

REGULATORY CHANGES 2016 – 2017, AFFECTING RADIATION PROTECTION PRODUCTS IN EU

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CLASSIFICATION OF PERSONAL IONISING RADIATION PROTECTION PRODUCTS & GOVERNING EU REGULATIONS

All products require CE marking for sale in EU, either under “PPE” or Medical Device regulations, or both

A “Personal Protection Equipment” (“PPE”)

- Defined by “ability to wear such products”
- Regulated by Council Directive **CD 89/686/EEC (“PPE”)** –*in future by EC Regulation # EU 2016/425* - with CE marking by CD 93/42/EEC
- Classified as “**Class 3**”, of “complex design”
- Such as x-ray aprons for occupational use, thyroid shields, glasses and protective eyewear, gloves and including caps/hats and protective headwear
- Characteristic – used to protect in/against scattered radiation, not direct/primary beam (except gloves)

CLASSIFICATION OF PERSONAL IONISING RADIATION PROTECTION PRODUCTS & GOVERNING EU REGULATIONS

B “Patient radiation shielding”

- Regulated under Medical Device regulations (“MDD”) under **MDD 93/42/EEC** - with CE marking by CD 93/42/EEC
- Classified as:
 - **MDD Class 1A** if non-sterile
 - **MDD Class 1B** if sterile
- Such as gonadal and ovarian shields, eye/thyroid/breast protection products (vs CT), patient drapes and drapes to reduce occupational dose/exposure in specific procedures
- Characteristic – used to protect in/against potential direct (CT) or “fringe” primary radiation (except patient scattered for drapes to reduce occupational dose/exposure)

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C “Other Personal radiation shielding”

- Regulated under both CD 89/686/EEC “PPE” and as Medical Devices under **MDD 93/42/EEC** - with CE marking by CD 93/42/EEC
- Classified as:
 - MDD **Class 1A** if non-sterile, MDD **Class 1B** if sterile
 - PPE – **Class 3** (complex design)
- Such as “half-aprons” (can be worn for occupational protection or as patient shields), dental aprons (patient shields, but are “wearable”)
- Characteristic – used primarily to protect in/against scattered x-radiation.

Note: PPE for occupational protection against gamma radiation from radioisotopes are a special category of PPE, should be based on 100% Pb, tested to 150 kV

STATUS OF IEC 61331:1994 & IEC 61331:2014 WITHIN “PPE” REGULATIONS (CD 89/686/EEC and/or EC 2016/425)

- IEC 61331:1994 and :2014 are non-mandatory Standards and have no force, in law, per se (‘by themselves’)
- Their relevance is a result of the Notified Bodies (“NB’s”) for PPE being required to ensure adequate/proper testing and/or marking Standards to ensure performance and user safety for CE marking/certification
- Such required use of Standards are at the discretion of the NB’s, unless a harmonized EN Standard exists, which makes such use mandatory (EN 61331 not harmonized)
- Prior to Sept 2016, most PPE Notified Bodies elected to adopt the **IEC 61331-1:1994** narrow-beam method as the basis for protection testing and CE certification
- In May 2014, IEC issued a revision to the 1994 version, **IEC 61331:2014**, not then adopted by NB’s for PPE

PPE REGULATORY CHANGES MAY 2014 to JAN 2017

May 2014-July 2016

- Expert disagreement on the new IBG methodology, and unknown measurement uncertainty of IEC 61331-1:2014
- Delayed its adoption by most NB's for CE 2014 marking

July 2016

- A “**Lab Guidance Note**” was issued by Dr. Buermann (PTB, Braunschweig), Convenor of 62B/MT 47 IEC committee, to more explicitly define test methodology for the Inverse Beam Geometry (“IBG”) method with defined experimental measurement uncertainties (7%)

Sept 2016

- The PPE Notified Bodies for RPP collectively adopted use of the new IEC 61331-1:2014 (Parts 1 and 3), including use of the Lab Guidance Note as “state of the art”, effective for new (uncertified) products after Jan 2017

PPE REGULATORY CHANGES MAY 2014 to JAN 2017

Sept - Dec 2016

- The Notified Bodies clarified the status of 'old' products, previously/currently CE certified/marked under the old IEC;1994 Standard
- Such "old" pre-certified product would continue to be able to be sold in EU, with differentiating label and User Information, until; expiry of their Article 10 EC-Type certificates (2023), alongside 'new' product compliant/CE marked to the new IEC 2014 Standard

Feb 2017

- The EC Commission issued a new PPE Regulation, EU 2016/425, replacing CD 89/686/EEC with transition until **April 2019** (when 'old' product becomes illegal)

WHAT'S NEW IN IEC/EN 61331:2014 ? (vs 1994 STANDARD)

Part 1 (Test Methods, Definition of Attenuation Equivalence)

- Useable for all materials, lead, part-lead, lead-free
- **New Inverse Beam Geometry (“IBG”) measuring method** (broad beam, close pancake detector) capturing more transmission, including secondary/fluorescent emissions (previously largely missed by IEC 1994 narrow beam)
- New definition of Attenuation Equivalent (as mm Pb/LEV)
- Wider range of beam qualities 50/70/90/110 kV, with option to include special category to 150 kV (for CT)
- Recognition of use for occupational protection in scattered beams, tested in direct beams with spectra roughly equal to scattered beams from 60/80/100/125 kV tube voltage
- Introduction of -7% tolerance for measuring uncertainty
- Reduced beam filtration/HVL (vs DIN 6857)
- Tables of attenuation factors, build-up factors, first HVL's

WHAT'S NEW IN IEC/EN 61331:2014 ? (vs 1994 STANDARD)

Part 3 (Apron/product specifications, labeling/marketing etc.)

