

EC MODULE 'SH2' CHECK LIST

The following simple 'check list' of objective criteria that a Notified Body would look for when requested to assess a contracting entity under Module SH2 has been summarised from the EC Module and guidance which should be consulted for more detailed information.

Assessment Modules for Subsystems

SB Type Examination Type Examination Certificate (1) RS, CC, I	SG Unit Verification E CC (trackside) I M (fixed)	SH1 Full Quality Assurance Not used	SH2 Full Quality Assurance With Design Examination RS, E, CC, I, M
SD Production Quality Assurance RS, CC, O (DE), M (on-board) QS Approval (4) Certificate of EC Verification (6) EC Declaration of Verification	SF Product Verification RS, CC, M (on-board) Certificate of EC Verification (6) EC Declaration of Verification	QS Approval Certificate of EC Verification EC Declaration of Verification	Design Examination Report (3) QS Approval (4) Certificate of EC Verification (6) EC Declaration of Verification

What must an SH2 compliant system be capable of?

1. Identifying the Quality objectives and organisational structure of the organisation, as a whole and specifically the project organisation relating to the subsystem
2. Identifying the relevant manufacturing techniques, processes and systematic actions that will be used to produce a compliant subsystem.
3. Documenting the relevant Quality Control and Quality Assurance techniques, processes and systematic actions that will be used to ensure a compliant subsystem.
4. Examinations, Checks and Inspection
 - a. Documenting the examinations, checks and inspections that will be carried out before manufacture, assembly and installation, including periodicities. This applies both to product and services that will be used to produce a compliant subsystem.

- b. Documenting the examinations, checks and inspections that will be carried out during manufacture, assembly and installation, including periodicities. This applies both to product and services that will be used to produce a compliant subsystem.
 - c. Documenting the examinations, checks and inspections that will be carried out after manufacture, assembly and installation, including periodicities. This applies both to product and services that will be used to produce a compliant subsystem.
 - d. Examinations, checks and inspections shall cover all of the following stages:
 - i. Overall design
 - ii. Constituent assembly
 - iii. Subsystem integration and final assembly
 - iv. Test and commissioning
 - v. In service validation (where specified in TSI)
5. Documenting the quality records that will be kept to evidence a compliant subsystem, such as:
 - a. Inspection Reports
 - b. Test Data and Reports
 - c. Calibration data
 - d. Qualification reports (suppliers and product)
 - e. Personnel competency qualification
6. Document a system to identify the technical design specifications, including applicable ENs, that will be applied to produce a compliant subsystem design, including its management
7. Documenting a system to identify and justify the means of achieving a compliant subsystem design where ENs are not used, including its management.
8. Document the Design Control techniques, processes and systematic actions that will be used when designing the compliant subsystem.
9. Document the Design Verification techniques, processes and systematic actions that will be used when designing the compliant subsystem.
10. Document the methods used to monitor the achievement of the required design.
11. Document the methods used to monitor the achievement of subsystem compliance and quality during the production phase.
12. Document the methods used to monitor the effectiveness of the quality management system.
13. Document the responsibilities and powers of the management of the main contractor with regard to overall design and subsystem compliance and quality, including in particular the subsystem integration management.
14. Allowing permanent right of access to the locations of design, production workshops, stores and pre-fabrication areas, assembly areas, testing facilities and more general all premises which the Notified Body considers necessary for the successful completion of its surveillance activities.