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Pattern evaluation and pattern approval

Essai de modèle et approbation de modèle

OIML D 19 Edition 1988 (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States.

The two main categories of OIML publications are:

- **International Recommendations (OIML R)**, which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;

- **International Documents (OIML D)**, which are informative in nature and intended to improve the work of the metrological services.

OIML Draft Recommendations and Documents are developed by technical committees or subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis.

Cooperative agreements are established between OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may apply simultaneously OIML publications and those of other institutions.

International Recommendations and International Documents are published in French (F) and English (E) and are subject to periodic revision.

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PATTERN EVALUATION and PATTERN APPROVAL

CHAPTER I

GENERAL

1.0. Introduction

This International Document is addressed primarily to two groups — OIML Secretariats and legal metrology officials — concerned with pattern evaluation and pattern approval of measuring instruments. OIML Secretariats are responsible for the drafting of International Recommendations for measuring instruments subject to pattern evaluation and approval. Legal metrology officials are responsible for the adoption and implementation of pattern evaluation and pattern approval requirements.

Because of its general nature, this International Document has wide applicability in such fields as weights and measures, environmental protection or medicine. It includes advice, procedures, and influencing factors bearing on the conduct of pattern evaluation and on the pattern approval decision that follows it.

Pattern evaluation and pattern approval are components of a system of legal metrology controls designed to provide government with the means for assuring the adequacy of measurements covered by law or regulation. They are quite distinct steps in the metrological control system. Pattern evaluation is an objective process of determining facts concerning a pattern, while pattern approval is the decision, based on these facts and involving judgment, to admit or not to admit the subject pattern to legal use. The approving official will often not be the official(s) who carried out the evaluation. The view is taken in this Document that these officials are distinct.

A pattern approval relates to both the subject pattern and to the applicant who requests the pattern approval. It conveys license to the applicant to produce and/or sell instruments of a specific type with the implication that they are likely to conform to the approved pattern. It conveys to the users of these instruments and to verifying officials that the pattern conforms to legal requirements and is adequate for use in approved applications. The pattern approval process, therefore, constitutes an important component of official efforts to assure the quality of measurements in certain areas of public concern. However, because many variables, conditions, and limitations bear on the manner of pattern evaluation, it becomes necessary to choose between available alternatives and to plan pattern evaluations to accommodate the particular cases at hand.

Up to a point these choices are forced by the nature of the pattern and its application, the resources available for pattern evaluation, and applicable regulations or national practice. Beyond these factors there usually is some freedom of choice which can be turned to advantage in accommodating different situations as they present themselves. This International Document covers some of the available alternatives, such as shifting emphasis and effort from pattern evaluation to initial verification or vice versa or, cooperation by the manufacturer in the course of pattern evaluation. Traditionally, manufacturers and legal metrology agencies have functioned more or less independently of each other, with the manufacturer designing and producing and the agency evaluating and approving. The burdens of the ever-increasing number, variety, and complexity of instruments draw emphasis to the importance

of government-manufacturer cooperation. Modern designs, complex electronic circuitry, and fast-changing technology complicate the pattern approval process so that increasingly flexible approaches to it are necessary. At the same time, design criteria become more restrictive tools than heretofore and represent only a last resort, whereas minimum performance criteria become more attractive in that they tend to remain applicable while not standing in the way to innovation.

A companion International Document, «Initial and Subsequent Verification» is also available; it may prove to be useful when an appropriate balance between pattern evaluation and initial verification is being considered.

1.1. Definitions

The terms in this Document are taken from the 1978 edition of the Vocabulary of Legal Metrology (VML), where appropriate. Definitions of terms not found in the VML are presented below. Terms 1.1.8 through 1.1.10 are taken from ISO Guide 2, «General terms and their definitions concerning standardization, certification and testing laboratory accreditation».

1.1.1. Request for pattern approval

Taken together, all the documents, instruments, fees, etc. submitted to the concerned legal metrology agency when approval of a pattern is requested.

1.1.2. Pattern approval process

The sequence of all the steps taken in the course of the evaluation and approval or rejection of a pattern, starting with the submission of the request for pattern approval and culminating in a certificate or notice of pattern approval or rejection.

1.1.3. Copy of a pattern

An individual instrument which conforms, within specified limits, to a given pattern in all respects.

Note: The word « pattern » has been commonly used to refer to the definitive model of a measuring instrument as well as to the class of instruments that conform to it. The instruments produced by the manufacturer to replicate the pattern constitute a different class. The question of whether an instrument of this class conforms to the pattern is normally the subject of initial verification. Pattern approval not only implies the recognition that the pattern conforms to requirements but, generally, also relates to the instruments of the class produced by the manufacturer; it usually conveys that these may be sold as legal for use and submitted for initial verification.

1.1.4. Modification of a pattern

A change in a pattern that does or may alter some of its metrological or technical characteristics, its ranges, or its applicability.

1.1.5. Modified pattern

With reference to a given pattern, a pattern which has been subjected to modification.

1.1.6. Validity of pattern approval

A period of time during which the pattern approval is recognized by the approving legal metrology agency as being in effect.

1.1.7. Jurisdiction

The sphere within which a particular government or a given agency of such a government has power to make or enforce law or regulation.

Examples: The spheres of legal authority of (1) a particular national government, (2) a particular provincial government, (3) the legal metrology agency of a particular country, and (4) the agency of a particular city government charged with enforcing pollution laws.

1.1.8. Testing laboratory

A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of materials or products.

1.1.9. Laboratory accreditation

A formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests.

Note: The genetic term «accreditation» can cover the recognition of both the technical competence and the impartiality of a testing laboratory or only its technical competence. Accreditation is normally awarded following successful laboratory assessment and is followed by appropriate monitoring.

