

TOPAS

Traffic Open Products and Specifications

TOPAS 0602

Product Registration - Guidance for Technical Assessors

Revision	Date	Scope	Authorised by
C	17/2/22	Final	Board
B	20/12/17	Final	Board

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1 INTRODUCTION

Purpose

1.1 To assist those organisations performing the role of Technical Assessor for Applicants to TOPAS for Product Registration and provide consistency for the benefit of TOPAS and Applicants.

Note. Please check the TOPAS website to ensure you are using the latest version of this Guidance.

Context

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

1.3 The TOPAS Product Registration process, TOPAS 0600, requires that Applicants shall submit a Technical File to an **Independent Technical Assessor**, typically a UK Approved Body, a suitably UKAS accredited body, or equivalent organisation approved by TOPAS.

1.4 The Technical Assessor shall at the request of the Applicant, perform an assessment 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

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

2 CRITERIA FOR QUALIFYING AS A TECHNICAL ASSESSOR

2.1 The role of TOPAS Technical Assessors requires that they are independent of the Applicants for Product Registration such that all assessments they carry out are truly impartial.

2.2 It is also important that Applicants can have confidence in the provision of a continuous service by their Technical Assessor.

2.3 As such the following criteria are required to be met to qualify as a Technical Assessor for TOPAS.

- At least two full financial years of accounts. *
- Operate a defined and documented information control system (at least equivalent to the requirements of ISO9001) which includes auditing services within its scope. *

Note. Items marked * may require supporting evidence to be provided as a pre-condition for acceptance as a Technical Assessor and may be requested thereafter should TOPAS request them.

2.4 TOPAS mandate that records of all Technical Assessments should be retained by the Technical Assessor for a minimum of 15 years (the expected life cycle of traffic related products)

2.5 Technical Assessors shall not perform Technical Assessments for clients with whom they have any vested interest, other than for the services procured by the business in support of Product Registration, testing or other arms-length transactions.

2.6 Any Technical Assessor found to be in breach of these criteria may, subject to the decision of the TOPAS Management Board, be removed from the list of approved Technical Assessors.

Candidates For Technical Assessor

2.7 Any Body wishing to be recommended as a Technical Assessor may contact TOPAS at enquiries@topasgroup.org.uk 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.

3 TECHNICAL ASSESSMENT GUIDANCE

3.1 This section of the guidance is laid out to follow the order of process an application is expected to follow.

Readiness for Technical Assessment as described in TOPAS 0600.

3.2 Applicants prepare a Technical File as required by the TOPAS Specification(s) relied upon, and against which Product Registration is being sought, 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.

3.3 The Applicant will identify in their Declaration of Conformity those TOPAS Specifications (one or more) which their Product is intended to meet.

Variants

3.4 Applicants may include clearly identified variants of a Product in the same Application (using Appendix 1 of form T001). Where variants offer different levels of compliance against the specification, this shall be clearly identified in the Statement of Compliance and in Appendix 1.

3.5 Variants which have not been identified will not be covered under the registration.

3.6 Variant ranges which do not uniquely identify individual variants are not usually permitted, in particular those which may alter the functionality of the product and those which are not included within the stated permutations.

3.7 Where an Applicant's part referencing may lead to ambiguous variant references (for example 12345/XXX or A2347-???) the Applicant must provide a statement to specify the intention and limitation of the referencing system.

3.8 **Note** : Under TOPAS 0600 the addition of variants to an existing Registration may in certain circumstances constitute a new Application.

Evidence of compliance

3.9 Each TOPAS Specification includes an Appendix Z. This lists those items of supporting evidence that must be contained in the Technical File for that particular type of product.

3.10 References may also be made from the product specification to supporting specifications including TOPAS 2523 and TOPAS 2130 that define interfaces between equipment and environmental performance respectively.

3.11 Compliance with applicable legal requirements is a necessary precursor to the Applicant obtaining TOPAS Product Registration

3.12 For the avoidance of doubt the TOPAS process is additional to all those items legally required which includes, inter alia:

- Legally required certifications
- Any required non-governmental certifications that hold some right or license that you need eg Bluetooth, wifi, USB
- Optional certifications
- Certifications for which compliance is legally required but for which testing and certification are not required (eg ROHS, WEEE, REACH)

3.13 It is not part of the requirements of the Technical Assessment process that the Assessor undertake testing or other activities to obtain compliance on behalf of the Applicant. This is the Applicant's responsibility.

