

GUIDE TO THE CONTENT, REVIEW AND STORAGE OF TECHNICAL FILES

This guide sets out to explain the nature of Technical Files for the ATEX Directive, together with the basic details of how SGS Baseefa Ltd handles Technical Files in accordance with Annex VIII of the Directive. It also deals with long term storage of inactive Technical Files, prepared in the course of other certification activities.

THE TECHNICAL FILE

The ATEX Directive 2014/34/EU (formerly 94/9/EC) uses two terms: "The Dossier" and "The Technical Documentation" but common usage is the term "The Technical File". (The Term "Technical File" is not used with the IECEx Certification Scheme, but its role is fulfilled by the ExTR issued by the IECEx Certification Body.)

Whether the Technical File is in support of EC-Type Examination in accordance with Annex III, Internal Control of Production in accordance with Annex VIII, or Unit Verification in accordance with Annex IX, the technical requirements are the same. The difference lies in who is responsible for acceptance of the validity of the file.

Historically, manufacturers of electrical equipment have been used to certification bodies, such as SGS Baseefa Ltd., preparing the Technical File for them. The file would consist of the certificate, plus the report on examinations and tests, plus the manufacturer's drawings, which had usually been modified after discussion to show the relevant detail to demonstrate compliance with the standard, along with the instructions for installation and use. In contrast, the ATEX Directive presumes that the manufacturer will prepare the Technical File which, for certain conformity modules, will then be validated by the Notified Body.

A Technical File is made up of all the documentation necessary to back up a manufacturer's Declaration of Conformity with specified criteria in accordance with the ATEX Directive. This includes both a full description of

the equipment and the results of the appropriate conformity assessment process.

The best words to describe the purpose of a Technical File are given in Annex III of the directive:

"The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product."

To this end, all the Annexes (III for Type Examination, VIII for Internal Control of Production and IX for Unit Verification) list six aspects to be included in the Technical File.

A GENERAL DESCRIPTION

This would include type identification and performance information, as well as an outline description. This should provide sufficient overview such that the particular equipment could be recognised, and any specific interface details that might be necessary are made clear.

DESIGN AND MANUFACTURING DRAWINGS, LAYOUTS, SCHEDULES, ETC.

For a Technical File to have a life beyond just one single manufactured item of equipment, there is an art in preparing the necessary drawings, to ensure that they do not contain surplus information that might lead to unnecessary modifications to the Technical File throughout the life of the product. On

the other hand, the drawings do need to contain everything that is relevant to demonstrate compliance with the directive or the harmonised standards.

Both the specific Quality Management standard for Ex Equipment (ISO/IEC 80079-34) and the IECEx Operational Document on the preparation of documents for certification (OD 017) recommend the use of two sets of drawings, one for certification purposes (called Schedule Drawings) and one for manufacturing purposes. The manufacturing drawings need more information, some of which may be subject to frequent change, but there is a robust procedure to ensure that the manufacturing drawings still reflect the Schedule Drawings. Similarly, it would normally be recommended to reference Schedule Drawings in a Technical File.

DESCRIPTIONS AND EXPLANATIONS NECESSARY TO UNDERSTAND THE DRAWINGS AND THE OPERATION OF THE PRODUCT

Our experience at SGS Baseefa Ltd. is that this information is usually split between the general description, the drawings (often with copious notes) and the installation, maintenance and operation instruction document, rather than identified separately. Where the symbol "X" is used with the certificate number, there will be a need to explain the purpose of the particular Specific Conditions of Use that it refers to.

LISTS OF STANDARDS OR OTHER SOLUTIONS TO MEET THE EHSRS OF THE DIRECTIVE

The wording used in Annex III is "- a list of the harmonised standards applied in full or in part the references of which

have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied”

This clearly allows the use of solutions not in the harmonised standards, but does require a full description of each solution (and, by implication, the rationale for it achieving equivalent safety). The description of the solutions will often be incorporated with the result of the examinations. Note that the justification of equivalent safety can sometimes be very arduous, but use of a non-harmonised standard may sometimes be appropriate.

CALCULATIONS AND EXAMINATIONS

This is the argued case for compliance with the EHSRs, either via harmonised standards or “other solutions”. For example, drawings might show tolerances but there is a need to demonstrate how the build-up of tolerances and concentricities can affect rotational clearances if they are relevant to the protection. Many of the requirements in the standards can be fulfilled without a test and there needs to be a record of that fulfilment. A dimensional measurement on a sample is usually regarded as an examination, rather than a test.

TEST RESULTS

Although calculation and examination will provide most evidence of compliance, there are some requirements that can only be demonstrably met by conducting tests on sample equipment; for example, temperature rise, or deformation after impact.

TECHNICAL FILES FOR NON-ELECTRICAL EQUIPMENT

There is an inherent difference in the way that the harmonised standards for electrical and non-electrical equipment approach protection. For electrical equipment, it is presumed that the electricity is a potential source of

ignition. For non-electrical equipment the same presumption regarding mechanical ignition sources cannot be made and it is first necessary to determine if a potential ignition source exists and then under what circumstances it may become active.

The Ignition Hazard Assessment required by EN ISO 80079-36 is an organised method of identifying where and how protection is required. As SGS Baseefa Ltd., we were responsible for drafting the simple example of the mechanical parts of a solenoid valve that appeared in Annex B to the first edition of EN 13463-1, the predecessor to EN ISO 80079-36. We were concerned that the other example in that edition of the standard (that of a complicated conveyor belt installation) might overface those who had comparatively simple equipment. Most equipment will fit between the two extremes. The examples in the second edition of EN13463-1 were changed to show different aspects related to a slightly different way of expressing the ignition risk assessment. The examples now given in EN ISO 80079-36 are very much more comprehensive, but all standards follow the same principles of hazard assessment and mitigation.