1.1.10. Accredited laboratory

A testing laboratory to which accreditation has been granted.

CHAPTER II

INSTRUMENTS SUBJECT TO PATTERN APPROVAL

2.0. General

Legal metrology controls may focus on the measuring instruments used (traditional legal metrology), on the general qualifications of laboratories making measurements (laboratory accreditation), or on the ability to obtain acceptable measurement results (proficiency testing). While these approaches often exist side by side, pattern approvals, and therefore also instruments subject to pattern approval, are part of only traditional legal metrology. The major questions that need to be answered to decide what instruments are subject to pattern approval are : what instruments fall under legal regulation ; what differentiates one pattern from another so as to require separate pattern approvals; and what is a sufficiently significant modification so as to require approval of the modification. These questions are discussed below.

2.1. Requirement of pattern approval

Control of whole categories of measuring instruments may be required by law. While this most often involves pattern approval, occasionally verification without pattern approval is deemed sufficient. The requirement of pattern approval stems from either the intended or the potential use of measuring instruments in activities where the quality of measurement is of public concern. Such uses may be identified as the measurement of quantities related to specified classes of objects, commodities, phenomena, materials, or conditions. For example, pattern approval of taximeters is generally required because of their intended use in determining taxi fares. However, pattern approval of volumetric measures might be required because of their potential use in commerce, even though some of these measures might only be used in households, laboratories, or factories. Certain instruments used in fields of measurement involving the public can be exempt from pattern approval (See point 2.4).

2.2. What constitutes a « different » pattern

When two types of instruments are very much alike, a decision must be made whether, from a legal metrology point of view, only one or two separate pattern approval processes must be followed. Guidelines intended to help with such decisions follow.

2.2.1. Different applicants or manufacturers

A pattern approval is granted to a specific applicant. Seemingly identical instruments submitted for pattern approval by different applicants, presumably produced by different manufacturers should follow independent pattern approval processes.

2.2.2. Superficial differences between instrument types

Different instrument types produced by a particular manufacturer that are identical in design, materials, components and measurement ranges, but that differ superficially in their color or other non-metrological appointments dan normally be regarded as being covered by a single pattern approval.

2.2.3. Different measurement ranges

One can generally consider as covered by the same pattern approval, instruments of a specific manufacturer which differ in measuring range and/or in scale intervals of measured quantities, provided that such differences preserve the performance of the instrument within permissible error limits.

2.2.4. Different components, materials, or manufacturing techniques

In general one can consider as covered by a single approval instruments manufactured by a specific manufacturer which differ from one another by the fact that they contain nominally identical components or materials obtained from different suppliers, if the various sources of supply do not influence the regulated metrological characteristics of the instruments. Similar considerations apply when the manufacturer employs different manufacturing techniques or, in electronic instruments, different wiring or layouts, to produce a single type of instrument. They also apply when different components are used as transducers between the measured quantity and the sensors of otherwise identical instruments. Example are load platforms of weighing instruments and connectors at the input of electronic instruments.

2.3. What constitutes a modified pattern

When a manufacturer makes changes in a type of instrument related to an approved pattern, approval of the modification may be necessary. The considerations in such cases are presented below.

2.3.1. Responsibility for determining occurrence of modifications

When a manufacturer makes a change in a type of instrument manufactured to replicate an approved pattern, three possibilities exist:

— the changed instrument is still a replication of the approved pattern ;

— the change is sufficient to require approval of a modification of the pattern ; or

— the change is so radical that a new pattern approval must be obtained as for a new type of instrument.

Guidelines concerning responsibility for taking action in such matters should be issued by the legal metrology agency. These should address both the question of action threshold and the procedures to be followed by responsible parties. Action thresholds can be based on the considerations given in point 2.2.

The following two possible procedures for use in such cases by grantees or manufacturers should be considered by the agency; preferably they should have the option of using either one.

2.3.1.1. Notification of change in instrument type

The grantee of the original approval or the manufacturer notifies the legal metrology agency that a change has been made or is contemplated for an instrument produced to replicate an approved pattern. They cite the existing pattern approval, detail the changes, and give any data, analysis, and conclusions concerning the technical or metrological consequences of the changes. On the basis of the notification, the agency decides whether to require further action as regards approval of a pattern modification, or a new pattern approval, and informs the grantee or the manufacturer accordingly.

2.3.1.2. Request for approval of modification

The grantee of the original approval or the manufacturer, after taking account of official guidelines and deciding that a change is significant, requests approval of a pattern modification, or possibly a new pattern approval, citing the existing pattern approval, detailing the changes, and giving any data, analysis, and conclusions concerning the technical or metrological consequences of the changes.

2.3.2. Evaluation for modification of a pattern

When a manufacturer seeks approval of a modified pattern, the legal metrology agency must first determine whether the changes constitute only a modification. Then, on the basis of both the previous evaluation of the original pattern and the modification as described in submitted documents or embodied in a submitted instrument, it must decide how to evaluate the modified pattern. Possibilities include only an evaluation of documents when the metrological consequences of the modification are quite predictable from these documents; a partial pattern evaluation when the modification clearly affects only specific characteristics or portions of the instrument; and a limited pattern evaluation when it seems necessary to check whether, or to what extent, the modification affects the various metrological characteristics of the pattern.

The evaluation of the modification can result in approval, modification of the approval, a new approval or the rejection of the modified pattern.

