

X-Ray Protection – Changes in the recommended test method

History of the test method

IEC and EN 61331-1 and 61331-3 were revised in 2014. The test method standard, EN 61331-1:2014, lists a number of test methods, including Narrow Beam, Broad Beam, and Inverse Broad Beam tests. The product standard, EN 61331-3:2014, specifies the Inverse Broad Beam method (known as IBG) for testing of protective aprons and other devices. The IBG method was a significant improvement over the original test method, as secondary radiation and fluorescence emissions are measured, and a range of X-ray energies tested.

In 2015, some Notified Bodies expressed concern with testing techniques being used by laboratories. Ludwig Büermann of PTB (Physikalisch-Technische Bundesanstalt, Germany's national metrology institute), the Chair of the IEC working group for the 61331 standards, published a detailed methodology for the test method in 2016. This is known as Inverse Broad Beam with Guidance Note (IBG*).

The Co-ordination of PPE Notified Bodies Vertical Group 5 - Protective clothing and gloves (VG5) approved a Recommendation for Use (RfU) in 2017, which recommended the use of the IBG* method.

Practical experience with the IBG* method showed that it was lengthy, costly, and did not show any significant improvement for test results. Dr Heinrich Eder of the Bavarian State Office of Weights and Measures (LMG), conducted a three-lab trial, and found no benefit from the IBG* method.

Dr Eder then published a paper in late 2017 which suggested a modified Broad Beam method, known as BBG*. An interlaboratory trial using this method was conducted in 2018 with four laboratories, which showed good agreement. The BBG* method is said to be simpler, cheaper, and more testable by end-users, and has broad support from suppliers and laboratories.

In May 2019, VG5 agreed a new RfU, which recommends the use of the BBG* method. This was finalised and sent to Notified Bodies in July 2019. This RfU has to go through an approval process with the PPE Expert's Working Group (the European Commission and the EU member states) before it is published on the EU's website, however Notified Bodies can apply this RfU now.

Complying with the PPE Regulation – the 'state of the art'

X-Ray protection is Personal Protective Equipment, and must meet the Essential Health and Safety Requirements (EHSRs) of Regulation (EU) 2016/425, the PPE Regulation, when placed on the market in the European Economic Area (EEA).

EN 61331-3 is not a harmonised standard, and so does not enjoy legal 'presumption of conformity' with the PPE Regulation. However, it is recognised as the most suitable standard to use as a 'technical specification' to show compliance with the relevant EHSR.

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The Regulation obliges Notified Bodies to inform manufacturers if there is a change in the state of the art, which might mean that PPE no longer complies with the relevant EHSRs.

Manufacturers have the following obligations under the PPE Regulation:

- To adequately take into account changes in technical specifications;
- To interpret and apply the EHSRs in such a way as to take into account the state of the art and current practice at the time of design and manufacture;
- To ensure that the PPE continues to fulfil the applicable EHSRs in light of the state of the art;
- To ask the notified body to review the EU type-examination certificate in the case of a change in the state of the art.

BTTG's policy for X-ray protective clothing

The European Commission's PPE Guidelines refer to a change in the "state of the art" as being reflected by an updated version (of a standard or specification) with significant changes on safety clauses. It states that a revision (of a harmonised standard) does not necessary reflect a change in the "state of the art".

In light of this interpretation of 'state of the art', BTTG consider that the changes in test method, from Inverse Broad Beam (IBG), to Inverse Broad Beam with Guidance Note (IBG*), to modified Broad Beam (BBG*), do not constitute a change in the state of the art.

The different test methods measure the same property of the core material, the attenuation of X-rays. There have been no suggestions that the original 2014 Inverse Broad Beam (IBG) method is unsafe or not suitable for measuring X-ray attenuation.

Type-examination (Article 10 and Module B) Certificates

Existing PPE Directive Article 10 / PPE Regulation Module B certificates issued by BTTG, using testing to the original EN 61331-1:2014 Inverse Broad Beam method (IBG), remain valid until they expire. They do not have to be updated to the BBG* method, however Manufacturers wishing to update their certificates may do so, by supplying updated testing.

Manufacturers making new applications or renewing existing certificates will, by default, be asked for testing to the modified Broad Beam method (BBG*), however testing to the Inverse Broad Beam method (IBG) method will still be accepted.

Summary

- It is the manufacturer's responsibility to interpret the relevant Essential Health and Safety Requirements, and to propose a technical specification to comply with them.
- The test method for X-ray protective clothing now recommended by VG5 and the wider industry is the modified Broad Beam (BBG*).
- If manufacturers consider this to be a change in the state of the art, they should update their type-examination certificates; there is no mandatory timescale for this.
- If manufacturers do not consider this to be a change in the state of the art, there is no compulsion to update certificates.
- BTTG consider that both the original Inverse Broad Beam method (IBG), and the new BBG* method, satisfy the relevant Essential Health and Safety Requirement.
- BTTG recommend the use of the BBG* method, but will still accept the IBG method for type-examination.
- Other Notified Bodies may have different policies.