Certification of explosives for civil uses by the Health and Safety Executive ((GB Explosives Notified Body (GB-ENB)) - Information Handbook.

Contents

[1. Background and Scope 3](#_Toc450032081)

[2. Reference documents 3](#_Toc450032082)

[3. Definitions 3](#_Toc450032083)

[4. Operation of GB-ENB as a Certification Body 4](#_Toc450032084)

[4.1 General 4](#_Toc450032085)

[4.2 Organisation of GB-ENB within the Health and Safety Executive. 4](#_Toc450032086)

[4.3 Personnel of GB-ENB 5](#_Toc450032087)

[4.4 Impartiality and Independence 6](#_Toc450032088)

[4.5 Quality Assurance 7](#_Toc450032089)

[4.5.1 Internal Quality audits 7](#_Toc450032090)

[4.5.2 External Audits 7](#_Toc450032091)

[4.5.3 GB-ENB Management Board 7](#_Toc450032092)

[4.5.4 GB-ENB Impartiality Group 7](#_Toc450032093)

[4.6 Documentation 8](#_Toc450032094)

[4.6.1 Records 8](#_Toc450032095)

[4.6.2 Confidentiality 8](#_Toc450032096)

[5. Procedure for Applying for Certification 8](#_Toc450032097)

[5.1 Information about the Procedure 8](#_Toc450032098)

[5.2 Application 9](#_Toc450032099)

[5.3 Responsibilities of the Applicant: 9](#_Toc450032100)

[5.4 Provision of a quote for assessment. 10](#_Toc450032101)

[6. Preparation of the Assessment 10](#_Toc450032102)

[7. Requirements of the Assessment 11](#_Toc450032103)

[7.1 Requirements for Module B Assessment 11](#_Toc450032104)

[7.2 Requirements for Module C2 Assessments 12](#_Toc450032105)

[7.3 Requirements for Module D or E Assessments 12](#_Toc450032106)

[7.3.1 Scope of audit 12](#_Toc450032107)

[7.3.2 Unannounced visits 13](#_Toc450032108)

[8. Additional information on the Assessment 13](#_Toc450032109)

[8.1 General 13](#_Toc450032110)

[8.2 Sub-Contracting 13](#_Toc450032111)

[8.2.1 Audit 14](#_Toc450032112)

[8.2.2 Testing 14](#_Toc450032113)

[9. Assessment/Audit Reports 14](#_Toc450032114)

[9.1 Assessment Reports [Module B -EC Type examination] 14](#_Toc450032115)

[9.2 Audit Reports 15](#_Toc450032116)

[10. Procedures for Granting, Maintenance, Extension or Withdrawal of Certification 15](#_Toc450032117)

[10.1 Certification Decision 15](#_Toc450032118)

[10.2 Changes to Scope 16](#_Toc450032119)

[10.3. Use of Certificates and Compliance Markings 16](#_Toc450032120)

[10.4 Misuse of Certification 17](#_Toc450032121)

[10.5 Stopping the use of a Certificate 18](#_Toc450032122)

[11. Appeals and Complaints about the Certification Process 18](#_Toc450032123)

[11.1 Appeals 18](#_Toc450032124)

[11.2 Complaints 18](#_Toc450032125)

[12 Contacts 19](#_Toc450032126)

# 1. Background and Scope

This handbook describes the policy provisions adopted by the GB-ENB to ensure conformity of its certification and audit activities with respect to Directive 2014/28/EU “Explosives for Civil Use (recast)”.

It provides a guide for Applicants seeking CE certification of their products, and states the Rules for Certification of Explosives for Civil Uses that must be followed prior to and during the certification process.

A summary of Applicants responsibilities is given in Annex A.

# 2. Reference documents

GB-ENB is accredited to European Standard ISO/EN 17065:2012 “Requirements for bodies certifying products, processes and services”.

GB-ENB complies with the requirements of document EA 2/17, EA (European Co-operation for Accreditation) “Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes”.

GB-ENB complies with the requirements of the UK Statutory Instrument No. 315 (The Explosive Regulations2014 (Amendment) Regulations 2016 (ERAR2016), which implements Directive 2014/28/EU in the UK.

GB-ENB follows the guidance in “The ‘Blue Guide’ on the implementation of EU product rules 2014”.

# 3. Definitions

This document contains certain terms and definitions, which are described in the following table:

| **Term** | **Definition** |
| --- | --- |
| Notified Body | A body that has been Notified in the European Union to carry out the work within the framework of European Directive 2014/28/EU (GB-ENB Notified Body ID number 0519). |
| Applicant | The organisation or client that submits products for CE certification. |
| Certification document | A document issued to the Applicant as the outcome of certification activity (EC type examination certificate, assessment decision, Approval to affix). |
| Certificate holder | The organisation or client having product certification that is currently valid. |
| Appeal | A request by an organisation to reconsider a decision previously made with respect to CE assessment. |
| Complaint | An expression of dissatisfaction, by an applicant or certificate holder, with services or price provided by the Notified Body. |
| Audit | A visit to the Applicant or their manufacturer(s) by the Notified Body (or their representatives) in order to obtain data from records, statements of fact or other relevant information to evaluate the compliance of specified manufacturing requirements. |
| Withdrawal | Revocation/cancellation of the certificate or attestation of conformity document. |
| ESR | Essential Safety Requirements detailed in Directive 2014/28/EU. |

# 4. Operation of GB-ENB as a Certification Body

## 4.1 General

The legal authority for GB-ENB to award CE certification is delegated from the Secretary of State for Work and Pensions in the UK, who recommends Notification to the European Union.