2.4. Instruments exempt from pattern approval

Certain categories of measuring instruments, though subject to control, may be exempt from the requirement of pattern approval. These categories should be specified in regulations along with detailed requirements as to the technical and metrological characteristics, and conceivably also as to the form, constituent materials, and construction of specific exempt patterns or categories of patterns. Such exemptions are inevitably coupled with requirements for verification and instruments are automatically accepted for initial verification. Instruments to be considered for exemption from pattern approval requirements generally are conventional instruments of such design and construction material whose metrological qualities do not vary much with time or single instruments and systems composed of approved components. Examples of such instruments are liquid-in-glass thermometers and drinking measures for alcoholic beverages.

CHAPTER III

PATTERN APPROVAL PROCESS

3.0. Alternative pattern approval processes

The pattern approval process is shown in Figure 1 in context with the complete control process which includes all steps from the design of an instrument to the subsequent verification of instruments. More steps are shown in the figure than will ever be used in practice in relation to any one pattern. The figure thus represents a number of alternatives, only one of which would be followed in any given instance. The most commonly used pattern approval process follows steps 4, 5 and 6.

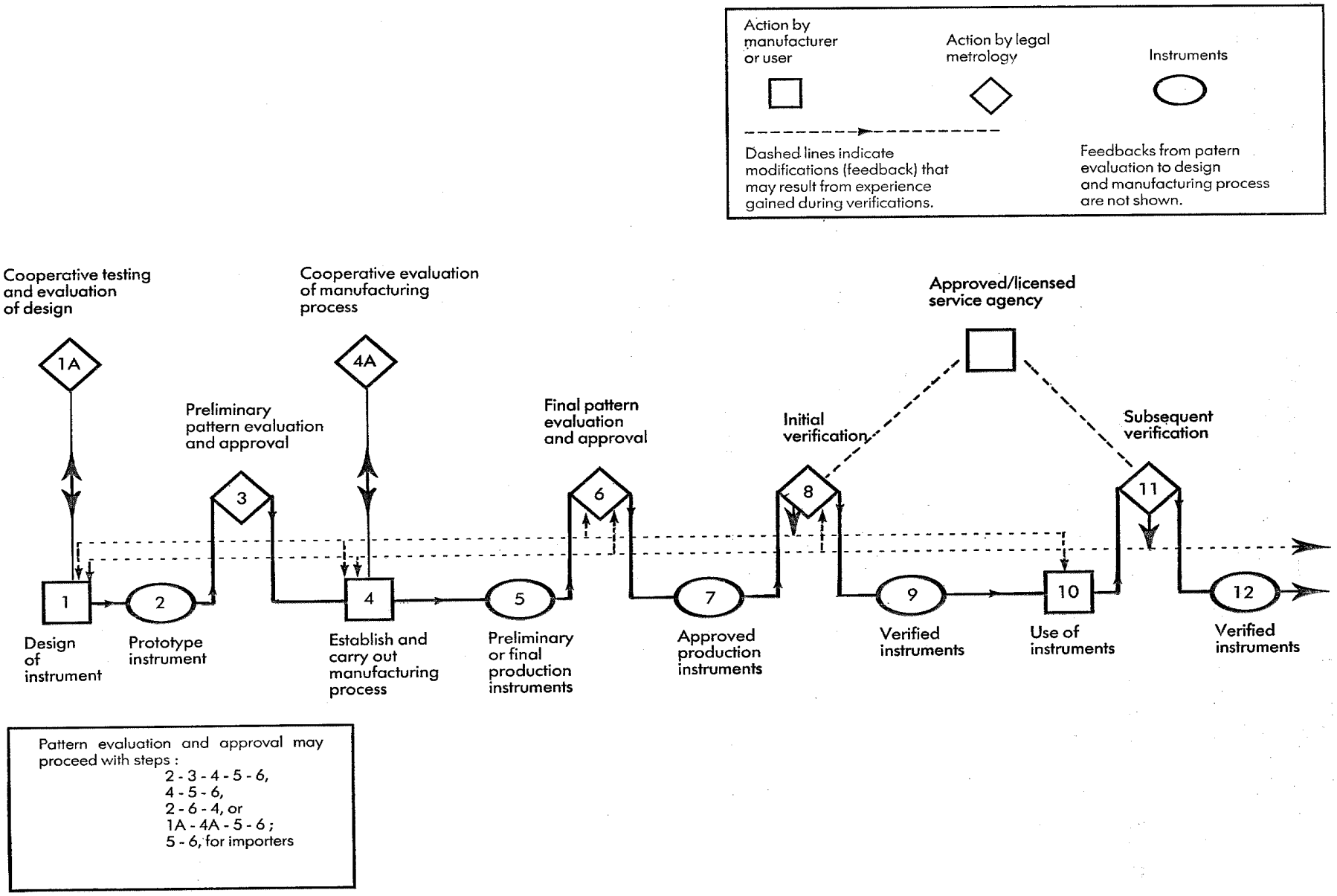
A departure from the traditional step 4-5-6 process, which is being considered by some, follows steps 1A-4A-5-6. In step 1A agency representatives discuss a new design with the manufacturer and witness preliminary tests at the earliest possible time. When the manufacturer has an informal indication that the instrument seems acceptable to the agency, the manufacturing process is established. A production instrument (5) is later submitted to the agency for final pattern evaluation and approval (6); thus, evaluation can be substantially shortened in view of the earlier cooperation.

