### **Analytical Instrumentation**



In 2007, the EN 50014 series of technical standards began to be withdrawn and, in their place, superseded by EN 60079 counterparts which align more with their IEC equivalents.

This has an impact on manufacturers of ATEX products certified to EN 50014 series, who have a requirement to ensure that compliance is maintained in line with current requirements.

Four years on and products certified to EN 50014 standards are still available on the market, leading to some confusion over whether such products must be re-certified to the newer harmonised standards, or whether the products are still acceptable to be used in "Hazardous Areas".

To help clarify the issue, Sira's Certification Manager, David Stubbings, discusses the recent changes in technical standards and the points you need to know in order to comply with the Directive.

### **The Legislative Situation**

The ATEX Directive requires that technical knowledge, which can change rapidly, must be taken into account as far as possible and utilised immediately. This has led to questions over who decides what is the latest technical knowledge (sometimes referred to as 'The state of the art').

Generally it is accepted that the issue of new or revised standards is an advancement of technical knowledge, although if the standard doesn't incorporate a technical change affecting the product, why would there be a need to update the certification? Firstly, the manufacturer must determine whether changes to the standards apply to their product. Secondly, if the changes affect the testing of the product and the requirements are more onerous, the certification or technical file should be updated.

The Clarification Sheet N° ExNB/10/397/CS, published by the *Co-ordination of Notified Bodies Equipment for use in potentially explosive atmospheres on Council Directive 94/9/EC (ATEX)*, helps define equipment modifications in relation to introduction of new technical standards. It defines modifications to standards (and thus the impact on manufacturers and their certified products) into three main areas -

- Minor and editorial changes
- Extensions
- Major technical changes

Their guidance is listed below:

# Case 1: Equipment certified to earlier standards where there are only changes classified as 'Minor and editorial changes'

- The manufacturer continues to use his existing certificate. It is still considered to demonstrate compliance with the EHSRs of the Directive.
- The EC Type Examination Certificate and the marking of equipment are not modified (for standards in the EN 50014 series, the marking remains "EEx" as the equipment does not necessarily comply with the standards EN 60079-0, etc.)

Due to the standards listed on the manufacturer's EC-Type Examination Certificate no longer being harmonised (and therefore having lost their automatic presumption of conformity with the EHSRs) it is necessary for the manufacturer to record the correct (changed) status of the standards in his Declaration of Conformity.

The manufacturer also has the option to engage a Notified Body to carry out all examination and tests according to the revised standards, if he so chooses.

## Case 2: Equipment certified to earlier standards where there are changes classified as 'Extension'

The manufacturer has the option to continue with the existing design (see Case 2a) or to use the extension if this will be of advantage (see Case 2b).

• Case 2a: The manufacturer can continue to use the existing EC-Type Examination Certificate without modification as the basis for a Declaration of Conformity, because the extension of requirements do not contract the former requirement but provides additional options which are not used.

Due to the standards listed on the manufacturer's EC-Type Examination Certificate no longer being harmonised (and therefore having lost their automatic presumption of conformity with the EHSRs) it is necessary for the manufacturer to record the correct (changed) status of the standards in his Declaration of Conformity.

• Case 2b: If conformity with the extension of requirement is presumed, the manufacturer engages a Notified Body to carry out those examinations and tests according to the revised standards which are different from the standards mentioned on the existing EC-Type Examination Certificate.

Upon confirming compliance, the Notified Body issues a statement or supplement to the existing EC-Type Examination Certificate, confirming compliance with the new harmonised standards. (In the case of change from the EN 50014 series of standards to EN 60079-0, etc., the marking may change from "EEx" to "Ex".) The EC declaration of conformity, the instructions and the marking are updated to show compliance with the new harmonised standards.

It should be noted, however, that the issuing of a new EC-Type Examination Certificate or a supplement to the existing EC-Type Examination Certificate will have no retroactive effect and, therefore, will not affect products placed on the market and/or put into service whilst the manufacturer was in possession, where appropriate, of a valid Certificate.

## Case 3: Equipment certified to earlier standards where there is changes classified as 'Major technical changes'

• The manufacturer cannot continue to use the existing EC-Type Examination Certificate without modification as the basis for a Declaration of Conformity, as it no longer can be considered to confirm compliance with the EHSRs of the Directive.

The manufacturer must engage a Notified Body to carry out all examination and tests according to the revised standards which are different from the standards mentioned on the existing EC-Type Examination Certificate. Upon confirming compliance, the Notified Body issues a supplement to the existing or a new EC-Type Examination Certificate, confirming compliance with the new harmonised standards.

The EC Declaration of Conformity, the instructions and the marking shall be updated to refer only to the new standards and the new EC-Type Examination Certificate.

### **Next Steps**

Of course, the most important thing to ascertain is the extent the introduction of these new standards has on your certified equipment – are they minor changes, extensions or major technical updates?

As a starting point, Sira offers the following recommended action for manufacturers of equipment certified to older standards:

- Review your product against the recently issued standards (EN 60079 series) and determine
  whether there have been any changes that affect your product. Sira has a guidance
  document available upon request which will help with this task. A reasonably up-to-date list
  of ATEX standards is available on the European Commission website.
- Check that no new standards have been introduced that affect the product (e.g. EN 60079-28, optical radiation)

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- If there have been changes that bring in more onerous requirements, then have your certification revised and updated according to the guidance in Clarification Sheet N° ExNB/10/397/CS.
- If there are no more onerous requirements, then modify your Declaration of Conformity to refer to 'Compliance with the following standards' (i.e. remove the reference to harmonised standards). You should continue to reference the older standards that are listed on your certificate, until it is upgraded to the latest EN 60079 standards.
- It may also be wise to include a note under the standards, on your Declaration, stating 'the requirements of these standards have been checked against [EN 60079-0 and EN 60079-11 etc as applicable] and there were no differences affecting the latest technical knowledge for the product identified on this declaration.

#### **Repairs**

Repairs must be undertaken by a competent person, therefore end-users must satisfy themselves that their chosen repair company is competent to carry out the work.

When repairing electrical equipment, a workshop not affiliated to the original manufacturer will more than likely struggle to obtain technical detail to assist them in the repair. These types of repairs are limited to those where visual observation is sufficient to determine the specification of replacement parts.

For non-electrical equipment, any component that is ATEX compliant should be replaced with an identical replacement part. Other items such as seals or bearings can be replaced on a like for like

basis. If you are working on equipment certified before ATEX, you can still follow the guidance above, except that any component part marked with an old style certificate number (i.e. without 'ATEX' in it - Ex 98E1096U) will not be possible to buy in Europe. Someone could have the right part in store, and therefore it would be considered to be already 'placed on the market', if it was purchased before 1st July 2003, so it would be suitable to fit it.

#### **Modifications**

The company repairing ATEX equipment must decide whether the modification is 'substantial'. This is another woolly term that we must grapple with. My recommendation is that you consider a substantial modification is one that affects the explosion safety features of the original product or one that changes the intended use of the product. An example would be a flameproof motor, where modification of the endshield to incorporate a new accessory has led to new flamepaths, or a change to the original flamepath dimensions (note that simply dressing or polishing existing flamepaths to remove pitting would not be considered a substantial modification).

Alternatively it could be that the motor has been rewound to have a different rating. In the cases illustrated, these modifications require the company to have the modifications considered by a Notified Body.

As a final note on repairs and modifications, be sure to keep records of all changes. For modifications, it will be best to keep all design information and a record of assessments so that anyone scrutinising the file later can see a reasoned argument for the conduct of the modification.