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OIML Seminar on Conformity to Type II ("CTT II")

ORGANISATION INTERNATIONALE
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INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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Second OIML Seminar on Conformity to Type ("CTT II")

Prague, Czech Republic

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Note: More information about the seminar, including the presentations given, is available on the OIML web site at: www.oiml.org/seminars/2011_CTT-II/

Introduction

Mr. Kool told Members that the current Seminar on Conformity to Type was a follow up to the one which had taken place in Utrecht in June 2011. Members should have received a program for the current Seminar and also a written report on the Utrecht Seminar. The session would begin with a presentation and report from Mr. O'Brien on the Utrecht seminar. This would be followed by a presentation by Mr. Frank Lienesch, of the PTB in Germany, on the IEC Conformity Assessment Systems and the UNECE (United Nations Economic Commission for Europe) international model for the harmonization of technical regulations based on international standards; Mr. Lienesch would explain in detail what that was and how it worked and how it could be used in the field of legal metrology. After lunch there would be a presentation by Mrs. Corinne Lagauterie on the information in OIML Certificates. These two presentations had both originated in discussions held in Utrecht, where it had been considered that there should be further discussion of these two issues.

After this there would be discussion of the definition of Conformity to Type in the hope of arriving at a consensus on what that definition could be. After the coffee break there would be a discussion on the way forward, chaired by the CIML President Elect, Mr. Peter Mason and hopefully leading to a draft for a Resolution to be voted on by the CIML later in the week.

Mr. Stephen O'Brien, CIML Member for New Zealand and Convener of the Working Group which had drafted the program for the June CTT Seminar in the Netherlands, told Members that a full report could be found with the day's program and also in the Seminars section of the OIML web site.

Mr. O'Brien said that he would be presenting the main points from the report to form a basis for the day's discussion. He hoped that as a result of the two seminars they would be able to develop a clear Resolution or set of Resolutions for the CIML to consider and vote on later in the week. He pointed out that his report was intended to inform through discussion. He had taken care to reasonably reflect the consensus views of the seminar participants, but the report, and in particular the recommendations contained in it, had not been subject to formal vote at the seminar. However, a number of people present at the current seminar had also attended the Utrecht one, and he invited them to comment after his presentation on any points they wished to make.

Mr. O'Brien told those present that the issues and concerns regarding the conformity to type of legal metrology instruments subject to OIML certification had been considered in a number of fora for some time. The Utrecht Seminar had been seen as an opportunity to focus on CTT and identify a potential way forward for CIML consideration.

The June Seminar had been attended by 43 delegates representing a cross section of legal metrology regulators, issuing authorities and industry associations. Representatives had attended from the Asia-Pacific and European regions. On the first day speakers had presented the experiences and perspectives of international conformity assessment bodies, EU and US manufacturers and regulators from the US, EU, Australia and New Zealand. The second day had taken the form of a panel discussion. This discussion had analyzed critical issues in relation to CTT and the perspectives of the participants. Mr. O'Brien wished to give an overview of the key points identified in the presentations and in the subsequent discussions. When CTT was looked at from the global perspective, he said, complexities existed around:

- finding an appropriate funding model;
- working out how to exchange information;
- dealing with global supply chains;
- responding to non-compliances; and
- avoiding duplication of existing EU, US and other national CTT schemes.

In spite of these complexities, conformity to type was seen as important for the maintenance of ongoing confidence in the OIML certification systems (the MAA and the Basic Certificate System) and needed to be the focus of a formal OIML Working Group.

Globally, Mr. O'Brien continued, regulators needed assurance that production instruments entering their economies were consistent with the OIML certified type. This was an issue of particular importance for economies outside the jurisdiction of existing regional or national CTT systems and without strong national CTT compliance and testing programs. At Utrecht, the need for a level playing field for instrument manufacturers had been highlighted. Supported by a fair regulatory system, this was critical to ensure fair and equitable competition and to avoid market distortion from non-compliant instruments. Independent pre-market surveillance and instrument testing were important elements to be considered in any CTT program to incentivize compliance by introducing the potential for detection of non-compliant instruments. It did however need to be noted that the OIML had no regulatory powers and that the Treaty was non-binding on its Member Economies. Developing effective responses to non-compliance identified within the global marketplace would need careful consideration and might be outside the scope of legislation in many jurisdictions.

Discussions at the Seminar, Mr. O'Brien continued, had highlighted among other things the fact that the term CTT had a variety of potential interpretations for individuals with regard to what it meant, where it would be applied within the supply chain and who would be responsible for it. To enable CTT to be effectively discussed and progressed by the CIML a 'working' temporary definition of CTT needed to be established. This definition would be discussed in detail, considered and hopefully agreed in the afternoon session. The informal consensus view of those present at the Utrecht Seminar had been that any OIML CTT activities should concentrate on pre-market assurance that "production meets type".

It had also been identified during the seminar, Mr. O'Brien explained, that mandatory national and regional CTT systems supported by legislative, administrative and enforcement frameworks were currently in place in some regions and economies (e.g. EU, USA, Japan). If the OIML wanted to improve CTT on a global level these existing systems needed to be considered and taken into account. For example, any potential OIML CTT activities would

need to recognize and complement the existing MID and legislative requirements within the EU and also the Verified Conformity Assessment Program (VCAP) under development in the US. The need to avoid OIML duplication of existing EU and US CTT programs must be balanced with the need for economies outside Europe and the US to have access to or guidance on developing CTT programs. Without some form of normative guidelines or co-ordination there was real potential for development of a proliferation of regional and national CTT programs that might have contradictory or duplicate requirements creating technical barriers to trade. The OIML also needed to consider the views and perspectives of developing economies. Without the support of a CTT program, developing economies had the real potential to become a 'dumping ground' for instruments that did not meet their type. The issue of 'dumping' measuring instruments was not just an issue that concerned developing economies. This issue was a potential problem for any economy that does not have an effective CTT program.

Mr. O'Brien said that it had been noted that instrument manufacturers had a number of questions regarding potential benefits, compliance costs and practical operation of an OIML CTT program or any activities in this area. The success of any CTT activity would rely on the support of instrument manufacturers, so effective consultation and manufacturer involvement would be critical. Also, any OIML activity must add value and not duplicate current requirements or impose additional compliance costs without clear benefits. This principle had been described in OIML Publication D 16 as "proportionality", in that it said that the actions taken to ensure confidence in the reliability of measurements should be costed and the costs considered with respect to the benefits. So it was clear that cost benefit analysis had to take place before any formal OIML activity was taken on. One way which had been identified for reducing costs associated with any CTT activities was to use a comprehensive risk management framework. Such a framework would be used to identify, analyze and evaluate risks, to ensure that limited global resources were effectively targeted where they were needed.

One key outcome identified from the Utrecht seminar was that understanding and application of the appropriate elements from the ISO/CASCO 'toolbox' of international standards and guides on conformity assessment was also needed to ensure that any OIML work on conformity to type was consistent with international best practice. It was also seen as important to obtain leverage from the knowledge and experience of ISO and the IEC in the CTT area.

One suggested potential way forward was to form a joint OIML UNECE working group tasked with a mandate from the CIML to apply the ISO/CASCO toolbox to the OIML Certificate Systems and to improve CTT in the global marketplace. A presentation later in the morning would give more detailed information on the IEC conformity assessment and the UNECE International Model for Members' consideration.

It had also been noted during the Utrecht seminar that, in parallel to any CTT activity, the content and quality of OIML Certificates and their documentation could be reviewed and potentially improved to better identify the certified instruments and clearly prescribe the responsibilities of manufacturers. Photographs and other identifiers could also be used. During the second session of the current seminar these ideas would be further explored in a presentation on information and the OIML Certificates.

As could be told from the number of points which Mr. O'Brien had raised, the Utrecht seminar had successfully highlighted and discussed a wide variety of issues and perspectives. After consideration of the presentations made on that occasion and the associated discussions, the following actions had been suggested for further consideration at the current seminar:

1. The CIML should draft a Resolution to formally assign responsibility for Conformity to Type to the work of an OIML Technical Committee. Due to the fact that Conformity to Type had overarching implications for all instrument categories and for both the MAA and Basic Certificate Systems, further CIML consideration needed to be given to where this work was assigned. Mr. O'Brien hoped that some of this consideration could take place that afternoon.
2. The second action point from Utrecht for Members' consideration was that was that a CIML Resolution be drafted formally to request this Technical Committee to develop a normative document or guidance document on Conformity to Type. This document would reference current programs in the US and the EU, identify 'best practice', and inform future global development work in this area.

CTT, Mr. O'Brien continued, was an area of work of strategic importance to the OIML and to the global legal metrology system. The Utrecht seminar had successfully highlighted and discussed a wide variety of issues and perspectives presented for CIML Members to consider. The challenge in moving forward would be to ensure that the constructive dialogue that had been held at the seminars was transformed into appropriate OIML activity.

Mr. O'Brien thanked Members for their attention and invited questions and comments.

Mr. Sanders thanked Mr. O'Brien for his presentation He stated that much UK legislation was based on EU requirements and that he had unfortunately been unable to attend the previous CTT seminar. He asked whether it was known how many countries used OIML Certificates as their legal documents. This was certainly not the case in the UK.

Mr. Kool replied that it was well known who was issuing Certificates but not who was using them.

Mr. O'Brien said that in New Zealand national approval was based on OIML approval, and he imagined that this would be the case in the majority of economies.

Mr. Patoray said that Mr. O'Brien had done an excellent job of presenting the overall tone of the previous seminar as well as its conclusions, indicating potential questions and future directions which might be examined. He considered this to be a topic of great importance. He had been actively involved in the development of the US VCAP system, so he had some knowledge of that system, which had additionally been explained in detail in a presentation at the Utrecht seminar. There were currently several systems in the world, and it seemed to him when he read the OIML Convention that it was possible to take all the information available on legal metrology in the global area and put it together into useful consolidated, harmonized information, not changing anything but putting it together so that others could understand and use it. From that, it would be possible to begin to develop a more harmonized direction, because all the information would be on hand. Mr. Patoray believed that much of the early work done for the creation of the Convention and the older documents had consisted of gathering much information, putting it together and finally being able to create Resolutions which would set up Work Groups to create the Recommendations. All this had taken time, but, from what he had seen in Utrecht and what was in the summary, in his view the preliminary work was now done, and it would be possible to proceed to conversations which would lead to taking the next step, even if it was only a small one, towards understanding how to put CTT into place.

