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**BABT 731**      **A Guide to the Appointment of Certification  
Liaison Engineers**

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BABT is the Telecommunications  
Certification body of TÜV SÜD



## **Foreword**

This guide explains the process for the appointment of a Certification Liaison Engineer (CLE) to authorise changes to products.

This guide is designed so that the essential information can be read quickly by reading the main text only. Where you require more detailed information, refer to the shaded sections.

The appointment of a CLE with a given scope provides confidence that all Engineering changes have been reviewed to ensure the original external design considerations have been retained through the change.

The appointment of a CLE does not change the requirements of any certification scheme under which a product is certified; neither does it vary the formal requirements as set out in the BABT Certification Regulations. The current version of these may be found at [www.BABT.com](http://www.BABT.com).

All BABT publications are available from:

<http://www.babt.com>

(See the download area in *Information Services*)

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## 1. Introduction

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With very few exceptions all products are subject to changes within their supply lifetime.

The appointment of a Certification Liaison Engineer (CLE) provides confidence that all changes are reviewed by a suitably qualified person to ensure that the original design objectives (including Regulatory, Certification, and procurement imperatives) are retained after the change takes effect.

A CLE may be appointed from:

- A Design Company
- A manufacturing Company

A CLE may review changes to products subject to:

- BABT Certification including continuing compliance
- Regulatory approvals or constraints
- Specific design objectives

A CLE is able to assess a change and readily establish whether the change potentially alters the certified/controlled aspects of the product. Where the change is within his scope of appointment and the change does not potentially alter the certified/controlled aspects of the product the CLE may authorise such changes. Otherwise the CLE will address the potential change through the body appropriate for the product and once a change is approved by that body authorise the change into the manufacturing process.

### **Certification Liaison Engineer**

A Certification Liaison Engineer (CLE) is appointed with a scope of operation including particular products, certification and regulatory instances within a general competence. Additional products may be simply added where they are within his/her field of competence. Since a CLE is appointed within a given operational context using particular specified engineering change procedures, any changes to those procedures, or change in the position of the CLE within the company/corporate structure, must be authorised by BABT for the CLE appointment to continue.

A CLE appointment is not transferable between companies outside the same corporate (or group) structure.

### **Products with two or more Certificates**

BABT operate a number of different certification schemes (e.g. CNC, Safety and EMC). Where a product (or product range) is covered by more than one type of BABT certificate then each change must be assessed for its effect upon each certification instance. It is recommended that at least one CLE cover the all types of certificate to avoid the necessity for multiple authorisation

## 2. Overall CLE Appointment Process

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An application for appointment as a CLE should be made including information:

- Defining the proposed scope, product range, and certification/regulatory requirements over which the CLE will be active;
- Demonstrating the competence of the nominee to perform the task;
- Demonstrating that an engineering change process/procedure is in force which ensures all change is assessed by the nominee.

BABT will review the application and once satisfied will issue a Certificate of CLE appointment with a scope of activity.

## 3. Making the Application

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### 3.1 Who to apply to

The application may be made to BABT in Walton-on-Thames.

Applications will be accepted by email, or fax as alternatives to mail. On receipt of your application, we will generate and send you a confirmation of the application.

Email: [customer.services@babt.com](mailto:customer.services@babt.com)

See also [www.babt.com](http://www.babt.com) for copies of the CLE application information, general information and news on CLE appointments.

### 3.2 Who can apply

Applications should be made by personnel from either:

- A Design Company; or
- A manufacturing Company; or
- A company which both designs and manufactures products.

A company may nominate more than one CLE to operate on the same range of products provided each CLE demonstrates they meet the requirements for appointment. Where multiple CLEs may operate upon a given certified product the Engineering Change process/procedure should identify the normal scope of activity of each.

Note: It is recommended that where possible such applications be submitted together to enable review of the engineering change process to take place once, and any interviews to be conducted on one day.

#### Multiple CLEs

Where a certified product is subject to frequent change (e.g. leading edge technology, or complex apparatus) or where any avoidable delay (e.g. due to leaves of absence or resource shortages) in the implementation of a change needs to be eliminated then it is recommended that more than one CLE be nominated for each certified instance.

### 3.3 Where to obtain an application form

Document BABT 732 is the pro forma application form for CLE nomination. It will normally be easiest to use this pro forma but, if you find another format more convenient, this will be acceptable provided that it contains all the information set out in the following section.

