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Principles of assurance of metrological control

Principes d'assurance du contrôle métrologique



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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PRINCIPLES of ASSURANCE of METROLOGICAL CONTROL

CHAPTER I

GENERAL

1.0. Introduction

Since its inception, OIML has worked to harmonize metrology laws and regulations among its Members. Efforts have been focused on requirements on particular measurements or instruments. Such efforts make up, and will continue to make up, the main task of OIML. A related task is to provide OIML Members with guidance on the ways of assuring metrological control and on methods to verify that such controls are effective.

Several approaches are presented and discussed in this International Document because there is more than one way to achieve effective metrological control. It is recognized that conditions and requirements differ from country to country and that the ideal control strategy for one country or region may not be ideal for another. Accordingly, this Document provides guidance and information that may be adapted to fit the circumstances of any particular jurisdiction.

1.1. Definitions

The terms in this Document are taken, where appropriate, from the 1978 edition of the « Vocabulary of Legal Metrology » (VML). Definitions of terms not found in the VML are presented below. The terms taken from the « International vocabulary of basic and general terms in metrology » are referenced « VIM ».

1.1.1. Device

Any physical artifact, apparatus, or item used in making a measurement. A « device » may be an active or passive measuring instrument (as in VML 6.1) or a measurement standard (etalon).

1.1.2. Measurement process

All the information, equipment and operations relevant to a given measurement.

Note: this concept embraces all aspects relating to the performance and quality of the measurement; it includes for example the principle, method, procedure, values of the influence quantities and the measurement standards (VIM 2.08).

1.1.3. Element of a measurement process

Any single factor that can affect the measurement result, for example, the instrument, the operator, and the procedure.

1.1.4. Element of a metrological control system

A particular procedure used or requirement imposed to accomplish one of the objectives of a service of legal metrology. Thus, pattern evaluation may be one element of a metrological control system; periodic verification may be another element, etc. (the diamond-shaped symbols in Figure 1).

1.1.5. Measurement system

A complete set of measuring instruments and other equipment assembled to carry out a specified measurement task (VIM 4.05).

1.1.6. State of statistical control (of a measurement process)

A measurement process is in a state of statistical control if the resulting observations from the process, when collected under any fixed experimental conditions within the scope of the a priori well-defined conditions of the process, behave like random drawings from some fixed distribution with fixed location and fixed scale parameters. A less rigorous but more easily understood definition is : a measurement process is in a state of statistical control if the amount of scatter in the data from repeated measurements of the same item over a period of time does not change with time, and if there are no unpredictable drifts or sudden shifts in the mean of repeated measurements on the same item.

1.2. Principles of metrological assurance

Certain principles are fundamental to achieving assurance of metrological control. The first principle is to consider the total measurement process before developing or changing a metrological control system. Analysis of the total process permits focusing attention and resources on those elements that most require control. It also permits the selection of methods that offer the greatest benefit for the control effort invested.

A second principle is to provide flexibility. Flexibility in legal requirements permits officials to be selective in the application of controls. It permits consideration of enforcement history in designing and scheduling testing programs for both instruments and prepackaged goods. Flexibility also permits legal authorities to distribute the burden of compliance to both user and manufacturer.

CHAPTER II THE METROLOGICAL CONTROL SYSTEM

2.0. Measuring instrument manufacture and use

Figure 1 presents key steps in the manufacture and use of a measuring instrument. These steps are represented by rectangular boxes in the figure. From the manufacturer's and user's point of view these are :

- determine the need for an instrument,
- design and produce a prototype,
- produce in quantity,
- place in service,
- use instrument,
- repair or modify instrument.

In this process, manufacturers and users must be aware of the legal requirements that must be met in jurisdictions in which business is carried on.

2.1. Metrological controls that may be applied

Metrological control systems can be designed to intervene at any and all steps in the process of manufacture and use. The particular intervention strategy employed is usually fixed by law. A highly restrictive legal metrology control system could include, by law and regulation, all of the following:

- pattern evaluation and pattern approval of measuring instruments,
- installation requirements,
- initial verification both at the factory and at point of use,
- specified frequency of subsequent verifications,
- environmental requirements,
- specified requirements on the operator, such as licensing,

- use requirements, such as the collection of data and the establishment of limits on items to be measured,

- specified service-personnel requirements such as licensing and verification of testing standards and instruments.

Figure 1 illustrates the application of legal metrology controls to the process of manufacturing and using a measuring instrument. When all the above-listed intervention strategies are used, much of the burden for meeting legal requirements is removed from the manufacturer and user, because legal metrology officials accept the responsibility for making both the effort and many of the decisions necessary in the control process.

The choice of strategy depends largely on how much of the responsibility for the total process the metrology officials can accept. Where legal metrology resources are limited, a strategy of very limited intervention in the process of manufacture and use may be employed. Such a strategy may also be based on the idea that the proper role of legal metrology is to assure accuracy in the user's measurement process by emphasizing enforcement rather than service.

Even if a strategy emphasizing enforcement is applied only at the point-of-use, it places the responsibility for accuracy on the user and the manufacturer who presumably have sufficient incentives to maintain accurate measurements. The threat of legal sanctions by metrology officials reinforces this incentive. The point-of-use, or end-point strategy offers protection to the public, the most vulnerable party in the measurement process.

2.2. Sources of measurement process accuracy degradation

Measurement processes and metrological controls change with time. Continually, new instruments are introduced into the marketplace, existing devices repaired and modified, instruments retired, and operators and verification officials replaced. Therefore, controls must be able to continually monitor measurement system performance.

In order to monitor a particular measurement system, one must understand the measurement process and be able to identify the elements that contribute to the degradation of measurement accuracy. It is essential to recognize that accuracy may degrade at any step in the process. Examples of factors which can cause degradation at various points in the process are given below.

2.2.1. Examples of accuracy degradation factors during instrument design and manufacture:

- designs which do not anticipate environmental conditions,
- designs which do not anticipate likely equipment combinations or configurations,
- designs which fail to minimize potential misuse of the instrument,
- factory tests which do not replicate all conditions of use, including environmental conditions,
- production units which differ slightly from approved patterns,
- sufficiently large statistical fluctuations in parameters of production units,
- production units « customized » for special applications so as to change the key metrological characteristics,
- day-to-day changes in production (for example, new sources of component supply or modifications to the assembly line) that cause variations in the final product.

