A GUIDE TO QAN AND QAR

In this document we bring together information on a number of issues where our customers have sought clarification.

THE APPLICATION PROCESS

SGS Baseefa Publication BAS-PS-006 contains details of the QA Notification/ Reporting process including background information, full details of obtaining and maintaining a Notification, and the terms and conditions that apply.

In summary, to obtain a QAN or QAR for the first time:

Complete an Application Form BAS-AF-003 and return it to us. This provides the information we need to give you a quote.

Please note, if the Notification is to apply to the certificates not issued or held by SGS Baseefa Limited, you will need to send copies of these. If your Quality System is certified to ISO 9001, we will need a copy of the certificate.

We may need more information, and if so will get in touch. We will give you a proposal which will include the normal costs up to and including the issue of the Notification, and the normal costs of the ongoing surveillance audits.

Once you accept the proposal, if you are not already registered with us, we need you to complete a Registration Document BAS-AF-001. In addition to providing all the necessary contact details, this confirms your agreement to the terms and conditions that apply to the service.

The next step is for you to send a copy of your Quality System documentation so we can check that it includes the necessary requirements for the products concerned.

You need to review ISO/IEC 80079-34 and make any necessary changes to include its requirements in your system.

We will provide a guidance checklist to help you at this stage, and let you know what documents we need to see.

If you are unsure about how to approach any aspect or need to clarify any of the requirements in your system, we will be pleased to help.

If there is any need to change the documentation, we will contact you and discuss the situation.

When the documentation is ready, and at a time when any related product certification work is at a suitable stage, we will agree a date for an initial assessment visit.

We will correspond with you regarding any problems the assessment may raise. Our aim will be to resolve these by correspondence, but in the event of more serious concerns a further visit could be required and in this case additional costs will be incurred which will be agreed before proceeding.

Once any non-conformities raised during the assessment are cleared, we will issue the QAN and QAR.

The first surveillance visit will normally take place between 6 and 12 months after the issue of the notification.

Normally, reassessments will be carried out every 3 years and surveillance audits will be carried out after 18 months if your QA System is ISO 9001 certified, or annually if not.

ANNUAL REVIEW OF Ex DOCUMENTS

ISO/IEC 80079-34 – 4.2.3 i) says:

"the manufacturer shall have a documented process to annually check the validity of all Ex-related certificates, standards, regulations and other external specifications."

A Manufacturer's claim that a product complies with the ATEX Directive (in their EC Declaration of Conformity) normally relies upon the EC Type Examination Certificate they have obtained for the product.

There is a time related problem with this, due to the fact that the versions of the Standards quoted in the Certificate will eventually be updated or replaced. When this happens, and the Standards are no longer harmonised (effectively, recognised as being valid for ATEX), some action is required by the manufacturer.

There should be a process that identifies when this, or any other action, is necessary.

SGS Baseefa makes relevant information available on our web site.

In short, when one or more of the Standards quoted on a Type Examination Certificate loses its harmonised status, a technical review is necessary, and the EC Declaration of Conformity has to change.

Further detailed information relating to this question can be found in documents on our web site, including revision and change of harmonisation status of Standards, current harmonisation status of common standards, comparisons between different versions of Standards that have changed, and an example EC Declaration of Conformity.

Although it is only ATEX that places a legal requirement on the standards up-date process, we recommend that IECEx Certificates should be treated exactly the same.

If you have any questions, please call us and we will be pleased to help.

QUALITY RECORDS – WHAT SHOULD BE INCLUDED IN THE QUALITY SYSTEM?

GENERAL RECORDS

Guidance is given in ISO/IEC 80079-34 on what records should be kept by a Manufacturer, and a minimum retention period of 10 years is suggested.

Regarding Non-conforming product, ISOIEC 80079-34 – 8.3 e) includes a requirement to keep certain records for a minimum period of 10 years in situations where non-conforming product has been supplied to a customer, i.e.:

- Serial numbers or identification of products supplied
- The customer who received the product
- The action taken to inform customers and the relevant notified body in the case of a non-conforming product
- The action taken to implement corrective and preventative action

REGULATORY REQUIREMENTS (ATEX)

There are some requirements in the ATEX Directive regarding records to be kept for a period ending at least 10 years after the last product is manufactured.

This depends on the Conformity Assessment Modules that apply, but examples are:

- Annex III paragraph 9 – Technical Documentation and copies of Notified Body certificates and variations, i.e.
  - Type Examination certificates and variations
  - Certified Schedule Drawings
  - Notified Body Certification or Test Reports
- Annex IV, paragraph 6 – The documentation of the quality system, updating the quality system, decisions and reports of the notified body.

