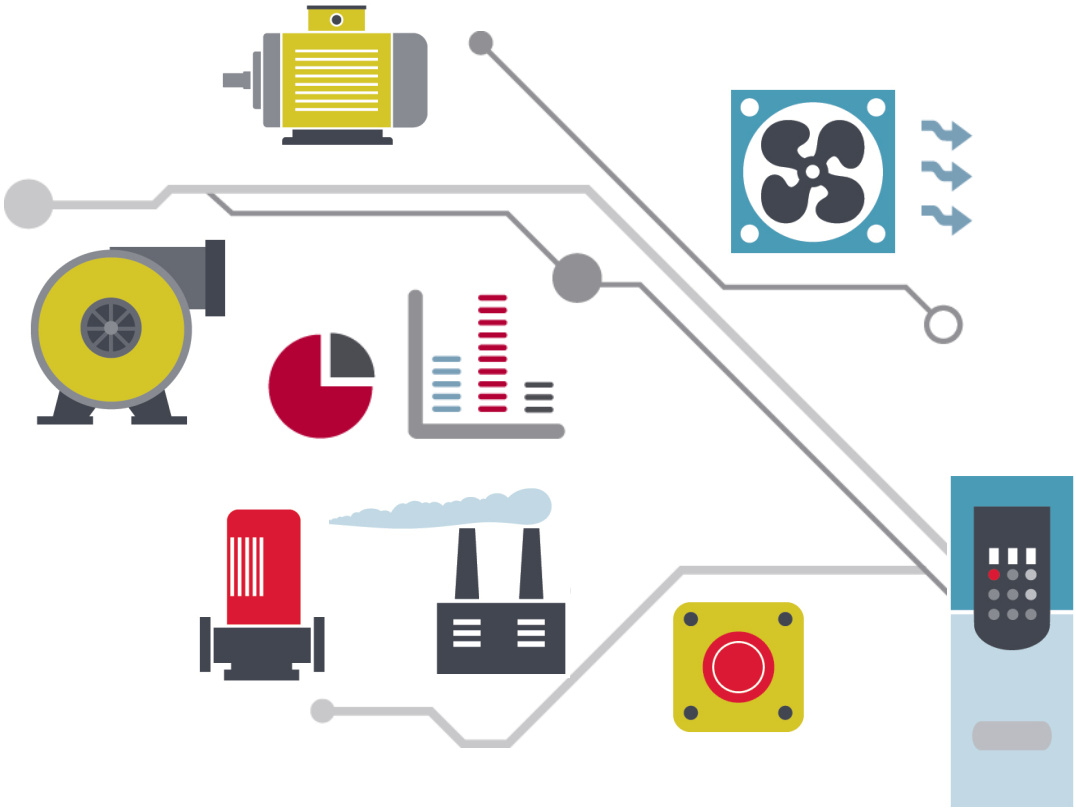
GAMBICA

Code of Practice
Hazardous Area Certification



First Edition
December 2016

Introduction:

The objective of this Code is to provide general guidance for both applicants and certification bodies when the applicant is applying for electrical equipment product certification through that certification body. It provides a framework for the running of a certification project from beginning to end.

Disclaimer:

Nothing in this Code shall contradict, override or overrule any contractual obligations on behalf of the Certification Body or Applicant.

Publication history

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GAMBICA ASSOCIATION Ltd. Flammable Atmospheres Group (FLAG)

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1. Scope:

This code addresses the working relationship between an applicant seeking to certify a product for use in a hazardous area (classified location, etc.) and a certification body that will assess and test the product against national and international standards and issue a certificate of conformity.

This Code applies to:

- An applicant.
- A certification body.
- All types of protection concept including but not exclusively:
  - Flameproof Ex d
  - Pressurization Ex p
  - Intrinsic Safety Ex i
  - Increased Safety Ex e
- All types of hazardous area certification including but not exclusively:
  - ATEX – all Categories of equipment
  - IECEx – all Equipment Protection Levels
  - National certification
  - Any territory worldwide

2. Deliverables:

- Certificates of conformity to the relevant standards.
- Test reports that document the assessment and testing.