Mr. Kool then invited Mr. Lienesch (PTB, Germany) to make his presentation.

Frank Lienesch

Before speaking of his work in UNECE Working Party 6, Mr. Lienesch would give an introductory explanation of what it was and how it worked. The Working Party had developed the SIEEE (Sectoral Initiative on Equipment in Explosive Environments) with common regulatory objectives (CROs) for such equipment. The official document, he said, could be seen on the screen. He would try to explain how the IECEx scheme worked together with the UNECE Working Party 6 model. At the end there would of course be a conclusion, which he hoped would lead to fruitful discussion.

Mr. Lienesch explained that the main industry using the UNECE SIEEE scheme was the petrochemical industry, including offshore, onshore, mines, the car manufacturing industry, all places where there was an explosive environment. The market was about two billion dollars. Initially the Working Party had interviewed these users to find out what their interests were. The petrochemical industries nowadays acted more and more globally, with a single engineering approach for their plants. On the one hand there were the big players such as EXXON, BP, Shell and so on, and on the other there were governmental organizations, in the countries where the mines or other sources were organized by the government. So there were global players and national players. The users wanted savings in installation, engineering and maintenance costs; they wanted to buy equipment more in bulk to get a better price per piece, and they would like to have benefits from global competition. Their problem was that rules and regulations varied from country to country. This was what UNECE had learned from the users.

On the other hand, there were the manufacturers, for example motor manufacturers, explosion proofing, meters, measuring devices, boxes to collect electrical installations, etc. The manufacturers' interest was to manufacture and sell their product worldwide without differences in requirements from country to country; they wanted importantly to avoid delays to the market; they would like a single global standard to deal with, and would like this to be an ISO or IEC standard and nothing else; they had to do explosion testing and they would like to do all this without double testing of their product, which was a very sensitive issue as a product might fail at one test house but pass at another. They wanted to place it on the market without further restriction and without special differences in domestic rules for the product between country and country.

Regarding the history and some special points about these products, Mr. Lienesch said that up to the 1970s Germany had had only national regulations. This was regarded in Europe as the old approach and today there was the so-called new approach, which was the ATEX Directive, which they were talking about, at national level there was nothing and they sought a Common Regulatory Objective (CRO), which was the goal that could be achieved.

In the area of standardization, Germany had previously had its own standards and this had changed to CEN/CENELEC, and now they used ISO/IEC Standards, which by European agreements had to be implemented to European CEN/CENELEC levels without technical changes. Format changes were allowed, as shown in the annex, but no technical changes. There had had to be education. At the beginning there had just been a product which was certified; this had changed and now there was certified product and support action equipment and of course it was possible to have a certificate for one product in various production places, so there was a need to go to all these places. This was what happened at present and of course at an international level it was accepted that they had to follow these product and production certificates.

There were various levels. For very high risk there was Zone 0 equipment, for high risk there was Zone 1 equipment and for normal equipment there was Zone 2. It was absolutely necessary to have third party certification for this purpose, certainly for Zone 0 and Zone 1 equipment and there was some ongoing discussion as to whether or not it was necessary for Zone 2 equipment. Most people said yes but others were not so clear.

The UNECE was believed by everybody at the beginning to be just for Europe, but this was not the case. The United Nations had been set up in 1947 and created UNECE, which was one of the five regional commissions of the United Nations. UNECE's major aim is to promote pan-European economic integration. Membership was open to all countries; there were at present 56 member countries, including the European Union, the non EU Western and Eastern Europe, South East Europe Commonwealth of Independent States, North America and all other interested countries in the United Nations. Working Party 6 is the only body within the UN system dealing with regulatory cooperation.

The Chair of Working Party 6 was Mr. Christer Arvius, and the Secretary was Mrs. Lorenza Jachia. Mr. Kool represented the metrology sector and Mr. Lienesch represented his own sector: equipment for explosive environments. There might be scope for a legal metrology sector here. Working Party 6 dealt with standardization and cooperation policies. There was a main meeting each year, the next of which would take place on 31 October to 2 November. There had been several other meetings in various places. All this information could be found on the web pages.

The sector initiative had begun in Geneva in 2007 with a questionnaire. First they had invited various regulators and interest groups and these had presented their systems. At the following year's main meeting in Geneva the terms of reference had been prepared. The next task had been to prepare the Common Regulatory Objectives, so they had had several meetings and in 2009 the first edition of the CRO rules had been produced.

Over the last two years, since 2010 in Berlin they had discussed the workshop concept. The problem was to bring the regulators together. For various countries it was very difficult to travel to Geneva, so the Working Party had decided to go to those countries, together with the United Nations and with IECEx. Importantly, market surveillance had been discussed in the current year. They had invited regulators and market surveillance authorities to introduce and explain what their problems were. Where there were problems with a product there was a need for a contact point for discussion of these at international level. In Europe there were the ATEX rules. Once safeguards were introduced to cover a problem in Europe, the next step was to offer the product in Asia, which was of course not so simple.

The intention of the CROs, Mr. Lienesch said, was to cover comprehensively all the issues in order to achieve a globally accepted safety level. They would like to provide a global best practice as a template for national regulation, focusing on main objectives, which should be easy to understand and open to national modifications, which were sometimes necessary. They would also like to specify the disputed rules and related responsibility of the parties involved so that it was clear who had to do what and what the stakeholder had to do. They were open for ongoing maintenance and modification.

This, Mr. Lienesch said, was what Mr. Klausmeyer had explained in Utrecht but he would say it again as it was important. They had very sensitive products and it was one thing to offer these products to the market, but if they could not be correctly installed they could never run safely. They therefore believed that installation and maintenance needed to be inspected if problems and accidents were to be avoided. Repair situations could also of course arise and should also be regulated. So because it was a loop, it was called a life cycle

approach. The groups accepted that this life cycle approach was needed. So when the manufacturer placed something on the market it had to be controlled by market surveillance; when it was with the operator the regulator had to ensure that installation and maintenance was correctly done.

Mr. Lienesch emphasized that UNECE Working Party 6 was always looking for IEC or ISO standards and seeking to realize them. Going into more detail on the CROs, Part 1 was requirements for the standard of equipment; this was a little like what they had in Europe; health and safety was important and so was avoidance of ignition sources. Therefore it was necessary to study the product to be sure there were no ignition sources during normal operation. Ignition sources were explained in the standard. To date this was only a European standard but the IEC was working on including it in their standard in the future. It was accepted that these special protections were essential for their product. There had to be a manual which must include installation, maintenance and repair, otherwise it was impossible for the user to work with it. Conformity assessment procedure was in accordance with an international certification scheme, in this case the IECEx. Because this was the only scheme in existence it was seen as a reference.

Part 2 dealt with use of the equipment: the user could specify the correct place for the equipment and classify the substances, ignition temperature and explosion groups such that everybody of importance would know what they had to do. They worked to IEC sound classification and protection level. There was another standard in America but the IEC one was accepted in Europe. Installation and equipment needed to be inspected and maintained, therefore there were standards. Requirements for the competency of persons were also very important, as were requirements for service facilities, so there had to be a repair shop. Every stage had to be explained, explored for risk assessment and documented.

Between parts 1 and 2 therefore, they had standards for production and testing, ISO/IEC standards on conformity assessment, the IECEx operational documents (in this case IECEx 02), rules for the certification of these products, an ISO guide, an IECEx document and explanations of personal competency. There was as yet no ISO standard for services, but Mr. Lienesch had explained the situation here.

Part 3, Standards reference list: It was not possible to have IEC standards at every level, but they believed that it was essential to have a harmonized list. This was also accepted by others outside Europe. The accepted standards were listed in the annex of their document and the standards had to be accepted by a standard acceptance rule. This was currently being done in the Working Party 6 meetings, together with experts from IECEx. After its acceptance, the standard could be applied by manufacturers and end users to show compliance with the regulation. All countries which had implemented this regulation enjoyed its advantages such as the free trade areas, exploring protective equipment and equal conditions for operating planning for explosions.

Conformity assessment bodies: each accreditation body had to be a member of ILAC/IAF. Accreditation of conformity assessment bodies and test laboratories had to be against applicable ISO/IEC standards and one member of the assessor team needed competency in explosion protection. This was very important and rather similar to a list of peers for peer assessment, because the competent people were listed on the web site; they had to fulfill requirements in order to be accepted as competent persons. Most of them came from notified bodies or test houses worldwide so it was a sort of peer assessment because they had to be able to travel to all the others to carry out the certification procedure.

Procedures and rules of the IECEx, were taken as a reference for conformity assessment.

Part 5 established a steering committee; they wanted to implement an explosion prevention steering committee like the standing committees they had in Europe. This had to be formed and operated under the umbrella of UNECE Working Party 6 and they could monitor the applications. All members who had implemented the CROs could participate in this group and of course their SC modified the acceptance groups, as explained above. Observers were also welcome.

Work was in progress on market surveillance, having begun in Split a couple of weeks previously. A market surveillance network was necessary, specializing in E-x equipment and this had to be formed and operated. This was tricky to do and they needed non conformance of E-x equipment and also an alert system. They hoped some hope would be forthcoming. UNECE Working Party 6 had the MARS group (on MARket Surveillance). Their strategy was to develop a general procedure for market surveillance, increasing cooperation with stakeholders and sharing the work of market surveillance internationally, and to increase the visibility of the market surveillance to the outside world. This was difficult: if there were problems with a product and that product came from somewhere in the world, the first necessity was to have a contact address from which to obtain and disseminate information.

