

15 NEW METHODS OF INTERVENTION OF THE STATE AND NEW TASKS FOR LEGAL METROLOGY OFFICERS

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Note concerning the English translation of this presentation

The original presentation was given in French. The English translation is a slightly shortened version and hence contains less detail. The French original is available from the Author or from the BIML.

Introduction

Traditionally and until these last years, the control of measuring instruments has been performed by State officers in France. Since 1988 some delegations of controls to private bodies were possible. A new decree published in 2001 has clearly established that :

- ❑ each time applicable, the conformity assessment of measuring instruments is performed in the framework of the quality assurance system (QAS) of the manufacturer, the repairer or the installer, approved by a designated body,
- ❑ if not applicable or in the case of no approved QAS, verifications are performed, according to the case, by bodies designated by the minister of industry or by bodies agreed by the prefect (local authority representing the State) where the body is located,
- ❑ the control is performed by State officers only when above mentioned modalities are not possible.

This policy is implemented on the one hand in order to provide flexibility to manufacturer, repairers and installers capable to demonstrate their competence by implementing a QAS, and on the other hand, both because of the increasing of the number of activities for State officers and the policy of the government to decrease the number of civil servants and to delegate some activities.

The 2001 decree defines four levels of metrological control :

- ❑ type examination (approval),
- ❑ initial verification (for new or repaired instruments),
- ❑ verification of installation (for instruments for which this operation is critical),
- ❑ control of in service instruments (periodic verification in particular).

In addition to the national control, procedures in application of European directives apply.

When the process of delegation of all these activities (called “first level activities”) is achieved, the essential activities of State officers will be :

- surveillance of operators,
- surveillance of instruments in service,
- market surveillance.

These activities are called “second level activities” because State officers are not involved directly in the conformity assessment process.

This document describes the new modalities of the State officers’ action in this context. Those are called the “new jobs in legal metrology”. Synergies between these activities, factors for success and difficulties will be pointed out.

Definitions

The following definitions apply.

Surveillance of operators

Set of activities implemented in order to check that operators respect their obligations and, in the case of operators having implemented a QAS, their commitments.

These operators are of two main types : firstly designated bodies, agreed bodies, or French notified bodies, and secondly manufacturers, repairers or installers.

Designated body means a body designated by the minister of industry for some activities of conformity assessment of measuring instruments. These bodies have to demonstrate their competence, impartiality and independence from manufacturing and repairing activities in particular.

Agreed body means a body agreed by a prefect for some activities of conformity assessment of measuring instruments. These bodies have to demonstrate their competence and impartiality.

French notified body means a body notified by France for conformity assessment in application of a new approach directive. Requirements made to designated bodies are similar to requirements made to notified bodies.

Surveillance of instruments in service

Set of activities implemented in order to check on the one hand that instruments in service are correctly maintained and verified and on the other hand, they are suitable for use and correctly and legally used.

Market surveillance

For instruments intended to regulated uses, set of activities implemented in order to :

- ❑ check that instruments placed on the market and put into service have been subjected to appropriate conformity assessment procedures, are conforming to statutory requirements and are correctly marked,
- ❑ undertake statutory corrective actions.

For instruments not intended for regulated uses, set of activities implemented in order to check that instruments put on the market are correctly marked.

Audit (definition according to ISO 9000 : 2000)

Systematic independent and documented process for obtaining audit evidence (1) and evaluating it objectively to determining the extent to which audit criteria (2) are fulfilled.

Facts, recordings...

Requirements

In depth visit (of surveillance)

Visit, in general expected, made at the head office or in an agency of an operator, intended to investigate whether the operator fulfils some of its obligations or some of its commitments, or that these commitments are appropriate.

In depth visits may be considered as small intermediate audits.

Unexpected visit of surveillance

Unexpected visit of an operator mainly intended to check the competence of its staff in real situation, and to check that the staff fulfils the obligations and commitments of the operator in the presence or in the absence of the State officers as well.

Global description of the situation

The 2001 decree foresees 3 categories of operators :

- ❑ private bodies in charge of certification (designated or agreed),
- ❑ manufacturers, repairers or installers having a QAS approved by a designated body (Laboratoire national d'essais-LNE in particular),
- ❑ manufacturers, repairers or installers having no QAS approved but having to request verification to a third party body.