2.2.2. Examples of accuracy degradation factors during installation:

- wrong model installed for conditions of application,
- untested combination of measuring instruments assembled into a complex configuration,
- all possible modes of operation of a complex ensemble of instruments have not been considered,
- calibration standards not sufficiently accurate,
- calibration or adjustment errors,
- confusing or inadequate calibration or verification procedures,
- inadequate protection from mechanical shock during installation or shipment to installation site, especially when device is calibrated prior to shipment.

2.2.3. Examples of accuracy degradation factors during use of instrument:

- operators not properly trained in use of instrument or in their legal responsibilities covering use of instrument,
- operator carelessness,
- excessive errors due to varying equipment and environmental conditions,
- interactions between instrument and adjacent equipment,
- failure to reverify accuracy of the instrument at appropriate intervals,
- instrument is used beyond operating specifications or legally permissible limits.

2.2.4. Examples of accuracy degradation factors during repair or modification of instrument:

- repairs that modify instrument performance (lower accuracy, increased environmental sensitivity, etc.),
- failure to recalibrate following repair,
- failure to reassemble instrument into its original configuration following repair,
- inadequate protection after recalibration, against mechanical shock during shipment or reinstallation,
- improperly trained service personnel.

Any one or combination of the above factors can result in measurement errors that exceed legal limits.

CHAPTER III MEASUREMENT ASSURANCE AND METROLOGICAL CONTROL

3.0. General

An essential goal of legal metrology is to ensure equity in the marketplace and to contribute to the health and safety of the general public. This goal cannot be reached unless the legal metrology service ensures that the entire measurement process, which includes the instrument, operator, environment, procedure and special characteristics of the item being measured, performs adequately. One must always carefully distinguish process performance from element performance, that is, from the performance of an instrument, operator, or other element of the process. Adequate instrument performance is a necessary condition for adequate measurement process performance, but is usually not a sufficient condition.

A large number of OIML International Documents and Recommendations provide excellent guidance on how to control the individual elements of a measurement process. Assurance of metrological control, however, involves more than the ensemble of the independent controls of these elements, no matter how well each may be controlled. Only by adopting a total systems approach can the elements of the process be put into proper perspective and the total process performance adequately assessed. The systems approach (sketched in point 3.2) may allow one to prove that measurements retain sufficient accuracy on a continuing basis to meet requirements although certain control elements may have been relaxed or eliminated. Considerable resources can be saved by using only the minimum controls required to ensure adequate accuracy. However, to realize such savings one must be able to quantify the effectiveness of the control methods employed ; this necessitates a total systems approach.

Excessive controls can stifle innovation and can be unduly costly. Assurance of metrological control does not necessarily require rigorous or redundant controls. The simultaneous use of several metrological controls when a single carefully-designed control mechanism would suffice, should therefore be avoided.

It should not be assumed that to assure metrological control, instruments can only be tested by a legal metrology or another government service. Testing must be accurate but, if laws and regulations permit, a qualified and authorized independent testing service can conduct the tests. Such a service organization should, however, be licensed or certified by the legal metrology service. It may also be possible to have pattern evaluation and/or initial verification tests performed by the manufacturer or his representative if the legal metrology officials have access to all data and can witness tests whenever they wish. Similarly, when instrument repair firms demonstrate their competence, they might be authorized to perform verifications following instrument repair. Where possible, these alternatives should be recognized in regulations, recommendations, and advisory documents.

3.1. The uncertainty of measurement

Several facts related to the quality of measurements stand out. First repeated measurements of any one stable quantity (for example, a mass standard) by the same method and under essentially the same conditions (that is to say by a particular measurement process) will differ slightly from each other, but the average of a sequence of such measurements tends to converge as the number of averaged measurements is increased, provided the process is in a state of statistical control (see point 1.1.6). Furthermore, this long term average (the limiting mean) will differ from that of other, similar measurement processes and generally will include a systematic error (offset) relative to the reference process (for example, the most accurate measurements of the same quantity made by the national laboratory of metrology) whose limiting mean or « best value » would be accepted

as correct. The uncertainty (at a given confidence level) associated with a measurement process (and hence any measurement made by that process) is a suitable combination of two contributions:

- a) the possible, but unknown, offset of the long-term average (limiting mean) of the process relative to the reference process,
- b) the allowance for statistical (random) variation about the limiting mean of the process.

The total uncertainty of a measurement, in general, depends on the instrument, the environment, the procedures used, the skill of the operator, data reduction (round-off procedures, algorithms used, etc.), and other elements. When the dependence on such influences is strong or the measurement is critical, special effort is needed to establish the validity of each measurement. On the other hand, when the measurement accuracy is relatively insensitive to elements other than the instrument itself, as is often the case in legal metrology, the use of a verified instrument may be sufficient to ensure correct measurements. Nevertheless, measurement uncertainty relates to the measurement process, not only to the instrument itself.

In the sections which follow, several methods of verifying that correct measurements are being made are discussed. Note that throughout this document primary concern is with measurement errors rather than instrument errors (intrinsic errors of measuring instruments). Wherever possible, a legal metrology control system should go beyond just ensuring that the controlled measuring instruments are adequate; it must strive to ensure that the end product, namely the measurements, are adequate so that the ultimate objectives of equity in the marketplace and protection of the health and safety of the general public are achieved.

3.2. Legal metrology control of measurements

One can regard the total effort of making controlled measurements in a given jurisdiction as a complex production process. The process outputs (the « product ») are the measurements actually made and the quality of that « product » should be evaluated and monitored, that is, controlled, just as the quality of factory outputs must be monitored. In fact, many of the concepts of industrial process quality control can be adapted to controlling measurements.

It is useful in this context to make the analogy between a legal metrology service and an electronic system : feedback control is used. A well-designed legal metrology service should also include feedback, that is, actual measurement accuracy should be sampled and compared against a reference signal (the minimum required measurement quality). If there is an undesirable discrepancy, a corrective signal to a preceding stage should return the output to the desired level. (This analogy will be clarified as the discussion proceeds).