Speaking of the workshop idea, Mr. Lienesch showed a slide of the countries involved in the IECEx scheme. These included a number of European countries, some in South America, South Africa, Russia, and of course Australia and New Zealand. The idea had been to implement these workshops in order to discuss various regions. It was important to know that at the moment there were two trains of development proceeding at different speeds. One train received highly regulated systems such as the European and North American ones, and the other many other regions, such as Arabia, Asia and other places, where such matters were not so highly regulated. The idea was for the Working Party to go to those countries, where there was a lot of gas and oil, and where there was a lot of interest in the scheme. So the American and European manufacturers were very much interested in the Working Party talking to those countries. For this reason the next meeting, in six months time, together with the IECEx, would be held in Dubai and the strategy would be to make an occasion of it, coming from the United Nations and inviting regulators from that region. The help for this came from IECEx. Six months later they would go to Singapore, and in two years to Rio de Janeiro. South America was very interesting because the ideas were warmly supported there and they hoped to have regulators from many South American countries such as Argentina and Venezuela.

The output was an extensive description of the metrology of the system, and they wanted to prepare guidance documents for the various stakeholders, because they felt that especially in those countries regulators did not have a perfect overview of the special problems involved in this equipment. Therefore they believed that detailed explanations should be given. They should explain actions and relationships within these initiatives, and therefore they needed a definition of the various stakeholders and how they acted together, for example the contact procedure between a manufacturer and the specification body or test lab, what was necessary to obtain a certificate, what was allowed and not allowed and so on. This was of course true for all the other groups, therefore at the moment the Working Party was preparing a document explaining how all these people had to work together. If there was a problem with market surveillance or with the product, the document would show whether it was necessary to go to the market surveillance authority, to the original manufacturer or to a regulator.

Mr. Lienesch showed a slide of the structure of the IEC, with the position of IEC's Conformity Assessment Board (CAB) and of the IECEx. He had recently learned that the OIML would have a Memorandum of Understanding with the IEC and would therefore be indirectly involved.

IECEx, Mr. Lienesch explained, was a single international IEC system with schemes covering certificates to standards that related to equipment and service in the areas relating to explosive atmospheres. It existed, in the words of its own propaganda, to provide an internationally accepted means of demonstrating claimed compliance with international standards. IECEx was a conformity assessment tool providing confidence that standards, service and personal covered by IECEx certificates met specified requirements of international standards.

The history of IECEx, Mr. Lienesch said, would be interesting for his listeners. It was a private organization, payment for which came from the test houses, from the certificates. These were online certificates for which everyone had to pay. Mr. Lienesch had not been in the PTB until the current year but he believed that IECEx had had a good idea in 1992 and decided to start this scheme. It had come from IEC standardization TC 31, but then it had taken four years before they had their first meeting, and another four years before they decided in 2000 that when they prepared test reports all the others had to accept them. This was the first decision to have no double testing. Now, ten years later it was still the case that they could show their test report to anyone and it would be accepted and a national certificate issued. This had been a very important step. Three years later they had decided to go over to the online certificate system and the first of these had been issued in 2003. It had begun in New Zealand and Australia, who accepted Ex tested-only certificates. These were also accepted in a number of countries such as Saudi Arabia and some Asian countries which did not have their own regulatory systems. Now they were promoting the idea that these certificates were accepted officially and not just through custom and practice. It was clear that these certificates would tend to be more attractive than the rival ATEX Certificates. This would be the future in this sector.

New schemes had then evolved, such as service and repair, competent persons and so on. In 2009 there had been formal endorsement of the IECEx and the UNECE. At present there were some 15000 reports and certificates on the internet. They could be downloaded very easily. A short overview of the IECEx management showed a standard management board and a conformity assessment board, very much the same structure as on an IEC level. Mr. Lienesch showed a slide of the internet site and how to access certificates on it. There was no paperwork, everything was on line.

The Ex certificates of competence and systems are always included the conformity assessment procedure. A product certificate without a production certificate could not work. Sometimes there were problems because the time period for the conformity assessment procedures might be three years and if the procedures were not continued the certificate would automatically be deleted. They had equipment for unit verification, mark, license, service and repair, standards and competent persons. The certificates were in accordance with ISO/IEC 17067 Type 5 certificates. The main difference between them was the surveillance. Type 5 allowed control over the whole time of production. Samples from the open market, and from the factory could be tested and inspected the whole time, and the quality management system combined with random testing or inspections, giving assurance of the protection offered by the service. For example these days by means of ATEX surveillance activities, all countries took ten products off the market and analyzed what they had found, learning about procedures through the interchange.

In conclusion, Mr. Lienesch believed that for accreditation of conformity assessment bodies, a competent assessor was necessary, for certification of product and production Type 5 and also comparisons. IECEx had started comparisons because they had found that in some cases there were different results. It was of course not good if a result could be positive or negative

depending on which test lab was used. Comparisons had begun two years previously and would continue, and he was sure that in the future anyone who wanted to have a certificate or be a test house would be obliged to participate in such comparisons. Standard procedures should be clear if difficulties were to be avoided. A market surveillance system was also important, with a communication system for its authorities, as was an alert system for non-conformance. Regulation also had to go together with a steering committee, observers, etc. Problems which might be discussed were national variations, national acceptance and peer assessment.

Finally, Mr. Lienesch asked what might be of interest to metrology in the scheme and whether they would like a sector in it. He thanked his listeners and invited discussion.

Mr. Kool thanked Mr. Lienesch and invited questions and comments.

Mrs. Lagauterie asked what kind of information was in the certificate which was put on the internet and whether there had been any problems of industrial secrecy with it.

Mr. Lienesch replied that it was like the European ATEX Certificates. Information such as test results was not in the online certificates; this information was a contract between the test house and the manufacturer. There was however a problem, in that once a test report had been completed by the IECEx scheme, these test reports had to be accepted by other test houses anywhere in the world; countries such as the Republic of Korea or Japan, although they did not do double testing, required a copy of the test results. Test results, written in German and not translated, also had to be sent to China and Brazil.

Mr. Johansen asked for more information about market surveillance. He wondered whether this was the same as in Europe, and asked what could be done if non-compliance was found – could a certificate be withdrawn? He also wondered about problems with secrecy.

Mr. Lienesch answered with a recent example. A cell phone had been on the market which did not fulfill the requirements of the standard. There had therefore been a safeguard clause in Europe. This safeguard clause was very interesting because the product had appeared in Germany but had been imported via internet from another country. It was therefore unclear which market surveillance was to deal with the problem, the German one or that of the exporting country. After some thought, the standing committee had ruled that a letter of complaint could be sent from Germany to the manufacturer. If the manufacturer did not respond, the complaint could be sent to the European Commission, who would send it to the other country. This resulted in a safeguard clause for Europe but the same product was still to be found in Singapore. So no legal EEC type examination certificate was available but the product was still on offer in Singapore. The dilemma was how to have an international platform where a problem with a product could be reported. It was not clear what sort of certificates were being looked for in Singapore. If an ATEX Certificate was withdrawn the owner still had his copy of the certificate, but if the IECEx online certificate was withdrawn it was deleted from the database and no longer usable by the company. This demonstrated one advantage of having certificates in online form.

Mr. Van Mullem asked whether, in the market surveillance example given, the fault found in Germany had also been found by market surveillance in Singapore or whether market surveillance existed only in Europe due to European regulations.

Mr. Lienesch said that he was a member of the ATEX market surveillance committee in Germany and this problem had been regularly discussed for two years, because it was not clear how it worked. In this case they had used IECEx and the test houses in Singapore to tell the authorities there that there was something wrong and that they should report this to their

market surveillance regulator. But they had done no more than that because it was not an easy matter to handle.

Mr. Mason asked Mr. Lienesch to give more information about the type of organization that IECEx was. Had it been created within the international petrochemical commission, was it one of a number of similar bodies within IEC, what sort of organizations were members of IECEx?

Mr. Lienesch replied that the members of IECEx were countries. These countries sent delegates who were either regulators or from test houses. Normally there were national groups which sent one representative to the IECEx meetings. IECEx was one of three IEC certification bodies, the others being IECE and IECQ. Each group sent a rapporteur to the parent organization to report on what the group had done. The IEC director had welcomed the joint venture between the IECEx and the UNEEC.

Mr. Kool asked whether it was not the case that, rather than countries being members of the IEC, the national standardization committees within those countries were the members.

Mr. Lienesch confirmed that this was the case but said that each country had one vote, though a representative of a group of stakeholders, rather than a government representative might attend. He added that all test houses had to contribute financially to the system.

Mr. Schwartz said that Members were there to learn about CTT in the OIML. He had seen some parallels between the OIML and IECEx. He asked Mr. Lienesch to confirm that IECEx had begun by accepting test reports on the basis of peer assessment or accreditation but had moved on from there to the life cycle approach. He asked Mr. Lienesch to give more detail about this process, and whether he thought that for its own CTT the OIML should aim straight to the life cycle approach.

Mr. Lienesch said that he was not very well informed about problems with metrology but products for the environment were very critical. In Europe there were the ATEX Directives about products placed on the market and directives on health and safety in the workplace. The second directive was not specifically a European one but just said that nationally there had to be some control. There was always national regulation for repair shops and the like, and the idea of the CROs was that it was not good to have national regulation, there should be an international approach covering the whole cycle of the product.

Mr. Kool said that this was an application of the UNECE project for harmonization of technical regulations between countries. He asked whether the CROs were formulated in such a way that that they could be almost copied into national legislation, incorporating elements of existing regulations.

Replying by an example, Mr. Lienesch said that Europe could incorporate these CROs but for the life cycle approach this was not possible because they had two directives for that. They were in very close discussion with the Commission, who to date believed that their approach was better than the approach in Europe, but they were trying to change the directive; at present the health and safety in the workplace directive could not be changed, so the whole thing was a long term project. Other countries which did not have so much regulation should find it easier to incorporate the CROs. Brazil, for instance, was sending signals that they were willing to follow this system.

Mr. Cao Xuan thanked Mr. Lienesch for his clear presentation and asked him how much internet certification cost.

Mr. Lienesch said the cost was 300 US dollars or euros, he was not sure which. Getting the certificate depended on the product. If a lot of tests had to be done, it would normally cost a

couple of thousand, and the conformity assessment procedure to go to the manufacturers depended of course on where the product was produced and which test house was used. But nobody was talking about costs in this area, because in this more specialist market it was more important to be speedy, to avoid double testing, for the user to have safe equipment, to have clear rules and so on.

Mr. Melhem asked a question about the conformity assessment body, CETL. He wanted to know whether there was not an overlap between already existing accreditation and CTT.