GB-ENB possesses considerable expertise in the CE certification of explosives under Directive 2014/28/EU. It achieves adherence to this Directive by implementing the requirements of the GB-ENB Quality Management System (QMS). The main objective of the QMS is to support high quality, efficient and effective certification services to applicants and certificate holders wishing to CE certify explosive substances and articles that are to be placed on the market within the European Union.

The Director of GB-ENB has overall responsibility for monitoring, implementing and maintaining the QMS and establishing the organisation required to facilitate accreditations.

Applications for CE certification of explosives are treated in a fair and equitable manner regardless of Applicant. The fees for such services are established on the basis of fixed rates and reflect the complexity of the activities involved. Fees are periodically reviewed by the GB-ENB Management Board. GB-ENB charges full economic costs to clients.

Applications for certification of an explosive article or substance will only be accepted if the Applicant can demonstrate that it complies with the ESRs detailed in Directive 2014/28/EU.

GB-ENB maintains listings of CE certifications. These are publically available via the GB-ENB website (www.hsl. gov.uk/explosives-notified-body).

## 4.2 Organisation of GB-ENB within the Health and Safety Executive.

GB ENB is based at the Health and Safety Executive (HSE) in Buxton. GB-ENB is a separate business entity to the wider activities of HSE in Buxton and has a distinct Management Board (internal to HSE), its own Quality Management System (QMS) and an external Impartiality Group. For the purposes of the directive, GB-ENB is considered to be a separate business entity due to the footnote to 4.1.1 of ISO/EN 17065:2012 (i.e. “A governmental certification body is deemed to be a legal entity on the basis of its governmental status”).

The GB ENB quality management system describes the organisation and structuring of the service.

Although GB-ENB operates under a distinct QMS, this adheres to HSE Buxton Quality Policy Statements (QPS) and follows the general structure of the overall HSE QMS systems as defined in HSE QMS procedure ‘Management, responsibilities for the quality management system’ (QPSC01).

As with all core business activities of the Health and Safety Executive, the certification and audit activities carried out by GB-ENB are self-insured according to UK government policy. GB-ENB or HSE Buxton neither offer nor warrant any indemnity or guarantee against loss or damage.

The following diagram demonstrates how the certification process is controlled.

HSE Buxton Quality Management System

GB-ENB Management Board GB-ENB Impartiality Group

GB-ENB Quality Management System

GB-ENB Rules for Certification of Explosive Articles for civil Uses

## 4.3 Personnel of GB-ENB

GB-ENB staff are employees of the Health and Safety Executive, a public body within the United Kingdom, and therefore personnel are independent of any pressure of a commercial or financial nature that may affect their judgement. Similarly, staff salaries are not dependent upon volumes of certification or financial results of the GB-ENB.

All certification procedures are non-discriminatory.

GB-ENB personnel are not designers, manufacturers or suppliers of explosives for civil uses.

Detailed information concerning the management, responsibilities and training of personnel are detailed in the GB-ENB QMS. The function of each staff member within GB-ENB is defined in the GB-ENB QMS along with records of qualifications.

All staff competencies are recorded according to the procedures required in the HSE Buxton QMS.

## 4.4 Impartiality and Independence

GB-ENB understands the importance of impartiality and potential conflicts of interest and operates a system of internal and external controls to ensure impartiality of operations and personnel associated with the provision of the certification service.

GB-ENB is responsible for all decisions relating to the granting, maintenance or withdrawal of certification. The other activities of the Health and Safety Executive do not affect in any way the confidentiality, objectivity or impartiality of the certification process.

To maintain impartiality, the activities of the GB-ENB are overseen by a distinct Independence Body (Impartiality Group) that is convened at HSE. Members of the Impartiality Group are selected and approved by the represented organisations. The membership of the Impartiality Group is selected from the various interested parties within the UK but with no single interest predominant. Where the Impartiality Group has concerns that are not adequately addressed by GB-ENB senior management, it can take appropriate independent action (e.g. raise issues with Industry Bodies, CBI etc.).

Separation of the activities of GB-ENB and the GB-ENB Impartiality Group ensures that the GB-ENB is free from any undue influence by any interested party who might wish to have a direct commercial interest in its activities. This separation allows the GB-ENB Impartiality Group to highlight any areas of concern relating to the impartiality of GB-ENB. Regular review of the impartiality of the activities of GB-ENB will be undertaken by the GB-ENB Impartiality Group.