3. Definitions:

- Applicant – a manufacturer or a person who acts on behalf of the manufacturer and who applies to a certification body for obtaining a certificate of conformity, test report, etc.
- Certification body – a body that has been accredited to provide hazardous area certification and/or other services. This includes an ExCB operating under the IECEx Scheme, a Notified Body operating under the ATEX Directive and a national certification agency operating within regional guidelines e.g. a Nationally Recognised Test Laboratory (NRTL) accredited to the US Regulations. This Code of Practice also includes any test laboratory or subcontractor that is working in conjunction with the certification body.

4. Workflow:

The workflow of a project through a certification body can take many forms and this Code does not seek to limit either the applicant or the certification body to any particular way of working. However, there are many aspects in common that are embodied within this Code.

Note: This workflow relates to the certification of a product being submitted for Certification **for the first time** (prime certificate). The process for the certification of a product already certified by another certification body may be shortened and stages may be omitted completely, depending on the international agreements in place between the certification bodies.

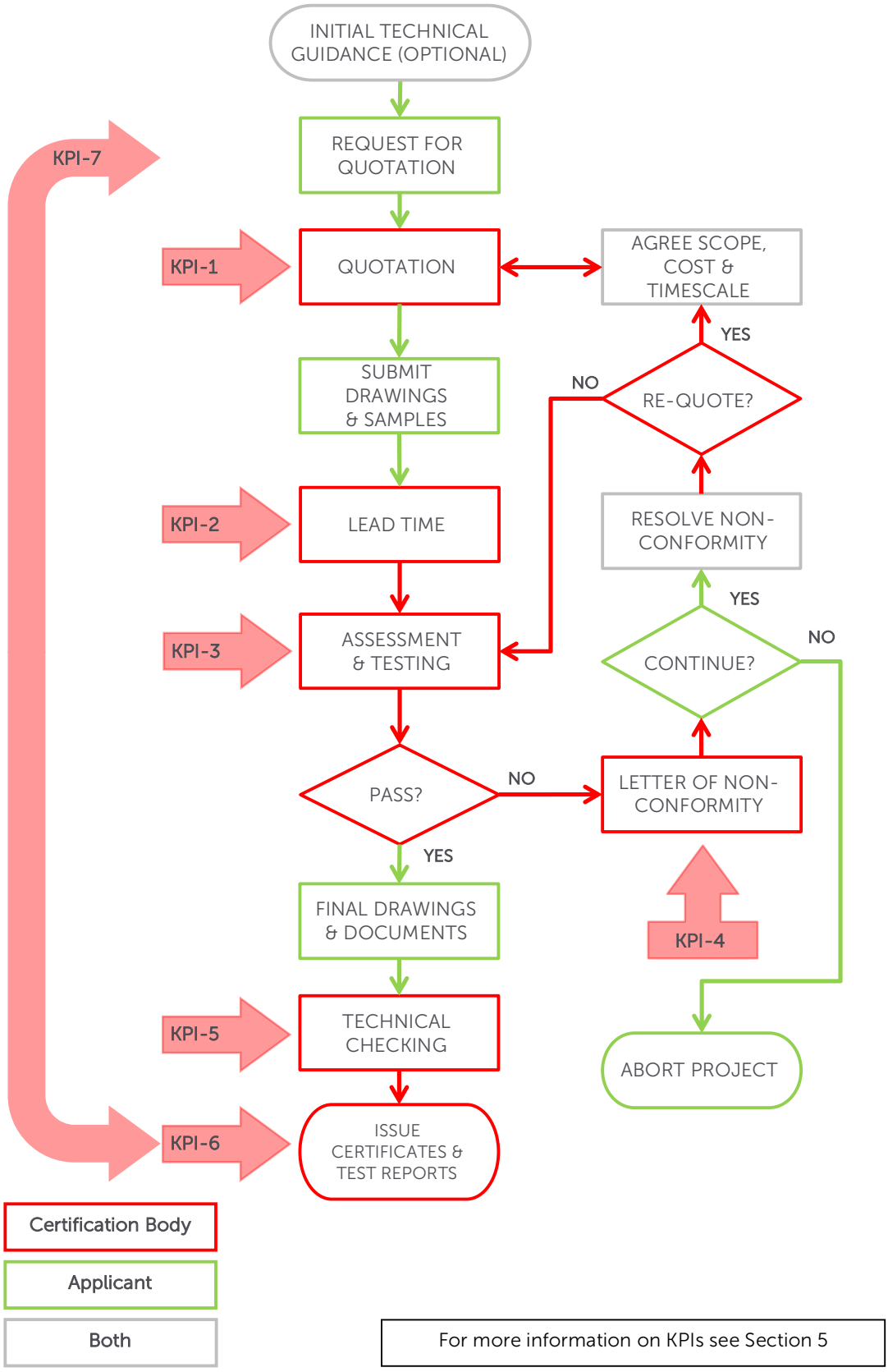

Fig. 1 Typical Progress of a Certification Project

4.1. Initial Technical Guidance:

4.1.1. Overview:

Although not essential, a project will often start with some initial dialogue with the certification body to introduce the product and discuss compliance with the standards. This can be a useful exercise for identifying potential issues at an early stage. Depending on the complexity of the product this technical guidance can take the form of an exchange of information by email, letter, etc. It can be a face-to-face meeting, a video conference or any other suitable means acceptable to all parties.

Depending on the policy of the certification body, this service may be funded by one of the following means:

a. Free of charge.
b. Charged for separately.
c. Included as part of a future project.

4.1.2. Responsibility of the Applicant:

- Optionally draft a certification plan.

Note this certification plan is different from the Certification Body's plan required by Clause 7.4 ISO/IEC 17065.

- The design of the product. The applicant shall not expect the certification body to know how the product works or be familiar with the intricate operational details.
- Provide sufficient information to enable the certification body to appraise the safety aspects of the product.
- The design of the product, particularly the safety aspects, is the sole responsibility of the applicant.

4.1.3. Responsibility of the Certification Body:

- As ISO/IEC 17025 and ISO/IEC 17065 prohibit them from being a 'consultant', the certification body may only provide generalised guidance on the resolution of any potential non-conformity of the product. Any guidance offered is non-binding and may later be disagreed with, particularly in the light of subsequent information that was not available during the initial provision of guidance.
- In the case of a product being submitted for certification which has already been certified in other geographies by a similar body, the certification body will comply fully with all international and national agreement that exist between such bodies and will not undertake re-checking or re-testing of the work of the first certification body without due cause. However, the

