GUIDANCE DOCUMENT

Checklist by the Approval Body concerning the handling of the factory production control aspects when

- preparing ETAG or CUAP
- writing and issuing ETA

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EUROPEAN ORGANISATION FOR TECHNICAL APPROVALS

Checklist by the Approval Body concerning the handling of the factory production control aspects when:

- **preparing ETAG or CUAP**
- **writing and issuing ETA:**
  - **specifying the tasks of the Manufacturer and the Notified Bodies involved in Attestation of Conformity**
  - **determining the characteristics of the product according to the performance of the production system and the consideration of the factory production control**

1 General remarks:

When the Manufacturer is CE marking his product, according to the CPD, article 13.3(a), it is assumed that the manufacturer is performing a factory production control (FPC) to make sure that the product does conform to the technical specification.
According to CPD and its Guidance Papers, this FPC is not an entire quality management system such as described in ISO 9001.

As a technical specification the ETA, its basis documents (ETAG or CUAP) and its supporting documents (control plan) shall state the requirements concerning production controls (including controls, tests,…) the Manufacturer or the Notified Bodies shall apply to demonstrate the product does conform to its specification and the correct system of attestation of conformity is applied.

During the instruction of an ETA request (when necessary, including CUAP preparation), **the Approval Body** shall wonder whether the manufacturer is able, through his production system (organisations, equipment, competence, factory production control) to warrant the reliability of the product characteristics that were announced and measured with the approval test programme.
Characteristic determination is accompanied by the determination of performance repetitiveness at the end of the manufacturing process and then by determination of the dispersion linked to the manufacturing process.
Furthermore, to write the technical specification, the Approval Body shall consider the existing organisation of the manufacturer to warrant the reliability of the product characteristics or to be specified as a complement to control and demonstrate the product characteristics by direct or indirect measurements.
For technical reasons (see ETA Format, § II.4.1 Manufacturing), the Approval Body performs a plant visit to consider the production system and the manufacturing process control performed by the Manufacturer, in order to determine the characteristic of the product and the requirements to demonstrate the production will conform to the technical specification and the correct AoC system is applied.
(In fact, that is concluded with the acceptance on the representativeness of the sample taken for the approval test programme compared to the whole production range (including the distribution of the production within the tolerances) on the one hand, and with acceptance on the FPC and specification of the tasks for the AoC on the other hand).
This task which is the responsibility of the Approval Body, could be done in cooperation with a Notified Body when he was designated by the manufacturer right in time in the ETA request instruction process; in that case, the Notified Body shall act on behalf of the Approval Body; intervention of the Notified Body may be combined with its AoC tasks.

Whatever the Attestation of Conformity level decided by the Commission is, with or without the involvement of a Notified Body, this FPC consideration has to be done by the Approval Body on the same bases. For fair competition between the manufacturers or/and the bodies, this task shall be harmonised within the Approval Bodies. The checklist is to be understood as a reminder (help) for the Approval bodies, nothing to "forget" in implementing the:

- Chapter 3: Evaluation of conformity and CE marking in the General format of the ETA for construction products /1/,
- Chapter 8: Attestation and evaluation of conformity in the ETAG /2/,
- Guideline for the ETA or Chapter 8: System for conformity attestation in Common understanding of assessment procedure (CUAP preparation) /3/.

2 Purpose of the checklist

The checklist

- is primarily to assist those involved in writing an ETAG/CUAP or an ETA
- agrees with the provisions of the CPD, Guidance Papers B and K and with the general rules of EOTA
- is a strong recommendation and not legally binding
- refers only to the determination of the characteristics of the product and to the AoC-system
- is for general use and should be reviewed by EOTA and elaborated further, amended or adapted to the special product under consideration
- should be taken by EOTA /Approval Bodies for reference when specifying the requirements linked to the determination of the characteristics of the product and to the AoC-system

3 Questions by the Approval Body (AB) when setting up an ETAG/CUAP/ETA for specifying the tasks for the Manufacturer and the Notified Bodies involved in AoC.

