



IECEX OD 024

Edition 2.0 2017-10

IECEX Operational Document

IEC System for Certification to Standards relating to Equipment for use
in Explosive Atmospheres (IECEX System)

IECEX Certified Equipment Scheme –

IECEX Rules of Procedure covering testing, or witnessing testing at a
manufacturer's, ~~or~~ user's or third party facility





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IECEX OPERATIONAL DOCUMENT

IECEX Certified Equipment Scheme

Ex OD 024 Edition 2.0

IECEX Operations Manual – IECEX Rules of Procedure covering testing, or witnessing testing at a manufacturer's, ~~or user's~~ or third party facility

This Operational Document, OD 024 sets out the procedures covering testing, or witnessing testing at a manufacturer's or user's, in accordance with the Rules and Procedures IECEX 02.

Document History

Date	Summary
2010 10	Edition 1.0
2012 05	Edition 1.1 to include Annexes B and C as Sample Agreement Forms.
2017 10	Edition 2.0 Addition of third party facilities. Clarification of requirements for partially witnessed testing. Approved at 2017 ExMC Meeting – refer ExMC/1298/DL, Decision 2017/81

IECEX OPERATIONAL DOCUMENT

IECEX OD 024

Title: IECEx Rules of Procedure covering testing, or witnessing testing at a manufacturer's or user's facility

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Readline Version

1 INTRODUCTION

- 1.1 There are various situations that necessitate that testing be conducted at a facility other than an ExTL. Examples of such situations are:
- Some manufacturers and end users who use the IECEx Certified Equipment Scheme have the capability in terms of personnel, facility and equipment to conduct a part of or all the tests stipulated in a given standard within the scope of the IECEx System.
 - The size of the product intended for testing is too large to bring to, and handle at the ExTL premises.
 - The product forms, and is to be tested as, part of an installation located at the end user site.
- 1.2 In recognition of the above conditions, and in response to identified needs to utilize existing capabilities other than those of an ExTL, this operational document has been established for testing to be conducted at such facilities under controlled conditions as specifically detailed and defined in this Operational Document.
- 1.3 Off-site testing and witness testing are currently being employed by ExTLs to accommodate the above situations. This Operational Document has been developed to recognize such existing practices and to provide a common approach so as to ensure consistency, transparency, and proper controls, and to maintain the credibility of the IECEx System
- 1.4 It is the intent of this Operational Document that testing carried out under these programs be performed with the same rigor as testing conducted at an ExTL
- 1.5 The activities of an ExTL defined in this Operational Document are carried out in conjunction with an ExCB, in accordance with the requirements of IECEx02.

2 DEFINITIONS

For the purpose of this Operational Document the following definitions apply:

ExCB Staff - Staff of an ExCB identified in ExCB competency records as being qualified to review test and assessment reports for the Test Standard in question.

ExTL Staff - Staff of an ExTL identified in ExTL technical competency records as being qualified to conduct testing to the requirements of the Test Standard in question.

Long Term Tests - Tests of a duration exceeding 7 hours without intervention by ExTL testing staff between the start and the end of the test.

Manufacturer Test Facility - Test facility owned by a Manufacturer which is being used to test specified products over which the manufacturer has complete production control.

Off-Site Testing - Program/procedure under which testing is conducted by ExTL staff or under their direction and supervision at a manufacturer's ~~or~~ user's or third party facility.

Partially Witnessed Testing – Testing witnessed by ExTL staff only on some parts of the agreed upon testing program.

Remote Witness Test - Testing witnessed live by ExTL staff using an electronic medium such as a video camera.

Site Assessment - Assessment carried out by ExTL staff to verify the ability and capability of a manufacturer, ~~or~~ user or third party test facility to participate in the off-site testing and witness testing programs.

Test Facility – For the purpose of this document, the term test facility refers to Manufacturer, User or Third Party Facility

Test Standard - IEC standard for a specific protection method used to test the product in question, and which is used in the IECEX System.

Third Party test Facility - Test facility not owned by a Manufacturer or User which is being used to test specified products.

User Test Facility - Test facility owned by a User which is being used to test specified products.

User - A person or organization which is normally the owner of the equipment and puts it to use.

