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News in Brief

for April 2021

Dear Reader,

Despite the increasing vaccination on going worldwide, many countries/regions still experience growing figures of people affected by the pandemic. India was pleased to see significantly declining figures when the situation suddenly turned around and now is totally out of control.

One may wonder how many pandemic waves and mutations we can expect and endure?

Other headlines worldwide this past month include amongst other the following sad 'anniversaries':

- 10 years of the terrible civil war in Syria, which has left the country in ruins.*
- 20 years with war in Afghanistan from which US/NATO have decided to withdraw, leaving uncertainty about what will then happen in this unstable country.*
- 35 years since the Chernobyl nuclear power plant disaster, which is the worst in history (..so far)*

Some good news is that heads of state in countries around the world, including China, USA and Russia have finally agreed to tackle the climate crisis with urgency.

For football fans in Europe, the fiasco for the attempt to create an entirely business-driven European super football league, is also good news.

The following articles in this issue of Nemko News in Brief are certainly at a quite different scale, but hopefully still found to be of interest.

- New U.S. testing program for medical devices on trial***
- The annual CB scheme statistics now published***
- Record growth in PC sales globally despite component shortage***
- Critical electrical energy situation in South Africa***
- Status of certain environmental regulations in Eastern Europe***
- Coming events***

Hoping that you continue to stay safe and healthy, and wishing those of you concerned a good celebration of the International Labor Day on 1st May.

Best regards

[Trond Sollie](#)

Editor

P.S. If you know of colleagues or others you think should get this monthly newsletter, please refer to [this link](#) for registration.

New U.S. testing program for medical devices on trial

The U.S. authority [FDA](#) has, amongst other tasks, responsibility for the safety of marketed medical devices.

In order to allow for greater consistency and predictability in the FDA's approach to conformity assessment, they have now set up a voluntary pilot accreditation program, which is denoted *Accreditation Scheme for Conformity Assessment (ASCA)*.

Under this program, more than 50 testing laboratories have now been accredited to participate, including Nemko.

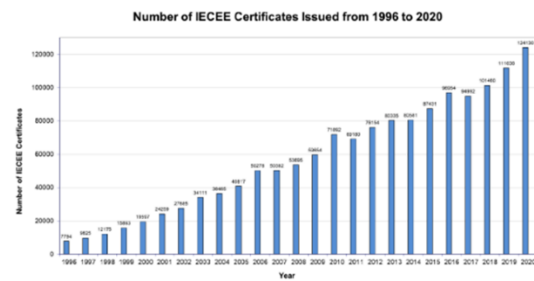
The ASCA program allows these accredited testing laboratories to assess medical devices for compliance with certain FDA-recognized standards. The establishment of the ASCA was mandated under the 2017 FDA Reauthorization Act and is expected to provide increased confidence in the premarket testing results for such devices.

At present, 53 testing laboratories located in various countries, including Canada, Japan, Germany, Israel, South Korea and China as well as the U.S., are authorized to conduct testing to one or more FDA-recognized versions of standards and test methods included under the scope of the ASCA pilot.

A list of the laboratories involved can be seen [here](#).

The FDA is expected to continue to review and accredit additional testing laboratories and expand laboratory accreditations to include additional recognized standards during the pilot program.

For further information and/or assistance with testing of medical devices for the U.S. market, please contact Marilyn.Laroche@nemko.com



The annual CB scheme statistics now published

The recently released statistics by the [IECEE](#), shows another record year with totally 124 130 international CB Test Certificates (CBTCs) issued in 2020, again an increase of about 10 % from the previous year. The graph at left shows the impressive annual growth in the number of CBTCs issued annually during the past 25 years.

There are now 54 Member Body countries in this scheme, with totally 90 NCBs (National Certification Bodies) and 556 testing labs, including Nemko's 19

labs located in different countries.

As an issuing NCB Nemko is still among the leaders, with 7616 CBTCs issued last year, and is now #1 NCB for the categories TRON (audio/video equipment) and EMC (Electromagnetic compatibility), #2 for HOUS (household appliances), #4 for OFF (office equipment), for ITAV (IT- & A/V equipment) and for MEAS (Measurement equipment).

Moreover, Nemko is also still a leader regarding the number of certificates recognized by other NCBs. Last year, Nemko CBTCs were used as the basis for 3332 national certifications in other countries, representing about 10 % 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 [this IECEE site](#).

Amongst other, one can at that site see a graph showing in which countries most products with Test Certificates are made, and the overwhelming figures of China in this regard.