One can diligently and carefully control each individual measurement process element (pattern evaluation, initial verification, etc.) to ensure a well-performing measurement process with an acceptable output quality. In the electronic analog, this corresponds to making each stage distortion-free and with proper gain by selecting high quality components and using the best available designs. While this approach may provide the technical « capability to perform », it does not ensure that this capability is properly used or maintained to yield accurate measurements. This « open-loop-system » approach is employed in most traditional legal metrology control systems.

An alternative approach is to be less careful in designing each stage, but to introduce feedback to reduce distortion and to control gain. In the legal metrology analog of the « closed-loop-feedback control system » the output (the accuracy of the actual measurements) is repeatedly sampled and data are fed back to allow corrections of the measurement process so as to restore the output to the desired level. This International Document explains how this approach can be used to assure metrological control.

3.3. The meaning of assurance of metrological control

An effective system (control system) for controlling measurements (controlled measurements) subject to legal metrology includes both a specification of the accuracy required of such measurements and provisions to ensure, with a specified degree of certainty, that these accuracies are attainable in practice in at least a given percentage of the controlled measurements actually made. In more detail, one is concerned with:

- the accuracy of the individual controlled measurement,
- the percentage of the controlled measurements, called the compliance percentage, made with at least a specified accuracy, and
- the level of confidence with which the compliance percentage is determined by the control system.

To assure metrological control, one must therefore specify the following three performance objectives at and above which performance is to be considered adequate:

- minimum required accuracy,
- minimum compliance percentage (or target compliance),
- desired level of confidence.

In the course of control of measurements, one then:

- compares the accuracy of each controlled measurement with the minimum required accuracy,
- analyzes the data to obtain the compliance percentage at the desired level of confidence, and
- compares the compliance percentage obtained to the target compliance.

Metrological control is assured as long as the compliance percentage equals or exceeds the target compliance on a continual basis.

When industrial quality control is applied to a production process, one maintains control charts based on periodic measurements of the production process parameters. Some aspects of measurement processes can be monitored in a similar manner: control charts can be kept showing the compliance percentage for each type of controlled instrument (gasoline dispensers, truck weighing devices, etc.) or measurement, with points plotted periodically (for example, monthly). In the same way as a production process can be in a state of statistical control a measurement process to control some instrument or measurement can be in a state of statistical control. This becomes possible if one gathers the proper data and analyzes them correctly. Examples of how this can be done are given in the Appendices.

It is unrealistic to expect a compliance percentage of 100. More realistically, legal metrology officials might decide on an objective of, for example, 80 % compliance at the 95 % level of confidence for some class of measurements. For other, more critical measurements ^(*), they might decide on an objective of 99.5 % compliance at the 99 % level of confidence.

Beyond specifying numerical objectives and providing means for determining the compliance percentage, an adequate metrological control system should also include some method for identifying the causes of a failure to meet the objectives so that corrective action can be taken to increase the compliance percentage to the level of the target compliance.

For critical measurements in which the dispersion of measurement errors is of concern, special objectives regarding maximum permissible errors can be established. For instance, in a radiological measurement, the maximum permissible error might be 1 percent. A 98 % target compliance might be established, with 95 % confidence level, that is, enforcement would be considered successful if these objectives were met or exceeded. However, one might require that no measurement error should ever exceed 3 % (note that a 100 % level of confidence is unattainable). Such a two-tier accuracy objective recognizes that, for some measurements, the impact of a measurement with an error that only slightly exceeds the legal limits may be minor, whereas the impact of a large error may be catastrophic.

3.4. Selecting control elements

In some cases, measurement process performance is so highly dependent on instrument capability and the failure modes of the instrument are so readily observable by the user, that pattern evaluation alone or coupled with occasional verification by sampling at the factory, is sufficient to achieve adequate control, although this cannot protect against fraud. A case in point is a liquid-in-glass thermometer that meets legal requirements when manufactured and that will generally remain accurate throughout its life unless the liquid column separates. In other cases, subsequent verification alone can serve the purpose. On the other hand, there are complex measurement processes for which pattern approval with frequent subsequent verification of the instrument involved does not ensure measurement adequate for the application. This might be the case for a process with a very highly operator-dependent accuracy. In such a case, a special control procedure, such as operator certification, may have to be developed.

Verification of the continued compliance of a measurement process with legal requirements is necessary wherever measurement accuracy may degrade with time. Frequent, periodic verification is usually appropriate for new instruments whose reliability is unknown. It may be possible to discontinue periodic verification or at least to lengthen the intervals between verifications if, as experience is gained, data indicate that the instrument does not degrade appreciably during its useful life. Also, experience may show that the verification intervals of instruments which appear to degrade with age should be shortened after several years of service.

Verification intervals should not be arbitrarily established and then held fixed, but should be adjusted on the basis of actual experience. Where possible, legal metrology officials should keep data by pattern (model number) and by serial number for each instrument so that those with consistently good performance and those with consistently poor records of compliance can be identified. Where data show that a pattern is highly reliable, surveillance can be reduced and resources reallocated to areas where compliance is poor.

^(*) Criteria for « criticality » include impact on health and safety, economic impact, etc.

3.5. Factors in selecting metrological controls

Attributes of good metrological control systems were given earlier. It is also useful to consider the following control related problems.

3.5.1. Excessive cost

Elaborate systems intended to independently verify all possible elements of a measurement control process may exact much expense without significantly improving metrological assurance.

3.5.2. Stifling innovation

Inflexible control systems may prevent the introduction of effective new technologies or discourage innovative new approaches to measurement. Such systems might, for example, involve stringent, design-oriented pattern approval requirements or very long delays in obtaining approvals.

3.5.3. Accuracy of measurements made by verification officers

One cannot properly assess the accuracy of controlled measurements unless the measurements made to check them have uncertainties much smaller than the smallest errors to be detected. Well trained inspectors using properly calibrated standards can be expected to make verification measurements of adequate accuracy. Still, unusual environmental conditions, deviations from approved procedures, etc. could degrade the inspectors' measurements.

3.5.4. Tests that do not adequately verify instrument performance

An example of inadequate verification tests relates to in-motion weighing devices (as are used to weigh railroad cars and trucks, or used with conveyor belts). Such devices are used in the dynamic mode but, because of difficulty in designing appropriate dynamic tests, are often subjected only to static tests. In such cases, it may be possible for device manufacturers to design devices that easily pass the static tests but are inaccurate in the dynamic mode.