Witness Testing – Program/procedure under which testing is conducted by personnel of the manufacturer, ~~or~~ user or third party, using their facility, equipment and personnel; and witnessed by ExCB or ExTL staff.

3 SCOPE

3.1 This operational document sets out the requirements covering the following programs:

- a) “Off-Site Testing”.
- b) “Witness Testing”.

3.2 Witness testing can be long term as described in Clause 7, remotely witnessed as described in Clause 8 or partially witnessed as described in Clause 9

3.23.3 The requirements of this Operational Document apply to equipment covered by the IECEX System.

4 OVERALL REQUIREMENTS

The following criteria apply to both off-site and witness testing programs.

4.1 All testing carried out under these programs shall be performed in accordance with the following:

- a) The requirements of this Operational Document.
- b) The requirements of the applicable IECEX Operational Documents.
- c) The relevant requirements of ISO/IEC 17025: 2005 as defined under each program.
- d) The relevant requirements of active ExTAG Decision Sheets; and
- e) The relevant requirements of the test standard(s).

- 4.2 The ExCB and their associated ExTL shall ~~wishing to use these programs must~~ have the relevant Test Standard(s) included in their IECEx scope of recognition.
- 4.3 The decision by an ExTL to conduct testing shall ~~under these programs must~~ be approved in advance by the ExCB.
- ~~4.4—A participating test facility shall be permitted to have an agreement with more than one ExTL, and where necessary, more than one ExCB for a given test standard Participating users must own the participating test facility.~~
- ~~4.54.4 Participating manufacturers must own the participating test facility; and own, or be in full control over all the production means of the product being tested.~~

5 REQUIREMENTS AND PROCEDURES FOR OFF-SITE TESTING

5.1 General Requirements

- 5.1.1 ~~Under this Operational Document, t~~he following principles shall apply:
- Testing is conducted directly by ExTL staff or under their direction and supervision. Personnel of the test facility manufacturer or user may assist in the preparation for tests and the conducting of agreed upon tests.
 - Both the ExTL and its associated ExCB remain fully responsible for the test results. In addition, the ExTL is also responsible for the preparation and content of the required test report.
 - Off-site testing shall must be identified in the ExTR.

- ~~5.1.2~~ An “Off-Site Testing Agreement” shall be signed between the ExTL and the test facility manufacturer or user. The ExCB may also sign the agreement.

~~The agreement shall, which shall~~ cover the following, as a minimum:

- The scope of work (specific tests) to be carried out at the participating test facility.
- The facilities and services to be provided by the test facility manufacturer or user.
- The right of initial assessment and re-assessment of the tests facility manufacturer or user by the ExTL and the right of the associated ExCB to witness these assessments.
- Use of data generated.

NOTE: Annex B provides a sample “Off-Site Testing Agreement” that maybe used.

5.2 Role and Responsibilities of the ExTL

The ExTL shall:

- Have the required quality procedures which adequately cover all aspects of off-site testing.
- Ensure that its staff involved in off-site testing is:
 - Qualified for the test standard involved and:-
 - Provided with the necessary initial and on-going training on the requirements of this Operational Document and referenced documents stated in 4.1..

- 5.2.3 Ensure that the required initial and on-going site assessments of participating test facilities are carried out by its qualified staff.
- 5.2.4 Define the role and responsibility of personnel involved in off-site testing on behalf of the test facility manufacturer or user.
- 5.2.5 Verify the competence of the manufacturer or user personnel to support the off-site testing program.
- 5.2.6 Perform testing at the ~~manufacture or user~~ test facility.
- 5.2.7 Prepare and sign the ExTR covering off-site testing for endorsement and issue by the associated ExCB.
- ~~5.2.7~~ Maintains final decisions and responsibility concerning tests conducted and test data obtained from Off-Site testing programs
- 5.2.8 ~~Sign the agreement stipulated in Clause 5.1.2 above.~~

5.3 Role and Responsibilities of the ExCB

The ExCB shall be responsible for the following activities:

- 5.3.1 Assessment of the quality procedures of the ExTL, applicable to the operation of off-site testing.
- 5.3.2 Ensuring that its staff involved in off-site testing are provided the necessary initial and on-going training on the requirements of this Operational Document.
- 5.3.3 Review and approval of all pertinent documents generated under this Operational Document by the ExTL.
- 5.3.4 Ensuring there is an appropriate agreement between the ExTL and the test facility manufacturer/ user, as per Clause 5.1.2 above.
- 5.3.5 Reviewing and issuing the ExTR covering off-site testing.
- 5.3.6 Determining the extent of any ExTL assessments it will witness.