Each type of operator necessitates an appropriate level of surveillance.

See French version for more details

Surveillance of agreed bodies in charge of verifications

In addition to the initial audit, the surveillance includes :

- ❑ periodic audits,
- ❑ in depth visits,
- ❑ unexpected visits of surveillance,

- instruction of the demand and general follow-up of the activity of the body.

The 2001 decree foresees that the agreement of a body is issued by the prefect of the department where the body is located and that the agreement is valid for all France. So it was necessary to develop rules for co-ordination between the DRIREs (local authorities in charge of legal metrology), as far as the instruction of the demand and the follow-up of the activity is concerned.

The pilot-DRIRE (of the region where the prefect issues the agreement) is responsible for this co-ordination, particularly for the organisation of audits and the transfer of information concerning the bodies for which they are responsible.

Each DRIRE performs its minimum programme of surveillance that is defined at national level. This programme takes into consideration the size of the body. The DRIREs reinforce the surveillance of a body according to their own observations or on request of the pilot-DRIRE.

Audits

The initial agreement is issued after the conclusion of an audit has been positive. Periodic audits are performed every two years and the agreement is renewed every 4 years (complete re-instruction). If necessary intermediate audits may be performed.

The audit team shall have competence in quality assurance aspects, legal metrology and the specific instrumental technology. In some cases, the team may include only one person provided he/she has all these competencies.

Audits are organised taking into consideration the entire national organisation of the body. For this it has to declare all its operators, all facilities and all procedures.

The qualification and the management of competencies of operators are of the responsibility of the body, but in the process of the audit the checking of the competence and suitability of procedures may involve any operator wherever is the location where it is intended to operate.

In depth visits

The head office of the body is subject to an in depth visit each year where no audit is to be performed. Each local agency of the body is subject to such visits every two years.

The duration of these visits depends on the size of the body and on whether it is the head office or a local agency.

During an in depth visit it may be checked that the body respects all its obligations and commitments but in particular those directly connected to statutory aspects and quality aspects having a direct connection with statutory aspects.

See French version for more details

The conclusions of each visit are recorded on a specific report.

Unexpected visits of surveillance

The knowledge about regulation, the competence of individual operators of bodies are checked in particular during unexpected visits of surveillance. It is also the occasion to

check they respect the obligations and commitments of the body. The unexpected aspect allows appreciating the quality of operations in the presence or in the absence of the State officers as well.

During this surveillance the operator is invited to repeat measurements he has already performed in the absence of the State officer. The results obtained in the presence and in the absence, and the quality of judgements on the conformity of the instruments are analysed. It is also checked he has all the necessary elements and that the standards are calibrated according to the rules.

Each body working in a region is subject to such visits whose number depends on the size of the body.

In order to allow this surveillance, the body has to notify to the DRIRE its programme of verifications. As soon as possible a software will be made available to them in order to notify automatically this programme when establishing it for their own purpose.

The conclusions of each visit are recorded on a specific report.

Instruction and follow-up

Instruction means initial or renewed agreement (every 4 years). At initial agreement the acceptability of the request has to be considered. In any case the instruction includes the organisation of the audit and the decision of agreement (or not).

The follow-up consists in particular to organise periodic alternate audits (alternate to renewal) and to manage available information (reports of visits in particular), in order to judge the quality of the work of the body (reinforcement of surveillance, corrective actions, suspension or withdrawal of agreement). As already said it necessitates organising the transfer of information between the pilot-DRIRE and other involved DRIREs.

Surveillance of designated bodies in charge of certification (or French notified bodies)

The surveillance of bodies designated by the minister of industry is similar to the surveillance of agreed bodies with the principal difference that the Sous-direction de la métrologie (SDM), representing the central administration, plays the role of the pilot-DRIRE.

The surveillance of LNE is adapted taking into consideration the quasi-permanent relationship between LNE and SDM.