3.5.5. Lack of complete data on non-compliance

In some jurisdictions, the legal metrology service provides advice to manufacturers, users, and service organizations to help them to:

- understand and meet legal requirements,
- keep instruments operational as long as possible, and
- select reliable instruments and to maintain them properly.

When a legal metrology service plays such a role, it should have good information concerning underlying causes of noncompliance. Even when this role is limited to the traditional one of ensuring equity in the marketplace, the service should have such information in order to devise an optimal control strategy based on the « systems approach » to metrological control. When measurement accuracy is unacceptable, the service should know whether the cause is poor design (pattern), improper instrument maintenance, operator error, a severe environmental condition, or something else.

High total control costs can result when data are insufficient to determine and then eliminate the causes of recurring problems. Nevertheless, because comprehensive data collection may be expensive, trade-offs must be considered. When computerized, data based management systems are available, however, it is economically feasible to collect and analyze large amounts of verification data. In the Appendix, an example involving gasoline dispensers illustrates the use of extensive verification data in identifying and eliminating a compliance problem.

3.6. Summary of systems approach to assurance of metrological control

- Minimum required accuracy, target compliance, and the related confidence levels are administratively fixed for each controlled measurement category, class of instrument, repair service, etc.,
- actual compliance levels are determined by measurement and data analysis for each controlled measurement category, etc.,
- sufficient data on relevant variables are gathered and recorded so that causes of noncompliance can be identified by data analysis,
- the total uncertainties of the measurements made by verification officers are continually monitored and kept so small that accept/reject decisions are negligibly influenced by these uncertainties,
- institutional factors (social, legal, and economic) are arranged so that rapid, appropriate action can be taken by legal metrology officials, manufacturers, instrument services, etc., to reallocate surveillance efforts or to correct conditions producing nonconformance,
- to the extent possible, tests are made under actual or simulated conditions of use.

3.7. Application of measurement assurance principles to actual situations

The Appendices provide examples of the application of the systems approach to specific cases. Appendix 1 deals with the assurance of control for gasoline dispensers, Appendix 2 discusses non-traditional ways of checking truck-weighing devices in the field, and Appendix 3 treats the selection of control mechanisms for clinical thermometers. One can examine the examples in the Appendices with the view that a well designed system of metrological controls is a system with feedback and adaptive response.

In statistical quality control, one examines data to determine the « assignable cause » whenever the data indicate that the production process is no longer in a state of statistical control. The same approach can be used in legal metrology when compliance data indicate less than the minimum required level of compliance (« state of statistical control for a measurement process » is defined in point 1.1.6).

If compliance data are periodically collected, say monthly, and plotted on a control chart, the chart will graphically indicate the degree to which assurance of metrological control has been achieved. In some real situations, the assessment of the success of the controls may, however, be more complicated because the measure of compliance may include factors other than the compliance percentage relative to the target compliance. A control chart, shown in Figure 2, is discussed in the context of Appendix 1.

When control includes pattern evaluation and initial verification by lot sampling at the factory, correlation analysis can also uncover assignable causes. In arriving at a sampling plan, one first decides what is a sufficiently low level of risk of accepting noncomplying instruments and of rejecting complying instruments. Next, one derives (from the level of risk decided upon) the target compliance and confidence level and then selects a sampling plan which will produce that level of confidence. Decisions to accept or reject any given lot are based on a comparison of the number of complying instruments in the lot, on one hand, with the target compliance, on the other (this may be an iterative process in which risks and cost of controls must be carefully balanced). Usually a sampling plan, for a lot of given size, will be roughly as follows: if x instruments of a lot are tested and z or more are found not to comply, the lot must be rejected; otherwise the lot is accepted. If pattern evaluation is thorough and the sampling plan valid and

rigorously followed, any desired degree of assurance of control can be achieved. This kind of correlation analysis and sampling plan are very much in place, for example, in the case of the clinical thermometers discussed in Appendix 3.

For thermometers, controlled as described here, the manufacturer normally maintains control charts, analyzes them to determine assignable causes, and takes the steps to eliminate these (adaptive response). If legal metrology officials reject thermometers, the manufacturer will undoubtedly want to search for correlations between nonconformance and manufacturing process variables. It is therefore in the manufacturer's best interest to control the process so as to minimize the number of rejected lots. If, for example, analysis indicates that most rejected lots come from a particular production line, the manufacturer can take appropriate corrective steps.

3.8. Metrological control of prepackaged goods

While much of the instrument-oriented philosophy described in this Document also applies to prepackaged goods, metrological controls for prepackaged goods may, in addition, take forms different from those used with measuring instruments. A system for controlling prepackaged goods, analogous to that of Figure 1 for controlling instruments, is shown in Figure 3.

When an organization decides to market a new prepackaged product (element 1 of Figure 3) it must be aware of legal requirements concerning acceptable package sizes, labeling, etc. (element 5 of Figure 3). In some jurisdictions, the packaging equipment (check weighers, filling machines, etc.) is subject to the legal controls outlined in Figure 1 (pattern evaluation, initial verification, etc.) ; in others, emphasis is placed on sampling and checking prepackaged goods at the factory or warehouse (element 7 of Figure 3), or the retail outlet (element 8 of figure 3). Appendix 4 gives an example of the application of the principles presented in this Document to the controlling of prepackaged goods.

APPENDIX 1

GASOLINE DISPENSER EXAMPLE

The metrological control mechanisms for gasoline dispensers vary considerably. In some jurisdictions pattern requirements are imposed and pattern evaluation is carried out. In others, only initial and subsequent verification are used. In still others, all of these plus certain other controls are used. Controls within any one jurisdiction may be different for different types of gasoline dispensers. For example, dispensers with mechanical gearing systems for readouts and for price computation have different failure mechanisms and react differently to the environmental influences than dispensers with corresponding digital electronic systems. The control strategy for each type should therefore be appropriate to the nature of the dispenser. When total measurement error is determined with initial or subsequent verification schemes which compare the actual and the displayed quantity of dispensed gasoline, at the dispenser site, sources of error overlooked during pattern evaluation can be uncovered.