### 3.4 Information required for an application

#### 3.4.1 About the Nominee

The following information should be supplied as a part of the initial application:

- Nominee's name, company name and address

#### Nominee

Although a CLE appointment is intended to operate as part of an engineering change procedure within an overall quality system, it is not normally expected that the CLE will be a quality engineer. There may be occasions where a particular quality engineer holds a suitable position and has the qualifications and experience to fulfil the role. Generally speaking, suitable people come from research, development or engineering departments because of the detailed, product-related technical knowledge required.

#### 3.4.2 Nominees Role and Experience

The following should be supplied as a part of the initial application:

- Brief CV (curriculum vitae or résumé) and/or training records demonstrating the technical training and experience of the nominee with respect to the types of certification to be covered;
- The nominee's current job description.

#### Training and Experience of the Nominee

The record should include statements of any academic or institute qualifications related to the areas of operation. Copies of Degree certificates etc are not normally required. Other training or experience information should be expressed in terms readily assimilated by the reviewing engineer.

BABT has no specific minimum requirements for qualifications and any qualifications are always considered together with relevant experience. It is unlikely, however, that anyone not holding a formal qualification in an electronic engineering discipline, or having less than five year's experience in the electronics industry with at least one year directly involved with radio or telecommunication terminal equipment, would be accepted.

### 3.4.3 Scope of operation

The following should be supplied as a part of the initial application:

- The type of company in which the CLE will function;
- List of general scope for which the nominee will operate;
- A list of Technology areas in which the CLE will operate (At least one must be selected.);
- List of the standards related to BABT Certification with which the nominee has access to and is experienced in.

#### Standards

This list should not normally be a simple rehearsal of immediate certified product standards but a wider understanding of standards applicable to the equipment. Note: This information will be verified during the appointment process.

### 3.4.4 Quality System Details

The following should be supplied as a part of the initial application:

- Where BABT have certified the quality system(e.g. ISO9001 or PQC) the BABT certificate number
- Where another Certification Body have certified the quality system then add details of the certificate number in the application form and include a copy of the current certificate and annex with the application
- A copy of the company's change control procedure/ or process; and
- A copy of all variants of change request/change authorisation documents; and

**Change request/Change Authorisation Documents:** It is recognised that while many companies operate a single document which evolves from request through authorisation, others have separate requests and authorisation documents, or streams of documents for different types of change. Consideration should be given to ensure hardware and software changes and/or enhancements and manufacturing short-term deviations are all included.

- Evidence that records of Engineering Change will be retained as required by each certification scheme.
- A copy of the organisation diagram showing the role of the CLE within the organisation.
- A copy of the documentation (or relevant extract from) which defines the scope of operation of the proposed CLE. This should include the Certification/regulatory requirements over which the CLE will be active and either a list of Products or a reference to such a controlled list.
- An audit schedule indicating that an audit to the requirements listed in Annex A of this document is scheduled within the next year;
- Where the CLE is not a member of design authority for any product within their scope a copy of the agreement between the design company and the company in which the CLE is active which defines the interface and responsibilities. ).
- Where the CLE is not a member of the company manufacturing any product within their scope a copy of the agreement between the manufacturing company and the company in which the CLE is active which defines the interface and responsibilities. ).

#### Audit

An audit to ensure the correct operation of the CLE process should occur at least once every 12 months. This may either be conducted as a part of an internal audit process or be included within the scope of an audit from an external body. (E.g. Where the company holds a PQC, or ISO9000 Certificate from BABT).

#### Position of the nominee within the company.

The details provided should demonstrate the position of the nominee within the engineering change process and that he/she has independence and freedom from undue pressure arising within the organisation which could influence the decision to approve or reject a change request.

### 3.4.5 Engineering Change Process Information

The following should be supplied as a part of the initial application:

- A copy of the company's change control procedure/ or process; and
- A copy of all variants of change request/change authorisation documents; and
- Evidence that records of Engineering Change will be retained as required by each certification scheme.

**Change request/Change Authorisation Documents:** It is recognised that while many companies operate a single document which evolves from request through authorisation, others have separate requests and authorisation documents, or streams of documents for different types of change. Consideration should be given to ensure hardware and software changes and/or enhancements and manufacturing short-term deviations are all included.

### 3.4.6 Additional Address Details

Only required where the invoice should be sent to another location, or where the Engineering Change records are held at an address other than that of the CLE nominee.