GB-ENB staff are required to declare any potential conflicts of interest to the Director GB- ENB who will report them to the Impartiality Group, annually. If, at other times, any employee feels that a conflict of interest has arisen for themselves (or for any other employee within the GB-ENB) they must formally highlight this to the Director GB-ENB at the earliest opportunity. The Director GB-ENB shall undertake an investigation to review whether impartiality has been compromised during the period and take appropriate corrective action.

GB-ENB treats all applicants equally, independent of company location, size, history or contract value.

GB-ENB applies an impartial and uniform pricing policy for conducting its certification service in the field of explosives for civil use and does not favour any Applicant relative to any other. Further details of pricing policy are explained in Paragraph 5.4 of this Handbook.

GB-ENB does not provide services that are likely to compromise confidentiality, objectivity or impartiality of its certification-related decisions. GB-ENB provides explanation of the requirements of the relevant Standard or explanation of any findings during certification but does not provide any service that offers advice or expresses recommendations in the context of an evaluation of products that may be certified.

## 4.5 Quality Assurance

### 4.5.1 Internal Quality audits

GB-ENB has an established process for carrying out internal audits in accordance with the requirements of ISO17065 and the results are reported to the GB-ENB Management Board and reviewed by the GB-ENB Impartiality Group. A review of the overall effectiveness of the GB-ENB QMS is undertaken annually.

### 4.5.2 External Audits

HSE Buxton and GB-ENB are regularly audited for compliance against the requirements of ISO17065.

### 4.5.3 GB-ENB Management Board

The GB-ENB Management Board consists of selected HSE Buxton and HSE employees. The Terms of Reference of the GB-ENB Management Board are given in Annex B. The Board meets regularly, at least annually, and reviews:

* Management systems.
* Process performance and the general running of GB-ENB.
* Recommendations for improvement.
* Resource management.
* Financial management of the certification system.
* Contractual arrangements.
* Procedures and feedback from the Impartiality Group.
* The number of EC Type Certificates valid, newly issued or withdrawn.

### 4.5.4 GB-ENB Impartiality Group

The GB-ENB Impartiality Group consists of nominated members selected by recognised industry groups such as Explosive Industry Group and The Institute of Explosive Engineers, with the agreement of GB-ENB, and selected employees of HSE Buxton and HSE. The Terms of Reference for the GB-ENB Impartiality Group are given in Annex C. The Group meets regularly, at least annually, and reviews:

* External audit feedback.
* Customer feedback to safeguard openness and impartiality.
* Customer complaints.
* Management Systems.
* Mechanism for safeguarding impartiality.

## 4.6 Documentation

### 4.6.1 Records

GB-ENB has an effective and coordinated record system for all its activities, which is defined in the GB-ENB QMS. The records contain the following documents:

* Certificates;
* Approvals to Affix the CE mark;
* Certification reports;
* All relevant test data;
* Details of sub-contracts and work conducted;
* Records of Quality Module Inspections.

All records shall be retained and securely protected for 10 years as required by Directive 2014/28/EU and ERAR2016.

### 4.6.2 Confidentiality

Much of the information held by GB-ENB is classified as OFFICIAL based on UK Government security classifications (previously Commercial-in-Confidence) and has been made available by Applicants for certification purposes only. It will not be released without prior agreement. All files are stored with the necessary security precautions. Everyone working on the files is bound by the obligation of professional confidentiality. Any outcome (test results, photographs, reports) can only be disclosed to the Applicant or the relevant enforcing body unless under written permission of the Applicant.

GB-ENB may be required to provide information upon request to Ministry, Market Surveillance Authorities or to the EU where there is risk of endangerment of persons.

# 5. Procedure for Applying for Certification

## 5.1 Information about the Procedure

By submitting an application for certification and contracting with GB-ENB for certification services, the Applicant acknowledges that they have read this Handbook (together with any other relevant guidance notes or documentation provided on the GB-ENB website) and agrees to comply with its requirements and also fully assumes the associated responsibilities.

A list of current costs for routine activities is given in Annex D.

GB-ENB applies the procedure for evaluation and certification described by Directive 2014/28/EU. This consists of applying the appropriate Quality Modules (Module B to E as described in Annex III of the Directive) depending on the selected procedure for demonstrating continued conformity to the Directive.

The assessment is made with regard to the ESRs in Annex II of Directive 2014/28/EU. Compliance may be evaluated using the series of harmonised standards EN 13630, EN 13763, EN 13857 and EN 13939 relating to explosive products for civil use, however these standards are not mandatory. However, a product that complies with the harmonised standards is presumed to comply with the directive. Any other standards or test methods that GB-ENB considers demonstrate compliance with the ESRs can be used.

## 5.2 Application

The application form that is on the GB-ENB website [www.hsl.gov.uk/explosives-notified-body](http://www.hsl.gov.uk/explosives-notified-body)) should be completed. The application should at least include the following:

* The name and addresses of the Applicant and manufacturer(s).
* The commercial name of the product(s) to be certified.
* Drawings and any technical data sheets.
* A statement from the Applicant stating that the application has not been rejected/certified previously by GB-ENB or any other Explosives Notified Body.