The service of legal metrology should ensure that the total uncertainty of measurements made by inspectors during verifications (including uncertainties arising from volume-prover calibration, misreading of scales by the inspectors, varying environmental conditions, etc.) does not exceed a few tenths of the error limits for the dispenser. If it does, these measurements and the inspector's accept/reject decisions may be in question.

The inspectors' volume provers should be verified against higher-level standards and carefully recalibrated whenever damage is suspected. The uncertainty in calibrating the provers should be quantified. Experiments involving redundancy and randomization should occasionally be carried out to assess verification accuracy and the impact of seasonal variations. An example is an experiment in which several inspectors retest the same dispensers, each using a randomly selected prover, from a group of nominally identical provers, at randomly selected times. The scatter in results provides an indication of the consistency of the measurements made by the inspectors. (For such checks one requires the actual dispenser and prover readings, not only records of whether the dispensers were in or out of compliance).

The following example, though hypothetical, is based on actual experience in one of the States in the United States and illustrates assurance of control for gasoline dispensers, with design requirements and initial and subsequent verification the only control techniques used. The error limits are established by law, and verification officers periodically verify each dispenser in the State.

Compliance data should be plotted on a control chart such as the one in Figure 2. As long as the inspectors' data indicate compliance in excess of the target compliance, let us assume 95 percent, the controls are considered to be adequate. If compliance drops below 95 percent and cannot be restored quickly, then more frequent subsequent verifications and the addition and/or substitution of other control elements should be considered. However, before changing the controls, the reasons for the poor compliance should be sought. (The use of dispensers is, of course, prohibited until they are repaired and shown to comply again).

Gasoline dispensers with errors which exceed maximum permissible errors only slightly, may be considered to be in a different category from dispensers with large errors. Because the severity of the consequent official actions may be influenced by the magnitude of such excess errors, it is advisable to maintain histograms of the error distributions. Figure 2 indicates a case in which metrological control had been achieved, that is, in which compliance exceeded the objective, from January to April. However, from May to June the compliance level is seen to have dropped. When

such a situation occurred in the jurisdiction from which this example is drawn, control could be restored rather quickly because excellent field verification data records had been kept of make, model, and serial number of each dispenser, inspector and date, volume prover used, and other pertinent facts. These data were stored in a computer so that possible correlations could be investigated to determine whether compliance was low in only a part of the jurisdiction or there was any correlation with such factors as : the verification officer, the prover used, the manufacturer of the dispenser or the individual or firm servicing it, the company owning the gasoline stations, etc.

Results in this case showed only the one correlation that compliance had deteriorated for one make and model of dispenser, but only for a particular range of serial numbers. Officials were able to resolve this problem quickly. The manufacturer of the noncomplying dispensers was known to be reputable and when approached by officials, cooperated in resolving the problem. It was found that the offending dispensers had been manufactured when a key component was unavailable from a regular supplier and that an alternative source of supply was used temporarily. It was hypothesized that performance had been degraded because the reliability of the substituted part, though manufactured from nominally equivalent materials, was lower than that of the original component. With official concurrence, the manufacturer replaced the questionable components and the dispensers returned to their previous, high compliance level.

Several points are worth noting in the above case : legal metrology officials had a quantified and well documented compliance objective. While they chose to rely on subsequent field verification, rather than on (initial) verification at the factory or on pattern evaluation, enough data were gathered to permit determination of the probable cause of unacceptable compliance.

Whether pattern evaluation and strict enforcement of adherence to the pattern might have prevented this problem is unclear. Because the manufacturer had no reason to believe that the alternative source of supply would result in lower reliability, officials would probably not have been notified of the alternative source of supply even if the device had originally been pattern-approved. Thus, one sees that, where device manufacturers are responsive and cooperative, control by only subsequent verification and control charts can be effective without prior pattern evaluation. Where device manufacturers are less concerned with the accuracy of their products than the manufacturer in this example, pattern evaluation may be a cost-effective supplement to field verification.

Demonstration of gasoline dispenser compliance with regulations is usually sufficient to ensure marketplace equity. However, unscrupulous vendors can find innovative ways to use an accurate dispenser to defraud customers, for example, by purposely failing to disengage the motor and pump after a delivery. In such cases, it is possible to begin another delivery at other than zero and to be paid twice for the same product. Even where such practices are not common, legal metrology officials cannot ignore this possibility. Vendors suspected of such practices can be kept under surveillance and/or special, unmarked vehicles, equipped with calibrated tanks, can be used. This is not to suggest that officials should emphasize such enforcement activities, but rather to make the point that instrument verification alone does not always ensure equity in the marketplace.

APPENDIX 2

PERMANENTLY INSTALLED TRUCK WEIGHING DEVICE EXAMPLE

Because permanently installed truck weighing devices must be assembled at the installation site, their initial verification in the field (element 9 of Figure 1), is an important part of their metrological control in many legal metrology jurisdictions. Since most of these devices are located out of doors, frequently in dirty environments, degradation of performance over time is probable, particularly if they are not adequately maintained. For this reason, many jurisdictions also perform subsequent verification (element 10 of Figure 1) on truck weighing devices.

Typically, an inspector visits the site periodically and uses a set of well calibrated weights to verify the performance of the weighing device over its range. If these weights are correctly calibrated and the inspector carefully follows valid procedures, this approach can provide considerable confidence that the device is performing correctly. With this approach one evaluates the device and its environment, but may not be able to evaluate the accuracy of the actual measurements, which may be affected by the device operator and the truck driver. For example, if the truck tare weight is determined with the driver not in the truck, but the loaded weight is determined with the driver in the truck, the net weight of the load is not measured correctly.

An approach that promises to permit longer intervals between comprehensive verifications, using classical techniques, is based on a group of « reference truck weighing devices » strategically located within the jurisdiction. The reference devices are verified frequently with check weights to establish their stability and errors. With tare weight carefully controlled, an ordinary truck is weighed on a reference device, driven sequentially to several nearby weighing devices that are to be verified, and then driven back to be reweighed on the reference device. Ordinary trucks of the varying sizes and configurations covering the range of weights, number of axles, etc., of interest for verification can be used as transfer standards in periodic « round robin » verifications of this kind (element 19 of Figure 1). Records of the measurements on each device are kept so that the data are sufficient to suggest the causes of any problems that may arise, in the same way as illustrated in Appendix 1.