- Address where the engineering change records are held (this must be provided in those cases where this differs from the nominee's address).
- Name (or duty) and address for invoicing (completion of this is not required where invoices are to be sent to the nominee)

### 3.4.7 Recommendation and Agreement

The following should be supplied as a part of the initial application

1. **A signed recommendation** by a management representative senior to the nominee. This shall confirm the following confirmation:
  - That the nominee has sufficient working knowledge and understanding of all the standards relevant to the certification of the products within his/her scope, and will be provided by the company with all reasonable facilities to keep such knowledge up to date.

#### Management Representative

This person should normally be someone with an engineering background who is competent to assess the competence of the nominee to perform the duties required of the CLE.

For small companies or instances where an Engineering Manager is the nominee then the recommendation may be made at peer level.

- That the nominee will be provided with the organisational freedom and authority to perform the role of CLE.
- That the nominee (or another appointed CLE) will be consulted on all proposed changes to the products within their scope and will directly authorise without consultation with third parties those which are not related to the certification critical characteristics of the product and which do not potentially affect conformance to any of the relevant standards.
- That the nominee (or another appointed CLE) will only authorise changes which are related to the critical characteristics of the product or which do potentially affect conformance to any of the relevant standards after agreement by the appropriate body.
- That an accurate record of all considered changes will be kept and shall be available for inspection by BABT (or agents acting on behalf of BABT).

And

2. **A signed agreement by the nominee** to only operate within his/her defined scope and ensure that BABT is informed of any proposed changes outside his/her scope.

Where engineering change requests may be authorised by the nominee using initials rather than a full signature a copy of the usual signature used for authorisation should be included (otherwise the nominee's signature on the agreement will be considered definitive).

## 4. Progressing the Application

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### 4.1 General

The following processing stages are performed in the course of a CLE application:

- Initial Assessment of the application
- Documentary Assessment of supplied data
- Interview of Nominee

### 4.2 Initial Assessment of the application

On receipt of your application we will review it and respond with a confirmation of receipt of your order. An invoice for the application fee will be raised and sent to the identified address.

#### **Incomplete Applications**

You will be advised of any immediate shortfalls in your application with our confirmation of receipt of order.

In the unlikely event of there being insufficient information to confirm your order we will contact you immediately identifying the required information.

### 4.3 Documentary Assessment of the application

#### 4.3.1 Review of Technical Competence

The requested general scope of operation will be reviewed against the training and experience details of the nominee; the requested scope of activity; and the declared list of relevant standards.

BABT may request further supporting evidence as necessary.

#### 4.3.2 Review of Procedural Competence

The job description will be reviewed along with the details of the organisational position within the company of the nominee and recommending management representative.

Where the nominee is employed by a company which is not the titular holder of the relevant certificate(s), then the relationship between these companies will also be reviewed.

#### 4.3.3 Review of Engineering change process

The company change control process/procedure will be reviewed for adequacy to ensure any change to a certified product requires the nominee's formal authorisation. All formal documents within the change procedure/process should be under formal document control.

All documents authorising change to certified product will be inspected to ensure that the nominee (in the role of CLE) has a separate and required sign-off on all changes related to the certified product(s).

The audit schedule and, where relevant, the audit checklist will be reviewed to ensure the requirements for CLE operation are formally assessed within the audit program.

### 4.4 Interview of the nominee

#### 4.4.1 Initial Interview

The initial interview will normally take place either via phone or via an e-mail trail.

The nominee will be interviewed to demonstrate his or her understanding of the standards involved in the certifications and to demonstrate a broad understanding of potential certification-affecting changes.

The interview will be conducted by a technical expert either within BABT or appointed by BABT for this task.

Where BABT have prior knowledge of the applicant, or the CV clearly demonstrates experience in a similar role BABT may forego the requirement for this interview.

BABT may require further information, or a person to person interview subsequent to the initial interview.

#### 4.4.2 Person to person Interview

BABT reserves the right to require a person-to-person interview as a part of the appointment process. Where such interviews are held at a venue other than a BABT or BABT group location, an additional charge may be made and a separate invoice may be required to cover the necessary costs.

#### 4.5 Appointment as a CLE

The certificate of appointment as a CLE will normally be issued when BABT is satisfied that the CLE is able to operate within the required scope using the specified process/procedures.

The Certificate has a validity of three years subject to the holder complying with the certification regulations and paying the fees due to BABT. At the end of the three years the CLE appointment will be subject to a full review.