When preparing/specifying the requirements for the AoC-system, i.e. stating:

- the tasks of the Manufacturer and the involved Notified Bodies,
- the product properties and the relating product manufacturing basic process,
- the certificate of conformity (if any),
- the declaration of conformity,
- the CE marking accompanying information,

the following criteria should be considered by the Approval Body:

	General	**Comments**
1	Does the formulation of the system of conformity attestation complies with the wording of the mandate and/or with the wording of Annex III 2. CPD?	
2	Is the product described sufficiently[1] according to the general format of the ETA, ETAG guideline or CUAP preparation?	
	Questions to be considered concerning the tasks for the manufacturer (see table attached)	
3	Are the tasks for the manufacturer within the fpc specified sufficiently[1]? (all systems)	
4	Are the tasks for the manufacturer specified sufficiently[1] in the test and control plan? (all systems)	
5	Are the tasks for the manufacturer concerning the initial–type testing (ITT) specified sufficiently[1]? * (Systems 2, 2+ and 4)	
	Questions to be considered concerning the tasks for the approved bodies (see table attached)	
6	Are the tasks for the testing laboratory for the ITT specified	

	sufficiently[1]? (System 1, 1+, 3) *	
7	Are the tasks for the inspection body for initial inspection of factory and of fpc specified sufficiently[1]? (System 1, 1+, 2, 2+)	
8	Are the tasks for the inspection body for continuous surveillance, assessment and approval of fpc specified sufficiently[1]? (System 1, 1+, 2+)	
9	Are the tasks for the testing laboratory for audit–testing specified sufficiently[1]? (System 1+)	
10	Are the tasks for the certification body for product certification specified sufficiently[1]? (System 1, 1+)	
11	Are the tasks for the certification body for certification of fpc specified sufficiently[1]? (System 2, 2+)	

	In addition to the previous questions the following should be considered concerning the manufacture of kits /4/	
12	Is the product/kit/component concerning the manufacture specified sufficiently[1] in the kit ETA or by making reference to another ETA or hEN?	
	Questions to be considered concerning the CE marking /5/	
13	Are the information (reference to the technical specification, intended use, characteristics) to accompany the CE marking specified sufficiently[1]? (all systems)	

Note (1): "Sufficiently" means: The tasks of the Manufacturer and the NBs have to be specified in such a way that the fitness for use of the new products can be assessed that the works in which they are employed satisfy the essential requirements (article 4 CPD). The Approval Bodies must satisfy the requirements of the CPD and must be able to assess the fitness for use of the products (article 10 CPD). It is up to them to describe the tasks in relation to the characteristics of the product and its manufacturing process. In section 3.2 of the ETA, the tasks of the Manufacturer (3.2.1) and of the Notified Body (3.2.2) shall be laid down by reference to the control plan which is a (confidential) part of the ETA and has to be applied for the attestation of conformity and the CE–marking on the basis of the ETA (see table below: Example: Tasks for the manufacturer and the bodies involved in AoC).

Note (*): The resulting specification shall specify the test series and results that can be re-used by the Manufacturer or Notified Body as ITT from the Approval Body work (approval test programme).

Considering those 13 criteria in the FPC evaluation, the Approval Body shall focus on the following 7 major themes part of any quality organisation/system:

1- General organisation
2- Working and proof documentation
3- Production
4- Information to/from the market
5- Corrective action
6- Preventive action
7- Conclusion

3.1- Means
3.2- Incomings
3.3- Control or validation of processes
3.4- Control of non-conforming products
3.5- Preservation of products

In the following clause 4, those 7 major themes are detailed in concrete/practical questions the Approval Body should be able to answer getting the responses from the manufacturer's dossier and production processes visit and consideration.

3.1 Example: Tasks for the Manufacturer and the Notified Bodies involved in AoC

The tasks of the Manufacturer and the Notified bodies involved in AoC shall be described in details.
The detailed description of the tasks can be laid down in tables or annexes of the ETA or in the control plan which is (confidential) part of the ETA.