Mr. Lienesch replied that it was common for accreditation and testing to be carried out in the same house, though some countries only had test houses. He could not, however, fully answer the question. In Europe, accreditation and testing had to be done in separate places; this was known as the “four eye approach”.

Mr. Melhem expressed surprise that IECEx certificates could be issued only by conformity assessment labs and not by accreditation labs, even ILAC recognized ones.

Mr. Lienesch replied that within the IECEx scheme there was a need for testing to be done by a certification body of the scheme. It was possible to be a test house within the scheme. In Germany there were four or five certification bodies and four or five test houses. These products sometimes needed several tests and some of the certification bodies were not able to do special tests, therefore they went to various test houses within the scheme, and brought the test reports together to make a certificate. This was a common approach, but within the IECEx group it was accepted. Accreditation had to follow ILAC rules.

Mr. Kool thanked Mr. Lienesch.

Corinne Lagauterie

Continuing on the same theme, Mrs. Lagauterie introduced herself as being the French CIML Member and head of the French Metrology Bureau. She would not be giving a very detailed presentation because she had already given one at the Utrecht seminar which was available on the web site for those who were interested in the European system. Since Mr. O’Brien had already given a comprehensive report on the Utrecht seminar; Mrs. Lagauterie would begin from some of the recommendations made during the discussions there. The reference address was given on the slide.

The aim of the current short session, Mrs. Lagauterie said, was to use the outcome of the seminar to stimulate further discussion. For the time being they were operating outside a defined frame, so discussion was free but would, she hoped, be useful to a TC in the future, depending on the decision that would be taken in the coming days.

The report on the seminar, Mrs. Lagauterie noted, contained the phrase “CTT is seen to be important for ongoing confidence in OIML certification systems”. Mrs. Lagauterie said this was what was about to be explored. During the Utrecht seminar she had made a presentation about the EU system, which was based on several pillars, and which had been followed by a discussion. After the presentation and discussion, there had been a recommendation first to try to improve the quality and extent of the content of the OIML Certificates and the related documentation. The reason for this was that certified instruments needed to be identified better and the manufacturers’ responsibility needed to be clearly prescribed, especially when they referred to these Certificates.

Mrs. Lagauterie's first idea, on being asked to make a presentation, had been to make a comparison between the testing requirements in different OIML Recommendations and

between the content of different Certificates. But then she had realized that this was not the right way to go. It was true that there were discrepancies between different Recommendations about the content of the documentation on the testing report, etc. She had also made spot checks on the existing Certificates that were available on the web site, and had found that although they all looked the same, there was a large variation in the information they contained. This was limited in some cases, a little more extended in others, and also some Certificates contained references to the documentation which was in the hands of the Issuing Authority, while others did not. It depended basically on the category of measuring instruments and on the different habits of the Issuing Authorities. Obviously, looking at the Certificates there was no easy way to identify the type of instrument being certified or its main feature. The metrological characteristics and the name of the instrument were to be found in virtually every Certificate but sometimes very little else.

Mrs. Lagauterie told delegates that she was going to open the floor for discussion on a set of questions. These were:

- What is missing that is needed, especially for those who did not have a legal framework to implement conformity to type or market surveillance?
- When the above was identified, was improvement easily possible within the existing system, possibly by providing some input to the Secretariats in charge of the relevant OIML Recommendations, or by a more general document that could be applied by all the Secretariats, as is done for some Documents such as D 11?
- Mrs. Lagauterie also wished to hear Members' suggestions for future work, which she felt would be useful for the afternoon's discussion.

Mrs. Lagauterie asked Members, especially those who had not attended the Utrecht seminar, for any ideas in response to the questions she had asked.

Mr. Sanders thanked Mrs. Lagauterie for her presentation, and asked her whether, when she had done her review of existing Certificates, it had been her professional opinion that there was a requirement for the Issuing Authority to provide more information or had the Certificates seemed to be of acceptable standard?

Mrs. Lagauterie replied that the Certificates had seemed acceptable under the existing system; they had all referred to the test report, which was what was required; some had referred to further documentation, which others had not done; some included the characteristics of the instrument, for example the technology used, which was not mentioned at all in others, which gave only a limited number of metrological characteristics, few in number, the temperature, and nothing more; so Mrs. Lagauterie could find herself in front of a small blue instrument with one type of technology or a large yellow one with quite another technology; there was no clue. Obviously, it was not possible to find in the existing layout of the Certificate sufficient clue to identify what had actually been certified. OIML Certificates thus differed fundamentally from other types of certificate being used, especially in Europe, but also in national activities, where there was at least a description of the technology used, the main features, the different devices which were present on the instrument, the sealing drawing, perhaps some indication of software, by which the type of instrument could be identified much better. This was, however, the existing system; it was not a mistake by Issuing Authorities, it fitted the frame that was given.

Mr. Melhem said that while he had been in Jordan he had also faced this problem. He agreed that the value of any report depended on its readability, and OIML Certificates were difficult to interpret, especially by metrology staff in developing countries. He considered that the

format example given in OIML R 76 should be followed, and one complete model should be provided for the Certificates to follow.

Mrs. Lagauterie agreed that this could give rise to the provision of a general document on which to format future Certificates. But it was difficult always to refer to R 76 because it was a very old Recommendation and not necessarily appropriate in all its aspects. She asked Mr. Melhem what he meant by "framework", as a framework for Certificates existed already. Was it for the table of figures, for example, to translate the format so that it would always be presented in the same way?

Mr. Melhem replied that he was indeed talking about the format.

Mrs. Lagauterie asked if this was in order that the format could be translated to help people to read the Certificate.

Mr. Melhem said that it should be possible to look at a particular place in the Certificate each time to find specific information. It was also not easy to understand the coding system used. This could be "Type XYZ, XXX", etc., and readers did not know what this meant, so some explanation should also be given. If a type approval mark was given it should not be possible for manufacturers to misuse it: for example, sometimes type approval had been given for one part of an instrument and not for the whole instrument, but in some cases manufacturers used this to claim that the whole instrument had been approved.

Mrs. Lagauterie said that as far as coding was concerned, manufacturers had the right to name their instruments in any way they wanted, but if she understood Mr. Melhem correctly, when there was a combination of letters and figures he would like to see an explanation of their meaning. Concerning the misuse by manufacturers of the approval mark she asked if Mr. Melhem would like to see in the text a warning that this was approval only for a part of the instrument.

Mr. Melhem explained that, for example, for blood pressure manometers the only thing that had been verified by the OIML was the blood pressure part. But the value of the blood pressure depended on the pulse rate. So if the pulse rate was not measured the patient could not be provided with an accurate blood pressure figure. So there was only approval for the blood pressure part of the instrument but not for the pulse rate part. But the purchaser had to buy the whole instrument and not just the part with the approval certificate.

Mrs. Lagauterie said that this illustrated her point that it was difficult to copy into one Recommendation something that had been good in another, or to have a universal system. If it was permissible to approve just one part of an instrument, then no criticism could be made of the manufacturer or the Issuing Authority. It was the job of the Secretariat to take appropriate action if it was needed. Certainly, however, if something was not covered in the test report this should be clearly mentioned.

Mrs. Van Spronssen suggested that it would be helpful to spell out how an instrument should be described. Sometimes there was only a number and at other times the description was very extensive with photographs and drawings. Perhaps it should be specified what had to be included in a description of an instrument.

Mrs. Lagauterie said that this was a suggestion of a list of essential features, including the sealing for example because this was essential for legal metrology. She asked for other suggestions for essential features.

Mr. Deleu said that a missing element which could be helpful in the future was a defining of essential tests or checks to be done afterwards, when the measuring instrument was already on the market or in use. In his opinion the Issuing Authority had knowledge of the instrument

and could define what tests should be done. In some cases this was already done for purposes of verification.

Mrs. Lagauterie asked whether in his suggestion of the critical tests for the next phase of verification Mr. Deleu was referring only to new technology. In some of the Recommendations there were lists of tests which had to be performed during the initial verification or during the period of inspection. She asked whether he was referring only to new technology or to all certification.

Mr. Deleu said he had been thinking of even repeating some tests; each type was not necessarily the same, and some might have special features not mentioned in the Recommendations.

Mr. Ben Hassine suggested that what was missing in this system of certification was a sort of labeling or logo on the measuring instrument. As the OIML was the legal authority in charge of certification approval, what was needed was an awareness of consumers. So when the measuring instrument was seen on the market it was not possible to know whether it had been submitted to OIML certification or not.

Mrs. Lagauterie asked whether this meant that Mr. Deleu would like to see the number of the OIML Certificate clearly identified on the instrument.

Mr. Deleu replied that there could perhaps be a sort of OIML logo.

Mrs. Lagauterie commented that this was another critical issue.

Mr. Patoray appreciated this question being posed at the CTT Seminar. He had experienced very similar discussion in the US eight or ten years previously, and the first question that had had to be asked there was what exactly the certificate was trying to do. The OIML Certificate was registered by the OIML but it referred back to an Issuing Authority. The certification body in each country was a little different but somewhere there was a package of information which was in the possession of the laboratory or Issuing Authority in that country. The Certificate itself contained very little information. If it was the only document that was used, then it must have enough information for people to make a determination of the type. If, however, it was only a reference document to direct the consumer to the big package of information, then the Certificate might contain little information. The answer given in the US had been that the Certificate was what the verification officer used on the site. He did not have access to all of the other information. So the authorities had to specify at least a minimum of information that the inspector or verification officer would have to have in order to verify the type when he had only a Certificate and was at the site and could not contact anyone else.

After answering that question, they had then looked at each type of device and they had found that each type had different information. It had not been possible to make one form to cover every type of device. But one of the things they had found to be of major importance was a simple picture of what they were trying to describe in the Certificate, a photograph taken in the laboratory or where the device was being evaluated. This made it easier to describe what they were identifying with the type. He was pleased with the current discussion which was aimed at making the OIML Certificate better and more usable; the aim was to make it the document that was actually used.