3.1. Reasons for initiating pattern approval process

The following is a list of reasons for requiring pattern approval, not all of which are valid in all jurisdictions:

— category of instrument for which pattern approval is required by law or regulation
— new type of instrument
— existing type of instrument not previously approved for legal use
— newly imported type of instrument

FIGURE 1


Action by manufacturer or user
Action by legal metrology
Instruments
Dashed lines indicate modifications (feedback) that may result from experience gained during verifications.
Feedbacks from patern evaluation to design and manufacturing process are not shown.
Cooperative testing and evaluation of design
Cooperative evaluation of manufacturing process
Approved/licensed service agency
1A
4A
Preliminary pattern evaluation and approval
Final pattern evaluation and approval
Initial verification
Subsequent verification
3
6
8
11
1
2
4
5
7
9
10
12
Design of instrument
Prototype instrument
Establish and carry out manufacturing process
Preliminary or final production instruments
Approved production instruments
Verified instruments
Use of instruments
Verified instruments
Pattern evaluation and approval may proceed with steps :
2 - 3 - 4 - 5 - 6,
4 - 5 - 6,
2 - 6 - 4, or
1A - 4A - 5 - 6 ;
5 - 6, for importers

— radically new intended application, within the jurisdiction, of an approved pattern
— extension of application of a pattern
— intended use of instrument type in a new jurisdiction (this does not necessarily imply import)
— modification of an instrument type replicating an approved pattern
— previous pattern rejection or withdrawal of pattern approval, coupled with newly presented facts concerning the pattern, improvement of the instrument type, or a change in regulations.

3.2. Steps of the pattern approval process

The steps of the pattern approval process are as follows:

Before pattern evaluation:

— submission of request
— examination of request
— decision to accept or refuse request (see point 3.6.1)
— identification of relevant regulations and requirements
— tentative evaluation plan
— identification of and arrangements for organization, facilities, equipment, and personnel needed for evaluation.

Pattern evaluation:

— examination of submitted documents
— revised evaluation plan
— examination and tests of instruments and/or devices
— report of evaluation, conclusions drawn, and recommendations.

After pattern evaluation:

— examination of report of evaluation in the light of applicable regulations and requirements
— decision to grant or withhold pattern approval
— framing of detailed conditions of pattern approval
— transmittal of pattern approval certificate or pattern rejection notice and other relevant documents to applicant
— deposition by applicant of specimen instrument(s) and/or device(s) of the approved pattern with the legal metrology agency
— public notice of pattern approval
— notification of verifying officials of pattern approval and transfer of relevant information and documents.

3.3. Who may request pattern approval

Depending on arrangements with manufacturers and on recognition from the agency involved, the following may generally submit requests for pattern approval:

— manufacturers
— manufacturer's sales representatives
— distributors of the manufacturer's instruments
— assemblers of systems constituted of subsystems produced by various manufacturers
— importers
— certain officials of the foreign services or consulates of other jurisdictions.

3.4. Material submitted with request for pattern approval

Depending on the regulations in the jurisdiction, a number of items may have to be submitted or, at the applicant's option, may be submitted with a request for pattern approval. These items are outlined below.

3.4.1. Information contained in the request

Requests or request forms may include the following information:

- name and address of applicant and applicant's representative
- name and address of the manufacturer of the subject instrument
- documents indicating the applicant's authority to represent the manufacturer
- category of instrument and its general purpose
- intended and other possible legal applications of the instrument
- reference to regulations under which the pattern is to be approved
- reference to those previous pattern approvals or rejections issued to the applicant or manufacturer, particularly from other jurisdictions, that may have a bearing on the present request
- manufacturer's designation and name for the instrument
- manufacturer's specifications of metrological characteristics of the instrument that are regulated for the subject category of instrument
- inventory of instruments, devices and materials, or of descriptive material, defining the pattern and sumitted with the request.

3.4.2. Supporting documents

The legal metrology agency can ask that certain documents be included with the request or the applicant may choose to submit them on an optional basis. These documents may include some or all of the following:

- description of the instrument, for example, detailed specifications relating to construction, assembly, adjustment, and internal operation of the instrument or to internal standards, safety devices, and self-adjusting mechanisms; also assembly drawings, detailed drawings, layouts, and schemtic diagrams (see point 6.7)
- sales literature, photographs, drawings, and documents intended for users, including instructions for installation and preparation of an instrument for service, and operating, maintenance, and repair manuals
- published papers describing the principle of operation of the instrument type or of primary devices
- reports of tests or calibrations carried out by an accredited laboratory.

3.4.3. The pattern

Generally one or more instruments or devices are submitted with the request for pattern approval; they constitute the pattern. A statement should accompany submitted instruments and devices which indicates whether they are prototypes, from a production line test run, or from an established production line. In certain cases definitive descriptions, such as engineering descriptions and assembly drawings, are submitted in lieu of actual equipment.

3.4.4. Fees

Fees are set in accordance with the procedures of the legal metrology agency. Such fees may be determined from a fee schedule for the various categories of instrument or according to the actual effort expended by the agency in evaluation.

3.5. Consideration of the request for pattern approval

The following questions should be considered by the approval authority:

— Is the applicant properly authorized by the manufacturer and acceptable to the legal metrology agency ? (see point 3.2)

— Do regulations require pattern approval of the instrument, also taking account of its intended or potential application ?

— Have all requested items of information, documents, instruments, etc, been submitted?

— Does the instrument or its description, submitted as the pattern, appear to be sufficiently definitive to serve as the pattern ?

3.6. Decisions preliminary to pattern evaluation

Decisions to be considered by the approval authority prior to pattern evaluation are outlined below.

3.6.1. Acceptance or refusal of the request for pattern approval

The decision to accept or refuse the request is based on a study of the documents submitted with the request for pattern approval. If the request has been lacking in some details, the legal metrology agency may ask that it be supplemented before the decision is taken. Even if it seems at this stage that the pattern does not meet requirements, the request should be accepted. An exception to this is refusal of the request based on a prior rejection of the subject pattern or of one closely, related to it.