GB-ENB will supply check lists specific to the explosive type to guide the Applicant on what tests and information is required.

When GB-ENB provides an estimate or quotation, or accepts an order for the evaluation of a product for CE certification, this does not imply that GB-ENB will issue such a certificate. Certificates will only be issued once the appropriate evidence has been supplied and reviewed, and the relevant requirements met.

Where the evidence supplied is insufficient for GB-ENB to provide a quotation, GB-ENB may return the application to the Applicant or, at our discretion, prepare a quotation based on assumptions that we will communicate back to you.

You may submit changes or additions at any time during the course of the work. GB-ENB will discuss the implications with the Applicant (cost, timescale, technical compliance etc.) and advise on the options available and how to proceed.

GB ENB aims for all projects to be completed to time and cost and to the satisfaction of the Applicant, however GB-ENB reserves the right to withdraw or abandon a project if:

* Within 6 months of the date of request of further information or samples, they are not received; or
* Designs or samples submitted are found to be non-compliant and revised designs or samples are not received within 6 months; or
* The accumulated time taken by the applicant to provide further information or samples or designs exceeds 6 months.

## 5.3 Responsibilities of the Applicant:

The main responsibilities of the Applicant are detailed in Annex A.

## 5.4 Provision of a quote for assessment.

GB-ENB conducts an initial assessment of each application for a set fee. This initial assessment examines technical evidence supplied and informs the Applicant of any additional information required and provides a full cost estimate to conduct the full assessment of the application.

Quotes are calculated from the time required to carry out the service based upon three types of examination:

* EC Type Examination (Module B): New applications, addition of similar products or technical changes to a certified product:
* Examination of Conformity to Type (Module C2): Audit or testing);
* Audit of certification according to Module D or E (paper assessment and audit visits).

In the specific case of EC Type examination, the time required for product evaluation depends upon:

* The complexity of the assessment of the product; and
* The data provided by the applicant (results of previous tests, similarity to products already certified).

For these reasons, and due to the large variety of explosives for civil uses, it is not possible to set standard prices for EC Type examinations.

In the event of unforeseen problems or expenses arising in the course of the certification process GB-ENB will inform you, and shall be entitled to charge additional fees to cover the extra time necessarily incurred to complete the service. Before additional charges are applied GB-ENB will write to you identifying the reasons for the additional charges.

# 6. Preparation of the Assessment

Once GB-ENB has agreed to the assessment, a member of GB-ENB will be assigned to it. GB-ENB will ensure that the assessor has the necessary qualifications to perform the assessment and that they are impartial and independent of any manufacturer.

The assessor’s remit will be to assess the application to the requirements for certification as defined by Directive 2014/28/EU Annex II and to provide explanations of the content of the Directive to the Applicant, if required.

The assessment will commence once an invoice raised against the quote has been paid by the Applicant.

For most products GB-ENB will endeavour to complete the assessment within 12 weeks of receipt of all the necessary information as requested in the supplied checklists. However, electronic initiation systems are particularly complex and require substantially more resource. Consequently, GB-ENB will indicate the assessment time period to the Applicant on a case by case basis.

# 7. Requirements of the Assessment

The assessment is performed in accordance with the requirements of Directive 2014/28/EU. The Figure below shows the modules used by GB-ENB to perform its assessments. The applicant must select Module B and one of the quality modules (Modules C2, D, and E). Applicants should note that failure to comply with the requirements of the associated quality modules will result in revocation of the EC Type Certificate.

[Note: Other modules are allowed under the Directive but are not supported by GB-ENB].



Figure demonstrating the Conformity Assessment procedures supported by GB-ENB

## 7.1 Requirements for Module B Assessment

Module B (EC Type Examination) is used to demonstrate that the product complies with the ESRs detailed in Annex II of Directive 2014/24/EU.

Compliance may be assessed by:

* Demonstrating that the explosive complies with the appropriate harmonised standard for explosive products for civil use (EN 13630, EN 13631, EN 13763, EN 13938 or EN 13938);
* Or by compliance with other standards or test methods that GB ENB considers are at least as rigorous as the harmonised standards and provide proof of conformity to the ESRs.

Any tests conducted to demonstrate compliance with the ESRs must either be:

Conducted by an ISO/IEC 17025 accredited test laboratory

**Or**

Conducted by the applicant in accordance with the requirements of ISO/IEC 17025. Selected tests would then be witnessed by GB-ENB staff to ensure compliance.

## 7.2 Requirements for Module C2 Assessments

Module C2 requires verification that the product complies with the Type certified during the Module B process. Generally, this is achieved by samples of product (that are representative of typical production) being tested.

GB-ENB requires these tests to be performed by an ISO/IEC 17025 test laboratory, or by the manufacturer in accordance with the requirements of ISO/IEC 17025 in the presence of a GB-ENB representative.

