

News in Brief

April 2020

Dear reader

During April, the Corona-pandemic has increasingly affected the lives of most people around the world, especially of course those who have been infected and become seriously ill, and in worst cases sadly died. It is at this stage impossible to predict the outcome for society, business, jobs, travelling etc. One thing is for sure, however, the world will not be the same as before.

Much are becoming delayed or otherwise affected, such as mentioned in some of the below articles in this April issue of Nemko News in Brief.

- ***The new European Medical Devices Regulation postponed.***
- ***Corona-virus impact on technical developments.***
- ***No further postponement for the new European safety standard for IT- and AV equipment.***
- ***The annual CB scheme statistics now published.***
- ***One more Nemko CB Testing Laboratory in Japan***
- ***Status of Nemko's local operations during the current virus crises.***
- ***Coming events***

Best regards

T.Sollie

Editor

The new European Medical Devices Regulation postponed

To allow the healthcare industry to focus more of its energy on fighting the Corona virus attacks, the European Parliament voted to postpone the application of the *Medical Devices Regulation* for about one year, until 26 May 2021. The Commission's official statement about this on 3 April may be seen [here](#).



With the current pressure on national health authorities and manufacturers of medical devices, there is a fear that there could be shortages or delays in getting the medical devices needed to fight the Corona virus, if having to follow the new rules of the *Medical Devices Regulation* as planned enforced from May this year. The proposal also had to be approved by the EU Member States and was then on 23 April published in the *Official Journal of the European Commission* [L130](#).

With the extra grace period, medical device manufacturers get a head-start on preparations to comply with the new requirements.

For further information or assistance with the new regulation, please contact Andreas.Nilsson@nemko.com



Corona virus impact on technical developments and product launches

Due to the Corona virus pandemic, slowdown in the roll-out of 5G technologies is now expected by many experts, not least resulting from delays in the decision-making processes. Specifically, the **3GPP** standard organization, which governs the technical specification for 5G technology, has suspended work on key portions of the standard. The delay is caused by lack of face-to-face meetings for at least three months.

Also other standard organizations are facing similar issues that will result in delay of vital standards and thus delay in design, testing and making of new products and systems.

Organizations creating and maintaining global standards experience that web-based technical committee meetings are far less effective than regular face-to-face physical meetings. A recent study shows several reasons for this, including challenges with reaching consensus when all the stakeholders are not present at the same location, and less efficient discussions when having to spread out in time, and also challenges with demonstration of complex technologies.

Another study shows that nearly 1/4 of electronics manufacturers/suppliers expect that the Corona virus outbreak will result in fewer new product launches in 2020. Some companies are already experiencing such impacts.

An example is given in a [recent article](#) in *The Wall Street Journal* about Apple delaying the production ramp-up of their 2020 flagship *iPhones* because of weakened global consumer demand and disrupted manufacturing across Asia.

No further postponement for the new European safety standard for IT- and AV equipment



The European standards committee for the hazard based safety standard *EN62368-1:2014* is CENELEC (CLC)TC108X.

The officers of this committee have recently received several requests from the industries which use the legacy standards for IT-equipment and audio/video equipment, (i.e. *EN 60950-1* and *EN 60065*), asking for an even further postponement of *the Date of Withdrawal (DOW)* for these standards.

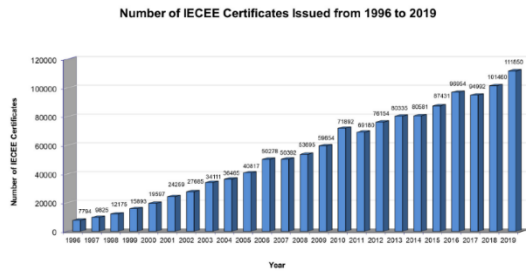
When *EN 62368-1* was published in 2014, it was given an extended transition period of 5 years, and subsequently even a further extension of 18 months.

The given justification for the requests from industry now is the impacts of the Corona pandemic on the whole economy and its potential consequences for producers and others involved in supply of electronic products.