3.6.2. Acceptance of results of tests carried out by other approving authorities

When a pattern, that has been approved in one or more jurisdictions, is submitted for pattern approval, the legal metrology agency may have the opportunity to curtail its pattern evaluation. Bilateral, regional, or international agreements between different nations may permit acceptance of patterns approved by another nation. In the absence of such an agreement, but depending on national law, the agency may be authorized to accept data obtained in or conclusions drawn in the other jurisdiction. Also, the agency, encouraged by an approval in another jurisdiction, may conclude that partial or limited pattern evaluation will suffice to account for differences in the requirements of the two jurisdictions. These alternatives are effective in reducing the workload of the approving authority and help to minimize the overall cost of the pattern approval process. Wherever possible, approving authorities should cooperate with each other in sharing results of pattern evaluation test data and should consider participation in formal arrangements for reciprocal acceptance of pattern approvals or acceptance of the test data leading to pattern approval.

3.6.3. Pattern evaluation considered together with eventual verification

When possible, the whole control process should be considered in making a tentative plan for pattern evaluation because shifting emphasis and effort from pattern evaluation to initial verification or vice versa is sometimes advantageous.

Modes of initial verification might be:

— verification of all copies by a legal metrology agency

— verification by sampling by a legal metrology agency

— manufacturer's quality control, under legal metrology agency supervision, by sampling

— manufacturer's self-certification.

Subsequent verification by a legal metrology agency could also be of all copies or by sampling.

On the assumption that pattern approval and verifications are carried out by different legal metrology agencies, or by accredited laboratories, the verifying agency should be consulted in making a tentative decision as to the eventual modes of initial and subsequent verification.

3.7. Choice of organization to evaluate pattern

When new technologies are applied to measuring instruments or when a legal metrology agency is faced with evaluating instrument categories with which it has not dealt previously, it may find that it lacks the facilities or personnel necessary to carry out some of the required pattern evaluations. In such cases it should turn for support to organizations that have the needed capabilities, including traceability to national standards. Depending on circumstances, such evaluation efforts may be cooperative; for instance, agency personnel might work side by side with the personnel of some other organization to conduct tests at the latters' facility.

Categories of organizations that can be considered in these cases are listed below. Not all these categories of organizations will be available in every jurisdiction or for every type of instrument:

— other government laboratories of the same jurisdiction

— laboratories of independent test organizations or of universities

— laboratories of associations of either manufacturers or of industries

— government laboratory in another jurisdiction

— facilities of a manufacturer.

CHAPTER IV

PATTERN EVALUATION PLAN AND EXAMINATION

4.0. General

As stated in previous chapters, pattern evaluation may include the testing of a prototype instrument, of preliminary production instruments, or of instruments from an established production line. The evaluation includes a study of the documents furnished by the applicant and related to the instrument that is the subject of the request. To the extent that certain test protocols are required by regulation, these should be followed. Occasionally the evaluating officials may have to establish special test procedures for new generations of instruments or for special applications of instruments in order to determine compliance with requirements.

The possible steps that can be taken in the course of pattern evaluation were discussed in Chapter 3 and detailed in Figure 1. The choices and considerations involved are indeed large in number. Many of these are indicated below. In each particular case, only some of these will be found to apply or to be necessary. In some cases, the evaluation process should be stopped after one or more deficiencies of the pattern have been found that give ample ground for pattern rejection. Additional specific suggestions will be found in the following OIML International Documents:

— Legal Qualification of Measuring Instruments (OIML D3)
— Principles of selection of characteristics for the examination of measuring instruments (OIML D 15)
— the draft documents under SP21-Srl, 2, 4 and 5.

4.1. Pattern evaluation procedures

The various kinds of pattern evaluation can be classified as to their extent and their purpose. These are outlined below.

4.1.1. Complete pattern evaluation

In complete pattern evaluation, all relevant aspects of a pattern, including metrological characteristics and technical provisions, are thoroughly evaluated to determine that the pattern complies with applicable regulations and that copies of the pattern can be expected to perform properly. Typically, a complete pattern evaluation is carried out when the pattern has not been previously evaluated.

4.1.2. Partial pattern evaluation

In a partial pattern evaluation, only a limited number of selected characteristics of a pattern are carefully evaluated to determine their compliance with applicable regulations. A partial pattern evaluation may be carried out when a pattern has been modified such that only certain of its characteristics can be expected to have been affected by the modification as may be the case, for example, when a new indicating device has been incorporated.

4.1.3. Limited pattern evaluation

In a limited pattern evaluation all relevant aspects of a pattern are evaluated, but not as thoroughly as in a complete pattern evaluation, to determine which of these appear to have deviated from those found during a previous evaluation. Characteristics that appear to have deviated can then be subjected to a more thorough evaluation. A limited pattern evaluation may be carried out when it is to be determined which of the characteristics of a pattern may have been affected by a modification or when the results of a previous pattern evaluation in another jurisdiction are available and tests are carried out to quickly establish confidence in the previous results.

4.1.4. Re-evaluation of a pattern

A legal metrology agency may, for good reason, decide to re-evaluate a pattern which it has previously evaluated. Such a pattern may or may not have once been approved. Normally, re-evaluation of a pattern is considered only for cause, that is, when important information concerning the pattern or its evaluation becomes known and either legal metrology officials or the applicant requests a re-evaluation. Generally, a limited number of specific instrument characteristics are examined in such a case, that is, only a partial pattern evaluation is conducted.

Re-evaluation may result in pattern approval, rejection, or an amendment of the previous pattern approval.

4.1.5. Evaluation for extension of application of a pattern

A pattern with a currently valid pattern approval may be evaluated to obtain a basis for approving a proposed extension of the application of the pattern. Such an extension might, for example, be in the range of the measured quantity, in the ranges of permissible influence quantities, such as ambient temperature, or in the kind of commodities that may be measured with instruments of the pattern. In most cases, partial pattern evaluation corresponding to the extension of application is sufficient, but it may again be necessary to perform a complete pattern evaluation.