Tasks derived from the CPD		**Subject of the tasks** (type of control)	**Chapter of the ETAG/CUAP or ETA that refers to the tasks** (test, control and minimum frequency of control)	**FPC evaluation, organisation, competence, means, assessment**
tasks for the manufacturer	factory production control (all systems AoC)	characteristics in table xy and documentation, quality manual	control and testing procedure incl. frequency see chapter xy	see clause 4, questions referred to in column Q1
	testing of samples taken at the factory in accordance with a prescribed test plan (all systems AoC)	prescribed test plan table yx	Control and testing procedure incl. frequency see chapter xyz	see clause 4, questions referred to in column Q2
tasks for the notified inspection body	initial inspection of factory and of factory production control (systems AoC 1+, 1, 2+ or 2)	parameters that refer to relevant characteristics in table xyz		FPC see respective ETA
	continuous surveillance, assessment and approval of factory production control (systems AoC 1+, 1 or 2+)	parameters that refer to relevant characteristics in table xyz.	The frequency of continuous surveillance shall be according table abc	
tasks for the notified testing lab.	initial type testing/ audit–testing of samples taken at the factory (systems AoC 1+, 1 or 3)	parameters see table 123	testing procedure see chapter xyz , agreement and acceptance of the results	
Tasks for the notified certification body	Certification of the conformity of the product (systems AoC 1, 1+). Certification of FPC (systems AoC 2, 2+)			

4 Questions by the AB when determining the characteristics of the product according to the performance of the production system and the consideration of the factory production control

This task can be subdivided into two parts:
- organisation, competence and means (equipment, …) consideration,
- technical consideration (mastering of the production parameters that are influencing the characteristics of the product, tests and controls).

Therefore the Approval Body has to answer to the two main questions:

Q1) Is the Manufacturer able, through his production system (organisations, equipment, competence, factory production control) to warrant the reliability of the product characteristics?

Q2) If yes, what is existing or to be specified as a complement to control and demonstrate the characteristics of the product by direct or indirect measurements?

The second question should be considered taking into account the particular technical requirements of the European Standard or EOTA Guideline on such type of products.

The relation between the following sub-questions and the two main questions is detailed in columns three and four.
In column five is a reminder (Mem) whereas the item the question is referring to is “necessary” (item referred to in guidance paper B) or “alternative”. The wording “alternative” is to be understood as an alternative approach to a necessary item or as a voluntary additional way which are in both cases decided by the manufacturer as the most convenient to its production organisation. The following codification is used: N=Necessary, A=Alternative

Number	**Questions**	**Q1**	**Q2**	**Mem**	**Comments/Answers**
1	**General organisation**	**-**	**-**	**-**	**-**
1.1	For which product or product family an ETA request is introduced and a FPC is assessed?	X	-	N	
1.2	How long has this FPC been running?	X	-	A	
1.3	Is the manufacturer running a quality management system?	X	-	A	
1.4	Is that FPC part of this system?	X	-	A	
1.5	Is this quality management system certified? By who? When? … (see certificate)	X	-	A	
1.6	How is the production organised?	X	-	N	
1.6.1	How many plants are concerned?	X	-	N	
1.6.2	What are the main production processes?	X	-	N	
1.6.3	What is purchased or subcontracted: raw materials, elements, part of the product (kit), …? Who are the suppliers?	X	-	N	
1.6.4	How are the incoming products mastered? (incoming controls, conformity verifications, audits of suppliers, …)	X	-	A	
1.7	Has the manufacturer planned to modify something soon?	X	-	A	
1.8	Is production under top management surveillance and decision?	X	-	A	
1.9	Are responsibilities and authorities defined and known in the production?	X	-	A	

