

## **6 PATTERN APPROVAL AND PATTERN COMPLIANCE IN AN AGE OF GLOBALIZATION – THE AUSTRALIAN APPROACH**

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### **1 The changing political and economic climate**

The manufacture of legal measuring instruments is becoming concentrated in highly industrialised countries, and increasingly controlled by multinational companies who are supplying the world market. Despite the fact that our client base has ‘globalised’ we (legal metrology authorities) still operate within our own strict national or ‘economic community’ boundaries, and impose our own legal and administrative requirements. National pattern approval requirements represent a significant regulatory barrier to international trade. In small markets like Australia, they impose significant costs on manufacturers and reduce market competition and product choice. The net result is an increase in consumer prices and slow adoption of new products and technologies.

This is a situation which will not be tolerated in the global economy of the 21<sup>st</sup> century. It seems inevitable that we will all be living and working in a climate of economic rationalism and market deregulation. This is a dangerous climate for legal metrology authorities. The fundamental nature of our regulatory role is not well understood by governments or by the community in general, and we are in danger of being dismissed by the younger generation of bureaucrats, as old-fashioned technocrats who create unnecessary barriers to trade.

Unless we, the international legal metrology community, start to respond to the challenges of globalisation and the associated political and economic imperatives, our prospects of surviving until 2020 do not look good.

### **2 Globalisation of legal metrology**

In essence, our proposal is that the OIML needs to make the transition from a ‘harmonisation and coordination’ approach, to an integrated global system of legal metrology. The globalisation of legal metrology should reflect the globalisation of industry and trade, whilst still respecting the sovereign rights of individual Member States.

The key elements of a global system would be:

- Mutual acceptance arrangements for type approval test reports based on OIML Recommendations;

- ❑ Pattern approval testing by a small number of specialised laboratories, located in major manufacturing countries and regional centres;
- ❑ A coordinated international pattern compliance program.

### ***Mutual Acceptance Arrangements***

A “Framework for a Mutual Acceptance Arrangements on OIML Type Evaluation” has been developed by the members of TC 3/SC 5 and has now reached its 9<sup>th</sup> Committee Draft. This has been a difficult process, but now appears to be close to reaching general acceptance. This will be a watershed decision in the life of the OIML, which will have a major impact on the future operations of all individual Member States and on the BIML.

### ***Rationalisation of pattern approval facilities***

The introduction of mutual acceptance arrangements will inevitably lead to a gradual rationalisation of pattern approval testing laboratories. It is anticipated that a small number of laboratories, located in the major industrialised countries and regional centres, will specialise in providing this industry service, and their reports will be accepted by most other Member States.

The main benefits of this approach would be:

- ❑ Economies of scale in providing industry testing services;
- ❑ A single international testing process, avoiding multiple testing and associated costs and delays for manufacturers;
- ❑ Reduction in regulatory barriers to trade;
- ❑ Maintenance of a high level of competence and quality systems within specialised laboratories;
- ❑ Ability of specialist laboratories to invest in new equipment and keep pace with new technologies.

However, there will be some critical issues to be addressed, in particular:

- ❑ The rationalisation of pattern approval testing facilities could mean that many Member States may lose their technical capabilities; and
- ❑ A single pattern approval test is unlikely to be acceptable as an adequate basis for international confidence in the long-term performance of an instrument; so
- ❑ A ‘safety net’ will be required, in the form of an international pattern compliance program.

### ***An international pattern compliance program***

For some time, there has been a recognition amongst OIML Members that there is a strong focus of resources on pattern approval testing, but very little focus on ensuring that production instruments conform to type. This leaves the whole system vulnerable to the selection of so-called “gold plated” instruments by manufacturers seeking pattern approval, who often openly acknowledge that they have difficulty in consistently achieving the standard in their production plants. This practice is perpetuated in an environment in which there is little market surveillance on the part of legal metrology authorities. With the implementation of mutual acceptance arrangements, it will become

even more important for Member States to ensure that the instruments released onto their markets comply with the appropriate pattern approval standards.

It is apparent that many countries are not in a position to carry out national pattern compliance programs, as such programs are essentially in the public interest and must be funded by government. With the decrease in global industry revenue from pattern approval testing, under an OIML MAA, many national governments will face a critical decision: to pay the full cost of maintaining testing facilities and operating an effective national market surveillance program, or to close their laboratories and to trust in manufacturer declarations that production instruments consistently comply with the approved pattern.

