

APPENDIX Z TECHNICAL FILE CONTENT

This appendix defines the necessary content for a Technical File (a collection of relevant documents) which must be reviewed by an appropriate Technical Assessor as part of the TOPAS Registration process (See TOPAS 0600).

Only the 'ticked' items are required to be present in a Technical File used to support TOPAS Registration against TOPAS 25***.

Ref	Item	Description	Required
1	Overview document	<p>A summary document outlining the product, specifying which TOPAS and other relevant specification(s) the product has been designed to comply with, together with a detailed table of contents for the Technical File.</p> <p>Where external certificates or documents are referred to these shall be included either:</p> <p>(a) within this overview document; or (b) supplied separately as part of this Technical File.</p>	✓
2	QA accreditation certificate(s)	A copy of the Quality Management Registration Certificates for the organisation applying for TOPAS Product Registration.	✓
3	Details of all required standards and regulations including CE/CA requirements that apply to the Product	<p>A list of all standards to be complied with.</p> <p>Including explicit CE/CA declarations of performance/conformity for those standards, including all certificates, shall be included in this Technical File.</p>	✓
4	A functional design description of the product	Title, document number, version and date of the overall System Design Document for the Product.	✓

5	Product part numbers	A list of top-level assembly part numbers and their issue states including all firmware / software part numbers and issues.	✓
6	Statement of Compliance (An example template can be found on the TOPAS website)	A clause-by-clause statement of compliance against TOPAS 25*** confirming compliance and/or listing caveats or deviations.	✓
7	Functional test procedures and results	A list of all functional test schedules and test result documents (by document number and issue) that substantiate the Statement of Compliance.	✓
8	BS EN 50293 EMC test procedures and results	(a) Title, document number, version and date of the EMC test performance requirement document. (b) Copies of the results of EMC testing undertaken by an appropriately qualified independent approved test house <u>must</u> be included in the Technical File.	✓
9	Optical test procedures and results required by this specification	(a) Title, document number, version and date of the optical test performance requirement document. (b) Copies of the results of optical testing undertaken by an appropriately qualified independent approved test house <u>must</u> be included in the Technical File.	
10	Environmental test results	(a) A list of relevant Environmental tests performance requirements defined in TOPAS 2130. (b) Copies of the results of the Environmental testing undertaken by an appropriately qualified independent approved test house <u>must</u> be included in the Technical File.	✓

11	Radio Equipment Regulations test results	<p>(a) A copy of the RER Declaration Of Conformity</p> <p>(b) Reference to the RER Technical Documentation for the product (by title, document number and version).</p> <p>(c) Copies of the results of radio testing, undertaken by an appropriately qualified independent approved test house <u>must</u> be included in the Technical File. The test results should be those identified in the RER Technical Documentation and should cover any specific IR2030 requirements for the type of radio used.</p> <p>(d) A copy of the Type Examination Certificate for radio equipment not covered by a Designated EN standard.</p>	
12	Primary Safety Test procedure and results	<p>For Traffic Control equipment:</p> <p>(a) The title, document number, version and date of the Primary Safety Test schedule.</p> <p>(b) A copy of the test results must be included as part of the Technical File.</p>	
13	Failure Mode Analysis	Title, document number, version and date of the product failure mode analysis requirements and results.	