One can also use a verification system based on sampling (element 21 of Figure 1) for this application. Such a system has the advantage of sampling the actual measurements made with the devices to be controlled. A truck that has just been weighed with the weighing device to be verified is selected at random and its driver is requested to bring it to the nearest reference weighing device for reweighing. This approach is feasible only where local laws, policies, or logistics considerations permit; also, some truck drivers may object to having their trucks rerouted to reference weighing devices. However, it has the advantage of realistically evaluating the entire measurement process (operator, device, environment, and measurement procedures).

In this last approach and in the round robin approach, one must consider possible special sources of error, for example, the truck fuel consumed in driving between the device being verified and the reference device; also ice, snow, rain, or dirt picked up by the truck between device sites. Such error sources should be assessed for each particular verification plan and either should be eliminated or appropriate corrections should be made. In any case, good technical judgement should be exercised.

It is not intended here to recommend any particular method for verifying truck weighing devices, but to illustrate the importance of exploring possible alternatives in assuring metrological control.

APPENDIX 3

CLINICAL THERMOMETER EXAMPLE

This example is intended to illustrate how metrological control for clinical thermometers can be assessed, not to recommend legal requirements for them.

In some countries, voluntary standards (norms) with which all thermometer manufacturers comply and a general policy of users to buy only thermometers guaranteed by the manufacturer to comply with these standards may reduce the need for legal controls.

Let us consider controls on liquid-in-glass clinical thermometers and/or on their use. Their accuracy is almost entirely determined by their quality at the time of manufacture and, provided the liquid column has not separated and the glass is not broken, their accuracy does not generally deteriorate. When thermometers have been checked at the factory and are used in hospitals only by trained nurses or technicians, the probability of incorrect measurements due to operator error, environmental conditions, etc., is low and one can dispense with initial and subsequent verification (elements 9 and 10 of Figure 1). In such cases, one usually does not impose legal metrology requirements on operator training or environmental requirements (elements 14 and 16 of Figure 1). It is more usual to control liquid-in-glass thermometers by pattern evaluation (element 8 of Figure 1) following the International Recommendation No. 7 and/or by either 100 % verification or lot sampling at the factory (element 9 of Figure 1). (RI 7 does not specify what constitutes adequate assurance of metrological control based on pattern evaluation, lot sampling, and testing according to RI 7). If officials are satisfied with a manufacturer's quality assurance, their verification may be limited to periodically witnessing lot sampling and testing at the factory. It is inefficient and unnecessary for the officials to duplicate the manufacturer's quality assurance if it continues to be adequate.

Legal metrology officials and thermometer manufacturers should ensure temperature measurement accuracy by monitoring the errors of the temperature measurement process used to evaluate the liquid-in-glass thermometers. Regular measurements on stable control thermometers and the keeping of control charts [1, 2] can provide information on the process precision. Calibrations of standard thermometers by a higher level laboratory and round robins with other laboratories involved in temperature measurements at comparable levels of accuracy can provide information on systematic errors.

When, for example, the maximum permissible error for thermometers is $+ 0.1\text{ }^{\circ}\text{C}$, $- 0.15\text{ }^{\circ}\text{C}$, as recommended in RI 7, the uncertainty of the temperature measurement process used to test these thermometers should be quantified and shown to be much less than $0.1\text{ }^{\circ}\text{C}$. If RI 7 is chosen as the basis for thermometer pattern evaluation and for factory qualification, and this is supplemented with production lot sampling, a valid procedure for production lot sampling is still necessary even if a submitted pattern meets all the requirements^(*).

Legal metrology officials should also be concerned with whether rejected thermometers are destroyed, remanufactured or repaired, or relabeled and sold for less demanding applications. In any case, it should be ensured that, following the tests, complying thermometers are not confused with noncomplying thermometers. If marks are affixed to those that comply, immediately following the tests, this should not be a problem. Also, one should ensure that unscrupulous manufacturers do not include rejected thermometers in lots later submitted for testing, in the hope that the sampling process will miss them.

^(*) Examples of standards providing guidance on lot sampling are:

- ISO 2859 « Sampling procedure and tables for inspection by attributes » (see also ISO Guide3319).
- United States - ANSI Standards Z1.4 and Military Standard 105D.

The situation changes when one considers electronic, digital readout clinical thermometers. Subsequent verification is generally not needed for liquid-in-glass thermometers because of their stable properties, but should be considered for electronic devices whose performance may change as components age or fail. This is particularly true for a new technology for which pattern evaluation may not adequately assess all relevant factors.

In one instance, a hospital purchased a large number of electronic thermometers that had performed accurately and reliably in laboratory tests but which, when placed in service, frequently produced erroneous readings. The problem was traced to the electromagnetic fields of a nearby radio station. This suggests that, to achieve assurance of metrological control for electronic devices, control techniques should take electromagnetic interference (EMI) into account. Legal requirements (element 7 of Figure 1) could specify the ability of the instrument to reject EMI. One could then evaluate instrument patterns for susceptibility to EMI and other environmental variables. Another approach is to control the environment of device use by prohibiting device use in locations where EMI exceeds a specified threshold. But because most hospitals have no capability for measuring or controlling EMI levels, this is impractical. Because electronic thermometers may also be sensitive to other environmental conditions (ambient temperature, etc.) their subsequent verification, where required, should be performed under realistic conditions of use, for example, by checking them at regular intervals at the user location (for example, hospital, clinic, or doctor's office) against calibrated standards (for example, liquid-in-glass thermometers). Placing requirements on the user, rather than relying only on official inspections, conserves the resources of the legal metrology service.

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APPENDIX 4

PREPACKAGED GOODS EXAMPLE

In industrialized countries, complex machinery is frequently used to fill packages to predetermined levels, for example, machines to fill, with specified volumes or weights, paper milk cartons, beverage bottles, cartons of soap powder, and cereal boxes. An example is the group of devices installed in a conveyor-belt system that determines gross package weight, subtracts tare weight, and affixes labels showing net weight and price. A comprehensive but costly and inefficient approach to assuring control of package content is to subject such filling and weighing machines to legal requirements (element 7 of Figure 1 and element 6 of Figure 3), including pattern evaluation and approval (element 8 of Figure 1), initial verification at the factory producing the machines, (element 9 of Figure 1), subsequent verification of the machines (element 10 of Figure 1), etc. A simpler approach, that still assures metrological control, is to sample packages and check their contents for accuracy at the packaging plant or in the marketplace (elements 7 or 8 of Figure 3), but to place no requirements on the machinery. This approach has been successful in some OIML Member Countries.