The National Standards Commission has chosen the former option, with the support of the Australian government, because we have a legal responsibility to ensure pattern compliance, and because we believe in the deterrent value of a random surveillance program. However, this is an expensive option. On an international scale, a multiplicity of national compliance programs would be a very inefficient approach - given that many laboratories would be testing the same population of instruments.

Consistent with a global approach to pattern approval, we see the opportunity for a *global* approach to pattern compliance testing. We propose, for the consideration of Members, that participants in each Mutual Acceptance Arrangement establish a cooperative pattern compliance program for the instruments which are covered under the MAA. A coordinated program of sampling and testing of instruments, and the sharing of results, would provide an effective global surveillance program at a very small cost to individual Member States.

Of equal importance would be the opportunity for participants to develop joint policies and take collective action against non-compliant manufacturers. The risk of losing global market approval would be a major incentive for manufacturers to deliver compliant products to all markets at all times.

Figure 1 illustrates a possible global approach to pattern approval and pattern compliance by the members of a Mutual Acceptance Arrangement for a single OIML Recommendation. This model assumes that the BIML would employ a Data Manager for each MAA. That person would manage and disseminate information, and use the database to determine a sampling plan for pattern compliance testing. MAA members would pay an annual fee to cover the cost of pattern compliance testing and data management.

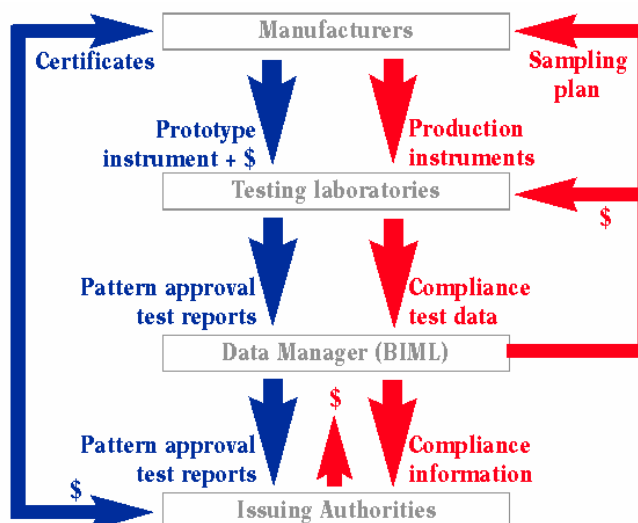


Fig. 1 A model for 'global' pattern approval and pattern compliance within an OIML Mutual Acceptance Arrangement

We recognise that this proposal is a radical concept, which would require considerable trust between the OIML Member States, and careful planning and design. There may always be some Members who will retain national responsibility for pattern compliance, for legal or strategic reasons. However, with a 2020 horizon in view, we present the global model for debate and consideration by the OIML.

The Australian approach to a national pattern compliance program, and our early experiences, may be of interest in this debate, and are outlined in section 3 below.

### 3 The Australian experience

#### *Strategies adopted in 2001*

In 2001, the National Standards Commission entered into its first bilateral Mutual Recognition Agreements - with NWML in the UK, NMi in the Netherlands, and the Ministry of Consumer Affairs in New Zealand. The key elements of these agreements are:

- ❑ Acceptance of test reports which conform to OIML formats (for the selected instrument categories);
- ❑ Mutual confidence in test results based on third party accreditation to ISO/IEC 17025 by a signatory to the ILAC MRA;
- ❑ A focus on agreements which will facilitate trade between Australia and its major overseas trading partners, and optimise benefits for Australian manufacturers and importers.

In parallel with the introduction of mutual recognition arrangements, the NSC also announced that it would implement a national pattern compliance program. Our objective in doing this was to make all manufacturers aware that we have an effective market surveillance system in place, and we expect production instruments to meet the approved pattern, whether they are initially tested in Australia or accepted under mutual recognition arrangements.

### ***Early experiences with mutual recognition arrangements***

In the early stages of processing pattern approval applications under our mutual recognition arrangements, we have encountered a number of issues.