5.4 Role and Responsibilities of the ~~Manufacturer or User~~ Test facility

Participating ~~manufacturer or user~~ test facilities are responsible for:

- 5.4.1 Making a formal application to participate in the program. The application may be made either to the ExTL or to the ExCB.
- 5.4.2 Signing the required agreement with the ExTL and, where necessary, with the ExCB.
- 5.4.3 Demonstrating that the facilities are in compliance with the relevant requirements of ISO/IEC 17025: 2005 and the requirements of this program.

NOTE: Laboratory accreditation of the test facility may be taken into account but is not a substitute for assessment according to this Operational Document.

~~5.4.3.4.4~~ Relevant requirements of ISO/IEC 17025: 2005 as listed below, apply shall include the following elements, as a minimum

- a) Critical consumables (4.6)
- b) Personnel (5.2)

- c) Accommodations and environmental conditions (5.3) including Power Supply of testing setup when relevant (e.g.: Long term testing, Heating) and humidity conditions (e.g.: ESD)). Refer to Annex XX (Annex II of IEC EE OD 2048)
- d) Equipment (5.5)
- e) Measurement traceability / calibration (5.6)
- f) Identification of test items (5.8); and
- g) Test results (5.10)

5.4.45.4.5 Designating competent personnel for the testing activities conducted at their facility.

5.4.55.4.6 Ensuring that assigned personnel follow the instructions of the ExTL staff conducting off-site testing at the facility.

~~5.5 Choice of ExCBs/ExTLs by the Manufacturer or User Test Facility~~

~~A participating test facility shall be permitted to have an agreement with more than one ExTL, and where necessary, more than one ExCB for a given test standard.~~

5.65.5 Site Assessment/Reassessment of the Manufacturer or User Test Facility

5.6.15.5.1 ExTL Staff shall carry out the initial site assessment of the participating test facility in accordance with the ExTL's procedure for off-site testing.

5.6.25.5.2 The continued validity of the initial assessment or reassessment shall be evaluated during each subsequent off-site testing project/visit. The evaluation shall consider the following factors:

- a) The scope of work defined in the agreement referenced in clause 5.1.2
- b) The frequency of visits
- c) The extent of organizational or equipment changes at the facility
- d) Other changes that affect the performance of the participating test facility relative to the conduct of off-site testing.

5.6.35.5.3 Where testing is conducted using test equipment of the ExTL, the site assessment shall cover the relevant requirements of ISO/IEC 17025: ~~2005~~ listed in clause 5.4.4, except for 5.4.4 (d) and 5.4.4(a) if critical consumables are provided by the ExTL.

5.6.45.5.4 Where testing is conducted using test equipment provided by the participating test facility, the site assessment shall cover the relevant requirements of ISO/IEC 17025: ~~2005~~ listed in clause 5.4.4.

Note: Where critical consumables are provided by the ExTL, 5.4.4(a) does not apply.

5.6.55.5.5 The ExTL shall document the results of any assessment/reassessment activity using the appropriate Assessment Report Form (Annex A), and provide a copy of the report to its associated ExCB for review and endorsement.

5.6.65.5.6 All documentation related to assessment/reassessment activities shall be made available as follows:

- a) For audit by the ExCB.
- b) For review during any subsequent peer reassessments conducted under the IECEx System.
- c) To the IECEx Secretariat upon request.

5.75.6 Requirements for Conducting Tests and Issuing Test Reports and Certificates

5.7.15.6.1 All testing carried out under the off-site testing program shall be performed with the same rigor as testing conducted at the ExTL, and using test procedures consistent with

those used by the ExTL. Such procedures ~~shall~~ must be approved in advance by the ExTL.

5.7.25.6.2 Where testing is performed using any test equipment of the participating test facility, the ExTL staff shall:

- a) Verify that the test instrument is properly calibrated by an ISO/IEC 17025: ~~2005~~ accredited calibration test lab, has calibration that is traceable to National Standards,
- b) Verify that the test instrument is suitable for making the required measurement and has the needed accuracy as required by the test standard involved.
- c) Become familiar with the use and operation of the instrument.
- d) Ensure that the instrument is functioning.