BABT may cancel the appointment of any CLE who acts contrary to the Certification regulations or does not pay the fees due to BABT.

You are entitled to make a formal representation to the Appeals Panel if you believe that you have been unjustly denied appointment, or had an existing appointment cancelled unfairly. In all cases, the decision of the Appeals Panel is final. Full details of the appeals procedure are given in the Certification Regulations.

### 5. Annual Continuation of the CLE appointment

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On an annual basis you are required to provide evidence with respect to the operation of the CLE within the requirements of this document.

The following information must be sent in writing to BABT (or presented to an agent of BABT on audit) by the anniversary of the appointment of the CLE:

- Summary list of all changes authorised by the CLE which need not involve the prior agreement of BABT; **and either**
  - An Audit report of the latest internal audit including the Engineering Change Process/Procedure and CLE operation; **or**
  - the date of the most recent audit visit by an Audit organisation authorised by BABT to include a CLE Audit within their audit program.

On receipt BABT will review the change descriptions and may ask for full details of specific changes to be provided.

Continuation of the CLE appointment is also subject to a satisfactory review of the decisions and payment of an annual continuation fee.

BABT reserves the right to require full details of all changes to be supplied and to repeat the CLE interview process. BABT may exercise this right at any time within a CLE appointment.

If you do not wish to continue operation as a CLE you should notify BABT, in writing, at least a month before the anniversary of the original appointment. You will not then be liable for the next continuation fee.

#### **Audits by BABT authorised organisations**

Where the CLE operates at an address which is visited for the purposes of a BABT quality system audit then it is recommended that the CLE audit is arranged to take place at the time of the quality system audit rather than the anniversary of appointment. Where you opt to take advantage of this option you should inform both BABT and your audit authority to ensure the necessary arrangements can be made. Where such an arrangement is made then the annual review may be aligned with the quality audit provided the time between CLE reviews does not exceed 12 months.

Note: The PQC scheme provides for this eventuality within the scheme and can readily accommodate the CLE audit.

#### **Internal Audit Personnel**

Where internal personnel are conducting an audit of the CLE function, they should be suitably qualified to assess both the procedural and technical aspects. A CLE however should not conduct an audit either of his/her own process or of another CLE operating any part of the same process as that for which they are themselves appointed.

**Audit Schedule and Checklists.**

Please refer to Annex A of this document for a summary statement of requirements which should form the basis of any internal Audit of a CLE. Furthermore a ready-made Audit Report (document BABT 733) is available which may be used to report back the findings of an audit of the CLE function.

## **6. Keeping your Appointment up to Date**

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### **6.1 General**

All changes which relate to the operation of the CLE should be advised to BABT in advance so the effect of them may be reviewed and appropriate action taken. The following sections list common types of change:

### **6.2 Change of CLE address or function**

Where a CLE changes address but remains with the same job description and reporting structure (e.g. Where a department relocates to another building) this will normally not affect the CLE function. However, where the CLE audit had been linked to another external quality audit of a particular location a change in address may cause this link to no longer be practical.

Where an individual appointed as a CLE has any significant change in function, a copy of the new job description and organisation chart should be sent to BABT for review. If an incompatibility of function is evident the appointment may have to be withdrawn.

### **6.3 Addition or removal of Certified Products**

Products within the general scope of CLE activity may be added or removed by submission of a written or e-mailed request. Where new standards are being used the request should confirm the CLE has access to and an understanding of the new standards.

Where all products within the scope of the CLE activity are cancelled, or removed from the scope of a particular CLE then the appointment will be suspended. At the annual review BABT will consider the status of the suspended CLE and may cancel the CLE appointment where there are no plans to include new or existing BABT certified products within his or her scope of operation.

### **6.4 Changes in the Engineering Change Process/Procedure**

All changes to the engineering change Process/procedure and supporting authorisation documents must be submitted to BABT for review and agreement prior to implementation.

## **7. Guidance on changes to Products and the application of a CLE**

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### **7.1 General**

Over the lifetime of a product understands that it is likely that you will want to make a number of changes.