A selection of tests will be made to satisfy GB-ENB that supplied samples conform to the Type. Harmonised standards will be used in preference to other tests. Product testing will occur approximately every 2 years. This periodicity may be reviewed depending on the results of previous testing.

In some instances it may be impractical to test product samples. For example, the product may not perform as designed unless heavily confined (as in a borehole) or where specialist test equipment may be required. In such instances, GB-ENB will visit the production facilities to examine control of the final product, any in-production testing, to witness appropriate tests and review customer complaints. Where necessary, the Applicant will make available or ensure the availability of any specialist equipment and personnel necessary for the testing of the product.

Site visits will occur approximately every 2 years. This periodicity may be reviewed depending on the results of previous site visits.

## 7.3 Requirements for Module D or E Assessments

These modules require an audit visit to the manufacturer(s) or importer followed periodically by additional audit visits along with a yearly check of quality documentation.

### 7.3.1 Scope of audit

The first audit visit consists of:

An assessment of the existing Quality System of the manufacturer, if one exists;

An examination of the manufacturing process and associated facilities;

An inspection of the processes / documentation used to ensure that the product is manufactured in accordance with the Type certified;

An examination of procedures implemented by the manufacturer to ensure compliance with the requirements of Directive 2014/28/EU (markings, archival procedures, compliance statements and procedures for informing GB-ENB of changes to scope etc.).

Subsequent audits shall occur at regular intervals once the initial audit has been completed. These occur approximately every three years. This periodicity may be reviewed depending on the results of previous audits. The audits cover the same aspects as the initial audit but may concentrate on specific areas of production, particularly if concerns have been raised in previous audits.

In years where there is no audit visit then the manufacturer must demonstrate production/product assurance by providing the following evidence:

* A copy of a valid certificate of conformity to ISO 9001:2008 or equivalent standard audited by a third party.
* A copy of the contents list of the quality manual.
* A copy of any documents defining the scope of the quality system.
* A copy of the report of the most recent audit of the quality system by a third party.

The cost of this check is as stated in Annex D (listed as re-registration of a quality system). During audit visits this check will be carried out as part of the audit.

### 7.3.2 Unannounced visits

Unannounced audit visits may be performed by GB-ENB if there are concerns that there have been changes in manufacturing or monitoring rules, or that there is doubt over the conformity of a certified product, provided that verification cannot be achieved by other means.

# 8. Additional information on the Assessment

## 8.1 General

During the period of assessment, GB-ENB will only take instruction from the Applicant directly, unless expressly stated otherwise in writing by the Applicant in which circumstance GB-ENB may engage with manufacturer(s), importers or other organisations as authorised by the Applicant.

At the completion of an assessment project GB-ENB will normally either make samples available for collection by the Applicant or their representative, or arrange for sample destruction and disposal as agreed at the time of the application. The Applicant will be liable for any costs incurred in return or disposal.

## 8.2 Sub-Contracting

GB-ENB may need to sub-contract or outsource part of the certification evaluation process; this may be either auditing or testing.

### 8.2.1 Audit

The evaluation of a product is carried out by GB-ENB staff or conducted under their control; GB-ENB retains full responsibility for the evaluation and ensures that the certification decision is not outsourced.

GB-ENB ensures that the organisation to which the task has been subcontracted is both competent and impartial. The Applicant will be informed of the intention to subcontract and asked to confirm acceptance in case there may be a conflict of interest not identified by GB- ENB.

A formal subcontract is established with GB-ENB through the Commercial Support Team. The external subcontractor will be required to comply with the confidentiality and conflict of interest requirements of the GB-ENB.

### 8.2.2 Testing

GB-ENB may subcontract testing to check compliance with the ESRs. The subcontracted test-house or organisation will not themselves deem to be a Notified Body.

* Testing will only be subcontracted to a laboratory accredited with ISO/ IEC 17025. The only exceptions when examination or testing may be subcontracted to a non-accredited test house are where there is a short term peak in the work load, incapacitation or non-availability of key staff, or the malfunction of key equipment necessitates the use of a non-accredited test house.

Tests conducted by the client are not considered to have been sub-contracted, since GB-ENB staff witness selected tests and examine test facilities, test methods and results during regular auditing to ensure conformity.

# 9. Assessment/Audit Reports

CE assessment/audit reports are made and issued based on the information and samples provided by the Applicant/certificate holder, or on their behalf. They are responsible for the actions taken as a result of the assessment/audit report outcome. GB-ENB, our employees, agents or subcontractors, shall not be liable for any actions taken or not taken on the basis of such an assessment or audit report. Furthermore, GB-ENB will not be liable for any incorrect result arising from unclear, incomplete, misleading or false information provided to it.

## 9.1 Assessment Reports [Module B -EC Type examination]

Module B is used to demonstrate that the product complies with the ESRs detailed in Annex II of Directive 2014/28/EU. The report is internal to GB-ENB and is used to demonstrate what information GB-ENB has used in order to assess the product against Directive 2014/28/EU. The report includes:

* A description of the application;
* A description and identification of the relevant product(s);
* Details of the evaluation, referencing any test reports that have been used to check compliance;
* The conclusions of the assessor and their recommendation on whether to proceed to CE certification.
* GB-ENB may take into account tests of conformity undertaken by the Applicant or their manufacturers, as appropriate.