5.7.35.6.3 Where personnel of the participating test facility are assisting in testing activity (such as placement of thermocouples, recording test results, etc.) the ExTL staff shall:

- a) Provide clear and concise instructions as to the type and extent of assistance provided;
- ~~b) Examine the work done prior to commencing and during testing;~~
- ~~c) Verify when relevant (e.g.: Long term testing, Heating) that the Power Supply used is appropriate (Voltage, Frequency stability, Total Harmonics set as follows, unless the standard is more stringent) Refer Annex II of IECEE OD 2048~~
- ~~b)d) Verify humidity level where it can affect electrical test (e.g.: Electrostatic Discharge (ESD))~~

5.7.45.6.4 Test sample(s) must be representative of production and properly and uniquely identified. In cases where multiple samples are required for testing, they are to be identifiable to the testing for which they were subjected.

5.7.55.6.5 Test reports/records prepared shall meet the following criteria:

- a) Be the relevant IECEX Test Report Forms.
- b) Be signed /reviewed in accordance with the relevant procedures of the IECEX System.
- c) Record the date of testing and identification of the all test samples.
- d) Indicate the name and address of the ~~test facility~~ ~~manufacturer or user test facility~~ used
- e) Indicate what tests have been carried out at the ~~manufacturer or user~~ test facility.
- f) Record all test instruments used in testing.
- g) Incorporate applicable test data.
- h) Show the following statement: "The test facility was deemed to have the environment and the capabilities necessary to perform the tests indicated in the test report".

5.7.65.6.6 When an ExTR is based on off-site testing, a reference to the use of the ~~manufacturer or user~~ test facility shall be included ~~as "Additional Information" in the ExTR, and its associated on-line ExTR summary.~~

6 REQUIREMENTS AND PROCEDURES FOR WITNESS TESTING

6.1 General Requirements

6.1.1 Under this program, the following principles shall apply:

- a) The ~~manufacturer or user~~ test facility uses its own test equipment or calibrated and traceable equipment which is within their control.
- b) Testing is carried out by personnel of the ~~manufacturer or user~~ test facility.
- c) The ExTL involved witnesses the testing.
- d) Both the ExTL and its associated ExCB remain fully responsible for the test results and the content of the test report.
- e) Witnessed tests must be identified in the ExTR.

- 6.1.2 A "Witness Testing Agreement" shall be signed between the ExTL and the ~~manufacturer or user~~ test facility. The ExCB may also sign the agreement, which shall cover the following, as a minimum:
- The scope of work (specific tests or test standards) for which the participating test facility is qualified to carry out.
 - The facilities and services provided by the manufacturer or user test facility
 - The right of initial assessment and re-assessment of the manufacturer or user test facility by the ExTL and the right of the ExCB to witness these assessments by the ExTL.
 - The supervisory role of ExTL staff witnessing the tests.
 - Use of data generated.

NOTE: Annex C provides a sample "Witness Testing Agreement" that maybe used.

- 6.1.3 An "Off-Site Testing Agreement" shall be signed between the ExTL and the test facility. The ExCB may also sign the agreement.

The agreement shall cover the following, as a minimum:

- The scope of work (specific tests) to be carried out at the participating test facility.
- The facilities and services to be provided by the test facility.
- The right of initial assessment and re-assessment of the tests facility by the ExTL and the right of the associated ExCB to witness these assessments.
- Use of data generated.

NOTE: Annex B provides a sample "Off-Site Testing Agreement" that maybe used

- 6.1.36.1.4 The IECEX Secretary shall maintain and publish a Register of participating manufacturers and end users, together with the associated Test Standard(s) for which they are qualified.

6.2 Role and Responsibilities of the ExTL

The ExTL involved shall be responsible for the following activities:

- Have the required quality procedures which adequately cover all aspects of witness testing.
- Ensure that its staff involved in witness testing is:
 - Qualified for the test standard involved and:-
 - Provided with the necessary initial and on-going training on the requirements of this Operational Document.