	(also, see 3.1.4)				
2	**Working and proof documentation**	**-**	**-**	**-**	**-**
2.1	Do the manufacturer works according to written prescribed procedures or instructions or drawings?	X	X	N	
2.2	Are those procedures updated, available, known and applied by the users?	X	X	N	
2.3	Is the application of these procedures adequately recorded?	X	X	N	
2.4	Are the FPC documents clearly identified, reviewed, controlled and approved according to a procedure prior to issue (initial or revision)?	X	X	A	
2.5	Are obsolete documents clearly identified and withdrawn to prevent any unintended use?	X	-	A	
2.6	Are production, verification, control, check and test adequately recorded to provide evidence of the application of the FPC and of the conformity of the product?	X	X	N	
2.7	Are the data checked before acceptance of the records?	X	X	N	
2.8	Do those records allow traceability of the product? (also, see 3.3.5)	X	-	N	
2.9	Are those records identified, stored, protected, kept, easily re-consultable and destroyed according to a described procedure?	X	-	A	
3	**Production**	**-**	**-**	**-**	**-**
3.1	**Means**	**-**	**-**	**-**	**-**
3.1.1	Did and does the manufacturer determine and does he provide and maintain the infrastructure needed to achieve conformity to product requirements? Infrastructure includes, as applicable: - buildings - workspace - associated utilities - process equipment (both hardware and software) including control or test equipment - supporting services (such as transport or communication)	X	X	A	
3.1.2	Did and does the manufacturer determine the necessary competence for personnel performing work affecting product conformity to product requirements?	X	X	A	
3.1.3	Does he provide training or take other actions to satisfy these needs? Does he evaluate the effectiveness of the actions taken?	X	X	A	
3.1.4	Does he ensure that its personnel are aware of the relevance and importance of their activities (their responsibilities) to contribute to the constant quality of the product?	X	X	A	
3.1.5	Does he maintain appropriate records of education, training, skills, experience and responsibilities understanding?	X	-	A	
3.2	**Incomings**	**-**	**-**	**-**	**-**
3.2.1	Did and does the manufacturer determine and does he purchase the incomings needed to achieve conformity to product requirements?	X	X	A	
3.2.2	Does the manufacturer use customer property provided for use or incorporation into the product?	X	X	A	

3.2.3	Does the purchasing information describe clearly and efficiently the product to be purchased, including where appropriate - requirements for approval of product, procedures, processes and equipment, (including intended verification arrangements and method of product release where the manufacturer or its customer intends to perform verification at the supplier's premises) - requirements for qualification of personnel, and - quality management system requirements?	X	X	A	
3.2.4	Does the manufacturer ensure the adequacy of specified purchase requirements prior to their communication to the supplier?	X	-	A	
3.2.5	Does the manufacturer ensure that purchased product conforms to specified purchase requirements?	X	X	A	
3.2.6	Are the type and extent of control applied to the supplier and the purchased product relevant to ensure its own product achieves conformity to product requirements?	X	X	A	
3.2.7	As a particular case, does the manufacturer evaluate and select suppliers based on their ability to supply product in accordance with the manufacturer's requirements? Are its established criteria relevant?	X	X	A	
3.2.8	Does the manufacturer record the results of evaluations and any necessary actions arising from the evaluation?	X	X	N	
3.3	**Control or validation of processes**	**-**	**-**	**-**	**-**
3.3.1	Does the manufacturer produce under controlled conditions: - are information describing the characteristics of the product available? - are work instructions available, as necessary? - are the used equipment suitable? - are monitoring and measuring devices available and used? (also, see 3.3.1.1) - are monitoring and measurements implemented? and, (also, see 3.3.1.2) - are release, delivery and post-delivery activities implemented?	X	X	N	
3.3.1.1	**Control of monitoring and measuring devices**	-	-	-	-
3.3.1.1.1	Did and does the manufacturer determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements?	X	X	N	
3.3.1.1.2	Does the manufacturer ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements?	X	X	N	
3.3.1.1.3	Where necessary to ensure valid result, are measuring equipment	X	X	N	

	a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) adjusted or re-adjusted as necessary; c) identified to enable the calibration status to be determined; d) safeguarded from adjustments that would invalidate the measurement result; e) protected from damage and deterioration during handling, maintenance and storage.				
3.3.1.1.4	Does the manufacturer assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements? How does the manufacturer take appropriate action on the equipment and any product affected?	X	X	N	
3.3.1.1.5	Does the manufacturer maintain records of the results of calibration and verification?	X	X	N	
3.3.1.1.6	When used in the monitoring and measurement of specified requirements, does the manufacturer confirm the ability of computer software to satisfy the intended application? Does the manufacturer undertake this prior to initial use and reconfirm as necessary?	X	X	N	
3.3.1.2	**Monitoring and measurement of products**	-	-	-	-
3.3.1.2.1	Does the manufacturer monitor and measure the characteristics of the product to verify that product requirements have been met? Does the manufacturer carry out this at appropriate stages of the product realisation process in accordance with the planned arrangements?	X	X	N	
3.3.1.2.2	Does the manufacturer maintain evidence of conformity with the acceptance criteria? Do records indicate the person(s) authorising release of product?	X	X	N	
3.3.1.2.3	Does the manufacturer prevent product release and service delivery proceeding before the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?	X	X	N	
3.3.2	Are any processes for production where the resulting output cannot be verified by subsequent monitoring or measurement validated? (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.) Does this validation demonstrate the ability of these processes to achieve planned results?	X	X	A	