Dual Applications for the Same Product

3.14 More than one Applicant can seek Registration for a Product. Where an Applicant relies on the Technical File of another party, they shall provide evidence that they are permitted to use the file. If they are relying on the Registration of another party, they shall similarly demonstrate that they have permission to do so and that at the time of their Application the Technical File is still correct and valid.

Technical Assessment

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

1. The Technical File contains all those items identified in appendix Z of the specification(s) against which Registration is being sought.
2. All third-party test certificates are present and corresponding test house reports show that all tests have been passed.
3. All non-compliances with the applicable TOPAS specification(s) are identified, and described in the compliance matrix
4. All non-compliances with the applicable TOPAS specification(s) are referenced with the Declaration of Conformity on the Statement of Compliance Appendix 2 (non-conformance sheet).

3.16 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 explicitly for TOPAS but reports may be produced for the Applicant.

3.17 Where there is any concern, Technical Assessors and/or their clients should contact TOPAS at (enquiries@topasgroup.org.uk) for clarity.

Technical File Review

3.18 In review the Technical Assessor must satisfy themselves of the following:

- Completeness of the technical file.
- Completeness of the compliance matrix.
- Presence of all third-party test results as required by Appendix Z.

Technical Files Contents

3.19 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, and reports where required, are present, complete and indicate acceptable performance. It is for the applicant to ensure that test house has the appropriate and in date test certifications.

3.20 For documentary evidence developed and provided by the Applicant (non-third party) the Technical Assessor shall review the content of these items to satisfy themselves of completeness of the evidence and satisfactory outcome of testing or validation of the Product's performance and functionality.

3.21 Where the applicable Specification(s) identifies that third party testing is required then in-house testing by the Applicant is not acceptable. The test house(s) used shall not have any organisational relationship with the Applicant other than the contractual process for the undertaking of the testing.

Completeness of compliance statements

3.22 Technical Assessors should be alert to the presence of non-compliances or carefully worded caveats to compliance statements and where necessary seek further clarification from the Applicant.

3.23 Experience suggests that interpretation of Specifications and assertions of compliance are probably the part of Product Registration that most often leads to delays and dialogues. Technical Assessors are urged to check that Applicants have fully assimilated the specifications for which they are seeking Product Registration AND that Applicants are aware of the context in which their product will be used.

3.24 Applicants are not permitted to modify or disregard the requirements of the TOPAS specifications except as permitted within the Specification itself.

3.25 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.

3.26 Where there is concern regarding the terminology of the clauses within a specification the Technical Assessor should contact the TOPAS administrator via email in the first instance who will ensure the position is clarified.

3.27 Where a technical file contains caveats, exclusions of the applicable specifications against which product registration is being sought, documentary evidence of these must be clearly evidenced in the technical file and referenced in the Declaration of Conformity. The Technical Assessor shall confirm this as part of the signing off.

3.28 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 at (enquiries@topasgroup.org.uk) directly to resolve such matters prior to making their application.

The Statement of Compliance

3.29 The value of the clause-by-clause statement of compliance is that it assists the Technical Assessor in assuring that applicant has read, understood and implemented the requirements of the corresponding specification(s).

3.30 Some clauses may contain multiple requirements and where these occur in specification it is recommended that the Compliance Matrix breaks out each part of the requirement and affirms compliance separately.

3.31 Some clauses are optional, or the user may select one of several options. Where this situation arises the Applicant shall indicate the option or options that are provided, and for those options not being provided, shall say so.

3.32 Where a Product does not comply with a requirement, or where there is a choice of options under a requirement then the Applicant shall state in their compliance matrix that they are not compliant. The Applicant may indicate whether they provide an alternative implementation or functionality to achieve the intentions of the Specification.

3.33 In completing the compliance matrix it is important that the Applicant state what evidence they rely on to confirm compliance. A simple tick or cross will be insufficient.

3.34 Applicants may provide a multiple test list which incorporates several clauses of the TOPAS specification and which can be cross-referenced. They may also state evidence such as field testing etc, but documented evidence must be referenced in their technical file in accordance with the Appendix Z requirements.

3.35 A template compliance matrix (Form T006) can be found on the TOPAS website that technical assessors may encourage applicants to use.

Note. It is not the function of the technical assessor to verify any such evidence, merely to ensure that it is identified.

Evidence for Appendix Z

Sufficiency of compliance evidence

3.36 For the purposes of obtaining TOPAS registration, unless explicitly permitted by the relevant TOPAS specification, it is not sufficient for Applicants to rely on the testing or certification of third-party components (adapted or otherwise) used in the implementation of their Product. The Applicant shall demonstrate evidence that the final product to be registered, in its entirety, in its intended operating environment, meets the requirements of the applicable Specification(s).