4.2. Tentative pattern evaluation plan

A plan for evaluating the submitted pattern is developed in some detail on the basis of the following:

— the intended or possible applications of the instrument type
— the requirements of regulations concerning both the category of instrument and the applications
— the tentatively decided modes of verifications
— the amount of information and data submitted with the request
— information already available from prior pattern evaluations of related instruments and devices
— the facilities, equipment, and personnel available for pattern evaluation

The tentative plan should specify, as relevant, the following:

— characteristics, parameters, and conditions to be tested or examined
— the test methods to be used, document studies to be conducted, and inquiries to be made
— the scope, extent, or limits of those tests, studies, and inquiries.

Such specifications can, for the most part, be assembled by reference to existing International Recommendations that contain requirements and tests applicable to pattern evaluation of the particular subject instrument or device.

4.3. Choice of test sites

Pattern evaluation may be carried out at different sites, such as the factory, a laboratory, and a user location. The decision of test sites is usually coupled with that of the choice of testing organization.

4.4. Study of submitted documents

The documents to be examined in the light of the requirements laid down in regulations and for purposes of pattern evaluation include the request for pattern approval, the pattern itself to the extent it is defined in documents, and any supporting documents. These documents should, as need arises, be referred to again in the course of any later tests.

If the pattern is presented in the form of documents, rather than as actual instruments, it should be determined that the information given defines a pattern sufficiently well, quite aside from the question of the pattern's adequacy. If this is not the case, further information should be sought, the submission of instruments should be required of the applicant, or rejection of the pattern should be recommended.

The conclusions of this examination should be summarized to become part of the report of pattern evaluation. This summary should make reference to the particular document, passage, or data on which important specific conclusions are based.

4.5. Conduct of the pattern evaluation

4.5.1. Metrological examination

The metrological examination includes the evaluation of instrument characteristics prescribed in the International Recommendation relevant to the instrument under evaluation. In addition to evaluation of metrological performance, the following instrument features might also be examined:

— scale interval
— scale range
— scale marks, spacing, and numbering
— statement of scale units and of instrument constants
— resolution and line widths of scale marks, recorder chart paper, or oscilloscope screens, least significant digit of a digital readout
— potential for and provisions to minimize parallax
— provisions for properly or uniquely applying the measured quantity to the instrument (loading) and potential for improper loading.

4.5.2. Technical examination

The applicable International Recommendation will cover important elements of the technical examination. The following might also be considered for examination if not specified in the Recommendation:

— mechanical adequacy of instrument supports and enclosure
— location of controls with a view to error-free operation
— adequacy of identification of controls
— readability of scale and dial numbering
— visibility of instrument readout for operator and customer
— security from inadvertent disconnection of the connectors of communication lines
— potential for and safeguards against operator fraud.

4.5.3. Administrative examination

The applicable International Recommendation may or may not prescribe an examination of the administrative features of the instrument. These might include:

— resistance to tampering of enclosure and external adjustments
— provision of locks and of locations for seals, stamping, and calibration tags
— placement of name plates
— adequacy of name plates, including identification of manufacturer and pattern, serial number, and instrument rating
— presence and prominence of important restrictions of use and other cautions
— security of attachment of calibration or conversion charts to instrument.

4.5.4. Choice of test points

The relevant International Recommendation will normally include test methods which prescribe test points. These may include :

— points corresponding to commonly encountered values

— end and mid-points and points of overlap of ranges

— equally spaced or logarithmically spaced points in a range

— points reflecting reference and extreme conditions

— points near previously discovered resonances of an instrument

— points located where theoretical analysis of the instrument's equations indicates poles, zeroes, or exceptionally high or low sensitivities.

CHAPTER V

PATTERN EVALUATION REPORT

5.0. General

The output of pattern evaluation should include both a report of objective findings and a report of conclusions drawn and recommendations made concerning pattern approval. While these may be given in a single document, it will often be advantageous to relegate them to separate documents as indicated below. Separate documents are especially appropriate when evaluation and approval are the responsibilities of different officials.

There are many reasons for writing and then maintaining these reports as a permanent record: the conclusions and recommendations are aimed at the approving official; the report of objective findings should be available for future reference in the event the findings are challenged; a modification or an extension of the approval or of the period of validity of the pattern is applied for; there is a change in related regulation, etc.

5.1. Report of pattern evaluation

The report should be a permanent, objective record of the evaluation process and its results, against which possible future evaluations can be compared and which can support the pattern approval or rejection decision, if it is challenged (conceivably in court), by the applicant, manufacturers, or users. It should identify the values of measured metrological characteristics and their uncertainties and instruments, devices and salient documents examined, personnel and laboratories that carried out the evaluation, provide a summary of tests carried out, and list any special procedures, standards, and equipment used in the process. It should contain important data, ambient conditions, and the time data were taken or it should identify the place where such data are stored. To the extent that findings are not based on measurement but on visual inspection, they should be as objective as possible in each instance.

5.2. Conclusions and recommendations resulting from pattern evaluation

It is assumed here that the personnel carrying out the pattern evaluation process do not make the approval decisions. The report giving conclusions and recommendations should provide the basis for such a decision, for a definition of the pattern, and for the contents of a pattern approval certificate or rejection. The report might be structured in five parts, as follows.

5.2.1. Summary of findings of evaluation

The summary should list the characteristics, attributes, and conditions of the instrument that are subject to regulation along with both the required limiting values or qualities and the corresponding values or qualities determined during the evaluation. Each item that demonstrates failure to meet requirements should be clearly identified as such. The list may be followed by a discussion of important conclusions to be drawn from it.