	Did and does the manufacturer establish arrangements for these processes including, as applicable: a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.				
3.3.3	Where appropriate, does the manufacturer identify the product by suitable means throughout product realisation?	X	X	A	
3.3.4	Does the manufacturer identify the product status with respect to monitoring and measurement requirements?	X	X	A	
3.3.5	Is traceability a requirement for the product? Where traceability is a requirement, how does the manufacturer control and record the unique identification of the product?	X	X	N	
3.4	**Control of non-conforming products**	**-**	**-**	**-**	**-**
3.4.1	Does the manufacturer ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery? Are the controls and related responsibilities and authorities for dealing with non-conforming product defined in a documented procedure?	X	X	N	
3.4.2	Does the manufacturer deal with non-conforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application?	X	X	N	
3.4.3	Does the manufacturer maintain records of the nature of non-conformities and any subsequent actions taken (including concessions obtained)?	X	-	N	
3.4.4	When non-conforming product is corrected does the manufacturer subject it to re-verification to demonstrate conformity to the requirements?	X	X	N	
3.4.5	When non-conforming product is detected after delivery or use has started, does the manufacturer take action appropriate to the effects, or potential effects, of the non-conformity?	X	X	N	
3.5	**Preservation of products**	**-**	**-**	**-**	**-**
3.5.1	How does the manufacturer preserve the conformity of product during internal processing and delivery to the market?	X	X	N	
3.5.2	How does the manufacturer identify, handle, package, store and protect the product to preserve its conformity?	X	X	N	
3.5.3	Are constituent parts of the product concerned? How are they preserved?	X	X	N	
4	**Information to/from market**	**-**	**-**	**-**	**-**

4.1	How does the manufacturer determine and implement effective arrangements for communicating with the market in relation to product information: - CE marking? - and accompanying information including: - particular use conditions? - characteristics? - installation procedure?	X	X	N	
4.2	Does the manufacturer register and treat market complaints?	X	-	A	
5	**Corrective action**	**-**	**-**	**-**	**-**
5.1	Does the manufacturer take action to eliminate the cause of non-conformities in order to prevent recurrence?	X	-	A	
5.2	Does manufacturer ensure that corrective actions are appropriate to the effects of the non-conformities encountered?	X	-	A	
5.3	Does the manufacturer establish a documented procedure to define requirements for a) reviewing non-conformities (including customer complaints), b) determining the causes of non-conformities, c) evaluating the need for action to ensure that non-conformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken?	X	-	A	
6	**Preventive action**	**-**	**-**	**-**	**-**
6.1	Does the manufacturer determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence?	X	-	A	
6.2	Does the manufacturer ensure that preventive actions are appropriate to the effects of the potential problems?	X	-	A	
6.3	Does the manufacturer establish a documented procedure to define requirements for a) determining potential non-conformities and their causes, b) evaluating the need for action to prevent occurrence of non-conformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing preventive action taken?	X	-	A	
7	**Conclusion**	**-**	**-**	**-**	**-**
7.1	Is the system applied by the manufacturer able to prove to third party (Notified Body for example) that the product achieves conformity to product requirements?	X	X	N	

Annexe 1

Details to the questions in checklist clause 3

1 To avoid any confusion by creating other terms and wordings than specified in the CPD or in the mandate no deviations from the official documents are requested.