Mrs. Lagauterie thanked Mr. Patoray for his support and agreed that a photo could be useful, though she pointed out that nowadays in a type approval certificate a whole range of instruments might be covered. For weighing machines, this could range from the small counter scale to the large weighbridge, so the use of pictures might be limited but it could

possibly be replaced by some reference to the construction of the instrument. She conceded that there might be a lack of information for the people actually using the Certificate. If it was used by a national authority with the purpose of delivering a national type approval certificate, they could ask the manufacturer or Issuing Authority to provide the complete information. But if the instrument was put directly on the market and the only accompanying piece of paper was the reference to the OIML Certificate, then of course there was a need for more than was in the Certificate.

Mr. Sanders said that Mrs. Lagauterie had mentioned that one of her own personal suggestions would be clear diagrams for sealing the instrument. He would recommend that there should also be a very simple way for the inspector to identify the software contained in the instrument, how to find the checks, etc.

Mrs. Lagauterie agreed that this was an important feature nowadays. If the correct software was not used, the instrument could look the same but perform very differently.

Mr. Patoray said that many national certificates were being issued all the time on a national basis. These might or might not be based on the tests done for the OIML Certificate. With the MAA in particular, many of the utilizing participants used the MAA as their test report to issue their own certificates. He asked whether it would be possible to gather some certificates from other regions or economies referring to the same or similar devices and review their content, in order to understand what information was necessary.

Mrs. Lagauterie agreed that it would be a good idea to compare the content of several national type approval certificates based on the same MAA Certificate. She considered that it was essential to have reference not only to the test report but also to the technical file held at the Issuing Authority, because this was a sign to users that they had a clear reference to give if they wished to obtain more information.

Mr. Vinet referred to the suggestion of asking countries to provide copies of their certificates; he cautioned that countries like Canada which issued their own certificates, even if they had accepted an OIML MAA Certificate, might not necessarily ask their inspectors to refer to the OIML Certificate. National certificates might contain more than the OIML needed, in contrast to countries where OIML Certificates were the main source of the national ones.

Mrs. Lagauterie replied that the purpose was not to greatly extend the information contained but to compare what was common necessary information. Of course this comparison could not be made without the help of national representatives, who could explain why something was or was not needed. Experience in Europe had been similar: in the past each country had had national approvals in a different format, some giving more details with instruction from verification offices and others very like the current European certificate. Now, however, they all worked on approximately the same level. Some WELMEC guidance documents were available to help with finding the appropriate information in different places in the different languages. The idea was not to enlarge the OIML Certificates greatly but to identify a few missing points which could helpfully be supplied.

Mrs. Martens said that they had just heard that when speaking of OIML Certificates it was important to know what they were for. She knew that up to the present OIML Certificates could be used as the basis to issue national type approval certificates. But Mrs. Lagauterie had referred to the possibility of OIML Certificates being used in some countries in place of national type certificates, accepted directly by the countries. This might be a good idea, but it would be a different task and the content would have to be very different. She had never before heard of this idea.

Mrs. Lagauterie replied that Mrs. Martens worked in the most popular field of legal metrology; national type approvals of weighing machines were used almost everywhere as a basic part of weights and measures. But for some other instruments some countries already used OIML Certificates directly.

Mr. Harvey asked whether Mrs. Lagauterie was also suggesting a standard format for national certificates.

Mrs. Lagauterie said that this was not the case.

Mr. Harvey said that it might be useful for countries to have some guidance as to what they should include in their national certificates if they were accepting test results from OIML Certificates.

Mrs. Lagauterie said that in Europe, to facilitate the work of local inspectors who were used to their national format and were sometimes shocked by the format of certificates from other European countries, WELMEC had issued some guidance documents so that even if they did not speak the language they knew where to find the important information. Most of this information was given in figures and in words already translated into many languages. It was by no means mandatory.

Mr. Komissarov wanted to ask two questions: first whether both types of OIML Certificate, the Basic Certificate and the MAA Certificate, were being spoken of, or just one.

Mrs. Lagauterie said she was speaking of both.

Mr. Komissarov's second question referred to the important OIML Document D 27 *Initial verification of measuring instruments using the manufacturer's quality management system*, which analyzed the quality management system of manufacturers. He asked whether this situation might be reflected in a future general certificate.

Mrs. Lagauterie thought there was no direct link to the fact that the manufacturer had an assessment of his quality system. This was totally independent. There might be a system where a manufacturer had approval of his quality system but nevertheless afterwards the instrument was put into service and then it came under the national legislation. It might have to be repaired and then verified after the repair. In some countries this would be done by inspectors, and in others by repairers' quality system, but none of these people were the manufacturer and they did not know exactly all the details, and even in the manufacturing company, not everyone in the field knew everything about the type and so on. So there were a lot of people who might need to find information in the certificate. It was not only linked to approval of the manufacturer's quality system.

Mr. Kool asked whether there would be any benefit in having a model or template for an OIML Certificate attached to an OIML Recommendation. There was already Part 3, the Test Report Format; there could be a Part 4 which was a format for the Certificate, indicating what information for that particular type or category of instrument should appear in the Certificate.

Mrs. Lagauterie thought that that would be useful. It could be based on a general document which would push the Secretariat to include it and give some general directions to be followed, but certainly it would be a good idea.

Mr. Kool pointed out that this tied in with the last question Mrs. Lagauterie had put on the screen – what should be suggested for future work? He had already heard something about a document that could be developed. He asked Mrs. Lagauterie to expand on this.

Mrs. Lagauterie said this was just an idea. To make things move, sometimes it was necessary to try to put them on paper. She reminded delegates that at the moment this was a totally free

discussion, but that later on there would be discussion of which TC should be made responsible for this matter. She was sure there was already a TC which could undertake this activity. Discussion was still open on that.

Mr. Kool asked whether participants thought it would be a good idea to have a guidance document for what should be in a Certificate.

There being no response, Mrs. Lagauterie commented that perhaps people thought that if they showed interest they would be asked to undertake the task.

Mr. Kool thanked Ms Lagauterie. He asked Mr. O'Brien to begin his presentation on how to define Conformity to Type.

Stephen O'Brien

Mr. O'Brien said that it had been thought that before discussing potential Resolutions to put forward in this area, it would be useful to clarify the definition of CTT.

Discussion at the Utrecht seminar had highlighted that there were a number of different interpretations of exactly what this meant, where it would be applied within the supply chain and who was responsible for it. Before discussing CTT it was necessary to define clearly what was meant by the term, specifically in reference to OIML work. This definition would also be useful when any CIML Resolutions on work on CTT were considered later in the week. CIML Members had a wide variety of backgrounds, roles and national responsibilities and it was necessary to have a working definition of CTT to prevent misunderstanding and failures of communication. So creating and agreeing this definition was an essential first step before considering what (if any) role the CIML should or could play in this work.

To facilitate this process, Mr. O'Brien had created what he called a "straw man working definition" for participants' consideration. Basically he meant by this something temporarily put in place until it could be replaced by something real and more substantial. He was therefore putting before them a definition developed for their consideration from what he understood to be the consensus of the Utrecht seminar and intended to support discussion in the current workshop. He had also looked at D 16 *Principles of assurance of metrological control*, and the *International Vocabulary of Metrology*. He pointed out that he had no knowledge of CTT definitions which were used within the EU or US, so he would appreciate input from those who had that knowledge.

In thinking about what OIML CTT might look like, the first point Mr. O'Brien wished to make was that any OIML CTT activity would be voluntary for participants, OIML economies and manufacturers. This was important to note because the OIML had no regulatory powers and the OIML Treaty was non-binding on Member States.

One of the key terms associated with CTT was that of conformity assessment. Mr. O'Brien had taken the following definition out of D 16, so it was about testing and evaluation of a measuring instrument to ascertain whether or not a single instrument, instrument lot or production series of instruments complied with all the statutory requirements applicable to this instrument type. So if CTT involved conformity assessment, this introduced the question of against what criteria the assessment would be made. One answer to this might be that such an OIML assessment could be made against a selection or subset of the requirements prescribed in the relevant OIML Recommendation that had been used to approve the instrument. Such assessment would include examination of the instrument, and limited testing of influence factors such as disturbance factors, endurance and performance. Mr. O'Brien made the point that this type of conformity assessment could only be carried out in a

suitably equipped and competent laboratory. By necessity, CTT testing would need to be completed in the laboratory of an OIML Issuing Authority or another suitably qualified and authorized laboratory.

Another key component in consideration of a definition of CTT was where it would fit within existing legal metrology controls and at what point within the supply chain it would occur. Provisional answers to these questions were that CTT was a voluntary form of metrological supervision, distinct from but complementary to existing legal metrology controls such as national standards for instrument types, legal units of measurement, type approval, initial and subsequent verification. CTT was distinct from those forms of metrological control but also intended to be complementary to them.

Mr. O'Brien asked where in the supply chain CTT would occur. Primarily, he said, what was being talked about was a pre-market surveillance activity involving conformity assessment of a production instrument before it was put into service or used for the first time. The focus was on a production instrument or instruments, obtained either directly from the manufacturer or from a wholesaler or importer in the case of an economy without domestic production. CTT could also include quality systems surveillance of a manufacturer or manufacturer's representative.

Mr. O'Brien explained that he had pulled all these points from the Utrecht seminar together into a draft definition of CTT. He reminded the audience again that this was a "straw man" suggestion, a basis for discussion. His proposed definition was:

> *"OIML Conformity to Type is a voluntary system combining pre-market and quality system surveillance activities focused on the conformity assessment of measuring instruments to give assurance that manufactured or production instruments meet the requirements applicable to the approved type".*

Mr. O'Brien invited comments and suggestions for improvement or modification of the suggested wording.

Mr. Mason, probing further about Mr. O'Brien's use of the phrase "market surveillance", said that his own understanding of this phrase was that it was the activity which took place after production but before putting into service or initial verification, so that in fact it was part of a continuum of controls which started with type approval, might then take some form of production control, as for example Annex D or Annex F of the Measuring Instruments Directive, then a stage which was market surveillance, where enforcement authorities might identify a product they wanted to test. There was then verification and re-verification, which might be called in-service testing. He asked whether this was the sense in which Mr. O'Brien was using the phrase, or whether he saw market surveillance as something more, which covered the in-service arrangements throughout the life of the measuring instrument.

Mr. O'Brien replied that his definition of the term was the same as Mr. Mason's but that he had used as a reference D 16 , which clearly talked about market surveillance taking place before the instrument was put into service. The reason he had the term "pre-market surveillance" was that the Utrecht Seminar had shown that there was a measure of confusion because some economies used the term" market surveillance" also when the instrument was in service.