5.2.2. Recommendation of the examiner(s)

The recommendation can, for example, be one of the following:

— approval (unqualified)
— approval (qualified)
— rejection (unqualified) ; the main reasons for rejection should be given
— recommendation that the pattern be rejected, but that it may be approved in the future, if specified modifications are made to satisfaction as may be demonstrated by a partial reevaluation of the pattern
— recommendation that the pattern be rejected, that the applicant be adequately informed about its deficiencies, and that the pattern be accepted for a complete reevaluation in the future, provided the applicant declares that the deficiencies have been corrected.

5.2.3. Definition of the pattern

The report should include a definition of the pattern. This definition may be in the form of the evaluator's description of the pattern, including a listing of characteristics and the values of the associated parameters with their maximum permissible uncertainties; it may be in the form of the manufacturer's description and drawings appended to the report; or it may be in the form of reference to a copy of the pattern deposited by the applicant. Combinations of the above and, perhaps, of reference to certain components of the instrument that have been deposited can also be used to define the pattern.

5.2.4. Additional basis for pattern approval certificate or rejection notice

A variety of information and recommendations, in addition to that mentioned above may be reported. Depending on the case at hand, the report may include appropriate items drawn from the following list :

a) application of the pattern
   — approved ranges
   — maximum and minimum capacity
   — reference conditions
   — normal conditions of use
   — approved subjects of measurement: physical quantities, commodities, materials, objects, or phenomena which may be measured
   — special restrictions on application

b) accuracy
- — accuracy class
- — nominal instrument error(s)
- — maximum permissible error(s)
- — required use of calibration charts, corrections, or instrument constants

c) requirements on manufacturer
- — special requirements on manufacturing or quality control procedures, if applicable, under accreditation programs
- — required inspections and tests in lieu of initial verification, including sampling plan
- — required name plate information and stamps, marks, and seals affixed at the factory
- — required availability for inspection by legal metrology agency of manufacturer's facilities

d) administrative requirements
- — required notification of legal metrology agency concerned or registration of instruments upon sale, purchase, installation, putting into use, recalibration, or repair of instruments
- — required notification of legal metrology agency concerned upon changes in specified components or materials in the type of instrument (see point 2.2.4)

e) requirements for use
- — installation requirements
- — requirements dealing with ambient influence quantities at site of installation or permanent use
- — legally required auxiliary equipment, identification of the measuring instruments in conjunction with which it may be legally used
- — legally required maintenance procedures
- — required interval and sources of recalibration and maximum permissible uncertainties of recalibration
- — required procedures for use of instrument.

5.2.5. Proposed initial and subsequent verifications

The report should include recommendations concerning verifications in relation to the following items :
- — characteristics to be verified
- — acceptable values and uncertainties of parameters of verified characteristics
- — maximum permissible error (s) of the pattern
- — intervals between verifications
- — verification sampling plans
- — verification procedures
- — required verification equipment and its characteristics and limits of error
- — required qualification of inspectors
- — manufacturer's role in initial verifications
- — sites of verifications
- — location of required marks and seals
- — possible exemption from verification.

CHAPTER VI

PATTERN APPROVAL DECISION

6.0. Factors influencing pattern approval decisions

Pattern approval judgments are made with reference to the requirements laid down in law or regulation, keeping in mind the application of the pattern and, for example, the durability and reliability of instruments of the pattern. The pattern evaluation process that leads to the approval of a pattern, though generally carried out conscientiously, is based on a very small number of instruments and can generate only limited data. It follows that even the best judgment in granting pattern approval or setting the conditions of approval may sometimes later turn out to be less than optimum. Judgments that, in retrospect, prove to be faulty might, for example, relate to the incidence of failure or the rate of deterioration of the copies of a pattern or to the verification intervals or verification procedures which are made conditions of pattern approval. Because such judgments can in fact be too optimistic or too pessimistic, legal metrology agencies should welcome opportunities to revise earlier pattern approval decisions so as to improve compliance with regulation or to reduce unnecessary work or expense.

The data gathered during both the initial and subsequent verification of a larger number of copies of a given pattern will, when systematically analyzed, often yield information not available from pattern evaluation. Such feedback can be used as the basis for revising the conditions of approval when the situation warrants this. Depending on circumstances, the experience gained during verifications may justify later changes in the pattern approval concerning instrument design, manufacturing process, application of the pattern, or required verification procedures; in extreme cases, it might even result in withdrawal of the approval.

6.1. Decision considerations

The approving official decides whether to issue a pattern approval certificate or a rejection notice and conveys the decision to the applicant as appropriate, together with other documents that may be relevant. The pattern approval may be a full or a provisional approval as discussed below.

6.1.1. Full pattern approval

In general, pattern approval must be regarded as full or complete despite the fact that any one approval is subject to a variety of conditions which limit the scope of the approval. These conditions may be inclusive or exclusive as in « ...only for use in measuring the volume of water... » or « ...not for use in measuring corrosive liquids... ». The possible conditions of approval are many and include:

— restricted application of copies of the pattern
— requirements or exemptions related to verifications of copies of the pattern
— requirements concerning installation, safeguarding, or recalibration
— period of validity of the pattern approval.

6.1.2. Provisional pattern approval

Under some circumstances a pattern may be approved for legal use before pattern evaluation has been completed. It is granted with the understanding that further evaluation will take place before (full) pattern approval can be considered.

Provisional pattern approval, for example, may be granted after only partial or limited pattern evaluation when an urgent need for use of copies of the pattern exists but the legal metrology agency is temporarily unable to carry out a complete pattern evaluation. The approval should be qualified by obtaining written agreement from the applicant that existing copies of the pattern will be modified or retrofitted if required by the (full) pattern approval. A provisional approval could also be given when new technology is involved and the metrology service wishes to study the instrument in use.

