GUIDE TO SERVICES CONCERNING QUALITY ASSURANCE ASSESSMENT

This guide sets out the basic details applicable to the Quality Assurance Services offered by SGS Baseefa Ltd.

Quality Assurance Services can only be offered to those who register with SGS Baseefa Ltd in accordance with the General Terms and Conditions applicable to all SGS Baseefa Services (see BAS-PS-003).

This document covers:

- The following modules of the ATEX Directive
  - Production Quality Assurance (Annex IV)
  - Conformity to Type (Annex VI)
  - Product Quality Assurance (Annex VII)

  The requirements relating to the modules Product Verification (Annex V) and Unit Verification (Annex IX) are given in our Guide to Verification Services
- IECEx Quality Assessment Reports

ASSESSMENT OF MANUFACTURING LOCATIONS

Whereas previously we had two separate, though related, standards to apply (EN 13980 for ATEX and OD 005 for IECEx) both services now use a common standard ISO/IEC 80079-34. The European version of this document (EN 80079-34) contains additional Annexes related to quality aspects of the construction of non-electrical equipment. All these standards have been written with the same clause structure as ISO 9001 and are applied in amplification of the more general standard.

PRE-ASSESSMENT SERVICE

As a certification body, we cannot provide a consultancy service to create a suitable Quality System on your behalf. However, we have a great wealth of experience in the application of quality techniques to equipment for use in potentially explosive atmospheres, as well as other areas. If you are not sure about interpreting the requirements for a particular type of equipment, we will be only too pleased to provide you with assistance. As with most things, getting the right information at the start of a process is usually the best way forward. To take advantage of our pre-assessment service, please contact us and we will arrange for you to visit us at Buxton, or for one of our staff to visit you.

QUOTATION AND ORDER

To assist us with preparing a quotation for you, we ask you to complete our QA Customer Questionnaire form (BAS-PS-003). From the information in the questionnaire, we will prepare a free, no obligation, quotation. If you wish to accept the quotation, you only need to post or fax the acceptance slip and we will do the rest. Provided you have already formally registered with us, we can also act on an email acceptance of the quotation.

DOCUMENT REVIEW

We conduct an initial document review to establish that your documentation system covers the necessary requirements. This ensures that there is a sound basis for an assessment to take place. On completion of the document review we will advise you of any omissions or problems. If necessary, we will check that you have taken action to correct these nonconformities, either before or during the assessment, depending upon their criticality. It may be appropriate, under certain circumstances, for the document review to be carried out at your premises.

ASSESSMENT VISIT

The purpose of the assessment visit is to examine and report upon the implementation of the requirements. Activities and records will be examined on a sample basis to check whether the system described in your documentation is in place, is being adhered to and is effective.

In addition, where practical, a product audit is conducted during all assessments and subsequent routine surveillance visits.

On completion we will give you the documented findings of the assessment and discuss with you the recommendations regarding the issue of the appropriate ATEX and/or IECEx documents and any necessary follow-up required.

CHANGES TO YOUR SYSTEM

After your assessment visit, you should consult us prior to making any significant changes to your system. Less significant changes should be notified to our auditors during routine surveillance visits. It will normally be possible to evaluate the changes you wish to make during the normal course of routine surveillance visits but it is possible that extra time may have to be spent in extreme cases.

If the assessment was based partly on the existence of an ISO 9001 Quality Management System Certificate from an acceptable certification body, you must inform us immediately should that certification become invalid for any reason. Note that ISO 9001 QMS certificates from a certification body that has been accredited by a member of the International Accreditation Forum (IAF), such as UKAS in the UK, is generally acceptable, whereas QMS certificates issued by a non-accredited certification body, or a certification body accredited by an accreditation body that is not a member of IAF are generally not acceptable.

ROUTINE SURVEILLANCE

We will make routine surveillance visits to confirm that your system is being maintained. The dates for these visits will be arranged with you beforehand and the frequency will depend on whether or not you are undergoing routine ISO 9001 audits from an acceptable QMS certification body. If such audits are to be taken into account, we will ask you to let us see copies of the audit reports.

Should any nonconformities be raised during the routine surveillance visit, we will ask you to confirm your proposed corrective action within one month and provide confirmation of implementation of the agreed action within a further two months.

If there are serious nonconformities, or a significant number of less serious ones relating to a particular area, or if you fail to take corrective action in the agreed time, we reserve the right to conduct a reassessment to confirm that the action taken is acceptable. In extreme cases, we reserve the right to suspend or withdraw the QA Notification and/or QA Report pending an acceptable outcome. If an IECEx QA Report is suspended or withdrawn, this will usually result in appropriate action in respect of the IECEx on-line certificate database and your certificate can be marked as suspended or cancelled.

ISSUE AND RENEWAL

ATEX QA Notifications are issued for a period of three years and are renewed automatically, subject to continued compliance with the requirements. A QA Notification is issued to the actual manufacturer of a product, i.e. to the company that takes responsibility for production.

In most cases this will be the same company that has been responsible for the design of the product and who holds the type examination certificate. However, it is possible that the responsibilities for design and production are split, perhaps even with more than one company responsible for production. In this case, other locations may need to be audited.

IECEx QA Reports are similar. In that they have a three year validity period, but they are different in that a new Report results from each audit.

CONTACT INFORMATION

To learn how SGS Baseefa can help you exceed customer expectations, visit www.sgs.co.uk/sgsbaseefa or contact baseefa@sgs.com for more information.