

TOPAS

Traffic Open Products and Specifications

Product Registration - Technical Files Guidance Note for Technical Assessors

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A Guidance Note for Technical Assessors

Purpose

To assist those organisations performing the role of Technical Assessor for Applicants to TOPAS for Product Registration.

Context

TOPAS manages Product Registration, the UK'S successor to the Type Approval process, for road traffic control and VMS equipment.

Under the TOPAS Product Registration process, Applicants shall submit a Technical File to an **Independent Technical Assessor**, typically a Notified Body, suitably UKAS accredited body or equivalent organisation approved by TOPAS.

The Technical Assessor shall at the request of the Applicant, perform an audit of the content of the Technical File. If the Technical Assessor is satisfied as to the completeness of the file, they shall countersign a Declaration of Conformity previously filled in by the Applicant.

Terminology

Any capitalised terms used in this guidance have specific meanings as defined in TOPAS 0600.

Guidance

Readiness for Technical Assessment

Applicants prepare a Technical File as required by the TOPAS Specification relied upon, and complete their sections of the corresponding Declaration of Conformity. These are both submitted to the Technical Assessor with a request that the Technical Assessor verifies the satisfactory completeness of the Technical File and Declaration of Conformity.

The Applicant will identify in their Declaration of Conformity those TOPAS Specifications

(one or more) which their Product is intended to meet.

Each TOPAS Specification includes an appendix Z. This lists those items of supporting evidence that shall be contained in the Technical File.

The Technical File shall include the results of third party environmental, EMC and optical testing. It will also include reference to the results of functional testing and a statement of compliance all as defined in the appropriate Appendix Z.

Once their audit is complete, if the Technical Assessor is satisfied that the Technical File contains the relevant certification and evidence of compliance with all those items legally required, reference to functional test results and a clause-by-clause Statement of Compliance against the specification clauses (i.e. all those items legally required and also those identified in Appendix Z) they may counter-sign the Declaration of Conformity.

Some specifications include a number of optional facilities. These are frequently identified by separate sections or appendices. Where a manufacturer seeks Registration to the core and only some of the optional parts of a Specification then only those parts will appear in the Statement of Compliance and in the Declaration of Conformity. The technical file contents should also reflect such options and choices.

Applicants are not permitted to modify, disregard nor supplement the requirements of the TOPAS specifications except as permitted within the Specification itself. Non-compliances with clauses of the specification must be provided in the statement of compliance. All non-compliances must be fully described fully addressing their effect on the performance of the product.

The TOPAS process is additional to all those items legally required. Compliance with such

is a necessary precursor to the Applicant obtaining TOPAS Product Registration. It is not part of the requirements of the Technical Assessment process that the Assessor obtain any mandatory compliance on behalf of the Applicant.

Technical Files Contents

For those items of information in the Technical File that are provided by a third party, e.g. independent test house, the role of the Technical Assessor is to confirm that the certification of performance is present, complete and indicates acceptable performance.

For documentation developed and provided by the Applicant the Technical Assessor shall review the content of these items to satisfy themselves of the completeness and satisfactory outcome of testing or validation of the Product's performance and functionality according to the Applicant's ISO9001 quality and document control system. It is not necessary that the specific test results are provided, only that there is evidence from the Applicant of such testing being performed and addressing all functions required in the applicable specifications.

Where a technical file contains caveats, exclusions or alterations (or any other incomplete representation of the applicable specifications against which product registration is being sought), documentary evidence of these must be referenced in the Declaration of Conformity in addition to being verified as correctly reported by the Technical Assessor.

In the event that the Technical Assessor deems the Technical File to be incomplete or there to be excessive non-compliances they should advise the applicant to contact TOPAS directly to resolve such matters prior to making their application.

Technical Assessment

The Technical Assessors shall review the Applicant's Technical File ensuring that:

1. All mandatory and legislated certification is present and meets prevailing UK requirements. (Specifically this includes compliance with all applicable ENs to the classes required in TSRGD.)
2. All third party test certificates are present and corresponding test house reports show that all tests have been passed.
3. The Technical File contains all those items identified in appendix Z of the specification(s) against which Registration is being sought.
4. All non-compliances with the applicable TOPAS specification(s) are identified and described in the statement of compliance.
5. All non-compliances with the applicable TOPAS specification(s) are referenced on the Declaration of Conformity (non-conformance sheet).

In respect of their role in the Product Registration process the Technical Assessor is not required to

- Undertake any testing or functional checks of the equipment
- Prepare any additional reports or documentation for TOPAS

Completion of the Technical Assessment

Only when they are satisfied that all the required items in the Applicant's Technical

File are present and correct as stipulated in Appendix Z of the TOPAS specification, and any additional evidence required as above has also been attached shall the Technical Assessor countersign the Declaration of Conformity.

The role of the Technical Assessor is complete on countersigning the Statement of Compliance.

In the event that a Technical Assessor is unable to countersign the Statement of Compliance for example where requirements of the specification are incomplete or the Applicant has made substantial modifications, alterations etc., they should advise the Applicant to seek clarity with TOPAS.

Product Changes & Modifications

Where an applicant requests a re-assessment of a product previously registered with TOPAS due to significant change (as determined by TOPAS 0600), such re-assessment by a Technical Assessor shall be a complete and full assessment. Determination of significant change is not a requirement of the Technical Assessor, but of the manufacturer and TOPAS.

Should a Technical Assessor require clarity on any TOPAS specification then they should contact TOPAS through enquires@topasgroup.co.uk

Additional Services

The Technical Assessor may, in addition to countersigning the Declaration of Conformity, provide their own certification to permit traceability within their own document management systems.

In addition to the validation of the completeness of the Technical File the Technical Assessor is not precluded from

providing other independent advisory services to the Applicant, for example, assisting in the compilation of the Technical File.

Any Body wishing to be recommended as a Technical Assessor may contact TOPAS directly with details of experience, knowledge and qualifications within the Road Traffic Control sector. If approved, TOPAS will include your company details on its website for the benefit of manufacturers.

End of Guidance

TOPAS Management Board November 2017