Surveillance of manufacturers, repairers and installers

The surveillance of manufacturers corresponds to market surveillance (see afterwards). The surveillance of repairers and installers is of the same nature, but in order to avoid ambiguity the expression “market surveillance” has been kept dedicated to placing on the market and putting into service of new (or considered as new) instruments, according to the meaning given to this concept by the Commission of the European Union. On the other hand, for questions of homogeneity and similitude, manufacturers are kept at the level of the same chapter than repairers and installers.

Moreover, the surveillance of manufacturers, repairers or installers may provide information on the behaviour of these operators, but also on the one of the bodies they charge of the certification of instruments.

Whenever they act in the framework of their approved QAS or have to request verification to a third party body, the manufacturers, repairers or installers have to respects a number of obligations that the certification bodies cannot check by themselves : in particular these bodies may not enforce the operators to subject the instruments manufactured, repaired or installed to the statutory certification procedures. This is the role of the State.

The rules implemented for this surveillance involve systematic preventive actions and a posteriori actions as well. The number and the type of visits are depending on the status of the operator.

Manufacturers

A manufacturer has to fulfil 2 essential obligations.

1- Subject manufactured instruments to the appropriate operation of metrological control.

Ensure conformity to type. This is a key point of the metrological control.

See French version for more details

Only in depth visits are foreseen, according to the type of necessary investigations. These visits may be unexpected or not.

The conclusions of each visit are recorded on a specific report. If appropriate the information is passed to the designated body that is concerned.

Manufacturers having an approved QAS are subject to specific attention in order to determine if the designated body in charge of the approval has taken all appropriate provisions in order to ensure the manufacturer respects its obligations, in particular concerning conformity to type.

Repairers and installers

Repairers and installers are also subject to an appropriate surveillance in order to check they respect their obligations.

See French version for more details

Surveillance of instruments in service

The surveillance of instruments in service consists essentially in verifying :

- ❑ instruments in service are correctly maintained and controlled,
- ❑ instruments are suitable for use and are correctly and legally used.

So it includes the surveillance of the users.

Indeed this activity is not really a new one for legal metrology, and very few will be said about it.

Instruments in use are correctly maintained and subjected to the applicable control

According to the category of measuring instruments, this surveillance is made in a systematic or in an occasional way.

Systematic means each years continuously or punctually as well.

Occasional means punctually a year for a category, with or without particular reason or for a particular instrument after complaint of a customer for instance.

The choice of the system (systematic or occasional) for a category depends on the importance or public concerned by measuring results.

Instruments are suitable for use and correctly and legally used

This surveillance is performed :

- ❑ at the same time than other activities,
- ❑ after complaints.

Modalities

The surveillance of instruments in service consists in checking that :

- ❑ instruments have been subjected to the applicable metrological control,
- ❑ sealing are presents,
- ❑ instruments are in an apparent statutory state,
- ❑ in a general way, users fulfil their obligations.

It may involve metrological tests or may be purely administrative.

Market surveillance

The market surveillance is a concept developed by the Commission of the European Union for application of “new approach” directives. It consists in obligations made to the States. In addition to requirements in the directives, the whole concept is developed in a guide on the new approach.

The aim is to guaranty that provisions in the directives are respected in the whole European Union, and so to ensure consumers protection, but also a fair competition between manufacturers. The State is responsible for this.

For instruments put on the market and put into service for statutory purposes it consists in ensuring they are properly marked, have been subjected to the appropriate procedures and fulfil requirements.

Practically it consists in checking the manufacturer or its representative has respected all its obligations concerning the measuring instrument put on the market (proposed for sale) and put into service. This may be done at the manufacturer’s factory, on the location of saling or of delivery, but also using information provided by performing other activities of legal metrology. Preventive actions made with professionals can contribute to the market surveillance.

By principal it stops at putting into service. However when it is possible to demonstrate the responsibility regarding the product in service, the resulting information may be taken into account for market surveillance. For example actions may be undertaken against the manufacturer if it can be demonstrated that an instrument in service has never received the appropriate making or in a general way, that a flaw did exist before putting into service.

A new instrument put recently into service and not respecting metrological requirements can provide indication that an action of market surveillance would be appropriate. Repressive actions of market surveillance may only be undertaken when the systematic aspect of a flaw is established, the instrument being placed and used in normal operating conditions.

