Status of New IEC 2014 Standard, SGS/BTTG Testing

Over the past 12 to 18 months, several problems have surfaced using the new standard IEC 61331-1:2014 test method, including lab variability and consequent dubious certifications. To rectify the situation, the PPE Notified Bodies (NB) have assembled a group of experts to assess the issues and find workable solutions. This panel includes several expert physicists, all four potential testing labs, the three PPE NB and representatives from leading manufacturers.

An alternative broad-beam testing method has been proposed, that promises to be simpler with less inter-lab variability. This new method has been successfully evaluated in Germany and includes all the same features of the current inverse broad beam (IBG) method. Measurements of all transmitted radiation, including fluorescence, are performed with a detector in contact with the shield and represent real skin dose.

The new method is now under testing using the same samples at the four different labs. The testing should be complete soon and the results will be compared between labs and with the IBG results. In the meantime, the NBs have agreed that they collectively have the power and jurisdiction to write and adopt such modified methods for CE marking under PPE.

There are additional items on the expert panel's review agenda, including dropping the 50 kV beam quality, as diagnostically irrelevant in practice and insignificant to dose. This review process is likely to complete, and hopefully be adopted, by July 1, 2018, including the final NB proposal for modified testing for CE Mark. The revised testing procedure can be implemented by the vertically integrated PPE NB group without delay and subsequently ratified at one of the semi-annual PPE meetings.

Regarding product changes, the new modified broad beam (BBG) test method also generates slightly higher mm Pb values than the current IBG method, for lead-free and part-lead products. These higher Pb values, combined with a probable removal of the 50 kV beam quality requirement, may enable future area-weights to drop approximately 4% compared to present.

Review Process Timetable

The review process started in November 2017, including NB participation, assembling the experts group, and reviewing the potential new test method.

Regarding lab participation, pending adoption of the new test method, a variety of labs dropped out, declined participation or did not have accreditation for IBG testing. The result is that no testing or new certification has been done since January 2018.

However, if the BBG method timetable goes according to plan, 2 to 4 labs should be available to test with the new method as of August 2018. These labs can expect a rush of companies requesting new testing and certification. The targeted deadline for all recertification is December 2018.

Regulatory Change to PPE

Aside from the use of the IEC 2014 standard, regulations governing EC PPE are changing, effective April 2019. Currently, the CE certification is based on EU CD 89/686-EC. The new regulation is EU 2016/425, effective April 2019. Most of the consequences of this change are documentation-based and related to NB responsibilities.

Expected Marketplace Consequences/Timing

- Q2 2018 will see no change.
- Q3 2018 will see testing activity by core manufacturers and potentially by some apron-making companies, but little result in products or the marketplace.
- Q4 2018 should be very active. Not only will apron manufacturers be looking to reduce inventories of 'old' care materials, but will also need new alternative materials to market according to the new standards required in 2019.
- Q1 2019 will see major transformations of products ahead of the April 2019 PPE compliance deadline.