The process is not difficult, but it does require the ability to ask questions and state the obvious. For example, a bearing is clearly not an ignition source in normal operation. However, bearings do reach end-of-life conditions which could be ignition capable, particularly if bearing collapse were to result in high speed rubbing between inappropriate materials.

The Ignition Hazard Assessment, whilst being probably the single most important part of the process, does not have an obvious position within the defined contents of the Technical File. For this reason, most Technical Files are not broken into sections in the way envisaged by the writers of the directive.

STORAGE OF TECHNICAL FILES

The ATEX Directive places requirements on the storage of manufacturers’ Technical Files.

Unlike other directives where there may be considered to be an allowance to assemble the Technical File after the event, ATEX clearly requires the Technical File to be a fixed and identifiable

document, available at the time of despatch of the equipment.

In the case of both the modules “Type Examination” and “Internal Control of Production”, the ATEX Directive specifies that the manufacturer (and importer, distributor or representative where applicable) shall keep the Technical Files for a period of not less than 10 years after the last item was manufactured. The same would apply to the Notified Body.

For Category 2 and Category M2 non-electrical equipment, the manufacturer has to deposit the file with a Notified Body, in effect giving the file the same traceability as a certification package. The directive, itself, does not give a reason, but there are probably two aspects: The European Commission want to ensure that there is a “safe” copy stored away from the manufacturer for security purposes and for access if the manufacturer goes out of business; it puts pressure on the manufacturer to actually create the report at the right time and prevents him from altering the report in the light of subsequent events, should there have been an incident involving the equipment.

(Note that Category 2 and M2 internal combustion engines, although non-electrical, have to go through the same conformity assessment process as electrical equipment.)

The European Group of Notified Bodies for the ATEX Directive have agreed that it is necessary to have a charging regime for file storage which encourages the manufacturer to advise the body when production of a particular item has ceased, and thus limit the time commitment for storage.

SGS BASEEFA LTD. CHARGES ARE BASED ON THE FOLLOWING:

- Files created as part of Type Examination – free for 10 years
- Files transferred from EECS or other Notified Bodies – free for 10 years
- Files where SGS Baseefa Ltd. is responsible for the production phase – free for 10 years after the issue of the last QA Notification or Verification certificate

After the initial free storage period for each of the above, we reserve the right to charge for continuing storage in line with the charges for deposited files.

Deposited files for Category 2 or M2 non-electrical equipment (i.e. files where SGS Baseefa Ltd. had no part in the preparation of the file, and no part in the production phase) – an initial fee valid for storage for a period up to 13 years but subject to “roll forward” by renewal every three years. (i.e. after three years the manufacturer is asked if the equipment is still in production and, if so, the renewal fee covers storage for the following 13 years, thus ensuring that the file is stored for at least 10 years after the last date of production.)

Current fees can be checked with SGS Baseefa Ltd.

RECEIPT OF “INTERNAL CONTROL OF PRODUCTION” FILES

It is a mandatory requirement in the ATEX Directive that Technical Files created as part of the “Internal Control of Production” module for Category 2 and Category M2 non-electrical equipment are deposited with a Notified Body and that the Notified Body should acknowledge receipt of the file. We provide a formal receipt that confirms that the file has been deposited but that we have not looked at it.

It is recommended that the Technical File is sent to us as a sealed package that we will retain unopened, thus avoiding any possible ambiguity of the contents of the file received by us. This may be achieved, for example, by sealing the file in an envelope which is subsequently

enclosed with a covering letter in an outer envelope for mailing purposes. Note, however, we will not insist that the file is sealed but, in these circumstances, the separation of any of the content of the file from the main body of the file is at the risk of the manufacturer. We will, however, take all reasonable steps to ensure that the file remains intact.

You may send us supplementary information to add to the file but you may not remove it from our premises, since to allow you to do so would defeat the object of the independent retention. It will be treated confidentially and only copied to those who have a statutory right of access, such as the European Commission.

Should you misplace your copy of the file, we can arrange to supply photocopies at an appropriate charge. If the file is sealed, we will, of course, have to open it to provide this service.

TECHNICAL FILE REVIEW

When requested, we will review the content of any Technical File deposited with us on a purely optional and voluntary basis. We will confirm, by the issue of a formal “Review Receipt” that, in our opinion, the file, as passed to us, contains appropriate data to substantiate a Declaration of Conformity to the Directive. In doing so, we will not take responsibility for the veracity of the information in the file, but confirm that the way the information is presented

allows a conclusion that the equipment is compliant. The fee for this service includes the initial 13 year storage period and, as it depends on the complexity of the equipment, will be quoted on receipt of the file.

Manufacturers of non-electrical equipment, particularly when compiling their first Technical File, have found this service invaluable in giving them confidence that they have prepared a valid technical case for compliance.

VOLUNTARY CERTIFICATION

Should you prefer (or your customer require), we can, of course, proceed with full Type Examination on a voluntary basis. This is particularly popular with some types of Category 3 electrical equipment (e.g. motors and luminaires) where, historically, certification in some form has been regarded as the norm.

In this case, we issue a Type Examination Certificate as an accredited certification body, rather than as a Notified Body, as the ATEX Directive does not mandate Notified Body involvement for Category 3 Equipment. This service is also available for Category 2 and Category M2 Non-electrical Equipment should it be required.

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.