Whether one samples packages at the packaging plant, in the retail marketplace, or both, depends on the product, local regulations, and the nature of the particular packaging industry. The selection of suitable controls for prepackaged goods and of adequate sampling plans are complex subjects that are beyond the present scope ; this document addresses only very general aspects of assuring metrological control for prepackaged goods.

Control by sampling can take place at the retail level but may be more efficient at the packaging plant for packages whose characteristics do not vary appreciably with time. Ideally, legal metrology officials establish a compliance goal for each type of prepackaged item. These goals can differ for different types of goods. By recording and analyzing field data, officials determine the actual compliance percentages to be compared with target compliances. When target compliance is not met, increased surveillance or additional or different controls should be considered.

Metrological control is assured when, for example, data show that, at 95 % confidence level, less than three percent of a valid sample of, say packages of soap powder, weigh less in the marketplace than the weight stated on the packages. Required confidence levels and target percentages may vary from case to case, but metrological control is assured if these parameters are quantified and continually monitored and if corrective action is taken whenever a compliance percentage is too low.

The above approach is highly effective but few, if any, legal metrology services have the resources to perform the sampling and testing necessary to obtain such a high level of assurance for all controlled prepackaged goods. A pragmatic solution of the problem is to increase surveillance of packagers with noncompliance histories and to decrease surveillance to the level of occasional spot checks for packagers who have consistently complied with requirements. When a spot check turns up noncomplying items at one location, inspectors in other areas can also be alerted to increase surveillance of the package types involved. Frequency of sampling and of inspection, as a function of previous compliance history, can be written into regulations as an incentive for packagers to give full measure and as a means for decreasing inspection work loads.

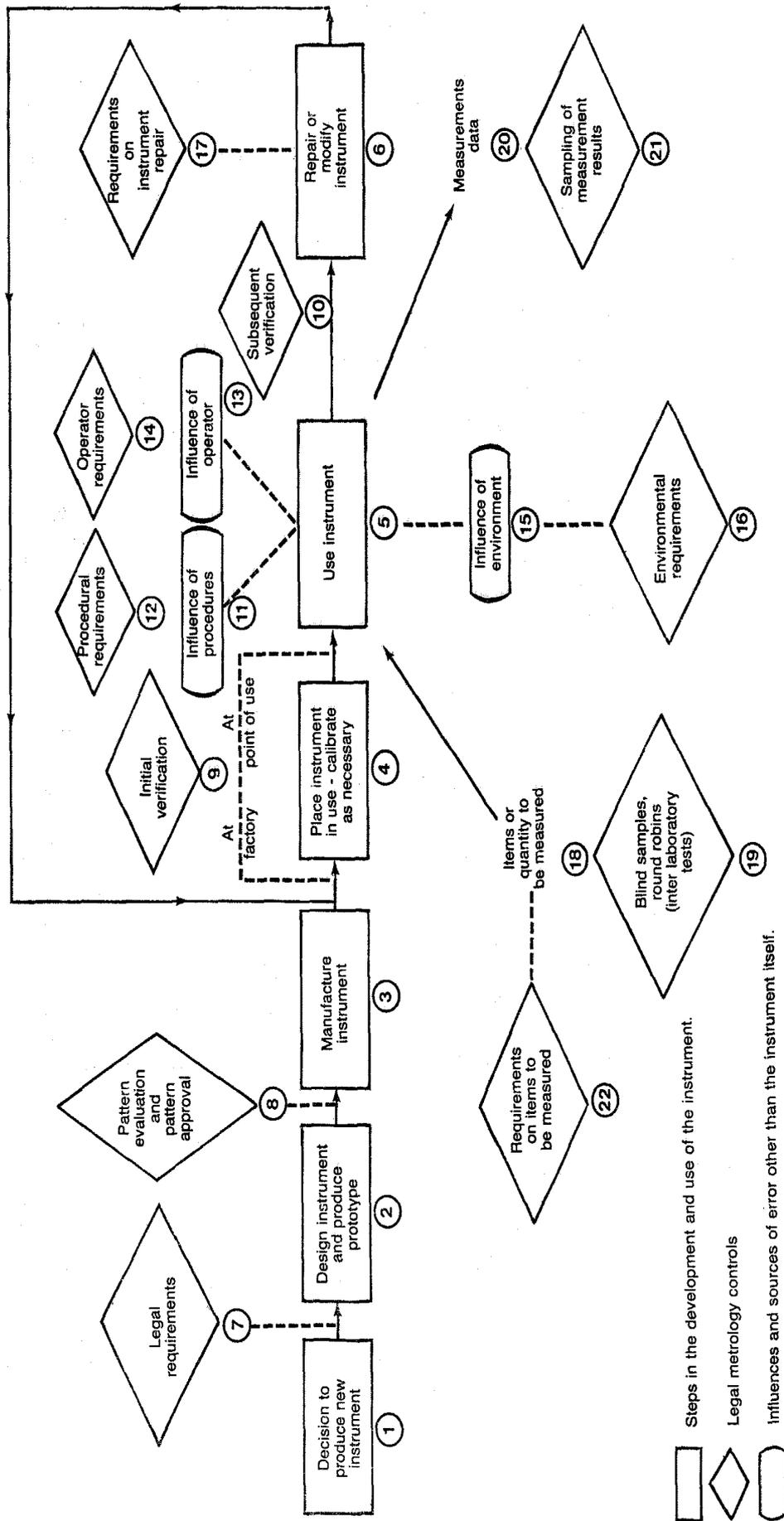


Figure 1 : Features of a generalized system of metrological controls on measuring instruments (and systems)