- There are slight differences in interpretation and application of OIML requirements between testing laboratories. There is an ongoing need to discuss and resolve points of interpretation, to ensure uniformity of practice, and this is a constructive process for all concerned. However, this experience suggests that the implementation of an OIML MAA could involve a major exercise in clarification and alignment of procedures. It will be important to ensure that agreed interpretations are systematically incorporated into revisions of OIML documents by the relevant Technical Committees.
- There are some differences in methods of testing and the design of testing equipment between laboratories. In some cases these can lead to differences in test results and performance evaluations. This is an area which warrants further investigation.
- It is a practice of some OIML Issuing Authorities to outsource some components of pattern approval testing to third parties, including instrument manufacturers. This practice compounds the problems of uniformity of interpretation and methodology, and raises significant questions of confidence in the capabilities of the third party and the independence of test data. At the present time, the NSC does not accept third party data under its mutual recognition arrangements.

### ***The design of the Australian pattern compliance program***

All pattern approval examinations include tests of an instrument's performance under different influence factors, particularly temperature, humidity, voltage, and electromagnetic radiation. These aspects of performance cannot readily be assessed under normal operating conditions, and problems may go undetected during trade use. The NSC has implemented a systematic pattern compliance testing program to address this issue. The steps in this process were as follows:

- A complete listing was made of all instruments with a current Australian pattern approval, indicating all models included on each approval certificate.
- It was decided that each instrument would be subjected to each of the 'influence factor' tests over a 5-year period. The program commenced with temperature testing, as this was considered to be the most critical.
- A pattern compliance database was designed. This allows for a planned testing schedule to be entered for each instrument, and for the progressive recording and analysis of test results.
- Two non-compliance categories were defined, to assist in interpreting and reporting the findings of the program:
  - Minor failure: less than or equal to 1.5 X MPE
  - Major failure: greater than 1.5 X MPE
- Consultations were held with manufacturers and agents, to seek their voluntary participation in the program for a trial period. They agreed to supply randomly

selected instruments from stock, on request, and we agreed to advise them of the results of the test and discuss any non-compliance issues without penalty.

***Early experiences with the pattern compliance program***

The program is in its very early stages, and has so far been limited to nonautomatic weighing instruments.

However, some significant issues have already emerged.

- Australia does not have many manufacturers of weighing instruments, so the majority of instruments are imported via local agents. In some cases the local agents have been cooperative, but in some cases we have had to wait for overseas manufacturers to supply a ‘suitable’ instrument, as stocks are not always held in Australia. This leaves the process open to selection of a ‘gold plated’ instrument, which defeats the purpose of the program.
- Although this initial program is voluntary, we would expect to take action against non-compliant manufacturers after the trial period. As the majority of instruments are distributed through agents, it will be very difficult to have any impact on instruments already sold into the marketplace, so that any rectification will only apply to new instruments. Unilateral withdrawal of approvals in Australia could prove controversial, and would have limited impact on manufacturers, unless supported by other OIML Members. We are not aware of any simple mechanism for sharing information or taking collective action.
- The results of 27 tests scheduled for stage 1 of the program are shown in Figure 2. In summary:
  - 9 instruments complied with the test requirements;
  - 9 instruments had a minor failure;
  - 1 instrument had a major failure;
  - 4 instruments are no longer manufactured; and
  - 4 instruments have still not been supplied by manufacturers.

Instrument N°	Pass	Fail	Comments
1		x - Major	Failed -10, TEOZ all Temps
2		x - Minor	Failed 40
3	x		
4	x		
5		x - Minor	Failed TEOZ 20 - 40
6	x		
7		x - Minor	Failed TEOZ 20 - 40
8			No longer made
9	x		
10			Out of business
11		x - Minor	Failed TEOZ 20 - 40
12		x - Minor	Failed -10 and 40
13		x - Minor	Failed -5, +5
14			No longer made
15	x		
16			Nothing supplied
17			Nothing supplied
18 (LC)		x - Minor	Failed MDLOR -10, 20
19 (LC)	x		
20			No longer made
21 (LC)			Nothing supplied
22 (LC)		x - Minor	Failed -10, +5
23 (Ind)	x		
24		x - Minor	Failed 40 and $V_{min}$
25 (Ind)			Nothing supplied
26	x		
27 (Ind)	x		

Fig. 2 Results of 27 tests scheduled for stage 1 of the program

- Incidents of non-compliance have been discussed with the relevant manufacturers. In all cases they were surprised and concerned by the findings, were keen to discuss the results in detail, and have initiated remedial action. This has been a very constructive outcome.