~~6.2.3~~ Carry out the required initial and on-going site assessments of the participating test facility and Verify when relevant (e.g.: Long term testing, Heating) that the Power Supply used is appropriate (Voltage, Frequency stability, Total Harmonics set as follows, unless the standard is more stringent)

a) Voltage stability: +/- 3 percent maximum

b) Frequency stability: +/- 2 percent maximum

c) Total harmonic distortion: maximum 5 percent

~~6.2.36.2.4~~ Verify humidity level where it can affect electrical test (e.g.: ESD)

~~6.2.46.2.5~~ Ensure the presence of ExTL staff at the participating test facility during testing to witness all aspects of the tests carried out by personnel of the participating test facility, except as permitted under clause ~~86.9~~ and ~~96.10~~.

~~6.2.56.2.6~~ Check the competence of personnel assigned to conduct testing on behalf of the participating test facility to perform the required tests.

~~6.2.66.2.7~~ Prepare and sign the ExTR covering witnessed testing for review and endorsement by the associated ExCB.

~~6.2.7~~ ~~Sign the agreement referenced in 6.1.2 above.~~

6.3 Role and Responsibilities of the ExCB

The ExCB shall be responsible for the following activities:

6.3.1 Ensuring that its staff involved in witness testing is provided with the necessary initial and on-going training on the requirements of this procedure.

6.3.2 Assessing the quality procedures of the ExTL applicable to the operation of witness testing.

6.3.3 Review of documentation held by the ExTL covering site assessments/reassessments of the participating test facility, and contractual arrangements.

6.3.4 Ensure there is a proper agreement between the ExTL and the participating test facility, as per 6.1.2 above.

6.3.5 Registration of the ~~manufacturer or user~~ test facility with the IECEx Secretariat and updating of the current information in the Register.

6.3.6 Reviewing and issuing the ExTR and IECEx Certificates based on witness testing.

6.4 Role and Responsibilities of the ~~Manufacturer or User~~ Test Facility

Participating ~~manufacturer or user~~ test facilities are responsible for the following:

6.4.1 Make a formal application to any ExTL or ExCB responsible of a ExTL to participate in the witness testing program.

6.4.2 Identify the scope of testing it wishes to conduct at its facility.

6.4.3 Sign the required agreement with the ExTL, and where necessary the ExCB involved.

6.4.4 Demonstrate that the facility is in compliance with all the relevant requirements of ISO/IEC 17025: 2005 and the requirements of the witness testing program. Relevant requirements of ISO/IEC 17025: 2005 shall include the following elements, as a minimum:

a) Critical consumables (§4.6):

- b) Personnel (§5.2);
- c) Accommodations and environmental conditions (§5.3), including Power Supply of testing setup when relevant (e.g.: Long term testing, Heating) and humidity conditions (e.g.: ESD). Refer to Annex XX (Annex II of IECEE OD 2048).
- d) Equipment (§5.5);
- e) Measurement traceability / calibration(§5.6);
- f) Identification of test items (§5.8); and
- g) Test results (§5.10).

NOTE: Laboratory accreditation of the test facility may be taken into account but is not a substitute for assessment according to this Operational Document.

- 6.4.5 Appoint appropriate personnel to be responsible for the verification of the ExTL witness testing arrangements.
- 6.4.6 Conduct testing in accordance with the applicable test standard(s), instructions given by the ExTL staff witnessing the test, and all the relevant provisions of the agreement.
- 6.4.7 Sign the test report as required.

~~6.5 Choice of ExCBs/ExTLs by the Manufacturer or User Test Facility~~

- ~~6.5.1 A participating test facility shall be permitted to have an agreement with more than one ExCB or ExTL for a given test standard.~~
- ~~6.5.2 A participating test facility shall not be permitted to use more than one ExCB or ExTL for the same product model.~~

~~Note - a participating test facility shall be permitted to address a test report for the same model to more than one ExCB/ExTL for the purpose of issuing a CoC.~~

~~6.6.5~~ 6.5 Site Assessment/Reassessment of the ~~Manufacturer or User~~ Test Facility

~~6.6.16.5.1~~ 6.5.1 Qualified ExTL staff shall carry out site assessments of the participating test facility in accordance with own internal quality procedures.

~~6.6.26.5.2~~ 6.5.2 The initial assessment shall be performed after an application is received from the participating test facility and prior to conducting actual witness testing.

