

**Brussels, 18 November 2014**

## **Orgalime's comments on the OSHA's draft version of the technical areas of the NRTL Program Directive**

### **1. INTRODUCTION**

Orgalime welcomes the opportunity given by the Occupational Safety and Health Administration (OSHA) of the United States to send comments on the draft version of the technical areas of the Nationally Recognised Technical Laboratories (NRTL) Program Directive in advance of the formal notice and comment period.

The US is one of the largest markets for European mechanical, electrical and electronics engineering exports. In 2012, the export volume of Orgalime products to the United States accounted for 33% of the total EU exports to the USA. Trade in the other direction is also very significant. Total trade amounts to some 150-160 billion Euro.

Trade relations between the EU and the US are also reflected in the mutual direct investment, and the US is one of the largest markets in terms of outward direct investment made by the European engineering industry outside of Europe.

### **2. ALIGNING LABORATORY AND CERTIFICATION BODY REQUIREMENTS WITH INTERNATIONAL STANDARDS**

We welcome as a step in the right direction OSHA's intention to align and approximate laboratory and certification body requirements with ISO/IEC standard 17025:2005 "*General requirements for the competence of testing and calibration laboratories*" and ISO/IEC standard 17065:2012 "*Conformity assessment -- Requirements for bodies certifying products, processes and services*" for the review and application process of NRTLs.

However, OSHA is suggesting further management and general policies than the ones described in ISO/IEC standard 17025:2005 and ISO/IEC standard 17065:2012, although these are applied efficiently by a large number of countries and regions with important manufacturing activities.

We consider that additional requirements undermine a possible harmonisation of the accreditation procedures or future mutual recognition of test results from accredited bodies in the US and the EU.

One particular deviation is the setting of a minimum number of two factory visits in chapter 7.9. We consider that each NRTL should be allowed to adopt its own risk-based approach to determine the frequency with which it performs factory inspections. Thereby solid quality management systems would be rewarded by fewer inspections. In this framework, we consider that the obligation to have at least two factory surveillance visits per year should be revised (7.9, D).

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*Orgalime, the European Engineering Industries Association, speaks for 40 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.3 million people in the EU and in 2013 accounted for some €1,800 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.*

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Moreover, we consider that if a minimum number of obligatory factory visits are deemed necessary, then they should be evaluated according to a market-risk based approach and not on a product-risk based one. Thereby, the fact that products are intended for use in hazardous locations should not constitute a reason, in this framework, to have a minimum of factory visits per year (7.9, C.i).

### **3. MUTUAL RECOGNITION OF PRODUCT TESTS, CERTIFICATIONS AND APPROVALS**

The use of international standards for the review and application process of NRTLs should lead to an obligatory mutual recognition among NRTLs for the product tests, certifications and approvals.

We consider that this would have a number of positive effects. Namely:

- Competition among NRTLs would be set in more equal terms, as manufacturers would have the possibility to choose among all NRTLs for the full certification of their products or for components only. Thereby, each NRTL would have reasons to develop and tailor its offer for services according to manufacturers' needs.
- The certification process would become simpler for manufacturers, whether based in US or the EU, and its cost could be significantly reduced.
- It would facilitate future steps towards mutual recognition of NRTLs' test reports with those of EU accredited conformity assessment bodies.

Overall, further use of accreditation might also help increase confidence between NRTLs and thereby, we would hope, lead to mutual recognition of test results.

Moreover, OSHA or a government nominated body conforming to ISO 17011 could join the International Laboratory Accreditation Cooperation (ILAC) as an accreditation body and sign the ILAC Mutual Recognition Arrangement (MRA).

This MRA provides acceptance of accredited laboratory data and inspection results. The long-term aim is the fully accepted use and recognition of accredited laboratories (NRTLs), including results from accredited laboratories in other countries.

Furthermore, we consider it important, that the Directive suggests clear rules of the acceptance of inspections and test data from organisations functioning as part of the recognition systems of the International Electrotechnical Commission IEC for safety of products (IECEE-CB System) and for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx System).

Therefore, we believe that all certification bodies should accept inspection reports, coming from IECEE-CB or IECEx. In that context, 7.4.G. and 7.4.H should be modified accordingly and 7.4.I should be deleted.

### **4. A SINGLE NRTL MARKING**

We believe that it is necessary to reinforce the trust and recognition among NRTLs and economic operators, users and inspectors, by improving the visibility of the OSHA NRTL programme.

This could be reached by establishing a single "NRTL-marking" which would signify that the body that certified the product bearing this marking has acted under the NRTL programme. This marking would be placed in combination with the individual mark of each certification body.

Moreover, such a symbol would also introduce greater transparency in the certification system, as it would be much easier for regulators and customers to identify whether the certification body is an NRTL or not.

A similar result has been achieved by the use of CE marking on products sold in the EU.

## 5. CONCLUSION

Orgalime considers that the mutual recognition of NRTLs and alignment of laboratory and certification body requirements with international standards will have a positive impact on US market operators and end-users.

Moreover, it has the potential to facilitate US trade with the EU (where the European Accreditation system is already producing satisfactory results since 2010 (date of entry into force of Regulation EU 765/2008)) and thereby would represent a real and pragmatic step towards further developing the transatlantic market in the framework of the ongoing TTIP discussions.

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