6.2. Documents conveyed to the applicant

A pattern approval certificate, rejection notice, amendment to an existing approval certificate, or similar document reflecting the approval decision should be sent to the applicant at the earliest possible time. These are covered below. When the definition or description of the pattern is not part of the approval certificate, it should be the subject of a separate document which must accompany the certificate. The approving official should also consider sending to the applicant copies of, or excerpts from, the reports of pattern evaluation and of conclusions and recommendations. More detailed test data not contained in these reports may, when appropriate, also be conveyed.

6.2.1. Pattern approval certificate

A pattern approval certificate should contain the following information. Part of this information may, in certain instances, be conveyed by reference to more general official documents, such as regulations.

— identification of the request for pattern approval, applicant, manufacturer, and approving authority and official; regulations complied with and jurisdiction(s) where approval is valid; specific instruments, components, and salient documents examined

— date of approval and, if applicable, of its expiration

— comprehensive definition of the pattern and its variants ; the definition may be the subject of an appended document

— approved application of the pattern, its accuracy requirements on its manufacturer, administrative requirements, and requirements for its use. When, in lieu of initial verification, heavy reliance is placed on the manufacturer's quality control, inspections, and tests, a separate document may detail the requirements on the manufacturer.

6.2.2. Extension of pattern approval

An extension of pattern approval may be granted for a previously approved pattern when one or more of the original conditions of approval are extended. Typically, the original period of validity or the permitted application of the pattern are extended. The application may, for example, be extended to a higher point in the measurement range or to an additional class of merchandise. Normally the decision concerning an extension of pattern approval is based on only a partial pattern evaluation.

6.2.3. Amendment of pattern approval

A currently valid pattern approval may be amended, for example, because of changes in regulations, modification of a pattern, or extension of its application. The document approving a proposed amendment of pattern approval should include the following:

— identification of the currently valid pattern approval and of any prior amendments

— reason for the amendment

— amended provisions of the approval, preferably also quoting verbatim any earlier provisions deleted or superseded by it.

6.2.4 Pattern rejection notice

A pattern rejection should be communicated to the applicant and include the following information :

— identification of the request for pattern approval, applicant, manufacturer, and rejecting authority and official ; applicable regulations ; specific instruments, components, and salient documents examined ; and manufacturer's instrument type for which application was made

— date of rejection

— characteristics and the values of their parameters found to be deficient as well as the corresponding acceptable values ; other conditions not fulfilled.

When reasons for rejection are based on relatively small deficiencies or when deficiencies can be easily rectified, the notice may, at the option of the official, list changes in the pattern that would make it acceptable and, perhaps invite resubmission of the request after these changes have been made.

6.3. Pattern approval mark

Pattern approval may convey the privilege or the obligation to affix a pattern approval mark to instruments manufactured to replicate the pattern or to instruments of the pattern as demonstrated by verification. Typically such marks identify the jurisdiction, pattern approval certificate number, and year of approval. In some instances this mark must be supplemented with a mark indicating verification. Depending on regulations and circumstances, the legal metrology agency may require that pattern approval marks be affixed by the manufacturer, importer, or verifying official.

The pattern approval mark should be visible, legible, and indelible; in some cases its location on the instrument may be specified. When approval has been provisional or limited in some special way, the approval mark should convey this fact.

Instruments exempt from pattern approval may carry a special mark.

6.4. Period of validity of pattern approval

Depending upon applicable laws and regulations, pattern approval may by granted for an indefinite period or may lose validity at a predetermined time. The question of when and why a pattern approval may lose validity is discussed below.

6.4.1. Expiration of pattern approval

The expiration time of a pattern approval may be prescribed by regulation or may be set at the time of pattern approval on the judgment of the approving official acting within regulations. When or just before a pattern approval expires, extension of pattern approval may be requested. Some pattern approvals are given without a limit to the period of validity.

6.4.2. Withdrawal of pattern approval

Pattern approval may be withdrawn for various reasons. These include deficiencies in the pattern not discovered before approval; changes in regulations to take account of more stringent needs, advances in the state-of-the-art, or new technologies; unfulfilled stipulations of approval; and failure of too many copies of the subject type of instrument to replicate the pattern.

6.5. Public notices

Decisions of pattern approval or withdrawal should be announced in public notices at the earliest possible time. These notices may be in official periodicals or special bulletins. Decisions that should be announced include granting and withdrawal of pattern approval, extension of the application or the period of validity of a pattern, and, in some instances, approval of a modification of a pattern. Such notices should identify the instrument covered by the pattern approval, give its approved application, and state any requirements relating to its installation and use. Notices may also give additional details or indicate how such details can be obtained.

6.6. Documents conveyed to officials responsible for verifications

Legal metrology agencies or officials responsible for pattern approval should notify verifying agencies and officials of their approval decisions and they should furnish the latter with such information as will be necessary or helpful in carrying out verifications. Depending on the practice in a given jurisdiction, the approving official may prescribe or recommend how verifications are to be conducted or only furnish information and data upon which the verifying agency can base its plans for verification. In any case, a copy of the pattern approval certificate should be conveyed. When the approving official prescribes or recommends the manner of verification, a document should be prepared covering such recommendations and conveyed to the appropriate officials.

6.7. Confidentiality of information

In the course of the control process, the legal metrology agency often becomes privy to proprietary information related to the pattern, manufacturing techniques, etc. The agency must protect this information and carefully limit access to it, or to data concerning the pattern generated by the agency, to properly authorized organizations or individuals, e.g., the applicant, the manufacturer and certain officials of the verifying agency.

TABLE OF CONTENTS

CHAPTER V — **PATTERN EVALUATION REPORT**

CHAPTER VI — **PATTERN APPROVAL DECISION**