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

3.38 TOPAS specifications provide a reference list which identifies required standards but this list is not exhaustive and any applicant must provide evidence of Declaration of conformity to any standards applicable, expressly including specific national annexes to those standards.

3.39 The TOPAS process is in addition to any UK legal requirements for the type of product being registered. Guidance on UK legislation is not given by TOPAS.

3.40 It is recommended that Technical Assessors are appraised of the UK legislation requirements required for the specific TOPAS specifications being assessed against.

Non-compliances

3.41 All non-compliances will be stated on the public TOPAS Register following successful application.

3.42 If non-compliance is related to legislation then the Applicant should be advised by the Technical Assessor that the Application will be rejected by TOPAS.

3.43 If non-compliance relates to requirements of the TOPAS specification, the Applicant and/or the Technical Assessor may wish to seek guidance from TOPAS prior to completion of the assessment process, particularly if the non-compliance is as a result of innovation or interpretation of specification content.

3.44 In the event of doubt Applicants and Technical Assessors should err on the side of caution and seek clarification from TOPAS.

Completion of the Technical Assessment

3.45 Once their Technical Assessment is complete, if the Technical Assessor is satisfied that the Technical File contains the relevant certification and evidence of compliance as above, the Technical Assessor may counter-sign the Declaration of Conformity and identify their unique Technical Assessment reference (see below).

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

3.47 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

3.48 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.

3.49 Where an Applicant requests Registration of a previously Registered Product to a new or different (second) Specification then the existing TOPAS Product registration Certificate will be useful evidence of compliance to those clauses in the first specification that appear unchanged in the second specification. However, the Application for the Registration against the second Specification will require a full Technical File for the second Application including a compliance matrix against the new specification. For example, the Registration of a product previously Registered to TOPAS2516 to TOPAS2541.

3.50 Should a Technical Assessor require clarity on any TOPAS specification then they should contact TOPAS via email to enquiries@topasgroup.org.uk.

Technical Assessors Unique Assessment Identifiers

3.51 Each revision of a Technical Assessment process is required to have the appropriate revision marking to ensure that no documentation is used erroneously by Applicants.

3.52 Where an application has been rejected by TOPAS then the requirement for further submission must include revised, re-numbered Declaration of Conformity by the Technical Assessor or a fresh document by a different Assessor to the original.

Feedback To TOPAS

3.53 As part of the process of improving and updating Specifications, Technical Assessors are encouraged to identify and report to TOPAS any requirement or clause in any TOPAS document that is ambiguous, or has been differently interpreted, or which is causing difficulties to more than one applicant.

3.54 Unless they are significant, where there are errors found in a published specification these will be noted for inclusion in future specification updates. It is the intention that the specifications are not updated too frequently.

3.55 Technical Assessors are advised to keep a watching brief on specifications that are under review and advise their customers accordingly. In some cases, the review may take some considerable time and it is a matter for the Applicant to determine whether they wish to wait. The TOPAS Board cannot advise on this but the applicant may wish to seek advice from experts in the field or from any working party engaged in the development of a specification (eg ARTSM WG4 members).

3.56 A meeting with the TOPAS Board for Technical Assessors to discuss issues will generally be scheduled annually but may at the requested by either a Technical Assessor or the TOPAS Board if there is a specific need.

Additional Services

3.57 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.

3.58 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, providing feedback to the Applicant through the process on the correct compilation of the Technical File. However, this is not explicitly required for the TOPAS role.

3.59 Technical Assessors are not permitted to undertake compilation of a Technical File on behalf of an Applicant if they intend to be the Technical Assessor for that Application.

4 TYPES OF SPECIFICATION

4.1 Some TOPAS Specifications apply to items that can be considered components or sub-assemblies and which are unlikely to be used alone, whereas others are specifications for entire systems.

4.2 As part of the Assessment process, Technical Assessors should therefore expect the compliance matrix to include references to all relevant TOPAS specifications identified, (e.g. to explicitly identify clause within any interface specifications, such as TOPAS 2523 and explicitly state compliance with those clauses).

4.3 Technical Assessors should be mindful of this contextual requirement during the assessment process.

5 BULLETINS FOR TECHNICAL ASSESSORS

4.4 TOPAS will issue bulletins to the technical assessors from time to time providing information relevant to specific requirements not covered elsewhere that need to be noted.

These will appear in a standard format as a single document.

End of Guidance

TOPAS Management Board

February 2022