Mr. Mason felt some more thought should go into this matter, because in European language there was the concept of placing on the market; market surveillance would take place after the product was put on the market but before it went into service. The European understanding of "pre-market" would be at the production stage.

Mr. Kool believed the terminology used in the European context was that it was the responsibility of the manufacturer to ensure that a product complied with all the requirements of the European Directives, and as soon as it did that, the manufacturer applied the CE mark. At that point it was placed on the market. It could be that an instrument was in some stage of completion where it did not yet fulfill all the requirements and could not be placed on the market. But, if he understood correctly, conformity to type to an OIML Certificate might lead to a point where it did not yet comply with all the national requirements. So there could be a gap between complying with OIML requirements laid down in OIML Recommendations and complying with the national requirements which allowed the product to be placed on the market. He was not sure how this should be dealt with - perhaps on a national level.

Mr. Mason commented that he was sure this problem could be dealt with by a little more attention to the wording. He thought they were moving towards a very clear understanding of the different stages, and also, clearly, the attention was focused particularly at the production stage, because it was at the production stage that techniques such as quality management systems controls could be introduced. He thought however that there was still a case for recognizing that there was a control stage, which the OIML would call market surveillance, which was the possibility of the authorities identifying products and subjecting them to full testing as part of a market surveillance program which was in the distribution chain. This was part of the refined enforcement that, certainly in the European context, was being encouraged through the rounds of requirements.

Mr. Harvey said that in Australia anything up until the point where the instrument was installed and used would certainly be regarded as being covered by CTT, as in the definition in front of them. After that, it was not possible to make the manufacturer responsible for the instrument because it could have been modified by the owner. The manufacturer no longer had any control over the instrument and it was then a question of post market verification, quality auditing and the rest.

Mr. Vinet said that one point was still unclear to him, with regard not only to the definition but to the viability of the system, and that was whether the wish was to open the OIML CTT program to testing done by different countries before the device was placed on the market. When pre-market surveillance was mentioned he understood that the device was not placed in service, but could have been sold and sent to a country and could have people, for example, from Canada or Australia assessing the device to see whether it met the OIML type approval. He wondered whether this was or was not to be included in the definition, or whether CTT should be limited to when the device was still in the control of the manufacturer’s quality system. Any lack of clarity on this point could lead to confusion and misinterpretation.

Mr. O’Brien said that the object at present was to define what was meant by CTT, and that Mr. Vinet was speaking of hypothetical questions about what sort of program the OIML might possibly implement in the future and the extent to which it included testing or other actions. In his view, if a program was introduced and if instruments were imported into Australia, they would want to be able to sample and test them as part of CTT.

Mr. Issaev considered that a voluntary system would not be very good for legal metrology. A mandatory system combining market and quality system surveillance would be more convenient because, for example if there were negative results from users of measuring instruments, it was necessary to check and test. So they were obliged to arrange these tests. Perhaps it would be possible to spell out that in certain circumstances the system would be mandatory because the instrument had already been put on the market. The situation was contradictory and he did not know how it could be expressed, but perhaps it was necessary to say, “in the case of such and such a situation, the system would be mandatory”.

Mr. O'Brien replied that the idea of a voluntary system had come from the Utrecht Seminar, where it had been clearly identified that in many jurisdictions regulatory controls were not available to make such a system mandatory. Also, by its very nature OIML requirements were not legally binding, so the thought had been that the system would initially be voluntary, and if a particular economy wanted to make it mandatory, then it was a matter for that jurisdiction.

Mr. Mason felt that he was now able to understand better the full significance of on the one hand what he had thought of as conformity to type, which was production based, and on the other a definition of it which included the market surveillance stage. The two real differences between these were, firstly who might initiate it. In the former case, the certified body clearly could not be associated with a production regime; indeed this was what would be expected of a notified body in the European context. Market surveillance on the other hand would normally be initiated by market surveillance authorities. That meant that the second stage would be mandatory according to what authority was choosing to undertake market surveillance. On the other hand, while there was a voluntary OIML system, it necessarily followed that anything which was connected with production controls associated with a voluntary certificate had itself also to be voluntary.

Mr. Harvey said it was certainly mandatory that the instruments must meet type. This was one of the fundamental controls in the legislation of almost every country. They were talking about whether CTT was implemented or not in a particular country. Some country might not want to implement this sort of control, they might be happy enough with what they had already. Other countries might see advantages in implementing them: this was where the voluntary aspect came in. It was certainly not voluntary for the manufacturers to meet the requirements.

Mr. Sanders thought that since they were trying to agree a definition of CTT, the proposed wording did that job very well, because it did not say who did what, so as it stood, it could include checks done by the manufacturer but also checks done by the state.

Mr. O'Brien added that the definition had been drawn up for discussions at the CIML, and that the one of the first tasks of the TC would be to give an agreed formal definition.

Mr. Issaev added that 20 years previously in his country they had approved a new type of measuring instrument. They had decided that for exactly five years it would be necessary to do control testing, not CTT, but in reality it had been testing for CTT. Especially for legal metrology, when the instrument was to be used in a regulated sphere of activities of society it was necessary to think about a mandatory system. So he proposed that more thorough thought should be given to this.

Mr. Johansen said that they were supposed to be talking about a definition but a lot of what was being said related to the solution. The problem was that this proposed definition included some elements which might or might not be part of the solution, for instance quality systems surveillance. This should not be part of the definition, which should be broad and not anticipate the solution. Regarding the question of mandatory or voluntary, in his opinion it could only be a voluntary system, in the sense that it was up to the manufacturers to determine whether they would do something extra to prove that they had followed quality. It was not up to the Member States – they had their own systems, which were not for the OIML to discuss. It was a system that manufacturers could voluntarily choose to join as a way of proving that they were better than others.

Mr. Kool agreed that it had always been the intention over the last several years to think about setting up a system which the manufacturers might use to show that they met the

requirements. Obviously they had an obligation to meet the requirements and in that sense it was mandatory, but there could be different ways to achieve that, an element of which could be voluntary certification, which was what was being talked about. He also pointed out that what was on the screen was not a definition of CTT but a definition of OIML CTT. The first term was “a system” so they were describing much more than CTT itself. They were trying to describe what a system did, which might include, as the definition said, pre-market and quality system surveillance activities. It was more than just what the instrument had to meet, it was what the system did.

Mr. Johansen agreed, but said that by including these terms they had laid down a track which meant that the system could only go in one direction. All this central part of the definition should, in his view, be dropped.

Mr. Patoray apologized for bringing in his past again, but the US had already gone through a lot of this with its own system. He agreed with Mr. Issaev that in CTT, although the certificate was voluntary, once the certificate had been issued, it was mandatory to be able to prove that the device continued to meet the type and therefore to be certified. That had taken a long time to discuss but had been the final position. The certificate itself was voluntary but conformity to the certificate was mandatory. For example, in the Unites States, if you wanted to keep the certificate you had to go through the process of VCAP – there was no choice. The choice was whether you wanted to keep your certificate or not. As to the other part of the definition, based on his current role in the OIML, Mr. Patoray cautioned that pre-market surveillance, as it was identified in the definition, would, he believed, be rather difficult from an OIML perspective, as it was not clear to him, who was doing that or from whom they would obtain the information. Someone physically had to conduct a test; in the case of quality system surveillance, that could be a third party audit that could be done in such a way. But he agreed with Mr. Johansen’s view that there was a solution contained in the definition, which limited options and choices instead of just defining what they hoped to achieve and then later determining the tools or methods for achieving it.

Mrs. Lagauterie said that she wanted to continue the discussion of the time at which market surveillance could be conducted. When examining instruments in service, occasionally one was found which had obviously had a non-conformity from the beginning. Sometimes this was very obvious, there was something misleading or the information was not correctly expressed, and although it had arisen during in-service control it related to the manufacturer and so was a market surveillance activity. So the question of time was not clear – if the instrument was already in service but the fault was obviously the responsibility of the manufacturer it might be necessary to act against the manufacturer even at this late stage.

Mr. O’Brien said that this was valuable feedback but that some of these issues needed to be sorted out at a later stage in a TC.

Mr. Klenovský thought the definition should define the goals and not the tools for achieving them, but he thought the first series of quality control tests could be sorted out with manufacturers but the later series could not be sorted without the cooperation of manufacturers. He did not see how manufacturers could voluntarily be involved in such an activity and if they were not involved then the system would be completely useless. He thought they should also look into what would happen when something viable was found, and what the consequences of any major non-conformities would be.

Mr. O’Brien agreed with the points that had been raised and also felt that they were probably jumping too far ahead. All these issues needed to be discussed in the TC. Basically, however, the direction for the definition had come out of the discussions at Utrecht, which was why

there was a certain focus on it. But he agreed that that focus should be removed so that discussion could be opened. It was not necessary to agree the definition at once, this could be one of the roles of the TC, who could come back with a more detailed definition.

Mr. Schwartz wondered whether a definition of CTT was in fact needed. What was required was some terms of reference or scope which they wanted to address, and he wondered whether it was not sufficient to say that if they spoke of OIML CTT they restricted themselves to pre-market activities very generally; that meant "production meets type". They could collect information on how this was done in different regions and start with a status report on what was already there. They did not need a definition of CTT. They just needed to say what they wanted to do, which was to support the idea of "production meets type", because they had found that this was a lack which they had to address.

Mr. Mason supported Mr. Schwartz's proposal. He thought that they had probably been talking about three points: the first was what they should be concentrating on in developing some new ideas. It was clear that they were looking at the production control part of the system, on which there was nothing in the OIML Certificate System at the moment, and what he thought was proposed was that the new group, in drafting a document, should come up with ideas on that.

The second element, which was where market surveillance and all the other activities mentioned came in, was what obligations should be placed on the issuer of a Certificate to take action if non-compliances were brought to his attention; these might come from the production control element or from the market surveillance element. Mr. Mason saw this also as appropriate terms of reference.

The third issue was what further information might be put into the Certificate System to make it more usable; these were the issues which had been suggested by Mrs. Lagauterie, and could be a third element in the terms of reference to be given to the group. All of these were important but they were distinct issues.