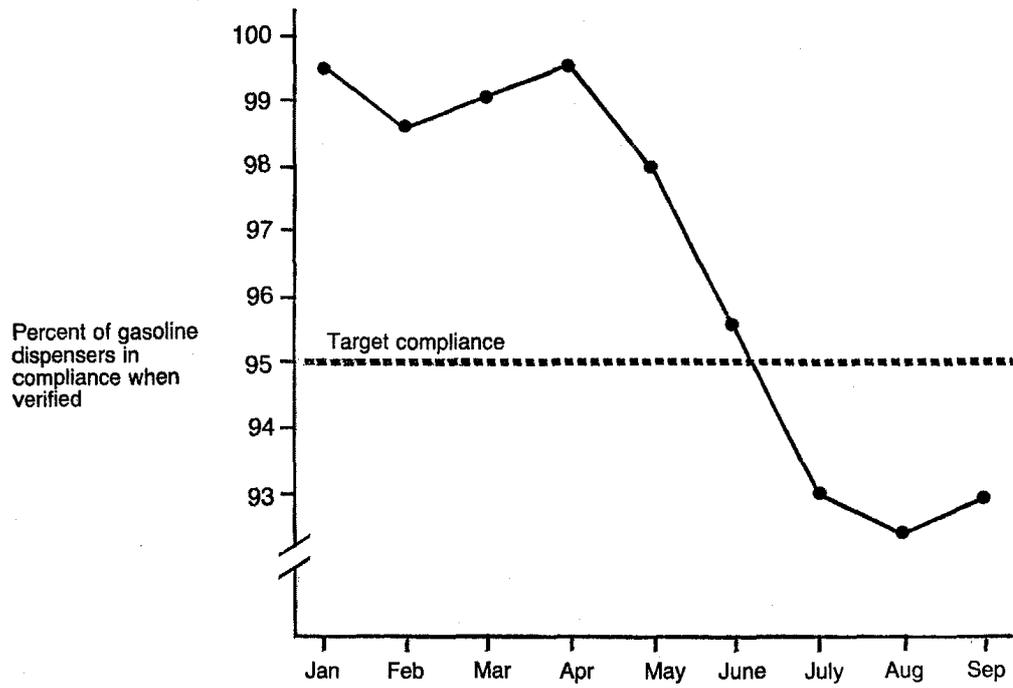


Figure 2: Hypothetical control chart for gasoline dispenser verification.
 It is assumed that approximately the same statistically significant number of randomly selected dispensers are verified each month.

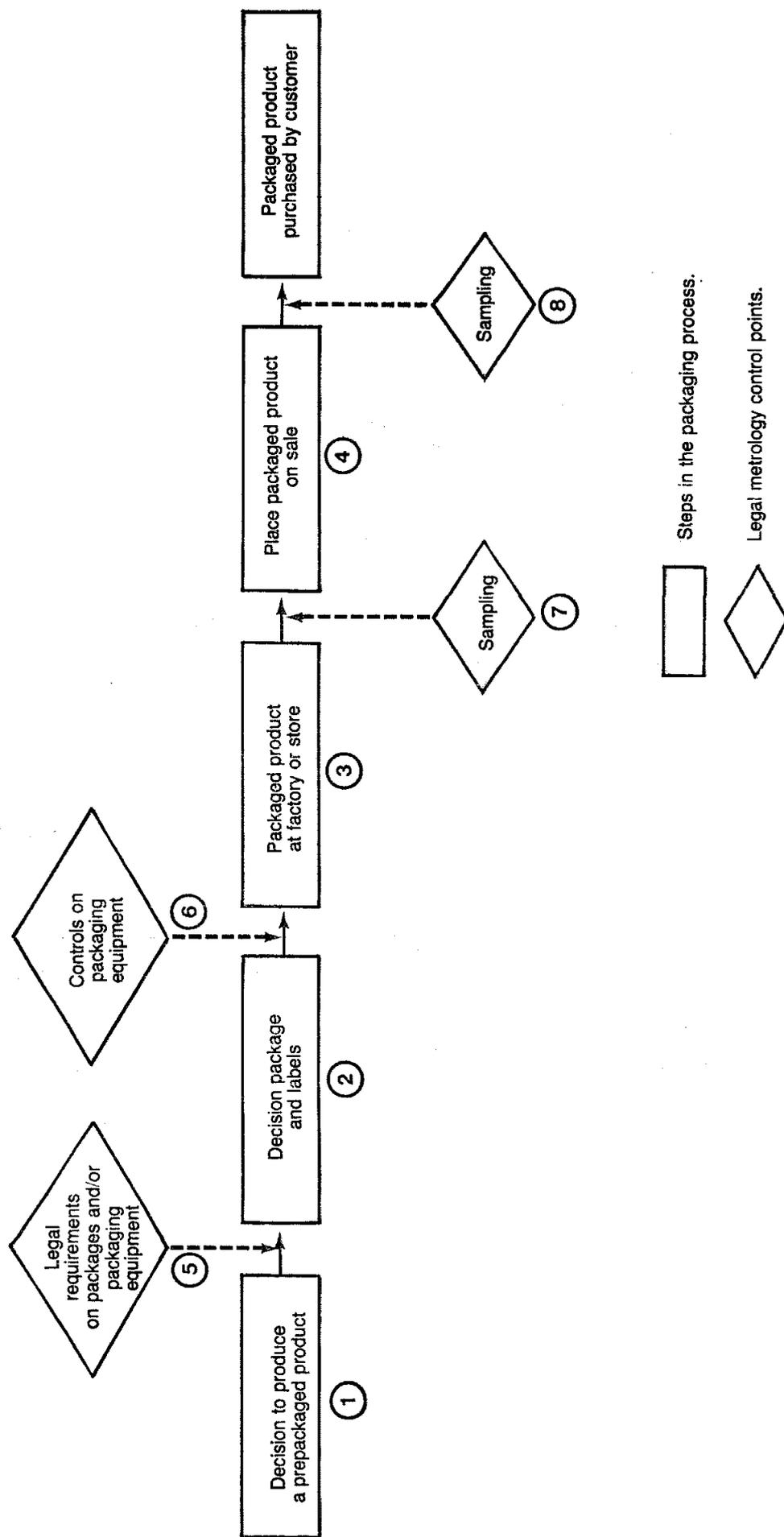


Figure 3 : Features of a generalized system of metrological controls on prepackaged goods

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