**Clarification Questions to the Test & Measurement Coalition for the Stakeholder Consultation**

# General Questions (Relevant to Exemption Requests 17a, 18a and 20a)

1. TMC represents manufacturers of category 9 industrial monitoring and control instruments. Please explain
   1. Who are the members of TMC producing this type of equipment for the European market?

Anritsu, Agilent, National Instruments, Danaher group: Tektronix, Fluke, Keithley. In addition our position is cross communicated with Thermo Fisher Scientific and JEMIMA the Japanese Electric Measurement Instruments Manufacturer’s association[[1]](#footnote-1)

* 1. What are other manufacturers of such equipment who are NOT members of TMC? How many such manufacturers are there in total approximately?

The question is hard to answer in the abstract as the members of the coalition represent (with one exception) the larger integrated companies that manufacture almost exclusively industrial T&M equipment. There is one clear notable exception: Rohde-Schwarz which is a large player in Europe and is not a member. Thermo Fisher Scientific is also not a member but party to relevant positions although they are in majority in another market than T&M. For the rest there are hundreds if not thousands of companies[[2]](#footnote-2) large and small that make one (generally) or more instruments – they are each taken individually minute compared to the T&M members although they could be large in other areas Emerson Controls, LeCroy, Chauvin Arnoux, Kenwood, Hameg Instruments, Mueller Electric, Simpson, Tucker Electronics, Scientific Atlanta, Honeywell and GE Controls would be examples of those. Through estimation from our own sales force we have reasonable grounds to believe that the T&M coalition represents 60% or more of the world market in industrial T&M equipment. The vast majority in number are very small companies making one instrument usually under contract manufacturing with companies such as Solectron. They are not subject to similar constraints as our members (for obvious reasons).

1. You mention several times that some of your members’ products need to be qualified according to certain standards and specific requirements.
   1. Please explain which standards these are, and which types of products need to be qualified according to these standards.

The understanding of this issue seems to be at the core of the difficulty T&M members have to make their problems understood to non-industry experts. The standards and qualifications can be separated into three types of qualifications: internal ones required in the light of quality assurance, external ones based on (para)legal standards (both national and international) that need to be passed and ones set out by the customers. It cannot be underlined enough that these qualifications are absolutely essential to guarantee stated performance to specs – any uncertainty around it would prevent a manufacturer from marketing a product as the exactitude of the instrument is a key element of the reputation of the producer. One mistake could jeopardize the confidence in his whole product range and indeed can have catastrophic consequences due to the system critical applications that our instruments tend to be used for.

INTERNAL QUALIFICATION

The equipment produced by all members of the Test and Measurement Coalition are warranted to perform measurements against published specifications. In order to assure these product specifications are correct, the equipment’s performance is verified during design and formally calibrated within production in their ability to perform measurements that are traceable to National metrology standards. This is the property of the result of a measurement whereby it can be related to stated references, either directly to one of the five independent units of measure: *temperature interval*, *linear distance*, *electrical current*, *frequency* and *mass* or a unit derived from these such as the Ohm.

Due to the nature of product design and verification activities, not all published specifications are required to be measured and calibrated during production. Type testing to verify product design changes are then necessary to revalidate the product design so it continues to meet published specifications. Recreating the test systems and associated test conditions, such as performing measurements over the specified operating temperature range, is a complex project.

In both cases, the measurements are performed within ISO 9001 or ISO 17025 management system requirements.

The National Physical Laboratory in the UK published “[Metrology In Short](http://resource.npl.co.uk/international_office/metrologyinshort.pdf)”[[3]](#footnote-3) which can be used to obtain additional information regarding metrological information, particularly in relation to measurement standards.

Technical Standards and Specifications. Everyday we take for granted that products will connect together and operate as intended: mobile phone placing calls; BluRay player connecting to TVs through HDMI ports; Wi-Fi connectivity; etc. The reason these work so seamlessly is that all are based out International standards or industry specifications. The products produced by the T&M coalition allow our customers to develop and manufacture products compliant with these standards, measuring their product performance against the standard or specification. Each piece of T&M equipment needs to assure it continues to meet any specified technical standard or specification when any change is introduced. There are thousands of such standards or specification, from multiple national and international bodies, a selection is provided below:

* CISPR:
* 3GPP2 -TIA: <http://www.3gpp2.org/>
* Bluetooth SIG - Special Interest Group <http://www.bluetooth.com/bluetooth/>
* CCSA - China Communicatons Standards Association [http://www.ccsa.org.cn](http://www.ccsa.org.cn/)
* CTIA - Cellular Telecommunications Industry Association <http://www.ctia.org/>
* ETSI - European Telecommunications Standards Institute <http://www.etsi.org/WebSite/homepage.aspx>
* IEEE
* IEC
* INCITS, InterNational Committee for Information Technology Standards
* JEDEC - Joint Electron Device Engineering Council

Lastly there is the practical issue that some kind of assessment needs to be made of the longevity of the new components as the specifications are guaranteed over long periods of use of the instrument in very variable conditions. Speeded aging whilst efficient does take time when it has to be done and can never be rushed further than a compression factor of ca. 7. This is in itself a critical impediment to assuring full transition of thousands of different products.

