SUB-CONTRACTING THE MANUFACTURE OF ATEX-CERTIFIED PRODUCTS

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 sub-contractor;
- 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 sub-contractors, 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, or 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 a 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 suppliers certificate or completed process/inspection/test records for each delivery.

Extract from SGS Technical Bulletin 'QA1 – A guide to QAN & QAR'