After extensive considerations and discussion, the Chairman's Advisory Group for CLC TC108X did in a meeting on Friday 24 April 2020 conclude not to start a formal process for further postponement of the DOW-date, which has earlier been decided to be 20 December this year.

CLC TC108X is in process of preparing an announcement ('*INF- document*') about this matter and which is expected to be available very soon.

For more information, please contact Morten.Andersen@nemko.com



The annual CB scheme statistics now published

The recently released statistics for 2019 by the **IECEE**, show that, with total of 111838 international CB Test Certificates (CBTCs) issued last year, the annual threshold of 100 000 is again passed, and is an increase of 10% from 2018.

The graph here shows the impressive annual growth in the number of CBTCs issued during the past 24 years.

As one of the present 87 issuing NCBs (National Certification Bodies), Nemko is still among the leaders, with 7747 CB Test Certificates issued last year.

Nemko is now #1 NCB for the categories TRON (audio/video equipment) and EMC (Electromagnetic compatibility), #3 for HOUS (household appliances), #4 for OFF (office equipment) and #5 for MEAS (Measurement equipment).

Moreover, Nemko is also still a leader regarding the number of certificates recognized by other NCBs. Last year, Nemko CB Test Certificates were used as the basis for 2703 national certifications in other countries, representing 8 % of the worldwide total. These figures prove the continuing success of the *Nemko Direct program* for international approvals and global market access.

More information is available at <http://www.iecee.org/certification/certificates/statistics/> .

Amongst other, one can here find figures indicating some growth in the newer CB scheme categories/services as the ITAV (for the hazard base standard, combined for IT- and audio/video equipment), BATT (batteries), INDA (industrial automation).

Also, there is a graph showing in which countries most products with CBTCs are made, and the overwhelming figures of China in this regard.

For more information, please contact Skule.Moe@nemko.com

One more Nemko CB Testing Laboratory in Japan

After successful onsite assessment by the IECEE, Nemko now has an additional* CB Test Laboratory (CBTL) in Japan. This is the **OKI Engineering** laboratory located at Honjo-shi, in the Saitama region (not far from Tokyo). Their accepted scope for CB scheme testing includes IT equipment, EMC, medical devices and measurement instruments.

The laboratory was founded in 1973 as an independent entity, separated from the *OKI Group* (a large Japanese industrial glomerate of companies), offering testing and analysis services to various industries, including safety and EMC testing of electronic products/devices.



With this latest addition, Nemko as NCB (IECEE National Certification Body based in Oslo, Norway) now has 18 associated CBTLs operating within the international CB Scheme, as may be seen at [this page](#) on the IECEE website.

For further information, please contact Skule.Moe@nemko.com

*) *Nemko's other CBTL in Japan for many years is Cosmos Corp. in the Matsutaka region, whose testing scope also covers other product categories, such as household appliances, audio/video equipment and electrical tools.*



Status of Nemko's local operations during the current virus crisis

China: The operation in Shenzhen is as normal, with restrictions on visitors in the lab.

Hong Kong: The operation in Tuen Mun is currently as normal. Shift work is being considered.

Taiwan: The operation in Taipei is as normal.

South-Korea: The operation in Youngin (Seoul area) is as normal, but international travels are restricted.

India: The operation in Faridabad (New Delhi area) is closed, per Governmental lockdown until 3. May).

Italy: The operation in Biassono (Milan area) is operating with visitation limits.

Germany: The operation in Karlsruhe is as normal.

USA: The operation in Carlsbad (San Diego area) is as normal.

Canada: The operations in Ottawa, Montreal and Toronto are as normal.

Norway: The operations at Lysaker (Oslo area) and at Kjeller are as normal

All the entities are continuously following the development and public advice on safety precautions.

For further information, please contact Yngvar.Sjoner@nemko.com

Coming events

15-16 June: 26th Annual Nemko Customer Seminar in Oslo, Norway

For information, please see [here](#).

The event is, however, postponed until further notice, depending on the Corona virus situation

GSO courses in the Arabic Gulf Region during 2020

Information about themes, places and times may be seen [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](#).