One of the essential obligations of the manufacturer is to ensure the conformity to the type.

The notion of market surveillance corresponds also to obligations made at national level.

Systematic action

The systematic action consists in verifying that manufacturers respect their obligations, performing scheduled in depth visits. This systematic action involves mainly preventive actions, information and discussion with manufacturers or importers acting as manufacturers in France.

The DRIREs dedicate a given percentage of their metrological activity to the systematic action of market surveillance.

Punctual activities

In addition to systematic aspects, the market surveillance involves punctual activities.

Punctual activities are often the only possible way to perform market surveillance for an instrument subjected to CE control (or C.E.E.) abroad. It consists in visiting locations where instruments are imported and performing visual examination and tests that are easy to perform on site.

Punctual activities necessitate specific credits in order to buy instruments sent to laboratories for fundamental tests to be performed.

Reinforced surveillance

The reinforced surveillance completes any form of systematic surveillance of :

- ❑ operators,
- ❑ instruments in service,
- ❑ the market.

It is implemented :

- ❑ when a DRIRE has noticed a need concerning an operator,
- ❑ on declaration of an anomaly declared by a certification body,

- ❑ after complaints,
- ❑ in a punctual way for non systematic activities,
- ❑ on request of the pilot-DRIRE,
- ❑ by any DRIRE on its own initiative, with or without particular reason.

Synergies

As already mentioned, each form of surveillance allows highlighting facts relating to other forms. That is in particular.

Synergies between forms of surveillance

The surveillance of a certification body could allow detecting problems on new instruments installed or in use, or on their use. According to the case the responsibility may be the one of the operator (see definition) or of the custodian or user.

2 The surveillance of instruments in service could provide information for market surveillance, particularly : are new instruments correctly marked ? However it is recalled that if the surveillance of instruments in service may provide information for the market surveillance, it is contrary to its basic principle, the latter stopping at putting into service, except if the responsibility of the manufacturer may be established.

The surveillance of instruments in service could provide indication on certification bodies, for instance have they correctly checked sealings, proceeded correctly to stamping, filled the metrological logbook.

3 The market surveillance at the manufacturer's factory could demonstrate the designated body having approved a QAS did not take appropriate provisions in order to ensure conformity to the type in particular.

In the case of a third party certification, it could show that the body did not perform correctly or made the verification on the basis of a non-valid certificate in particular.

Synergies linked to operators

Some operators have several metrological activities, for instance :

- ❑ verifiers for initial or subsequent activities,
- ❑ verifier and repairer,
- ❑ operator intervening on several categories of instruments.

Information got from the surveillance of an activity could provide information for other ones.

Factors for success and difficulties to overcome

New jobs and competencies

By no longer performing controls themselves, State officers will necessarily loose globally some competence. However it is not a fundamental handicap if appropriate provisions are taken for maintaining a level of competence sufficient for the new forms of surveillance.

To that aim, in a first step, the new jobs must be defined and may be classified so :

- ❑ Control of bodies *
- ❑ officer in charge of instruction and follow-up of files, and corresponding judgements,
- ❑ quality assessor,
- ❑ technical assessor,
- ❑ officer in charge of in depth visits,
- ❑ officer in charge of unexpected visit of surveillance.

* Classification partly applicable to surveillance of manufacturers, repairers or installers.

2 *Surveillance of instruments in service*

officer in charge of checking the presence of statutory marking and other similar aspects,

officer in charge of more metrological investigation (tests, suitability for use, legal use of instruments...).

3 *Market surveillance*

officer in charge of checking the presence of statutory marking and other similar aspects,

officer in charge of more metrological investigation (conformity to type...).

In a second step the competencies for each job must be analysed as far as is concerned :

- ❑ general metrology and legal metrology,
- ❑ instrumental techniques and regulation in the particular fields,
- ❑ quality assurance and audits,
- ❑ administrative law (European relations in particular) and juridical right (reports about offences).

This leads to define basic competencies that everyone must have and competencies for specialists, which results in appropriate training programmes.

Reflections on rules of qualification of State officers are under process.