The way forward

Mr. Mason thanked delegates for the contributions made so far and was sure that there would be many more to come. It seemed to him that there were three main points to be considered:

- Should the ideas under discussion be taken forward in principle? It must be recognized that they were of very great interest to many OIML Members;
- If that was the issue of principle, what guidance should be given about the scope of the work to be taken forward?
- What should be the forum for that? Should the informal Working Group arrangement continue or should it be put into the TC structure? If the latter, should it be an existing TC or should a new one be set up?

If these three issues could be decided, Mr. Mason said, a Resolution could then be drawn up for approval by the CIML. Noting that those present were satisfied that this was the ground to be covered, Mr. Mason then moved on to the issue of principle. He had not detected in anything said so far that there were fundamental objections to the direction which the work and analysis had taken. They had had the benefit of some excellent work by Mr. O'Brien and his colleagues, some excellent presentations, both those at Utrecht, which he had had the pleasure of reading although he had not been at the seminar, and those heard in the current seminar. However, if there was anyone with serious reservations, who believed that this was

not something on which the Bureau and the Membership should be spending their time, now was probably a good time to say so.

No such reservations having been expressed, Mr. Mason moved on to the guidance which should be given on the scope of the project. They had recently been looking at a definition of CTT, and the suggestion had been made that in fact at the current stage what was required was not so much a definition, in particular a definition of the expected solution, but rather a clear idea of the scope of the work that should be carried forward. Reflecting on the various items discussed earlier in the day, he had found it helpful to use his own version of the "life cycle" they had heard about that morning, which was used in the IEC. He defined this as the various points of control at which products could be identified as complying. This was the total conformity assessment route which the OIML looked to implement. It was clear from the day's discussions that the most important focus of attention so far was the one which he had called "production control". This might be "production meets type". It was the area where it might be desirable to invite the people who issued Certificates to play an extended role; this was clearly one of the possibilities that might come out of the document which would be produced. Several examples had been put before them: there was the US example, there were the MID structures of Annex D, and there was the IEC system about which they had heard in the morning.

As he had said earlier, Mr. Mason believed that two other issues had been identified. One of these built on what Mrs. Lagauterie had said about the nature of the Certificate; this was the box which he would call "type approval"; and he wondered whether it would be useful to ask whichever group would be looking at CTT also to develop the points Mrs. Lagauterie had highlighted in her talk.

The third element he wanted to raise concerned the market surveillance activity identified by Mr. Harvey and discussed earlier, i.e. the things that already happened because of the enforcement authorities picking up non-compliant products, but introducing into the OIML proposals a clearer set of obligations on the people who issued Certificates, to act and to do certain things, if a non-compliant product was identified.

Mr. Mason asked whether there were other elements that should be added to the three he had identified when specifying to the new group what to look at, or, alternatively, whether they should be asked to concentrate on fewer than those three. He invited comments.

Mr. Johansen said that he would like to go back a step. A number of solutions had been discussed in Utrecht and, so far as he could remember, they had come to the common understanding that a first step should be to gather information on what different countries and regions were doing with respect to CTT. In order for this information to be shared, it could be placed in a document. He did not think they had reached the stage of deciding who should do this or how it should be done, by a TC or in some other way, but they had felt it important both to find out what others were doing and to avoid repeating what was already being done.

Mr. Johansen added that he was afraid that whatever solution was suggested would not suit everybody. It must be realized that Europe had a completely different system from the rest of the world. In Europe it was the manufacturer's responsibility to ensure that what he put on the market fulfilled the requirement. There were different possibilities which already involved quality systems and other aspects. In the other countries he knew about, and indeed in his own country before the MID Directive, it was the Member State which gave approval, and in the majority of countries this was still the case. So there was a completely different approach between Europe and the rest of the world. Certainly if anybody tried to make a mandatory system it could not possibly be acceptable everywhere. If it was voluntary it might

just be possible. But he did feel that the first step must be to assemble in an official document all possible information about what was already happening in different places.

Mr. Harvey agreed that in Utrecht there had been a request for a guidance document to describe the requirements and options for CTT with reference to existing systems, although it had also been agreed that this would be done within the framework of a TC, simply because experience of Working Groups in the past had been less than satisfactory. He supported the suggestion that preparing such a document should be one of the no doubt multiple tasks of the TC.

Mr. Mason was sure that whatever TC undertook the work would take into account what had been said in the seminar and decide how far it ought to be incorporated. He had been trying to ascertain how much instruction Members felt would be given to the TC tasked with CTT.

Mr. Harvey said that both seminars had indicated a wish to evaluate the ISO/IEC systems to identify elements which might be useful in an OIML CTT system. This was another possible activity for the group.

Mr. Mason suggested moving on to some drafting work which had been in progress to build on Mr. O'Brien's proposed draft definition; this would also meet Mr. Schwartz's comment that what was needed was to define the scope of the exercise rather than to solely define what a particular phrase was going to mean or what the system might look like. They had removed from the definition any wording which might be said to pre-suppose a solution and tried to describe the work as being appropriate for some terms of reference. Having displayed the proposed re-wording on the screen, Mr. Mason asked for comments.

Mr. Sanders felt that the new wording was better than the old, but that it perhaps missed out the point made by Mrs. Lagauterie, that conformity information could often be found from instruments already in service, whereas the wording on the screen mentioned only pre-market activities.

Mr. Mason replied that that came back to the point he had made earlier on, i.e. that this would add a second strand to the work.

Mr. Harvey said that information about likely problems could be gained from looking at in-service instruments, but it would be very difficult to trace it back and get action from the manufacturer or be able to prosecute him. The manufacturer could say that the instrument had been in good order when sold by him.

Mr. Patoray suggested that pre-market surveillance was still a factor that limited the scope, and that the scope should be left at conformity assessment. This left it open to operate in pre-market, post-market or other fields to gather the information, because this might arrive in various ways. A meter might not be very robust and might break down quickly in the field, and the real problem would be that the evaluation had not been long enough or consistent enough to identify that problem with that particular device, or there might be issues early on. So to strike out the phrase "pre-market surveillance" would extend the scope of activity and give an open area the group could look at and it would not be limited either way.

Mr. Schwartz said he still had a problem with the heading on the slide "draft definition"; he would have expected something like "scope of future activities" or "terms of reference". He also believed that in Utrecht as well as the current seminar there had been a common understanding that they would like to start with the relatively easier pre-market activities and concentrate on these before taking on too many activities.

Mr. Mason concurred, adding that the work done by Mr. O'Brien had identified that in many respects this was the area which needed attention. Conformity assessment could cover all five

boxes shown on the previous slide and it was known that, at least theoretically, other activities and other structures already existed with market surveillance initial verification and in-service testing, so he had been worried that the wrong signal was perhaps being given to the group if they were asked to look again at the whole chain.

Mr. Issaev thought it might be possible to say "pre-market/market surveillance".

Mrs. Martens felt that it was important to stay with pre-market surveillance because as soon as the manufacturer had given the instrument to somebody else he could no longer take care of what might happen in use. If later it could be identified that a fault had already been present when the instrument was put on the market, there were already mechanisms for dealing with this. Her second point was that the scope that was on the screen could be misunderstood to be describing not an OIML system supervised by the OIML but something like guidance to Member States on how to do market surveillance.

Mr. Mason said that in his reading of the report on the Utrecht seminar it had seemed to him to be more about guidance to Member States than an instruction to set up an OIML system. He asked whether the Utrecht seminar had got beyond this point.

Mrs. Lagauterie said that the end of the sentence suggested to her that they were no longer looking at conformity to type, but conformity to the type that had been applicable when the instrument had been approved; to her this was something different. By referring only to requirements they seemed to be leaving aside all the conformity to the detailed documentation. Part of the issue seemed to have been lost.

Mr. O'Brien felt that requirements would include documentary as well as physical requirements but was interested to hear the views of others.

Mr. Harvey was not sure what Mrs. Lagauterie had meant – conformity to the actual type that had been approved, or conformity to OIML Recommendation requirements?

Mrs. Lagauterie said that this was exactly her point. Usually the word "requirements" was used to mean OIML requirements or requirements in the legislation. But a scale, for example, which was very different from the one which had been approved, could also satisfy these requirements. Yet it would not be in conformity with the type that had been approved, so it would be a misuse of the Certificate. It was simply a matter of wording. Later, when the sentence was read it would not be in conjunction with that day's discussions.

Mr. Mason did not think the wording was intended to cover the interpretation Mrs. Lagauterie had attributed to it. The words were no longer intended as a definition of CTT but as an invitation to a particular group to undertake work in a particular area.

Mr. O'Brien suggested removing references to requirements and substituting "…that the instruments meet the approved type".

Mr. Harvey said this raised the question of to what extent it must meet the approved type. As far as he was concerned, if it met the type within the OIML requirements it had met the type. He was, however, happy with the revised wording.

Luis Mussio suggested altering to "instruments which meet the same requirements as the approved type". What they had to meet was requirements.

Mr. Kool commented that the intention of an activity such as conformity to type was very much like what was done in a verification, which was to look at the instrument and then establish whether that particular instrument had an approved type. This could have features such as its shape, its composition, its components; as well as complying with all requirements and Recommendations it should also look like the instrument that had been approved. CTT

was in large part exactly that, to see whether there was a description of this particular instrument in a type approval Certificate.

Mr. Mason suggested moving on to the question of which forum should take the work forward. In terms of where the next stage should be conducted, he had understood that one of the conclusions from Utrecht was that while it was extremely valuable that the informal group put together by Mr. O'Brien had been able to take the matter forward to date, a draft Document, probably in the D series, was now being sought and that this would benefit from being subject to the disciplines of being developed in a TC or SC under the Technical Directives. He wanted first to check that it was now a common understanding that this work should be assigned either to an existing TC or to a new one to be established.

There being no dissent to this first question, Mr. Mason said that the next decision had to be whether it should be assigned to an existing TC or whether it was such an important and different block of work that a new Subcommittee (which in this case would probably be in the area of TC 3) should be set up to deal with it.

Mr. Schwartz recommended that such activities should be started within TC 3/SC 5.

Mr. Mason said that he had been unwilling to move straight to that conclusion because that SC already had a very heavy workload, being in particular involved in the work on B 3 and B 10, the maintenance of the CPR machinery and the general health of the Basic and MAA Certificate Systems.

