LITE TECH, INC.
975 Madison Avenue
Norristown, PA 19403

Phone (610) 650-8690
Toll-free (800) 647-5483
Fax (610) 650-8694

sales@xenolitexray.com

EU
Inter Company Memo
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Status of New IEC 2014 Standard, SGS/BTTG Testing

As you know, due to a number of problems in using the new standard test method, which has surfaced in the past 12-18 months (including lab variability and consequent dubious certifications), the 3 PPE Notified Bodies in concert, together with assistance, have assembled a group of experts to assess the situation and find alternatives. This working group includes several expert physicists, all 4 potential testing labs, the 3 PPE Notified Bodies (including BTTG) and representatives from several manufacturers and/or apron manufacturers.

An alternative broad-beam testing method, that promises to be simpler and reportedly better (less inter-lab variability), has been proposed. The new method, which has all the same features of the current IBG (inverse broad beam method), has been tested and reported upon in Germany and measures all transmitted radiation, including fluorescence, with detector in contact with the shield, representing real skin dose.

Further investigations have shown other test metrics to be inadequately defined and these too have been addressed.

The net result is that this variant of procedure is now under test with the same samples at the 4 different labs (for result comparison, both between each other and compared the IBG results). It should be completed in a few weeks.

In the meantime, and in parallel with this, the Notified Bodies have agreed that they collectively have the power/jurisdiction to write and adopt such modified methods for CE marking under PPE (if the method is proven to be better and agreed upon by a representative body of experts).

There are a few other items on this experts review agenda, including the dropping of the 50 kV beam quality, as diagnostically irrelevant in practice and insignificant to dose. This review process is likely to complete, and hopefully be agreed to, by mid-end June 2018, including the final NB proposal for modified testing for CE mark. The revised testing procedure can be put in place by the vertically integrated PPE NB group without delay and subsequently ratified at one of the semi-annual PPE meeting in Brussels.

The intent, if all goes according to plan, is to have all new certifications (to the modified IEC 2014) after that date, but even more importantly, **to have all existing products (already certified to IEC 2014 under present IBG) re-tested within a limited period** (e.g. by December 2018). This retesting will resolve prior certification/testing issues/disputes (e.g. several manufacturers' bilayer materials tested by BTTG).

Such timing fits nicely with the April 2019 PPE regulatory change deadline, after which date only newly certified products (to modified IEC 2014) will be allowed. In addition, the new BBG testing method also reportedly generates slightly higher mm Pb values (than the current IBG method) for lead-free and part-lead products (but not for 100% lead ones), which, combined with the probable removal of the 50 kV beam quality, may enable future area-weights to drop by about 4% compared to present. This would somewhat restore the +/- 15% weight-saving of such materials (compared lead), making them slightly more cost-effective.

In my opinion however, only construction using bilayers (e.g. Strata) will survive even the modified BBG version of the IEC 2014, leaving the leveled field/marketplace with the choice of heavy 100% lead, or new slightly lighter-weight bilayers.

Specifically, I cannot currently foresee admixed, old/current products such as Xenolite NLE/800, TBE/700 or B3E/600 (or competitive equivalents) meeting the modified new standard at any area-weights offering savings compared 100% lead (excluding the extra cost effect of such increased weights).

Limbo/Timetable

This review process started around November 2017, including gaining traction from the NB's, assembling the experts group and reviewing the potential new test method.

PTB dropped out of being available for lab testing in early 2018, delegating to the LMG Munich lab, which also dropped out of IBG testing in February-March 2018, pending adoption of the new test method. The NPL UK lab declined to be available for IBG testing due to complexity/cost and time, except for once a year in June—but even this is stalled now, pending the new method and the Innsbruck lab never received accreditation for IBG testing.

The result is that no testing or new certification has been done since December-January, in view of the flux. However, if the BBG method timetable goes according to plan, 2 to 4 labs should be ready/available to test with the new method as of July-August 2018 and they can expect a rush of companies (including Lite Tech) wanting such new testing/certification (although this may be a 'twice-through' process as weights/formulations are tweaked to minimize weights). Realistically, Lite Tech will target around September 2018 for Xenolite. Other companies may/may not be so quick off the mark, having to re-qualify and/or tweak formulations and reduce weight, however, the targeted deadline for all, December 2018, is approaching quickly.

Regulatory Change to PPE

Aside from the use of the IEC 2014 standard, the regulations governing EC PPE are changing effective April 2019.

Currently/prior, the CE certification is/was 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 Notified Bodies responsibilities.

Some of the documentation changes will need to be reflected however—for example, in new Tech Files by manufacturers, which will in turn trigger the need for new certificates (Article 10 and 11) by April 2019 (when old certifications will expire). Hence the need for any new test method to be universally in place for everyone by the end of December 2018, as such products will also need new certification under PPE EU 2016/425.

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 end result in products/marketplace.

Q4 2018 should be very active. Not only will apron-making companies be looking to reduce inventories of 'old' care materials (no longer useable for aprons after April 2019), but will also need new/replacement alternatives and plan to market the new standards required in 2019 while managing the transition.

Q1 2019 will see major transformations of products ahead of the April 2019 PPE compliance deadline (removal of the transition allowance for 'old' products).

Martin Lilley
Lite Tech Inc