These preliminary findings suggest that there could be a significant level of non-compliance of nonautomatic weighing instruments, particularly at the extremes of the temperature range. The sample size is small and most failures are minor, but this limited evidence is sufficient to justify the ongoing allocation of resources to this work. The program will be extended to other instrument categories, to build an overall understanding of compliance issues and to identify issues which need to be raised with manufacturers, and/or with the relevant OIML Technical Committees.

#### 4 Summary

In our view, the International Organization of Legal Metrology should respond to the economic and political imperatives of the 21<sup>st</sup> century by developing a global system for the pattern approval and pattern compliance testing of legal measuring instruments.

Mutual Acceptance Arrangements will be the first important step in this process. Such arrangements will significantly reduce technical barriers to trade, but are also expected to lead to a major rationalisation of technical facilities, resulting in a few large specialist laboratories in major manufacturing countries and regional centres.

We have proposed, for the consideration by the OIML, that a pattern compliance program be introduced as part of each MAA, to provide an effective market surveillance function for the global marketplace, on a cost-sharing basis. Early Australian experience with pattern compliance testing suggests that such a program is necessary.

## Discussion

**Comment:** A European manufacturer agreed with a number of views expressed in the Australian presentation (needs to develop international type approval and compliance systems, greater usage of OIML certificates, etc.) but disagreed with certain other views, especially the fact that the specimens which were submitted for type testing were carefully prepared for this examination by the manufacturer and were not really representative of the instruments which would thereafter be commercialized.

**Reaction:** It is true that mutual recognition based on OIML certificates already operates correctly between certain countries but it is not yet a global system.

**Comment:** What is, in Australia, the meaning of ‘testing laboratory’? Is it a laboratory that performs only tests, or tests and examinations? If it is a laboratory that performs only tests, then examinations have to be done by another body. Which one? If it is a laboratory that performs tests and examinations, then ISO 17025 will apply to that part of the laboratory which performs tests, not to the part that performs examinations. This is an important problem which exists as well in the future MAA which is being drafted by OIML TC 3/SC 5. The situation should be clarified.

**Reaction:** The agreement between Australia and certain other countries is an agreement between Issuing Authorities of OIML certificates. NSC examines test results which have been used as a basis for issuing the relevant OIML certificate. So at this stage NSC is dealing only with laboratories which are associated with OIML Issuing Authorities and the third party accreditation is simply an additional requirement for mutual confidence. It should also be noted that test reports have to be established according to OIML Recommendations.

**Comment:** What will be the fate of pattern approval in the long term? The necessary equipment is more and more expensive. In addition, the instruments submitted for approval by manufacturers are most often good instruments. Therefore, that is a possibility that, within ten or twenty years, pattern approval will just be a confirmation of actions already undertaken by manufacturers in order to design and produce good instruments.

**Reaction:** It is quite possible that in the future, manufacturers do their own self-assessment and consequently, there will be a need for an independent pattern compliance program as proposed in the presentation, in order to give the community a level of confidence concerning the assessment of



the quality of instruments that are being produced. So self-declaration by manufacturers will be reinforced by an independent assessment.

**Comment:** It has been mentioned that, possibly, there will in the future be fewer but more specialized laboratories. Will this appear through a sort of survivorship or Darwinian process, or a well organized process?

**Reaction:** At the very end, market forces will decide. However, governments may look at the situation of their own labs and decide about what to do concerning their future activities in relation to the anticipated revenues.

**Comment:** Accuracy of measuring instruments is no longer a problem. The problem is: 'What is an instrument'. This question is connected with software since if we do not know what software is, we do not know what the instrument is. The future will be about identifying what the instrument is, identifying what the software is, and 'sealing' the instrument in such a way that we have clarified what is the instrument under legal control.

**Reaction:** This comment is quite right. In Australia there are already lots of shops where the consumers' transactions (pricing, etc.) are monitored by software, the control of which has to be addressed in the very near future.

