on the equivalence of accreditation programmes operated by accreditation body members and is verified through peer assessment among accreditation body members of IAF.

Participating accreditation bodies (i.e. those that accredit quality management system certification/registration bodies) recognize each other's competence. A peer assessment process operated by the signatories provides the confidence-building mechanism for this multilateral recognition arrangement.

Peer assessments of signatories take place at intervals of approximately 4 years for the purpose of ensuring that the signatory bodies continue to meet the relevant requirements.

A.2.2 Regional

One example is the Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement (APLAC MRA). APLAC MRA is a regional recognition arrangement. This is a typical regional arrangement among laboratory accreditation bodies, as a means by which accreditation bodies recognize the technical equivalence of reports/certificates issued by one another's accredited laboratories and promote their acceptance by users.

Peer assessments of signatories to the arrangement take place at intervals of approximately 4 years for the purpose of ensuring that the signatory bodies continue to meet the relevant requirements.

A.2.3 Websites

Websites that can be consulted for examples are as follows.

International Accreditation Forum, inc. (IAF)	http://www.iaf.nu
International Laboratory Accreditation Cooperation (ILAC)	http://www.ilac.org
European Co-operation for Accreditation (EA)	http://www.european-accreditation.org
Pacific Accreditation Cooperation (PAC)	http://www.apec-pac.org
Asia Pacific Laboratory Accreditation Cooperation (APLAC)	http://www.aplac.org

A.3 Arrangements involving certification bodies

A.3.1 Acceptance of test reports

One example is the International Electrotechnical Commission (IEC) Certification Body (CB) scheme. The CB scheme is an acceptance arrangement since the signatories agree to accept test data reports from the other signatories under prescribed conditions. Confidence is built using peer assessment of testing capability. Legal limitations exist for this, since some of the signatories have legal obligations regarding how they may operate as a certification body. Stakeholder limitations may exist as well. The CB scheme is a multilateral approximation of similar bilateral arrangements between product certification bodies.

A.3.2 Recognition of certification results

One example is the International Certification Network (IQNet). IQNet is a network of certification bodies which operate a multilateral recognition arrangement in the field of management system certification/registration. Equivalence of competence and confidence are ensured by an initial assessment and periodic reassessment of its members to ISO/IEC Guides, International Standards and peer assessment rules. IQNet partners recognize each other's certificates. The members use the IQNet Mark and the IQNet presentation registration documents.

Another example is the IEC - IECEx scheme. The IECEx scheme is an acceptance arrangement. This scheme provides a means for manufacturers of electrical equipment for explosive atmospheres to obtain certificates of conformity that will be accepted in all participating countries as being equivalent to their national certification. A certificate of conformity may be obtained from any certification body accepted into the scheme. The certificate will attest that the manufacturer operates a quality system meeting the requirements of this scheme and ISO 9001. Manufacturers holding certificates of conformity may affix the IECEx Mark of Conformity to equipment that they have verified as complying with the certified design. The objective of the scheme is the worldwide acceptance of a single standard, a single certificate and a single mark.

A.3.3 Websites

Websites that can be consulted for examples are as follows.

IECEE - CB scheme	http://www.cbscheme.org
IECEx scheme	http://www.iecex.com
International Certification Network (IQNet)	http://www.iqnet-certification.com

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- [9] ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*
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NOTE In the future, new Guides and International Standards currently under development may be added to the above list.

1) To be published. (Revision in part of ISO/IEC Guide 2:1996)