~~6.6.36.5.3~~ 6.5.3 The continued validity of the initial assessment or reassessment shall be evaluated during each subsequent witness testing project/visit. The evaluation shall consider the following factors:

- a) The scope of work defined in the agreement referenced in clause 6.1.2
- b) The frequency of visits
- c) The extent of organizational or equipment changes at the facility
- d) Other changes that affect the performance of the participating test facility relative to the conduct of off-site testing.

~~6.6.46.5.4~~ 6.5.4 The site assessment shall cover the relevant requirements of ISO/IEC 17025: 2005 listed in clause 6.4.4.

6.5.5 The ExTL shall document the results of any assessment/reassessment activities using the appropriate IECEX Site Assessment Checklist (Annex A) and provide a copy of the assessment/reassessment report to the ExCB for review and approval.

6.5.6 These operations shall be conducted by the ExTL and may take into account assessments conducted by other ExTLs.

6.7.6 Requirements for Conducting Tests and Issuing Test Reports and Certificates

6.7.16.6.1 Prior to commencing the tests, witnessing staff of the ExTL involved shall:

- a) Prepare the necessary test plan and review it with personnel of the participating test facility assigned to perform the tests.
- b) Check the test set-up for correctness.
- c) Check that the appropriate test instruments are used and ensure that they are functional, and their calibrated accuracy is appropriate for the measurements to be taken.
- d) Verify that the test instruments are properly calibrated by an ISO 17025: 2005 accredited calibration lab and that calibration is traceable to National Standards.
- e) Provide the necessary work instructions and direction.
- f) Verify that the test sample(s) is/are representative of production and properly and uniquely identified. In cases where multiple samples are required for testing, they are to be identifiable to the testing for which they were subjected.
- g) Where equipment such as measuring systems are calibrated by the ~~manufacturer/user~~ test facility, ensure that such equipment is validated prior to use.

6.7.26.6.2 Witnessing staff of the ExTL involved shall be present during testing and shall continue to supervise and check all critical aspects of the tests. ExCB staff may be present during the test should they wish.

6.7.36.6.3 Test reports/records prepared by the ExTL shall meet the following criteria:

- a) Be the relevant IECEx Test Report Forms
- b) Include a unique identification number to permit correlation to the ExTR.
- c) Record the date of testing and identification of all the test samples.
- d) Indicate the name and address of the ~~manufacturer or user~~ test facility used.
- e) Indicate what tests have been carried out at the ~~manufacturer or user~~ test facility.
- f) Record all test instruments used in testing, indicating calibration status.
- g) Include applicable test data.
- h) Show the following statement: "The test facility was deemed to have the environment and the capabilities necessary to perform the tests indicated in the test report".
- i) Be signed by: the person who carried out the testing on behalf of the participating test facility under "Tested by"; the person who witnessed the tests on behalf of the ExTL involved under "Witnessed by"; and the person who reviewed the report, other than the witnessing staff under "Authorized by".

6.7.46.6.4 When an ExTR covers results based on witness testing, the following shall apply:

- a) A reference to the use of the manufacturer or user test facility, as well as the IECEx registration number shall be included as "Additional Information" in the on-line ExTR summary.
- b) All documentation related to assessment/reassessment activities shall be included as an attachment to the ExTR

7 LONG TERM TESTS

7.1.1 Long term tests are not required to be witnessed for the entire duration of the test. Such tests shall be witnessed at the start and at the conclusion of the test. Long term tests include thermal endurance to heat, thermal endurance to cold, resistance to light and other tests during which no change of test parameters occurs or during which no observation of the test sample is required.

7.1.2 The test sample(s) shall be identified prior to the start of the test and witnessed by ExTL staff.

7.1.3 The test set-up shall be subject to continuous monitoring of conditions. Verify when relevant (e.g.: Long term testing, Heating) that the Power Supply used is appropriate

(Voltage, Frequency stability, Total Harmonics set as follows, unless the standard is more stringent)

Voltage stability: +/- 3 percent maximum

Frequency stability: +/- 2 percent maximum

Total harmonic distortion: maximum 5 percent

Verify humidity level where it can affect electrical test (e.g.: ESD)

Unless standard provides more stringent conditions. Refer to Annex XX (Annex II of IEC 60060-1:2016)