certification body has legal responsibility for all documentation it issues and therefore must satisfy itself that all aspects have been fully covered. Within the IECEx Scheme, provision is made for the report receiving ExCB to contact the report issuing ExCB, after contacting IECEx, to seek clarification or to resolve any issues.

4.2. Quotation:

4.2.1. Overview:

Following any initial technical guidance, the applicant will submit a product for certification that is either in production or at a stage of development that gives a representative overview of the finished item and sufficient documentation and optionally a sample or space model to enable the certification body to prepare a quotation. The certification body may require that their own application form be used. The certification body will prepare a written quotation based on the provisional documents, samples, etc. provided by the applicant.

If the design is not finalised at this stage and changes are made later then the quotation may not be accurate and additional costs or time may be incurred.

4.2.2. Responsibility of the Applicant:

- Provide sufficient information with the request for quotation form (RFQ) to enable the certification body to prepare a quotation for the certification of the product. This information will be in the form of documents, drawings, sketches, calculations and possibly an initial sample or space model. Delays in providing additional information requested may result in the expected KPI times being exceeded.
- Agree the scope, cost and timescale of the project with the Certification Body.

4.2.3. Responsibility of the Certification Body:

- Inform the applicant whether insufficient information is available to enable them to prepare the quotation.
- Inform the applicant of the time that the quotation is likely to take to prepare.
- Agree the scope, cost and timescale of the project with the applicant.
- The following shall be included in the quotation:
  a. The total cost to provide the certification requested including any fees and levies.
  b. A list of the samples required for testing purposes or a statement indicating when samples will be requested if the exact samples cannot be determined at the quotation stage.
  c. An estimate of the time the project will take to complete from beginning to end.

d. The expected start time from receipt of all information, samples, Purchase Order, etc.
e. Validity period of the quotation.
f. Any assumptions that have been made that would affect the above.
g. Terms and conditions

Notes:

1. A breakdown of the costs and/or timescales may be provided as part of the quotation.
2. The certification body may require either part or full payment of the certification costs before the project begins. It is a requirement of the accreditation standards ISO/IEC 17065 and 17025 that the certification body should not find itself in a position where a threat to withhold payment is an inducement to issue certification. In SI 192 of 1996, the UK statutory instrument implementing the ATEX Directive 94/9/EC, Clause 13 specifically makes provision for the Notified Body to require full payment of fees in advance of starting the project. However, the UK Government has not yet issued a statutory instrument implementing the new ATEX Directive 2014/34/EU

4.3. Formal Submission:

4.3.1. Overview:

At this stage, the applicant and certification body will enter a legally binding agreement in accordance with the agreed terms and conditions. The onus is more on the applicant to make necessary preparation work as complete as possible, by having at least one engineer with good knowledge of the relevant standards and documentation requirements.

