

News in Brief

January 2020

Dear reader

Hope you have had a good start of the year!

Here follows this year's (and this decade's) first issue of our News in Brief, featuring the following topics:

- **Internet of Things and Cyber Security**
- **Deadline for Eurasian RoHS is soon**
- **Approaching enforcement of the new European Medical Device Regulation.**
- **Participation at IEEE Symposium on Product Safety Engineering**
- **New Nemko Director of Global Sales & Business Development**
- **Coming events**

P.S. Wishing readers who observe the Lunar Year calendar a really good holiday and happy celebration of the New Year of the Rat...and certainly hoping that the Corona virus outbreak is soon under control.

Best regards

[T.Sollie](#)

Editor



Internet of Things and Cyber Security

While electric safety of products has well established standards and certification schemes, the same cannot be said for cyber security. The number of IoT (Internet of Things) products surrounding us is rapidly growing, but it is well known that many IoT products are not secure. Regarding Cyber Security, it seems

that manufacturers cut corners and are repeating mistakes done by the IT industry 10 years ago! There are many examples of severe hacking attacks made through household appliances like connected air-conditioners, and even fish tank controls!

High security products have an established system in [Common Criteria](#) certification, but as this is both expensive and time consuming, it is not a suitable system for the high volume of IoT consumer products. In the absence of an established scheme suitable for consumer IoT products, several local certification schemes are emerging, all with low volume and low recognition.

The [EU Cyber Security Act](#) does, however, describe the establishing of a European/international certification scheme and at the recent [Cyber Security Act seminar](#) in Brussels (ref. photo above), a newly voted draft of the standard ETSI EN 303 645 was presented, named "[Cyber Security for Consumer Internet of Things](#)". More details are expected from the European Commission's work programme for European cybersecurity certification, which shall be published by 28 June this year. Already on 3 February, there is another relevant event in Brussels; the [Cybersecurity Standardization Conference 2020](#).

Nemko is currently pursuing cyber security services both within the Nemko Group and through partners. Some services are offered today, and the scope will broaden the in the near future.

For any questions or queries concerning cyber security, please contact geir.horthe@nemko.com

Deadline for Eurasian RoHS is soon

From 1 March this year (i.e. about 1 month from now), one must have RoHS certification for electrical products to be marketed in the Eurasian Custom Union, i.e. Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia.



It is estimated that before the 1 March deadline, several hundred thousand products need documentation showing compliance with this RoHS regulation to avoid the risk of being stopped at the border

Nemko has hosted two webinars on this topic. During the first (on 7 November last year), lot of questions were raised both during and after the webinar. During the latest (on 23 January this year), the issues raised during the first webinar were followed up and answered, many based on Nemko latest experience from real-time handling of relevant projects.

As reported in the November issue of this newsletter, it concerns the regulation EAEU TR 037/2016, which restricts use of the same 6 substances (lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers) as in the first European RoHS regulation.

The TR 037/2016 offers two compliance routes: *Certificate of Conformity (CoC)* or *Declaration of Conformity (DoC)*. One can chose either in-country testing of all homogenous materials in the product, or alternatively a quality management system approach based on the European standard EN 50581 or the international standard IEC 63000.

When assisting customers to obtain the necessary documentation, Nemko has currently efficient cooperation with three EAEU certification bodies, using the quality management system approach, together with a specially designed Russian Test Report Form.

For further information and/or application for EAEU RoHS DoC or CoC, please contact:

JonIvar.Tidemann@nemko.com or Morten@Smith.nemko.com .



Approaching enforcement of the new European Medical Device Regulation

Already in May 2017, the new European *Medical Device Regulation (MDR)* was published, then allowing a transition period of 3 years for manufacturers and others involved to adapt to the new requirements for medical devices to be marketed in the EU/EEA member states. The given enforcement deadline of 26 May this year is now quickly approaching. Recent surveys have shown that many companies are already behind in their readiness for the MDR and have weak understanding of the new regulation, including the data and documentation required.

The MDR replaces the *Medical Device Directive 2007/47/EC (MDD)* which originates from 1993, while the current amended version 2007/47/EC has been in force for about 12 years. The MDR, which also replaces the *Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC*, is intended to improve both the quality, safety, reliability and performance of the devices, having more emphasis on clinical evaluations and data. It requires transparency and traceability throughout the device lifecycle, and clinical evidence regardless of how long it has been on the market.

More information is available e.g. at [this link](#). For any questions, Nemko's partner Presafe (for certification of medical devices) may be contacted, c/o Cecile.Gudesen.Torp@dnvgl.com .

Participation at IEEE Symposium on Product Safety Engineering

Nemko participated at the recent IEEE Symposium on Product Safety Engineering (SPCE) in Austin, Texas, USA, with several presentations during the conference and a stand at the associated exhibition.

The event covered a wide variety of important product safety- and technical developments facing manufacturers.

Nemko's Director of Telecom, Tom Tidwell, presented on *5G wireless technology*, *Risk Analysis for the Radio Equipment Directive*, and *Hazards of Human Exposure to Electromagnetic Fields*, while Nemko's Telecom Project Manager, Michelle Furrow, presented on *Global Certification of Devices with a Radio Interface*, and *Modular Radio Approvals*.

In addition, the head of Nemko North America then, SVP Grant Schmidbauer, spoke as the event's Keynote speaker on the *Digital transformation of the TIC industry*, as well as presented on topics that included *Global Market Access Worldwide*, *Harmonization of IEC and EN 62368-series of standards*, and *New changes to the Mexico/NOM process*.

Nemko is, as always, an active contributor to IEEE Product Safety Engineering Society events and sees this as excellent opportunities to share expertise.

For further information, please contact Grant.Schmidbauer@nemko.com



New Nemko Director of Global Sales & Business Development

From 20 January, Mr. Doug Hughes is Nemko's Director of Global Sales & Business Development. In this role, he shall be instrumental in strengthening and growing Nemko's existing business. He brings a wealth of knowledge from more than 20 years' experience in managing sales of conformity assessment related services, including 13 years at a competitor, working with both the industrial-, consumer- and commercial business areas.

Focusing on growth, Doug has overseen service- and scope expansions to match current and future customer needs. In addition, he has added laboratories in new markets and has built strong partnerships which have led to several mergers and acquisitions.

Doug lives outside the city of Detroit, in Michigan, USA, but will be spending time in territory with the sales teams, focusing on expected expansion areas.

For further information, please contact Hannes.Skisaker@nemko.com



Coming events

14 February, IEC Academy webinar:

Circular Economy and Material Efficiency - Principles, terminology and their influence on IEC standards.

Registration for 9 a.m. CET [here](#) . Registration for 3 p.m. CET [here](#) .

12-14 May 2020, IEEE/PSES ISPCE, Chicago ,USA:

IEEE Symposium on Product Compliance Engineering (ISPCE).

For more information about IEEE/PSES , please check [here](#). For more information about ISPCE along with hotel and event registration, please check [here](#).

Receive invitations to Nemko webinars on current compliance issues

The webinars will be conducted in English, and one will be able to access the recordings afterwards, for own use and sharing with others.

Please register [here](#).