7.1.37.1.4 The conclusion of the test shall be witnessed by ExTL staff.

7.1.47.1.5 Records of the continuous monitoring system shall be reviewed by the ExTL and the ExCB.

7.1.57.1.6 The start and conclusion of tests do not need to be witnessed by the same member of the ExTL staff.

8 REMOTE WITNESSING OF TESTING

8.1.1 Remote witness testing may be used only where, based on past experience and prior site assessment, ExTL and ExCB staff have confidence in the ability of the persons performing the tests and the test equipment used. Confidence is based on the following conditions:

- a) The ~~test facility manufacturer~~ shall have successfully demonstrated their capability by way of similar tests witnessed by an ExTL~~had a minimum of three witnessed tests by an ExTL on similar equipment with satisfactory results.~~
- b) The ExTL and ExCB shall have a process to demonstrate that the necessary level of trust and confidence is maintained through periodic witnessing of testing by the ExTL and ExCB.

8.1.2 Where remote witness testing is carried out, the following procedure shall be followed:

- a) All test equipment calibration records requested by the witnessing entity shall be made available and correlated with the designations shown on the test equipment used.
- b) Details of the test plan and test set-up (including for instance placement of thermocouples, required photos, etc.) and testing date shall be discussed and agreed upon prior to commencing testing.
- c) ~~The ExTL Prior to commencing testing, detailed photos of the test set-up shall be sent to the ExTL and the ExCB for review and approval. If necessary, the witnessing entity~~ may require that "live" viewing in real time of the test set-up using a video camera be available to check the set-up prior to testing, and may require on-site examination of the test setup, including camera(s).
- d) Testing shall be witnessed live by the ExTL using an electronic medium such as a live video conference feed via video camera.
- e) Acceptance of tests and related data witnessed shall be determined by ExTL staff.
- f) The required agreement between the participating test facility and the ExTL and where necessary the ExCB, shall include a stipulation confirming that:
 - The condition of clause (d) above is understood.
 - Witnessing of tests does not imply acceptance of the data, if, in the opinion of the ExTL or the ExCB staff, the complexity of the tests or the results obtained may require further evaluation.
- g) Test samples used shall be distinctly marked.
- h) The ExTL or ExCB may request that test samples are provided for additional review.
- i) Remote witness testing must be identified in the ExTR
- ~~h)~~ j) In case of Long term testing and/or Heating tests, data obtained by application of 7.1.3 shall be provided.

9 PARTIALLY WITNESSED TESTING

Partially witnessed testing is a common practice currently used by ExTLs and ExCBs whereby witnessing only some parts of the agreed upon testing program is deemed sufficient.

Partially witnessed testing ~~is an option may be used only~~ where, based on past experience and prior site assessment, ExTL and ExCB staff has confidence in the ability of the persons performing the tests, the test facility and the test equipment used without full witness. Exemptions to witnessing are justified and documented.

The following scenarios ~~are allowed may be considered~~ for partially witnessed testing under this Operational Document:

- ~~a) Long term tests as described in 6.8 above~~
- a) Remote witnessing of testing as described in ~~8.9~~ above

When Partially Witnessed Testing is used for the remote witnessing of testing as described in 8 above all applicable requirements of 8 shall be complied with together with the requirements of this clause

- ~~b) —~~
- eb) Tests considered similar in nature to the relevant industrial standards (non-Ex Standards) of the relevant industrial standards (non-Ex Standards)

Relevant industrial standards are ISO and IEC based standards relevant for the type of equipment tested under the IECEX System. This includes tests such as thermal testing in air, drop, impact, electric strength and excludes all forms of explosion testing such as spark ignition testing, flame propagation testing, etc

9.1 General Requirements

The requirements in Clause 5, Off-site testing, and Clause 6, Witness testing, as applicable, are applied for partially witnessed tests with the following additions/revisions.