- Now adopted as part of CE certification requirements, with Part 1 test method dependence
- Introduction of “Ws” (surface density), or area weight, as kg/sq m, based on tested sample weight to achieve stated mm Pb Attenuation Equivalence (to be shown on label and User Information documents)
- Extra label/marketing information to show compliance with new 2014 Standard and applicable tested kV range
- Minimum Attenuation Equivalence (mm Pb) for products
- Extension of protective product scope to include
 - Thyroid collars/shields
 - Protective eyewear
 - Patient aprons for dental use
- Deletion of fixed apron dimensions (precluded prior use)

CONSEQUENCES AND EFFECTS OF USE OF NEWIEC/EN 61331:2014

- Most/all existing/old “admixed” lightweight PPE materials, part-lead or lead-free, will not meet the protection/mm Pb by testing to the new Standard – at current area-weights (except bi-layered products)
- If weights of such existing lightweight admixed materials are increased to comply, such weights are close to those of 100%-lead based materials, but then more expensive
- Even weights of 100%-lead based materials will increase due to elimination of the -10% mm Pb tolerance previously allowed by Notified Bodies (from DIN EN 61331-3:2002), combined with the need for at least +/- 5% manufacturing variances
- New products compliant with the IEC/EN 2014 Standard will, generally, be more protective than old products, but will be heavier and more expensive

SO ... WHAT PRODUCTS CAN I BUY/USE? WHEN? AND WHAT ARE THE BENEFITS

- The effects of the regulation changes are not retroactive, now, nor April 2019 (when EU 2016/425 transition ends)
- Current/'old' products, CE certified under the old IEC 1994 Standard (and EN) **are able to continue to be sold in EU until April 2019 - and used subsequently** (*the June 2017 expiry of IEC 61331:1994 (and EN) has no effect on use of this, by Notified Bodies, for on-going surveillance of prior certifications issued before Jan 2017*)
- New products certified to 2014 Standard **are typically heavier, more expensive, but have more protection.**
- Therefore if your personal dosimeter ("badge") exposures have been historically within limits, it may be a weight / cost advantage to stay with "old" product.
- If dosimeter readings are high, you may wish to buy new product (compliant with 2014 IEC/EN Standard)
- Beware of products certified to 2014 Standard, based on 2015-2016 testing, before use of the Lab Guidance Note

UNDERSTANDING “BI-LAYER” TECHNOLOGY

- 100% lead-based materials are not significantly affected by the new Standards, but most existing admixed materials will not meet the new Standard at lightweight
- Development of a new technology (**bi-layers or multi-layers**) will continue to provide lighter-weight materials meeting the protection required by the 2014 Standard
- In bi-layer construction, different attenuating elements, in separate, arranged layering “fractionate” the attenuation of the radiation spectra
- Outer layers/s of a lower Z element – facing the beam – more efficiently attenuate the 30-80+ keV part of the spectrum in the K-edge window of, eg Pb, Bi, or W – the high Z elements of the inner layers.
- The inner layer/s of high Z elements – facing the body – better attenuate the higher energy part of the spectrum (> 80-90 keV), but also absorb the secondary/ fluorescent radiation emitted isotropically by the outer low Z layers

FUTURE DEVELOPMENTS?

- Although the Notified Bodies have already moved forward in adopting IEC/EN 61331 (1/3):2014, there remains some on-going technical argument on the validity of the IBG test, and the range of beam qualities
- The technical argument revolves around the validity of results from the **only-partially irradiated detector** in IBG
- Simpler (and less expensive) testing alternatives by the fully irradiated broad beam geometry (“BB”) method reportedly reduce test uncertainties and could reduce weights by perhaps 4% (vs 100% lead)
- The absolute exposure from the **50 kV beam quality** (for the 0.35 mm Pb in most of EU), may be insignificant
- The filtration of the beam qualities and low first HVL’s (1.81 – 3.79) **make the beam qualities unrepresentative of interventional clinical practice** (HVL’s 3.5-6.5 mm Al)
- Harder beams would increase weight-saving further
- Will such discussions cause future changes?

PERHAPS INTERESTING “MARKET” INFORMATION?

- The EU market for RP PPE is supplied by about 20 EU “non-integrated” apron making companies/brands, plus imports, including some from the +/- 15 N American manufacturers (+ India, China etc.)
- The ‘core protection’ material for these 20 EU brands is manufactured by only 2 EU companies, plus imports from some of the 5 American ‘core protection’ manufacturers
- Only 3 of the approx. 45 apron makers (EU + N America) manufacture/control their own core material
- There are only 3 major CE certification Notified Bodies in EU for RP PPE – SGS, TuV-Sud and BTTG
- At present, there is only 1 approved/accredited testing lab for testing to IEC/EN 2014 - PTB, Braunschweig, DE

Thank you for your time
and interest!

Questions ?