In addition, it is also suggested that one way for maintaining competencies is to have State officers trained for periods by certification bodies, LNE in particular.

Sanctions

The confidence in the new metrological control system implemented in France will necessitate that the State implements an appropriate surveillance, will apply rigorously intended sanctions versus contraveners, and will demonstrate it and let it know.

The DRIREs have received instructions in order to perform correctly the new forms of surveillance above referred, to apply administrative and penal appropriate sanctions and to inform of their action.

For certification bodies, according to the fault, administrative sanctions are :

- recall or observation,
- advertisement,
- suspension of agreement (designation...),
- withdrawal of agreement (designation...).

For repairers or installers the withdrawal of their mark replaces the suspension or withdrawal of agreement (designation...).

Users that possess non-legal instruments, in particular that do not submit their instruments to the statutory control, are exposed to the refusing of their instruments or placing under sealings.

Penal sanctions are foreseen either specifically in the metrological regulation or generally in the penal Code.

Conclusion

The DRIREs have been instructed on how performing correctly above operations. However general instruction may not avoid State officers having to face situations that can not be foreseen.

In order to apply correctly the new implemented system and to face unpredicted situations, the State officers must have an appropriate background of competencies. So it is necessary to take appropriate provisions in order to get and maintain this competence by organising suitable initial and continuous training.

The delegation of certification activities to agreed or designated bodies must be done keeping the same level of metrological quality for measuring instruments. In the same way the flexibility provided to operators intervening in the framework of their approved QAS shall be seriously controlled, first by bodies designated for this activity, but also by a surveillance action of the State. This necessitates maintaining an appropriate level of supervision of the system, even if this system relies on confidence in a first approach, and to have a set of efficient administrative and penal sanctions at disposition. Sanctions must be applied rigorously each time necessary.

Discussion

Comment: Mr. Magaña added that in order to implement these changes successfully, it will be necessary to develop the training of staff members who will no longer act as legal metrology inspectors but who will

become responsible for assessment teams. In addition, it will be necessary to establish information and coordination networks.

Comment: Privatizing the tasks of market surveillance is an interesting idea. But who will pay for these services? The government, users or manufacturers?

Reaction: Certification activities will be paid for by those who apply for such certification (manufacturers or users of instruments). Periodic verification activities will be paid by the owners of the instruments. Concerning surveillance, which is organized by the state, it should remain free - with the exception of audits.

Comment: How will the control be organized in fields other than trade, i.e. health, safety and environmental protection? The concept of market surveillance is not perfectly clear with its preventive aspects: it is rather a repressive activity. Also, the principle of purchasing an instrument and checking it is not a market surveillance activity but rather a surveillance of the conformity assessment bodies.

Reaction: What has been said will apply to all categories of instruments subjected to regulations, and not only to trade instruments. Concerning market surveillance, it should be noted that measuring instruments are rarely offered for sale in manufacturers sale points. The action described in the presentation has therefore preventive aspects. As for the last comment, purchasing an instrument is, according to the EU Commission, the only solution to test it.

Comment: According to which criteria are the bodies responsible for metrological control designated by the Ministry of Industry or by Regional Authorities?

Reaction: If a limited number of highly competent bodies are to be designated, this will be done by the Ministry at central level. If a low competence level is sufficient, local administrations will be responsible for their designation. The matter of cost will also have to be considered since these bodies will not be allowed to combine control activities and repair activities. There are therefore several parameters which will guide the choice between the two possibilities.

Comment: Is it intended to have one single body for regulatory and accreditation activities or will the accreditation be left to the French Accreditation Committee? And will market surveillance over a two year period have a 100 % surveillance or a sampling surveillance?

Reaction: Accreditation will be carried out by the French COFRAC but technical experts will be provided by the metrology body. Concerning market surveillance, it has only been decided that each manufacturer will be visited yearly but no decision has been made concerning the percentage of instruments to be checked.

Comment: Is it intended that the surveillance of designated bodies will be in addition to the surveillance of their quality systems?

Reaction: Yes, this will be an additional action to certification and to accreditation which will be required for bodies carrying out type examinations and quality system approvals.