EXTERNAL STANDARDS

The most commonly known external standards are the old Weights & Measures[[4]](#footnote-4) type of qualifications that have been in existence since medieval times. In practice these are only a small part of what concerns T&M makers today but the concept behind many of these qualifications is the same. Our products must also adhere to safety and environmental standards. From a safety perspective IEC 61010 is one of the most notable. Which leads to necessary certifications such as CE, UL, CSA, TUV, FM, Ex, FCC (and many other by country for products with wireless capability), C-Tick, and more[[5]](#footnote-5). Other typical standards would be 4G, GSM or IEEE issued ones where again because of the system critical nature of the T&M equipment **certainty** around meeting the standard is essential – not a best guess or ‘*it seems to be working’ approach*. The T&M manufacturers produce for a global market and given the low volume in numbers of equipment must ensure that all national and international standards are met. Again T&M manufacturers will often go further than some standards particularly regarding EMC properties.

It would be the subject of a dissertation to list all possible standards for all possible types of equipment – which is exactly the reason that it takes so long to transform to compliance outside of the normal 7-8 years redesign cycle that manufacturers have.

The most infamous external standard, from an external regulatory perspective, any product which makes a measurement and expresses a SI quantity is required to meet the [Russian Metrology Law](http://www.vniims.com/download/102-fz_eng.pdf). Compliance with these requirements typically takes twelve months from submission to certification at a cost of thousands of Euros.

CUSTOMER STANDARDS

Many T&M products are designed to meet military and commercial contractual standards or derivatives by country. Customer Requirements; particularly those in the Aerospace and Defense industry, involve assessments of specific products in order for them to be approved for purchase. These evaluations are customer or even deal specific, and impose restrictions on continued supply of the product *as evaluated* and obligations for design change notification. Change notifications can trigger the need for some or all of the assessments to be repeated, or simply to have the product approval dropped. Specific details of such assessments cannot be shared for confidentiality reasons but it is very normal for a manufacturer to have an obligation to notify any change to the equipment to the buyer. The latter will then have a contractual right to demand a retest and qualification and they are likely to do so in any situation where a large number of components are changed. That is one of the key problems with the ceramic capacitors that appear from low hundreds to sometimes thousands of times in a piece of equipment and whose substitution tends to trigger a customer driven retest and requalification.

These requirements are in addition to the broadly understood need to comply with the EU’s EMC[[6]](#footnote-6) and Low Voltage[[7]](#footnote-7) Directive, typically through application of a relevant Harmonized Standards[[8]](#footnote-8),[[9]](#footnote-9). Testing can either be performed in-house by a manufacturer or through an external third-party. Engagement with a third-party safety certification agency such as UL or CSA is normal practice.

* 1. Please also indicate how long the approval procedures take approximately for the various standards/products and who is the qualifying body.

Each manufacturer is accountable for the Metrology specifications of their own products and so they are “qualifying body”. In alignment with our previously submitted input, product requalification can take between one and six month’s dependant of product complexity and the impact of the changes being evaluated. One of the issues being that qualification cannot start until near ready production samples are available – given the multitude of instruments that need to be brought into conformity this is a challenge in itself. The problem is then aggravated in the hopefully few cases that a replacement causes some kind of issue requiring a patch or further redesign. This starts the whole cycle over. Please reference the attached information that we have submitted before although it does not appear on the website – it should be noted that several of our detailed submissions appear not have been on the radar of OEKO so far and are not uploaded as received.



Regulatory product certification was also previously covered in the submission above (per product):

1. Regulatory compliance evaluations:
   1. EMC – several weeks
   2. Safety evaluation – several weeks
   3. Third-party certifications – weeks to months depending on Agency used.

Russian certification is issued by Rosstandart, the [Federal Agency on Technical Regulating and Metrology](http://www.gost.ru/wps/portal/pages.en.Main) on the recommendation of one of the Test Institutes such as VNIIFTRI [National Metrological Institute of Russia](http://www.vniiftri.ru/eng). As mentioned above compliance with these requirements typically takes twelve months from submission for certification and has a cost of thousands of Euros.

1. Members list of Jemima: <http://www.jemima.or.jp/english_top/outline/members_list.html> Note - we only have contact to Jemima itself and they are aware of what T&M do. [↑](#footnote-ref-1)
2. A simple search on a specialized site like dmoz.org will yield over 300 possible T&M manufacturers on the global scale. Instrumentation makers – which would include some players that aren’t really T&M type companies, yields another thousand. These companies are on the whole not significant as the coalition represents the only large integrated manufacturers. Most instruments sold sell in very small quantities sometimes only one a year, a high volume piece of industrial equipment would sell in the low thousands per year. The market is highly specialized and particular completely unlike the consumer electronics market that has comparatively fewer different types of products but volumes that are several factors larger than the T&M sector. [↑](#footnote-ref-2)
3. The National Physical Laboratory in the UK published “[Metrology In Short](http://resource.npl.co.uk/international_office/metrologyinshort.pdf) 3rd Edition” which was “commissioned by the iMERA “Implementing Metrology in the European Research Area” project, contract number 16220, under the 6th Framework Programme and jointly financed by the European Commission and the participating institutes.” [↑](#footnote-ref-3)
4. In Germany this would be the [Physikalisch-Technische Bundesanstalt (PTB)](http://www.ptb.de/) [*www.ptb.de*](http://www.ptb.de/) [↑](#footnote-ref-4)
5. For some additional details this link is useful: <ftp://ftp.ni.com/pub/devzone/EEpart1.pdf> [↑](#footnote-ref-5)
6. [EMC Directive (EMCD) 2004/108/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:390:0024:0037:EN:PDF) [↑](#footnote-ref-6)
7. [Low Voltage Directive (LVD) 2006/95/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:374:0010:0019:EN:PDF) [↑](#footnote-ref-7)
8. [EMCD standards](http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/electromagnetic-compatibility/index_en.htm) [↑](#footnote-ref-8)
9. [LVD standards](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/low-voltage/index_en.htm) [↑](#footnote-ref-9)