## 9.2 Audit Reports

These reports are produced to summarise the findings of an audit visit to a manufacturer in support of Modules C2, D or E, as appropriate. They include:

* A reference to the CE certificate to which the report relates;
* An evaluation of the quality system (if applicable);
* The observations made during the audit;
* A summary of the conditions and methods for manufacturing and monitoring production;
* An evaluation of compliance to requirements specific to Directive 2014/28/EU (markings, archiving);
* A summary of corrective actions / observations and associated agreed completion dates (where applicable);
* A statement, based on the audit evidence, confirming whether or not the CE certification can continue.

Following the first audit to a manufacturer, subsequent audits include similar items but may place greater or lesser emphasis on certain aspects depending on factors such as:

* Performance at previous audits;
* Complaints or safety concerns from customers/market surveillance authorities.

# 10. Procedures for Granting, Maintenance, Extension or Withdrawal of Certification

The procedures for granting, maintenance, extension or withdrawal of certification are defined under the terms of Directive 2014/28/EU.

## 10.1 Certification Decision

The certification decision is recommended by the GB-ENB assessor in the Module B assessment report on the basis of the evidence presented. The recommendation is then verified by appropriate GB-ENB staff based on the Module B assessment report, the initial audit report for the quality module (Module C2, D or E), and associated evidence.

The certification decision may be revised in the event of an appeal by the Applicant.

GB-ENB publishes a list of products and companies that have been CE certified by them. By successfully completing the certification process the Applicant agrees to this public declaration. In addition, provided that GB-ENB informs the Applicant first, the Applicant agrees to GB-ENB passing information to appropriate government organisations where there are concerns over the safety of the product.

## 10.2 Changes to Scope

The Applicant is required to inform GB-ENB of any modifications to the product or the manufacturing process or the quality system that is likely to affect the conformity of the product. Where GB-ENB becomes aware of breaches in this regard it will take appropriate action, which may include unscheduled audit visits. The certificate holder will be liable for any costs incurred.

A list of current costs for routine activities is given in Annex B.

## 10.3. Use of Certificates and Compliance Markings

GB-ENB will not commence any certification work or audit assessments until all fees and costs associated with the certification have been paid and received.

The company holding the CE certificate may make reference to it in their own documentation and use the CE mark as long as there is no risk of confusion with non-certified products. Any contravention of this requirement may lead to prosecution for fraud or misrepresentation.

The company holding the CE certificate shall facilitate GB-ENB in their tasks related to certification, particularly the organisation and conduct of audits and testing.

The certificate holder must:

* Keep a record of all complaints they receive relating to the compliance of the product with CE certification;
* Make the records available to GB-ENB on request;
* Take appropriate measures in response to complaints on certified products;
* Document the actions taken to address the complaint.

It is the responsibility of the company holding the certificate to ensure that their products comply with regulations specific to the product. CE certification does not replace this obligation. Consequently, the company holding the CE certification remains liable for any deficiencies and defects related to their products.

CE certification in no way infers a warranty, which shall remain the responsibility of the CE certificate holder.

Receipt of CE certification from GB-ENB by the Applicant does not transfer the responsibilities and liabilities of the Applicant to GB-ENB.

Any subsequent modification that the Applicant may want to make to the product shall be subject to an application to GB-ENB for amendment to the existing certificate.

Any modifications to the systems or quality assurance processes that may have an impact on the performance or safety of the certified product must be communicated to GB-ENB in writing, so that a decision concerning the right to use the certificate and CE mark can be made.

Certificates are strictly non-transferrable.

Copies of certification documents to others shall be reproduced in their entirety.

In the event of a merger, liquidation, conversion or absorption of a company holding certification issued by GB-ENB, the new company must notify GB-ENB of the changes.

Where the use of a CE certificate is discontinued, the company must inform GB-ENB immediately.

## 10.4 Misuse of Certification

Certification documentation issued by GB-ENB may be withdrawn in the following circumstances:

GB-ENB may withdraw a certificate if:

* The certificate should not have been issued (either through false information provided to GB- ENB or through our own error);
* The CE logo is being used inappropriately;
* The Applicant requests its withdrawal;
* The documentation is being used inappropriately;
* The product being manufactured no longer corresponds to the product certified;
* As a result of market surveillance findings with the European Union.
* If GB-ENB can no longer contact the company as it has been found to be no longer trading

GB-ENB may withdraw an Approval to affix the CE Mark if:

* The quality system no longer controls production sufficiently to allow confidence in the conformity of the product being manufactured;
* Examination of the product under the chosen Quality Module has shown that the product does not conform to the type or does not satisfy the requirements of the Statutory Instrument.
* The Applicant does not continue to follow the Rules for certification of explosives for civil uses at GB-ENB guidelines and responsibilities as presented in this handbook or on the GB-ENB website.
* At the request of an applicant as he no longer manufactures the product at that time

Prior to any decision relating to withdrawal of an EC Type Certificate or Approval to Affix the CE Mark during the monitoring and review process the testing and/or audit report will be communicated to the certificate holder with a letter of explanation. This will also apply if an Applicant has been found to contravene the rules of certification or been found to have misused a Certificate.