4.3.2. Responsibility of the Applicant:

- Agree the date by which they will submit all requested drawings, documents, samples, etc.
- Formally accept the quotation.
- If applicable, place a Purchase Order with the certification body in accordance with normal company working practice.
- If applicable, pay the initial invoice, in accordance with normal company working practice.
- Prepare and submit initial drawings, samples, etc. by the agreed date.
- Submit the requested samples by the agreed date.

4.3.3. Responsibility of the Certification Body:

- Acknowledge Purchase Order
- If appropriate, submit an initial invoice to the applicant.
- Open a project file.

4.4. Lead Time:

4.4.1. Overview:

This is the waiting time for the project to be scheduled into the workflow of the certification body. It normally begins when the applicant has submitted all drawings, documents, samples, etc. to the certification body.

4.4.2. Responsibility of the Applicant:

- Ensure that all drawings, documents, samples, etc. are submitted to the certification body by the agreed date.

4.4.3. Responsibility of the Certification Body:

- Review the application, data, samples, etc.
- Schedule the start date for the project into their workflow.
- Inform the applicant of the start date for the project.

4.5. Start Project:

4.5.1. Overview:

This is the date on which assessment work starts on the project.

4.5.2. Responsibility of the Applicant:

- Communicate with the certification body as appropriate.

4.5.3. Responsibility of the Certification Body:

- Start the project within the lead time quoted.
- Map out the assessment and testing activities of the project.

4.6. Assessment and Testing:

4.6.1. Overview:

During this period, the certification body will progress the assessment and testing of the product being certified, providing feedback to the applicant at regular intervals. Testing may be performed in-house or by external test laboratories under the control of the Certification Body.

4.6.2. Responsibility of the Applicant:

- Respond as necessary to any test house requests or requirements in a timely manner.
- Modify the drawings as required when the certification body requests additional information.

4.6.3. Responsibility of the Certification Body:

- Assess the drawings and samples against the requirements of the standards.
- Perform or organise any testing required on the samples.
- Draft the test reports and certificates.
- Report progress regularly against the agreed timescale.

4.7. Non-Conformity:

4.7.1. Overview:

If during assessment or testing, the Certification Body finds that the product does not conform to the standards or has failed part of the testing then they will inform the Applicant so that corrective action can start as soon as possible.

4.7.2. Responsibility of the Applicant:

- Respond to the certification body in a timely manner.

4.7.3. Responsibility of the Certification Body:

- Inform the Applicant as soon as the non-conformity and/or test failure has been found.
- Issue a letter of non-conformity with timescales that the Applicant must respond within.

4.8. Resolve Non-Conformity:

4.8.1. Overview:

The Applicant will work in collaboration with the Certification Body to resolve any non-conformity of the product. If it is necessary to repeat some aspect of the assessment or testing following a failure, then this may entail additional cost for which the Certification Body may wish to quote.

4.8.2. Responsibility of the Applicant:

- Decide if they wish to abort the project if it proves to be cost prohibitive.
- Work in collaboration with the Certification Body to resolve the non-conformity.
- Modify the design of the product as required to bring the product into conformity.
- Modify the drawings to reflect the modified design as necessary.
- Provide a timescale of when the Applicant will submit the issue resolutions.

4.8.3. Responsibility of the Certification Body:

- Work in collaboration with the Applicant to resolve the non-conformity.
- If necessary, provide a quotation for any re-assessment or re-testing that may be required.
- Only quote for the retesting of the failed aspects.

4.9. Technical Checking:

4.9.1. Overview:

Once the assessment and testing is complete and the applicant has submitted final drawings, documents, etc., a technical checker will review the certificates, test reports, drawings, etc. for accuracy and compliance with the requirements of the standards.

4.9.2. Responsibility of the Applicant:

- Resolve any remaining non-conformity in a timely manner.
- The applicant may review a draft copy of the certificates and test reports to ensure that they meet with his requirements.