2 A "sufficient" description of the product comprises the
- technical definition of the construction product including form, range, composition, constituents, components, or compliance with a ‘defined technical specification’ as appropriate,
- intended use of the construction product by indicating works in which the product is to be incorporated, installed assembled as far as necessary to clarify the intended use,
- relevant characteristics of the construction product by listing all the parameters, where appropriate, its constituents which have to be evaluated because of their relevance for the fulfilment of the ER by the works.

3 The manufacturer is responsible for the conformity of the product with the ETA. Therefore his tasks shall be clearly specified by giving details on
- specification and verification of raw materials and constituents,
- the methods and the extend of his permanent internal control of production,
- the test methods to be carried out during manufacture,
- the type and minimum frequency of controls,
- verification and controls and their frequency to be carried out on the finished product.

4 The provisions for the fpc shall be laid down in the ETA or in a control plan to which the ETA makes reference. "Control plan" as a comprehensive term and part of fpc system, comprises the "further testing of samples taken at the factory by the manufacturer in accordance with a test plan" and the frequency of testing. The control plan shall deal with the permanent internal control of production to be exercised and documented by the manufacturer.

5 The ITT defines the performance of the product; results from the approval testing can be taken into account. Therefore it should be clarified for the manufacturer which from the results of the approval testing he may reuse and which must be imposed.

6 to 11

The provisions for the involvement of the notified bodies, depending on the Commission Decision on the AoC are to be applied to the construction product in the ETA itself or in the control plan to which the ETA makes reference. The tasks for the notified testing laboratory, inspection body and certification body depending on the required AoC system shall include
- the characteristics of the product to be tested, watched, assessed and certified,
- the type and the minimum frequency of testing, of inspections and of surveillance,
- the special conditions certification bodies have to consider for issuing the certificate of the product (systems 1, 1+) and the certification of the fpc (systems 2, 2+).

12 Taking into account that the kit ETA shall make provisions concerning the
- characteristics, performance levels (declared values or classes) and manufacture of the components,
- composition of the kit,
- assembly of the components to the assembled system and installation of the assembled system in the works,

the kit ETA shall lay down for each of the components the tasks of the respective component manufacturer (see document on “Provisions of kit ETAGs/CUAPs on the content of chapter “Attestation of conformity and CE marking” of kit ETAs, ref. TB 03/46/8.2.2).

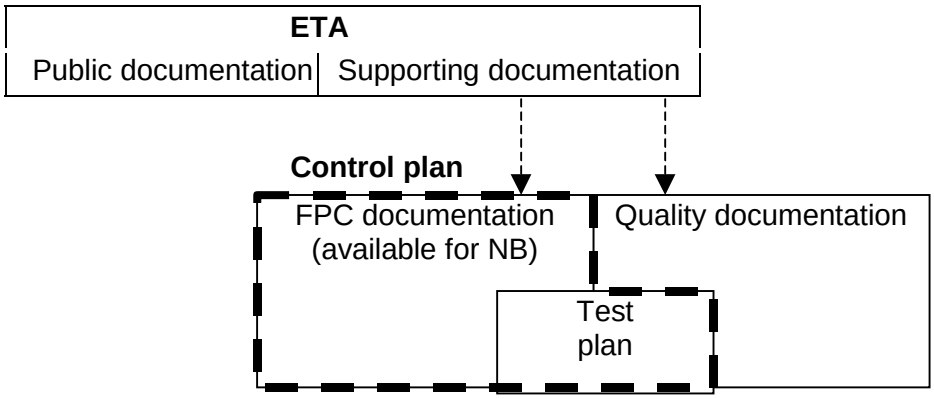
13 See Guidance Paper D

Understanding of the used terms:

"Control":
Type testing of samples, tasks within the fpc by the manufacturer and
type testing of samples, inspection, and continuous surveillance by the notified body.

"Control plan":
(Confidential) part of the ETA which describes the tasks for the manufacturer and the notified body if involved.

"Test plan":
Testing of samples taken at the factory by the manufacturer that may be planed by the manufacturer or further testing “prescribed test plan” (that means in addition to the initial fpc planed by the manufacturer) agreed between the approval body and the manufacturer to demonstrate the product does conform its technical specification.