#### **Review each change**

Whilst not all changes will be significant to the certification/regulation/design objectives for a product, each change, however small, must be considered for its potential effects and their relevance to the certification and conformance to the relevant standards

### **7.2 Authorisation of Changes to Certified Equipment**

#### **7.2.1 General**

Changes of different types are authorised by:

- BABT or  
a CLE or  
by another Body or  
by the design authority acting on their own responsibility

**Different categories of change**

Changes fall into the following broad categories

- Changes to product supporting items unrelated to the product certification or objectives. These include such items as packaging, warranty cards, cabling for non-certified ports
- Changes to aspects of the product covered by self-declaration outside the scope of the CLE
- Changes to the product which are believed not to have the potential to affect compliance to the requirements within the CLE scope
- Changes to the product which potentially affect the compliance to the requirements within the CLE scope which thus need testing
- Changes to extend the scope of the certification (which may or may not entail changes to the product)

**7.2.2 Changes to product supporting items unrelated to the certified product**

Frequently the scope of the product as defined on the certificate does not cover the whole supplied product. Packaging, information sheets, cables for uncertified ports, and adapters often form a part of the finished manufactured product but are not usually relevant to the certification. These are often not part of the product which is certified.

Such items are normally outside the scope of the certified product description are not subject to any external control.

**7.2.3 Changes to aspects of the product covered by self-declaration or other compliance schemes**

Where compliance to certain requirements has been demonstrated through a self-declaration and changes within that area of design do not impinge on an area within the activity of the CLE that type of change may be made without prior consultation with bodies listed in the CLE scope. For example, there are certain GSM requirements for which there is no agreed test method available.

Where the product has aspects of design necessary to comply with mandatory or optional requirements from other schemes, then changes within that area of design which do not impinge on an area listed within the CLE scope, may be made without reference to BABT.

**Regulatory requirements:** BABT Certificate holders are required to maintain compliance with regulatory and legal requirements pertaining to their certified products at all times

**7.2.4 Changes to the certified product which do *not* potentially affect conformity to the requirements within the CLE scope**

A CLE may assess changes which are within the scope of his/her authority using the change control procedure agreed at the time of his/her appointment as a CLE. The CLE may authorise the change without involving BABT, or other bodies.

**Modifications to embedded software**

BABT may accept modifications to software, which is stored in memory within the certified product, provided that you can give an assurance that the new version does not affect conformance to the relevant standards and is uniquely identified. If BABT determines that testing is necessary you will be advised.

**7.2.5 Changes to the certified product which potentially affect conformity to requirements covered by either a BABT certificate or regulation and need third party evaluation or testing**

For changes of this type BABT (or another interested regulatory body) must authorise the change to enable the certification to be maintained.

- **For changes to BABT Certified Product**

Where a change to the certified part of a product clearly requires testing full details of the changes (in duplicate) should be sent to a BABT recognised test laboratory with a copy of the covering letter (only) to BABT.

Where the need for test is in doubt or where the CLE has prepared a justification without test demonstrating that the product continues to conform to the certified requirements then full details of the

changes should be sent to BABT. BABT reserves the right to require that such changes be submitted to a test laboratory.

- **For changes to products covered by regulation**

The changes should be progressed by the means defined within the regulatory context of the product.

**When testing is required**, you should arrange with a BABT recognised test laboratory (or similar facility where this is prescribed by regulation) for samples of the equipment to be tested. The scope of BABT recognition of the test laboratory must include the standards relevant to your desired product certification (see the section on *Recognised Sources of Test Reports*). The test facility will determine what test work is necessary and will forward details to BABT. The test facility will send BABT its recommendations for testing and any relevant test results.

This test laboratory does not have to be the one which performed the original testing

BABT recognised laboratories are listed on BABT's web site at <http://www.babt.com>.

### 7.2.6 Changes to the certified product which extend the scope of the certification

Where you extend the functionality of the product to enable connection to another type of network interface, or create network interfaces designed to differing standards, then you should apply for an extension to the scope of certification/regulation within the rules applicable for that type of certification/regulation.

**For an extension to scope**, you additionally need to supply the test laboratory with two sets of documentation appropriate to the extension. These should include details of the new interface standards and supplementary information for addition to the Technical Documentation File. On completion of the testing the test facility will forward one set of documentation with the test report to BABT for evaluation.

### 7.2.7 Changes to Standards

When a standard is changed, the transition arrangements for equipment already certified may be set out in the standard in which case you should normally act in accordance with these arrangements.

However the CLE should seek clarification from the certifier and/or regulatory body to ensure that any mandatory transitional rules are applied correctly.