Mr. Schwartz commented that Mr. Ehrlich had been ready and willing to undertake this task and would acknowledge any support. He suggested that Mrs. Hockert might wish to add to what he said.

Mrs. Hockert confirmed US support for having the new work within TC 3/SC 5.

Mr. Harvey said that he knew Mr. Ehrlich had volunteered at the Utrecht seminar to do this work; however Australia had tabled two proposals. The first was to form a new SC, TC 3/SC 6, to deal with this conformity assessment activity; the second was to form a completely new TC, if the first proposal did not meet the approval of the Secretariat of TC 3. His own concern about putting the work in TC 3/SC 5, apart from the workload, was that that Committee was concerned with Mutual Recognition Systems, even though it was called Conformity Assessment. He thought it was more appropriate to have a true Conformity Assessment TC group working on CTT. He thought TC 3/SC 6 would be more appropriate; this would not prevent participation from the same group of people, but there could be other people who were more interested in CTT than in Mutual Recognition Systems.

Mr. Mason asked for comments.

Mr. Johansen would prefer the work to be done in a new TC or SC rather than in one of the existing ones. His reason was that he would prefer it to be looked at with fresh eyes rather than linked to other systems. In a new body there was more chance of a complete review of what was possible.

Mr. Mason commented that it might be difficult to find consensus on this. He felt that many of the proposals would come back to placing obligations on the people who were issuing Certificates under the MAA or Basic Certificates. This would suggest that the work going forward would be closer to what TC 3/SC 5 did at the moment than to conformity assessment.

Mr. Harvey said that if that argument was to be used, then the work would be closer to that of TC 3/SC 1 *Pattern approval and verification* or TC 3/SC 2 *Metrological supervision*. Both of

these were closer to CTT than Mutual Recognition Systems, which was the work of TC 3/SC 5, and one of them would therefore be more logical choices. However, his main reason for not putting the work in TC 3/SC 5 was that that group was currently looking at the acceptance of manufacturers' test results and he was concerned that CTT would be seen as a mechanism for accepting manufacturers' test results where manufacturers subscribed to a CTT system. That could of course eventually happen, but there was a danger that initially linking CTT to acceptance of manufacturers' test results, even by treating both in the same SC, could lead to distortion.

Mr. Mason asked how likely it was that either SC 1or SC 2 would volunteer to do this work.

Mr. Harvey replied that the US (Ambler Thompson) held SC 1 and the Czech Republic (Pavel Klenovský) held SC 2.

Mrs. Hockert said that the US would be prepared to compromise by having the CTT Committee in TC 3/SC 1.

Mr. Klenovský agreed with Mrs. Hockert 's proposal.

Mr. Mason said that this meant there was a preference for the work being done in TC 3/SC 1.

Mr. Harvey said that this was the case only if the work was to be done in an existing Committee but that he would much prefer it to be done in a new Committee.

Mrs. Hockert said the US would not support the work going to a new TC.

Mr. Patoray felt there seemed to be an impasse. As a compromise measure, if a new SC was set up, he offered the services of the BIML as its Secretariat. CTT seemed to him to be linked closely to the issue of Certificates, on which the BIML was already working. The BIML was already co-Secretariat of TC 3/SC 5, but would keep the two matters separate.

Mrs. Hockert said the US did not believe that the BIML should be the Secretariat. They could be the co- Secretariat, as with TC 3/SC 5.

Mr. Schwartz proposed that as the seminar had no decision powers, the three alternative proposals be put forward to the CIML for a vote.

Mr. Mason agreed. The purpose of the seminar was to put forward proposals for consideration by the CIML, which might eventually form the basis of a Resolution.

Mr. Harvey said that he could see merit in Mr. Patoray's suggestion of the BIML assisting the Secretariat in technical matters in situations where there was a voluntary system which did not necessarily have to be implemented. Documents had of course to be prepared by volunteer Members in TCs, but for voluntary systems and perhaps even the OIML mark, these could be handled by the BIML as Secretariat.

There being no further comments, Mr. Mason proposed moving on to the content of the Resolution the seminar might propose to CIML.

Mr. Kool said few participants had commented, and there appeared still to be opposite positions on whether the work should be handled by TC 3/SC 5, by a separate TC or by TC 3/SC 1. But if these three options were put to CIML one by one there might not be a majority for any of them.

Mr. Mason said that that problem would have to be tackled at the CIML. From the point of view of the Resolution, at the moment this space would have to be left blank. Two of the options would take the form of "The Committee requests … (either TC 3/SC 1 or TC 3/SC 5) … to do something", or alternatively, under the third option "The Committee resolves that a new SC shall be set up and asks it to do …", followed by the bulk of the Resolution. It was

better at the moment to concentrate on what should be in the rest of the Resolution. Returning to what they had called "the scope", he believed that the original idea had been to ask for a new normative document to be drawn up. Taking the conclusions from the Utrecht seminar, "... that a CIML Resolution is drafted formally to request a Committee to 'develop a normative document or guidance document on CTT', and then, 'to reference current programs in the US and the EU, to identify best practice and to inform future global development work in this area'". It was then necessary, Mr. Mason said, to find a way of importing into that Resolution the scope of activities which had just been discussed.

Mr. Kool queried the wording "normative or guidance document". He was not sure that a collection of descriptions of existing systems and best practice could be considered a normative document. It could still be a D-type document but only a guidance document.

Mrs. Lagauterie agreed, especially because "normative document" had a special meaning considering OIML Recommendations: it gave a presumption of conformity to the MID, so to use the wording for the document in question would be misleading, at least for some European countries.

Mr. Mason suggested removing that term. The proposal would then become "… to develop a guidance document", and then they would either use the phrase "conformity to type" or else import "the scope on" or "the scope for". They would then invite the TC to take into account the material gathered at both seminars – "… to take into account the information provided at the seminars held in June 2011 and October 2011". They could also then bring in the two key elements identified at the seminar, which were that the Committee should take into account the current programs in the US and the EU. They could then add "… and any best practice identified elsewhere". This pointed to looking at the IEC and other similar models.

Mr. Sanders was happy with the suggested wording but wondered whether they should weave in some words which would make it clear that they were not proposing a new OIML system, but rather guidance for countries perhaps to implement their own system.

Mr. Mason was not sure that they had got to the point where they were closing off options which the new Committee might be asked to look at.

Mr. Harvey said that he would like to add an additional work item, which would be to further identify and evaluate the critical issues that would need to be resolved before the establishment of an OIML CTT system. He was thinking of things like the legal and financial aspects of a potential system. He felt that it would be useful to look again at these and other critical issues.

Mr. Kool said that these matters had already been mentioned and would be in the minutes of the seminar. The text already said that the Committee should take into account the information provided at the seminars, so this would be included in the Committee's work and did not need to be detailed in the wording of the Resolution.

Mr. Harvey objected that the task as it stood was to collect existing practice into a guidance document, not to evaluate the critical issues, which in his view was a separate activity.

Mr. Mason was concerned that they might be moving too fast in terms of directing the new group to do something on a linear basis – not just draw up the document but perhaps move on to a second stage. In his view it was better to come back to that point when the document had been produced.

Mrs. Hockert agreed that the group should initially stay small and complete one task before expanding its scope.

Mr. Mason said that obviously the CIML would be debating the draft Resolution, and that no doubt all those who had spoken at the seminar would also participate in that discussion.

Mr. Kool returned to the three options which had been identified for completion of the work. The CIML would have to be asked to take a decision on this; he wondered whether something should be said about the procedure which would be used to accomplish this. His initial suggestion would be simply to offer the three options and ask for a show of hands to discover which had the least support, and remove that one from the options. Then they would vote between the two to see which was preferred, and after that a final Resolution could be drafted, which could be adopted or not.

Mr. Schwartz supported this proposal.

Mr. Mason asked whether there was support for this – it would be by straw poll – they had already had a straw man.

Mr. Johansen expressed qualified support for the idea, saying it depended on how the voting was done.

Mr. Kool explained that he simply wanted to ask for hands to be raised in favor of each of the three options in turn. There would then be a second vote after the option that had received the least support had been eliminated. The option with the majority would then be included in the draft Resolution.

Mr. Johnston did not think there were three options, but only two – an existing TC/SC, or a new one.

Mr. Kool said that two existing SCs were being considered, TC 3/SC 5 or TC 3/SC 1, which added to the alternative of creating a new TC 3/SC 6 made three options.

Mr. Johnston said it would be simpler to choose between an existing SC or a new SC. He did not think the question of whether it should be SC 1 or SC 5 would give rise to much debate.

Mr. Mason said that arguably if the choice was as clear as that, the CIML could make the decision. On the other hand, people who had not been present at the seminar would not have had the opportunity to consider the arguments being put forward. He could not work out which was the more favorable approach, but he thought the real choice was the basic one between an existing SC and a new one, because if it was a new Committee there would be the issue of finding a new Secretariat and taking up the Bureau's offer of support. Only if the decision was in favor of an existing SC should they consider the relative merits of the two existing SCs which had been put forward. On the basis that the vote would not in any case be binding, because it was simply advice offered to the CIML by those who had been participating in the discussion at the seminar, he suggested a vote by show of hands on the choice between an existing SC and a new SC. The choice would be for the CIML to make but they would have the opportunity to consider the weight of opinion among those who had heard all the arguments presented at the seminar in more detail than would be possible at the CIML. He asked whether those present were happy to proceed on that basis.

As there was no obvious dissent to this proposal, Mr. Mason asked those in favor of using an existing SC to raise their hands.

In favor of a new SC, hands were raised. Mr. Mason then asked for a vote on the choice between SC 1 and SC 5. Hands were raised in favor of SC 1 being the forum and then for SC 5. *(BIML note to this transcript: Numbers were not given verbally, nor was it made clear which option was preferred).*

Mr. Mason reminded those present that the vote was non-binding and was merely to advise the Committee as a whole of the sentiment of those Members who had attended the seminar.

He then thanked those who had participated, particularly those who had given presentations, and offered special thanks to Mr. O'Brien who had done so much work to get them so far in this process. He was sure this would give rise to lively discussion in the CIML later in the week.

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