(the Control plan describes the essential tasks of NB and Manufacturer)

References

/1/ General format of the European technical approval for construction products. Commission Decision of 22 July 1997 (97/571/EC)

/2/ Chapter 8: Attestation and evaluation of conformity in the ETAG, Guideline for the ETA. TB 01/39/12.1

/3/ Chapter 8: System for conformity attestation in common understanding of assessment procedure (CUAP preparation).

/4/ Reflection Note on provisions of kit ETAs with regard to the components and the AoC. TB 01/41/7.1.2, rev. 12.08.2002

/5/ CE marking under the CPD. Guidance Paper D

Annexe 2

Comments to the questions in checklist clause 4

Number	**Questions**	**Comments**
1	**General organisation**	**-**
1.1	For which product or product family an ETA request is introduced and a FPC is assessed?	Is it covered by the scope of an ETAG? In case of a kit, what are the components? Which ones are purchased or produced by the manufacturer?
1.5	Is this quality management system certified? By who? When? … (see certificate)	The answer to this question is just information to get more confidence that the FPC was running for several years, improved and is with a large probability efficient.
1.7	Has the manufacturer planned to modify something soon?	Starting the assessment, it is of interest to know if the manufacturer will modify its FPC and the reasons why.
1.9	Are responsibilities and authorities defined and known in the production? (also, see 3.1.4)	The FPC must be efficient. Therefore, responsibilities and authorities have to be designated at the right level and must be known by the production actors for adequate decision.
2	**Working and proof documentation**	**-**
2.4	Are the FPC documents clearly identified, reviewed, controlled and approved according to a procedure prior to issue (initial or revision)?	This question is a complement to 2.2
2.5	Are obsolete documents clearly identified and withdrawn to prevent any unintended use?	This question is a complement to 2.2
2.9	Are those records identified, stored, protected, kept, easily re-consultable and destroyed according to a described procedure?	This question is a complement to 2.8
3	**Production**	**-**
3.1	**Means**	**-**
3.1.1	Did and does the manufacturer determine and does he provide and maintain the infrastructure needed to achieve conformity to product requirements? Infrastructure includes, as applicable: - buildings - workspace - associated utilities - process equipment (both hardware and software) including control or test equipment - supporting services (such as transport or communication)	Considering the aspects under item 3 allows understanding and agreeing whereas the controls and tests performed by the manufacturer during the manufacturing process are adequate to insure the conformity of the product. Guidance paper B, §3.2.2, is promoting the approach where the conformity is demonstrated at different stages of production, but it is an alternative way to insure the conformity of the product. Controls and tests of the product in its final stage is the minimum approach that is required to insure this conformity. This question is in correlation with 2.1
3.1.2	Did and does the manufacturer determine the necessary competence for personnel performing work affecting product conformity to product requirements?	This question is in correlation with 2.1
3.1.3	Does he provide training or take other actions to satisfy these needs? Does he evaluate the effectiveness of the actions taken?	This question is a complement to 3.1.2
3.1.4	Does he ensure that its personnel are aware of the relevance and importance of their activities (their responsibilities) to contribute to the constant quality of the product?	This question is a complement to 3.1.2
3.1.5	Does he maintain appropriate records of education, training, skills, experience and responsibilities understanding?	This question is a complement to 3.1.2
3.2	**Incomings**	**-**
3.2.1	Did and does the manufacturer determine	Incomings consist of: incoming material, raw