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

Record growth in PC sales globally despite component shortage

Even though the pandemic has caused a constrained market and broken supply chains, which amongst other has resulted in a semiconductor shortage, figures from research of this year's first quarter have shown that global PC shipments increased over 30 percent from the same period last year, increasing from about 50 mill to 70 mill units. This is the fastest growth in the any year since one started tracking the PC market about 20 years ago.



One reason for this is said to be delays due the shipment chaos of early 2020. However, semiconductor shortages are now again adversely affecting the supply chain, with shipment lead times for some extending many months.

Unfulfilled PC demand from last year has carried forward into the first quarter, and additional demand brought on by the pandemic has also continued to drive volume. Apparently, however, the PC demand is expected to remain strong, even after stay-at-home restrictions ease as countries gain control over the pandemic outbreaks.

One particular growth area is education, after the pandemic forced schools etc to turn to digital platforms. Other areas with growth in demand is in gaming and the need for higher-performance notebooks in the enterprise market as well as an increase in demand for touchscreens.

Both for businesses, education and consumers, one sees much higher demands than expected, regardless of many countries beginning to reduce/remove pandemic related restrictions.

And it is expected that the component shortages will remain a bottleneck during 2021 as well.

In terms of sales volumes so far this year, the 5 top brands are Lenovo, HP, Dell, Apple and Acer.

More information about this topic may be seen e.g. [here](#) .



Helping the electrical energy crisis in South Africa..?

South Africa experiences widespread rolling blackouts as electrical supply falls behind demand, destabilizing the national grid and making life difficult

for the people in general as well as damaging the country's economy. It actually began already in 2007!

According to government officials, the solution requires the construction of additional power stations and generators, which certainly is not done 'overnight'.

In the meantime, amongst other [NRCS](#) (the *National Regulator for Compulsory Specifications*) is trying to contribute by making energy efficiency regulations more restrictive.

Examples are two draft regulations (**VC 9109 & VC 9110**), which have been developed and processed through the NRCS to facilitate the transition from inefficient incandescent and halogen lighting to more energy efficient, cost effect alternatives such as LED lighting products. The drafts set **requirements for energy efficiency as well as function and labelling of general service lamps (GSLs)**, which include general service incandescent lamps (GSILs), compact fluorescent lamps (CFLs), general service light-emitting diode (LED) lamps, organic light-emitting diode (OLED) lamps, and any other lamps that are used to satisfy lighting applications traditionally served by GSILs.

The two regulations, which can be seen respectively [here](#) and [here](#), are now out for public hearing.

There is also a proposed amendment to the regulation **VC 9008 for energy efficiency and labelling of electrical and electronic appliances**.

This compulsory specification from 2014 covers minimum energy and performance standards and energy efficiency labeling requirements for air conditioners, regular household appliances and audio/video equipment. The proposed amendment, which is still in the development process stage within NRCS, includes amongst other: -Expanded size of air conditioners covered, -Added stand-by power definitions, -Lowered passive standby power and -Added [MEPS](#) (based on [UNDP recommendations](#)).

Status of certain environmental regulations in Eastern Europe



Eurasian regulation for energy efficiency postponed.

The Eurasian Economic Union's Technical Regulation [EAEU TR 048/2019](#) concerning "Requirements for the energy efficiency of energy-consuming devices" has been decided **postponed for at least one year**. The presently indicated date of implementation 1st of September 2022. Actually, postponement for as much as 3 years is being considered in order for all parties concerned to be prepared for meeting the various requirements that are involved.

Annex 17 of the regulation which covers Computers & Servers, may be seen [here](#) (in Russian). This is apparently based on European Union's [ErP No.617/2013 Tier 2 Computer Regulation](#). But due to postponement it may possibly change before being implemented.

Ukraine planning to implement energy labelling.

Ukraine is preparing to implement European Union's Ecodesign requirements for several types of electrical equipment, and to adapt energy label requirements similar to those in the EU for the following types of products:

- Household dishwashers
- Household refrigerating appliances
- Household washing machines and tumble dryers
- Televisions
- Air conditioners
- Electrical lamps and luminaires

For further information and/or assistance with meeting the environmental requirements in Eastern Europe as well as in other countries around the world, please contact Jonlvar.Tidemann@nemko.com or Kenny.Ho@nemko.com.

Coming events

11 May 2021, Nemko Germany webinar on Functional Safety, (in German and free of charge).
Registration may be made [here](#).

Nemko Italy webinars 2021: Various topics presented in Italian.
Program for 2021 and links for registration are available at [this site](#).

IEC Academy courses and webinars
Information may be seen [here](#).

GSO courses in the Arabic Gulf Region
Information about themes, places and times may be seen [here](#).

Receive invitations to Nemko webinars on current compliance matters
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](#).