4.9.3. Responsibility of the Certification Body:

- Officially notify the applicant of any non-conformity remaining.

- Provide draft copies of the certificates and test reports for the applicant to review.
- Confirm estimated date for certificate release.

4.10. Issue Certificates and Test Reports:

4.10.1. Overview:

When the certificates and test reports have been finalised, the certification body will sign the original copies and either post them to the applicant in hard copy or by electronic means.

4.10.2. Responsibility of the Applicant:

- Review the certificates and test reports to ensure they meet with their requirements.
- Pay any final invoice due. This may be required prior to the certificates, etc. being released.

4.10.3. Responsibility of the Certification Body:

- Review the final certificates and test reports for typographical accuracy.

4.11. Communication:

4.11.1. Overview:

Good communication at all stages between the Applicant and Certification Body is essential for the smooth running and timely completion of the project.

Communication can be in the form of an email or letter in which issues or questions are raised or answered. These would be exchanged between the applicant and the certification body on a regular basis as required. Telephone calls can be useful in discussing a project but the results of those discussions should be confirmed by email or letter. Marked-up drawings may also be exchanged.

Delays in a project are often caused by poor communication either by the certification body not reporting a problem early enough or by the applicant taking a long time to resolve an issue. If the applicant takes a significant time to respond to a request for information, then the project will be delayed by a time at least equal to this delay and possibly longer, as the certification engineer will require to re-familiarise himself with the project and is unlikely to be able to restart work on a paused project immediately, thus incurring an additional Lead Time for rescheduling the project.

4.11.2. Responsibility of the Applicant:

- Confirm main contact for the project.
- Respond to questions or issues raised by the certification body in a timely manner.
- At the earliest opportunity, the applicant should report to the certification body anything that materially affects agreed certification parameters. This may change the scope of the project and incur additional charges.
- Agree timetable for regular updates.

4.11.3. Responsibility of the Certification Body:

- Confirm certification engineer assigned to the project.
- The certification body should communicate to the applicant a status report at key stages of the project; for example, when major tests have been completed successfully.
- Major non-conformities should be reported to the applicant as soon as possible so that corrective action can be taken early thereby not waste time progressing something that will not succeed. Issues should not just be saved up until the end of the project and thereafter inform the applicant that the product has failed.
- Agree timetable for progress reports

5. Key Performance Indicators (KPIs):

- Suggested benchmarks to be used as best practice targets in product certification:

KPI	Measured Quantity	Time for simple project	Time for complex project
1	Time from **Request for Quotation** to **Quotation**	1 week	2 weeks
2	**Lead Time** from receipt of **order and of the** requested data and samples to the commencement of **Assessment and Testing**	4 weeks	6 weeks
3	Overall **Assessment and Testing** (assuming no non-conformities)	6 weeks	12 weeks
5	**Technical Checking and authorisation** completed after **Product Pass**.	1 week	2 weeks
6	Dispatch the **Certificates and Test Reports** after **Technical Checking**	1 week	1 week
Project Total (assuming no non-conformities)		13 weeks	23 weeks

KPI	Measured Quantity	Time for simple project	Time for complex project
4	Issue **Letter of Non-Conformity** after **Product Fail**	1 week	1 week
7	Progress reports between **Certification Body** and **Applicant**.	Weekly or bi-weekly depending on the rate of activity	

- All certification projects vary in complexity from simple to highly complex. The actual times can be varied by agreement between the Certification Body and the Applicant at the quotation stage if the project is considered substantially different.
- **Applicants should respond to any request for information in a timely manner. To these KPIs must be added any time due to delay in provision of information by the applicant.**
- On occasion, the provision of additional information may result in the need for further clarification, in which case the timescales can expand considerably.

6. Related Issues:

Although not part of the certification process considered above, it is important to ensure that any related QA assessments are completed in due time to avoid potential delays in issuing the final documentation. This activity is normally undertaken in parallel for a first-time applicant and both the applicant and certification body need to correlate the activities.

7. Bibliography:

ATEX Directive 2014/34/EU	Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres. (Formerly 94/9/EC.)
IECEx 01	IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEx System) – **Basic Rules**.
IECEx 02	IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEx System) – **Rules of Procedure**.
NFPA70	National Electrical Code NEC®
C22.1	Canadian Electrical Code Part 1
ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17065:2012	Conformity assessment. Requirements for bodies certifying products, processes and services

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