	and does he purchase the incomings needed to achieve conformity to product requirements?	material, components, products, return of product or component after special treatment or transformation etc. They shall be treated as components (TB 01/41/7.1.2) This question is an alternative complement to 3.3.1.2.1
3.2.2	Does the manufacturer use customer property provided for use or incorporation into the product?	This question is an alternative complement to 3.3.1.2.1
3.2.3	Does the purchasing information describe clearly and efficiently the product to be purchased, including where appropriate - requirements for approval of product, procedures, processes and equipment, (including intended verification arrangements and method of product release where the manufacturer or its customer intends to perform verification at the supplier's premises) - requirements for qualification of personnel, and - quality management system requirements?	The manufacturer is responsible to decide the way he will control the incomings. This may include control of the incomings when delivered in its plant or control of the incomings by the supplier or any intermediate combination including audit of the supplier. To agree on the FPC or specify any requirement to the manufacturer or the notified body, it is of importance the AB knows the way the manufacturer is processing (questions 3.2.3 to 3.2.7). When important controls on incomings are performed by a supplier it might be a necessity the notified body has to inspect those controls. The contracts between the manufacturer and its supplier have to consider this inspection by the notified body. This question is a complement to 3.2.1 and 3.2.2
3.2.4	Does the manufacturer ensure the adequacy of specified purchase requirements prior to their communication to the supplier?	This question is a complement to 3.2.1 and 3.2.2
3.2.5	Does the manufacturer ensure that purchased product conforms to specified purchase requirements?	This question is a complement to 3.2.1 and 3.2.2
3.2.6	Are the type and extent of control applied to the supplier and the purchased product relevant to ensure its own product achieves conformity to product requirements?	This question is an alternative to 3.2.5
3.2.7	As a particular case, does the manufacturer evaluate and select suppliers based on their ability to supply product in accordance with the manufacturer's requirements? Are its established criteria relevant?	This question is a complement to 3.2.6
3.2.8	Does the manufacturer record the results of evaluations and any necessary actions arising from the evaluation?	Records are necessary when demonstration of the conformity of incomings is part of the demonstration of product conformity
3.3	**Control or validation of processes**	**-**
3.3.1.1	**Control of monitoring and measuring devices**	**-**
3.3.1.2	**Monitoring and measurement of products**	**-**
3.3.1.2.1	Does the manufacturer monitor and measure the characteristics of the product to verify that product requirements have been met? Does the manufacturer carry out this at appropriate stages of the product realisation process in accordance with the planned arrangements?	From guidance paper B: Depending on the specific case, it may be necessary to carry out: - the operations referred to under (1) and (2) - only the operations under (1) - only the operations under (2) (1): the controls and tests to be carried out during manufacture according to a frequency laid down. (2): the verifications and tests to be carried out on finished products according to a frequency which may be laid down in the technical specifications and adapted to the product and its conditions of manufacture.
3.3.1.2.3	Does the manufacturer prevent product release and service delivery proceeding before the planned arrangements have	CE marking of the product is to be considered as product release.

	been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?	
3.3.2	Are any processes for production where the resulting output cannot be verified by subsequent monitoring or measurement validated? (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.) Does this validation demonstrate the ability of these processes to achieve planned results? Did and does the manufacturer establish arrangements for these processes including, as applicable: a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.	This question is a complement to 3.3.1.2.2
3.3.3	Where appropriate, does the manufacturer identify the product by suitable means throughout product realisation?	This question is a complement to 3.3.1.2.2
3.3.4	Does the manufacturer identify the product status with respect to monitoring and measurement requirements?	This question is a complement to 3.3.1.2.2
3.3.5	Is traceability a requirement for the product? Where traceability is a requirement, how does the manufacturer control and record the unique identification of the product?	Traceability is a requirement for CE marking for products or batches
3.4	**Control of non-conforming products**	**-**
3.4.5	When non-conforming product is detected after delivery or use has started, does the manufacturer take action appropriate to the effects, or potential effects, of the non-conformity?	The manufacturer must inform customers
3.5	**Preservation of products**	**-**
3.5.1	How does the manufacturer preserve the conformity of product during internal processing and delivery to the market?	The product must be conformed to the technical specification, CE marking and declaration when it is delivered to the market
3.5.2	How does the manufacturer identify, handle, package, store and protect the product to preserve its conformity?	The product must be conformed to the technical specification, CE marking and declaration when it is delivered to the market
3.5.3	Are constituent parts of the product concerned? How are they preserved?	The constituents/product must be conformed to the technical specification, CE marking and declaration when it is delivered to the market
7	**Conclusion**	**-**
7.1	Is the system applied by the manufacturer able to prove to third party (Notified Body for example) that the product achieves conformity to product requirements?	Does the manufacturer apply adequately all tasks foreseen in this checklist to demonstrate the product conforms to product requirements?