Depending on the seriousness and frequency of the deficiencies the following sanctions may be implemented:

* Written warning of infringement and requirement for remedial action within a specified time period;
* Written warning of infringement and unannounced audit;
* Withdrawal of certification for the product.

Once a certificate or Approval to Affix has been withdrawn, GB-ENB will notify other authorities by publicising this on the GB-ENB website.

## 10.5 Stopping the use of a Certificate

Once GB-ENB has made the decision to withdraw the use of certification documentation GB- ENB will notify the applicant of their decision by traceable means. Within 14 days of receipt of the notification the applicant must:

* Stop all references to the certificate;
* Stop the use of documents in paper or electronic format, which display the CE certification logo;
* Refrain from making statements that are liable to be misleading with regard to their situation regarding certification;
* Stop the use of the certification mark on manufactured products;
* Remove the product(s) from the European market.

# 11. Appeals and Complaints about the Certification Process

## 11.1 Appeals

GB-ENB has an effective and fair appeals procedure detailed in the QMS. When an Applicant or holder of an EC Type Certificate wishes to appeal a certification decision then this should be in writing within 10 working days of receiving the decision. Upon receipt of an appeal the Impartiality Group appoints an appeals committee consisting of a chairman and two other members. GB-ENB staff cannot be appointed to this committee. A written report is provided by the committee after consideration of the appeal. The Director of GB-ENB sends the report to the Applicant within 10 working days.

## 11.2 Complaints

A complaint is regarded as any expressed dissatisfaction from any party with respect to any aspect of the operation of GB-ENB and should be made in writing. All complaints received by GB-ENB are recorded, investigated and reported on in accordance with the HSE Buxton QMS. All complaints and corrective actions will be reported to the GB-ENB internal Management Board and the Impartiality Group.

# 12 Contacts

HEALTH AND SAFETY EXECUTIVE (GB-ENB):

Health and Safety Executive,

(GB Explosives Notified Body),
Health and Safety Executive,
Room C1.06
Harpur Hill,

Buxton
Derbyshire,

SK17 9JN

UK

Email: enb@hsl.gsi.gov.uk

Website: [www.hsl.gov.uk/explosives-notified-body](http://www.hsl.gov.uk/explosives-notified-body)

HSE UK Enforcing Authority Website: http://www.hse.gov.uk/

CBI Website: news.cbi.org.uk

IExpE Website: iexpe.org

**Annex A**

**Summary of Applicant Responsibilities**

The main responsibilities of the applicant are:

Prior to certification

* To note that payment for any service by GB-ENB must be paid for before any work can commence;
* To supply in a timely manner such information, drawings, samples and facilities that GB-ENB consider necessary to perform their work to an agreed schedule;
* To confirm that the information given is correct and that no application to any other Notified Body has been made for the assessment of the product.
* To confirm that you are in full possession of all necessary intellectual property rights on the product;
* To ensure that all technical documentation and drawings supplied to GB-ENB are uniquely identified and dated;
* To note that changes or additions may be made during the course of the assessment work. GB-ENB will discuss the implications of the change with the applicant in terms of cost, timescale or technical compliance and advise on the options on how to proceed;
* To confirm that they are in full possession of all necessary intellectual property rights on the product.

Once an EC Type Certificate has been awarded

* GB-ENB must be informed of any modifications to these products or if there is a need to change the information on the certificates (e.g. company name);
* Where the CE certificate relates to an activity performed at a particular location (e.g. manufacturing or applicant address), the applicant will notify GB-ENB of any change of location, or the inclusion of additional locations, so that appropriate measures can be taken;
* GB-ENB must also be informed if the quality system is changed so that the products no longer fall within its scope, or if there is a need to change the module for demonstrating the conformity of the production to the type;
* The Certificate holder must note that failure to comply with the requirements of the associated quality modules (C2, D or E) will result in revocation of the EC Type Certificate.
* To use the CE mark only in the way described in Directive 2014/28/EU. In particular, on marketing and publicity documentation you will not represent the mark as your property. You will immediately discontinue any use of the CE mark that is unacceptable to GB-ENB.
* Copies of certification documents to others shall be reproduced in their entirety.
* The Certificate holder should Keep a record of all complaints they receive relating to the compliance of the product with CE certification;
* The Certificate holder should make records of complaints available to GB-ENB on request;
* The Certificate holder should take appropriate measures in response to complaints on certified products;
* The Certificate holder should document the actions taken to address the complaint.
* Within 14 days of receipt of a notification to withdraw certification the applicant must:
	+ Stop all references to the certificate;
	+ Stop the use of documents in paper or electronic format, which display the CE certification logo;
	+ Refrain from making statements that are liable to be misleading with regard to their situation regarding certification;
	+ Stop the use of the certification mark on manufactured products;
	+ Remove the product(s) from the European market.