## 7.3 Any Other Changes

The CLE must notify BABT if any of the information to the certificate becomes out-of-date; for example:

- The name or address of the holder;
- the status of the quality assurance system certification in which the CLE operates;
- New products are added to the CLE scope; or Product names are changed;
- Design and Manufacturing sites which either cease one of these activities, or appoint alternative manufacturing sites.

The Certificate Holder should also notify BABT if any conditions on the certificate cease to apply directly to the certified product.

## **Annex A CLE Requirements**

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### **Annex A.1 Quality System Aspects**

1. The manufacturing company within which the CLE operates shall establish and maintain an engineering change process to control all changes to product within the scope of the CLE activity.
2. All documents required to maintain the Engineering change process (including Procedures) shall be under issue-control.
3. All issues of the engineering change process and documents including the CLE authorisation shall be agreed by BABT prior to implementation.
4. The effectiveness and operation of the engineering change process and the operation of the CLE shall be audited on an annual basis by one or more qualified persons who are not themselves appointed as CLEs.  
(Note: This may be through internal or external audit).
5. The audit report and corrective action plan for any non-conformances shall be forwarded to BABT by the auditing organisation in a timely manner.

### **Annex A.2 Source Data for the CLE**

1. The CLE shall have access to copies of relevant BABT certificates for products within his/her scope of appointment.
2. The CLE shall have access to copies of the standards listed in BABT certificates for products within his/her scope of appointment.
3. Where the CLE is active on products for which a Declaration of Conformity is required the CLE shall have access to either the relevant TCFs or equivalent documentation defining the conformity criteria to be maintain.

### **Annex A.3 CLE Qualification**

1. The current job description of the CLE must be presented to BABT.
2. The organisation structure with respect to the CLE must be agreed with BABT prior to implementation or modification.
3. The CLE shall be able to demonstrate an understanding of the significant aspects of the standards listed in the BABT Certificates for products within their scope.
4. The CLE shall be able to demonstrate knowledge of the design and functionality of the products within their scope of activity inasmuch as the design and functionality affects the compliance to the controlled requirements.

### **Annex A.4 CLE Scope and Interaction**

1. Where the CLE is not a member of the design authority of the product an agreement must exist between the design authority and the manufacturing company such that:
  - a. The design authority undertakes to provide the CLE with all relevant information to operate upon the products within their activity;
  - b. The design authority undertakes to focus of all changes to the product through the CLE;
  - c. The CLE undertakes to only make authorise changes identified by the design authority.

2. Where the CLE is not a member of the company manufacturing the product an agreement must exist between the design authority and the manufacturing company such that:
  - a. The design authority undertakes to provide the manufacturing company with copies of the signatures and scope of all CLEs active on products manufactured at their location;
  - b. The manufacturing company undertakes to only implement changes authorised by the identified CLEs.
3. Where the CLE operates on a product where a third party takes authority for a Declaration of Conformity; or a third party holds a BABT Certificate for that product then an agreement must exist defining the extent of the delegated authority given to the CLE by the third party company.
4. The CLE shall maintain a list of the products on which they are active. This list shall identify the following for each product:
  - a. The product identities;
  - b. Any BABT Certification involving continued compliance held by that product(e.g. CNC, or Safety Certification);
  - c. List of relevant EU Directives , or national legislation under which compliance must be maintained;
  - d. Who has design authority on the product.

#### **Annex A.5 Engineering Changes**

1. All engineering change requests for products with BABT Certificates involving continued compliance shall be submitted for agreement to either BABT or to an appropriately appointed CLE.
2. All engineering change requests for products requiring a Declaration of Conformity shall be submitted for agreement to either an appropriately appointed CLE, or to the person responsible for issuing the original Declaration of Conformity.
3. All engineering change requests for products requiring neither a Declaration of Conformity nor covered by a BABT Certificate involving continued compliance shall be submitted for agreement to either an appropriately appointed CLE, or to an appropriate person within the design authority.
4. The CLE shall review all changes for their potential effect on the compliance of the product with the requirements appropriate to their listing in the CLE scope document.
5. The CLE shall record the result of all reviews to the extent necessary to justify the decision.
6. The CLE shall only authorise changes which either do not potentially effect compliance to the requirements defined for the product, or which have been agreed directly by the appropriate authority.
7. Records of all Engineering changes with details of the authorisation or rejection of the change with a justification for each action must be retained for a minimum of 2 years. Where authorisation or rejection has resulted from a third party evaluation the records shall include details of such evaluations.

Note: Where more than one CLE has a product within his/her scope of operation it is recommended that common records be maintained.