Please note that this requirement has been discussed by the European Commission's ATEX Standing Committee resulting in a clarification in the ATEX Guidelines Document (§ 194) which in summary says:

"The requirements in Annex IV, paragraph 6 of the ATEX Directive 2014/34/EU are fulfilled if the manufacturer keeps at the disposal of the national authorities at least the actual quality management system documents plus the following documents which have to be kept for a period ending at least 10 years after the last piece of equipment was manufactured:

- *audit reports and certificates of the ISO 9001 certifier. This will be one or two reports per year that include the actual state at that moment of the quality system with changes:*
- *audit reports and notifications of the notified body that issued the Production Quality Assurance Notification.*

USER INSTRUCTIONS

User instructions should be subject to document control procedures that ensure that they comply with the standard to which the product is certified, and/or the ATEX Directive. They probably will contain the conditions for safe use contained in certificates with the suffix /X, and the manufacturers EC Declaration of Conformity, but other means of providing this information are possible.

The instructions should be in paper form but may additionally appear on the manufacturers website.

According to the ATEX Directive Annex II – 1.0.6 (a) the user instructions supplied with each product must contain:

– a recapitulation of the information with which the equipment or protective system is marked, except for the batch or serial number (see 1.0.5.), together with any appropriate additional information to facilitate maintenance (e.g. address of the repairer, etc.).

1.0.5 lists the requirements for marking as:

- *name and address of the manufacturer,*
- *CE marking,*
- *designation of series or type,*
- *batch or serial number, if any,*
- *year of construction,*
- *the specific marking of explosion protection*  *followed by the symbol of the equipment group and category,*
- *for equipment-group II, the letter "G" (concerning explosive atmospheres caused by gases, vapours or mists), and/or the letter "D" (concerning explosive atmospheres caused by dust).*

Furthermore, where necessary, they must also be marked with all information essential to their safe use.

It has been agreed by the Notified Bodies, however, that the year of manufacture need not be included in the user instructions. They ought to say that it is marked on the product however, and give any information necessary to interpret any coded form of date e.g. certain digits within a serial number.

According to ATEX Directive, Annex II – 1.0.6 (b):

The instructions must be drawn up in one of the Community languages by the manufacturer or his authorised representative established in the Community.

On being put into service, all equipment and protective systems must be accompanied by a translation of the instructions in the language, or languages of the country which the equipment or protective system is to be used and by the instructions in the original language.

The translation must be made by either the manufacturer or his authorised representative established in the Community or the person introducing the equipment or protective system into the language area in question.

By way of derogation from this requirement, the maintenance instructions for use by the specialist personnel employed by the manufacturer or his authorised representative established in the Community may be drawn up in a single Community language understood by that personnel.

Since the instructions required by ATEX

(and by IEC/EN 60079-0) need to be controlled, it is recommended that the manufacturer prepares the instructions in two parts: Part A are those aspects related to explosion protection; Part B are those aspects related to the functioning of the equipment and are not related to explosion protection. It is only the instructions in Part A that will be controlled for certification purposes.

SUB-CONTRACTING

WHAT ACTIVITIES CAN BE SUB-CONTRACTED?

The manufacturer is defined as being "any natural or legal person who is responsible for designing and manufacturing a product with a view to placing it on the Community market under his own name".

However, any activity relating to the manufacture of the product may be carried out by a supplier or sub-contractor appointed by the manufacturer. A supplier or sub-contractor may be part of the Manufacturer's own organisation, or may be entirely separate.

ISO/IEC 80079-34 extract:

7.4.1 of ISO 9001:2008 applies, with the following addition:

a) While manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with the Ex Certificate shall not be sub-contracted.

DO SUB-CONTRACTORS HAVE TO BE AUDITED BY THE NOTIFIED BODY?

There is no single answer to this question and many factors have to be considered, for example:

- ability of the manufacturer to demonstrate compliance without such an audit;
- level of product verification carried out by the manufacturer after receipt from the subcontractor;
- criticality of the product, process or service;
- degree of difficulty, or variability in the manufacturing process;
- location of the supplier and hence the effectiveness of communications;
- does the supplier, in turn sub-contract the product, process or service.

These factors may make it necessary for the sub-contractor to be audited by the Notified Body, and they may insist on this being done:

ISO/IEC 80079-34 extract:

7.1.4 (f)

The manufacturer shall facilitate an arrangement whereby the (notified body) may also verify aspects of any suppliers operation that affects the type of protection.

ATEX Guidelines extract:

Due to the use of subcontractors, the manufacturer may not be able to demonstrate (to a Notified Body) that its own quality assurance system ensures the product complies with the requirements of the Directive. The production quality assurance (Annex IV) or the product quality assurance (Annex VII) system at the actual manufacturing plant premises, of the manufacturer itself and/or of subcontractors, need to be the subject of an assessment by a Notified Body, including periodic audit visits.

HOW CAN COMPLIANCE OF PRODUCT SUPPLIED BY A SUBCONTRACTOR BE DEMONSTRATED BY THE MANUFACTURER?

Again there is no simple answer. Some items may be critical but may be dealt with simply by showing that the supplier has acceptable ISO 9001 certification, and by obtaining a supplier's Certificate of Conformity. Other items such as encapsulated intrinsically safe assemblies will require a fully documented site assessment by the manufacturer and agreed controls (a "Quality Plan"), which are specified in the purchase agreement (purchase order or contract) and confirmed by a supplier's certificate or completed process/inspection/test records for each delivery.

For more information visit www.sgs.co.uk/sgsbaseefa, alternatively email baseefa@sgs.com.