

THE REVISION AND CHANGE OF STANDARDS USED IN SUPPORT OF ATEX AND UKEX CERTIFICATION

All standards are subject to a regular review and, if appropriate, revision. Under the requirements of the ATEX Product Directive 2014/34/EU, and the equivalent UKEX legislation UKSI 2016:1107 (as amended), this leads to a change in harmonisation status (ATEX) or designation status (UKEX) of the affected documents. A harmonised or designated standard offers a presumption of conformity with the Essential Health and Safety Requirements of the directive or UK legislation. A non-harmonised (non-designated) standard does not. Harmonised (designated) and non-harmonised (non-designated) standards are listed separately in the manufacturer's Declaration of Conformity

In this document, for simplicity, only terms related to ATEX (directive, harmonisation, EU-Type Examination Certificate, etc.) are used and should be understood to refer also to the UKEX legislation and terminology (legislation, designation, UK-Type Examination Certificate, etc.) unless otherwise clarified.

The process of harmonisation is a means by which the European Commission (and the UK Government) accepts that the technical content of the standard supports compliance with the essential health and safety requirements (EHSRs) of the directive.

It is normal practice for equipment to be designed and certified to the detailed requirements in the standards as the manufacturer's way of complying with the directive.

The purpose of this document is to provide the manufacturer with a brief guide on how to handle the situation where standards referenced in a certificate are changed, either by up-issue or by replacement.

Many years ago, the European Commission suggested that it was the Notified Body's responsibility to review every certificate it had issued and to advise the manufacturer accordingly. This would have proven totally unworkable and extremely expensive, so it was agreed that Notified Bodies should just have a responsibility to generally make manufacturers aware of standards changing and how to get specific information. SGS Baseefa publishes BAS-PS-010, a summary of publication dates and harmonisation status of standards and their revisions applicable to the majority of ATEX related standards, in order to fulfil this obligation.

Details of the changes from previous editions (and sometimes previous standards) are provided in Annex ZY of the EN version of such standards. The same list of changes can also be found in the foreword of the IEC version of the standards. As part of its publicity for international standards, IEC makes a preview available of all standards, which includes the foreword, and can be freely downloaded from the IEC web site.

In 2010, the European Group of Notified Bodies for the ATEX Directive (ExNBG) laid out a way of working for manufacturers which is amplified and explained here.

1. Check the differences between the standard to which your EU-Type Examination certificate refers, and the replacement standard, using the information in Annex ZY. Alternatively use the information in the foreword of the IEC version. Record a "Gap Analysis" relating how the changes apply to your product.
2. If the Gap Analysis clearly demonstrates that none of the changes apply to your product, your existing documentation (Report and Certificate) can be said to confirm that your product remains in conformity with current technological knowledge (which must, according to the EHSRs be taken into account as soon as practicable).

Amend your Declaration of Conformity to show that you are now claiming conformity with a non-harmonised standard, but that you have completed a gap analysis to show that it still relates to the "state of the art" for your particular product.

3. If you are not sure whether or not the changes apply to your product, seek advice from SGS Baseefa, ideally including a copy of your provisional gap analysis.

3.1 If the changes are not relevant, we will issue a supplement to your certificate, or create a new edition of your certificate, confirming that the product complies with the later edition of the standard. This new edition should now be listed as a harmonised standard in the relevant Declaration of Conformity.

3.2 If the changes are relevant, we will provide a quotation for performing the necessary evaluation and creation of the supplement or new edition of your certificate.

Every time a certificate is subject to a supplement or a new edition, such as for a minor change in the design, we recommend that you should ask us to take care of new editions of standards at the same time, thus keeping all your documentation up to date. Our experience is that at least 50% of certificates will require a supplement or new edition because of a change to the product, during the three-year overlap period, during which both the old and the new standards are harmonised.

Although the formal position within the IECEx Certification Scheme is slightly different, we suggest that both the ATEX certificate and the IECEx certificate should be revised at the same time.

If you have both a European ATEX Certificate and a GB UKEX certificate for the same product, we recommend that we undertake parallel action on both certificates at the same time, as this will be the minimal cost route.

Further information is provided at www.sgs.co.uk/sgsbaseefa

Recommended reading related to this document includes:

BAS-PS-009 – Declarations of Conformity and Standards Amendments

BAS-PS-010 – Harmonization Status of Selected Electrical and Non-Electrical Ex Standards

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WHEN YOU NEED TO BE SURE