**Annex B**

**GB-ENB Management Board – Terms of Reference**

1. To oversee the formulation and the implementation of policies relating to the operation of the GB-ENB so as to improve efficiency, and safeguard its independence and impartiality.
2. To supervise the finances of the GB-ENB and the pricing of the services offered by the GB- ENB.
3. To ensure that contractual arrangements are regularly reviewed, and amended as appropriate.
4. To review the number of EC Type certificates valid, newly issued or withdrawn and future levels of demand for certification, in order to arrange adequate resource to maintain an acceptable service. To review the procedures for handling the work of the GB-ENB, consider feedback from the Impartiality Group and make decisions on certificates in order to seek improvements from the GB-ENB and from applicants so as to achieve impartiality and an acceptable delivery time for certificates.
5. To consider recommendations and agree improvement actions from the annual reviews of the GB-ENB QMS (internal and 3rd party).
6. To delegate authority to committees/personnel to undertake defined activities, as required.
7. To set up appeals committees as required, to receive reports of these committees and to take the appropriate actions.
8. Review the competencies of GB-ENB personnel to ensure these correspond with the requirements of the business.
9. To approve interested parties to attend the GB-ENB Impartiality Group, in conjunction with the Certification Authority.

**Annex C**

**Version 2 (16 Aug 2017)**

**GB-ENB Impartiality Group – Terms of Reference**

1. Role

The main purpose of the Impartiality Group is to ensure that GB-ENB is free from any undue influence from any interested party by review of GB-ENBs procedures and the outcome of management and audit reports.

1. Membership

Representation on the GB-ENB Impartiality Group will be by agreement with the existing membership. Representation should encompass all major sectors of explosive manufacture in the UK with no one sector predominant.

1. Voting rights

Each represented organisation has one vote.

1. Management
	* 1. The Chairman is elected by those eligible to vote.
		2. Members of the Impartiality Group recommend to the GB-ENB Management Board relevant interested parties to attend the GB-ENB Impartiality Group.
		3. Where impartiality/independence issues are not considered to be adequately addressed by the GB-ENB Internal Management Board, the Impartiality Group may take independent action (notification to accreditation body or certification authority). The Impartiality Group shall ensure that client confidentiality is respected.
		4. Decisions emerging from documents and issues presented at the Impartiality Group should be made in a cooperative manner by mutual agreement. Voting is not the preferred option and should only be used when an agreement cannot otherwise be reached.
		5. Minutes are drafted under the responsibility of the Chairman. A first draft should be issued within 6 weeks of the meeting.
		6. Meetings are held at least annually. At the request of members, additional meetings can be organised.
2. Standing Agenda
	* 1. The agenda should consider, as a minimum the following:
		2. A review of the previous Impartiality Group minutes
		3. A review of the summary report from the previous Internal Management Board meeting to:
		4. Consider the formulation and the implementation of policies relating to the operation of the GB-ENB.
		5. Review resolved complaints since the last Internal Management Board meeting consider unresolved complaints and recommend appropriate actions if these have not been resolved using HSE Buxton internal procedures.
		6. Review GB-ENB staff Impartiality Declarations for instances of ‘conflict of interest’.
		7. Review responses from GB-ENB customer feedback requests to demonstrate openness and impartiality.
		8. Review actions from the annual GB-ENB QMS reviews (internal and 3rd party), particularly where these affect independence or impartiality.
3. Outputs

To produce a record of the activities of the Impartiality Group meeting for submission to the GB-ENB Internal Management Board.

**Annex D**

**GB-ENB Current Standard Prices**

The following prices are for use with most explosives applications. However, they are not applicable for Electronic initiating systems. Due to their complexity the price for the activities detailed in the Table will be considered on an individual basis.

|  |  |
| --- | --- |
| **Item** | **Cost (£)** |
| Initial Assessment | 1272(1) + VAT |
| Addition of a manufacturing site | 1159 + VAT |
| Registration of a Quality System | 680 + VAT |
| Re-registration of a Quality System | 680 + VAT |
| Registration/re-registration of a Quality System for an additional site of manufacture (cost per site) | 451 + VAT |
| Change of product name/withdrawal of a product | 519 + VAT |
| Change of company name | 519 + VAT |
| Change of certificate holder | 519 + VAT |
| Assessment of Technical changes to a CE marked product | Price dependent upon complexity of change  |
| Assessment of similar products for addition to a certificate | Price dependent upon number of products and degree of similarity to existing CE marked products |
| Quality Module Audit |
| All modules: contract set up/visit preparation | 1324 + VAT |
| Cost of full day Module D and E audit | 4247(2) + VAT |
| Cost of Module C2 visit or testing | Price on application |
| Notes: |  |  |
|  | 1. | Includes an estimate for the full assessment. |
|  | 2. | A half day audit will be charged pro rata. In addition to the audit cost, the company will be charged for travel, travel time and subsistence. |