9.2 Site Assessment/Reassessment of the Test Facility

9.2.1 ExTL Staff shall carry out the initial site assessment of the participating test facility including the following requirements of ISO/IEC 17025, as a minimum:

- a) Document control (§4.3);
- b) Purchasing services and Supplies (§4.6);
- c) Control of Nonconforming Tests or Calibrations (§4.9);
- d) Corrective Action (§4.11);
- e) Control of Records (§4.13);
- f) Personnel (§5.2);
- g) Accommodation and Environmental Conditions (§5.3), including Power Supply of testing setup when relevant (e.g.: Long term testing, Heating) and humidity conditions (e.g.: ESD)). **(These points deserve to be stressed as they may considerably impact the test)**
- h) Test and Calibration Items (§5.4);
- i) Equipment (§5.5);
- j) Measurement Traceability (§5.6);
- k) Handling of Test and Calibration Items (§5.8);
- l) Reporting the Results (§5.10).

9.2.2 ExTL Staff shall, as a minimum, carry out an annual assessment of the participating test facility in accordance with the relevant requirements of ISO/IEC 17025: 2005 using the IECEX Site Assessment Checklist (see Annex A).

9.2.3 Where required to verify the implementation of corrective actions, a Follow-up Assessment is conducted by the ExTL Staff.

9.2.4 A full re-assessment shall be performed by the ExTL Staff every three years.

9.1.19.2.5 Before test data can be accepted, the associated test method(s) must be on the active scope and been validated in accordance with requirements of this OD.

Redline Version

**WITNESSED TESTING
SITE ASSESSMENT CHECKLIST**

ANNEX A

ExTL DATA	TEST FACILITY
Date of Testing _____	Name of Facility _____
ExTL Representative _____	Address _____
Signature _____	Primary Contact _____
Date: _____	Phone/Fax _____
<u>ExTR File</u> No. _____	Quality Manager _____
	Phone/Fax _____
	Email _____

File No: _____

Date: _____

	Complies?			Comments/Auditor Notes
	Yes	No	N/A	
Documentation <u>control</u> (§4.3)				
Do external accreditations exist for the test site? (attach copies of certificates)				
Is the appropriate version of the test standard available for use?				
- Are the appropriate ExTL test procedures (or equivalent procedures) available? - Are other standards or test methods involved and are they available? (Attach a list of the additional standards or methods)				
Test Equipment (§5.5) & Measurement Traceability/Calibration (§5.6)				
All test equipment/measurement instrumentation must comply with ExTL Quality System requirements pertinent to the tests being conducted.				
Is the test equipment properly housed, maintained, and suitable to perform the required testing?				
Have you noted details of the test equipment used? (i.e. type, serial number, model, manufacturer, model, calibration date, etc.) (Attach a separate list if necessary)				
Does the instrumentation meet the requirements of the test standard?				
Is all instrumentation in current calibration? (attach proof of calibration, for on-site equipment)				
Is the equipment calibration traceable to national standards?				

File No: _____

Date: _____

	Complies?			Comments/Auditor Notes
	Yes	No	N/A	
<p>If an internal laboratory is used for instrument calibration</p> <ul style="list-style-type: none"> - Do calibration methods exist? - Are they under document control? - Can traceability of measurements be established? <p>(attach copies of methods and traceability documentation)</p>				
Is the equipment calibration provided with measurement uncertainty information?				
Do procedures exist for the laboratory to notify ExTL if prior used test equipment is received at calibration out of tolerance?				
Accommodations and Environmental Conditions (§5.3)				
<p>Are the room ambient conditions within the requirements of the standard(s)?</p> <ul style="list-style-type: none"> - Are they monitored? - Is monitoring equipment calibrated? <p>(attach proof of calibration and document ambient conditions throughout test)</p>				
<p><u>If relevant (e.g.: Long term test, heating) are the Power supply conditions appropriate and meeting the following minimum values:</u></p> <p><u>Voltage stability: +/- 3 percent maximum</u></p> <p><u>Frequency stability: +/- 2 percent maximum</u></p> <p><u>Total harmonic distortion: maximum 5 percent</u></p> <p><u>Unless standard provides more stringent conditions ?</u></p>				
Are the test utilities within test standard(s) requirements				
Is there effective separation from areas of incompatible activities?				
Is the condition of the test sample appropriate for the tests to be conducted?				
Identification Of Test <u>Items/Samples</u> (§5.8)				

File No: _____

Date: _____

	Complies?			Comments/Auditor Notes
	Yes	No	N/A	
Are samples clearly identified by the client and accompanied by the relevant instructions/operating manual?				
Are samples entered in a tracking database?				
Are samples locked? And is access secure from entry by non-authorized personnel?				
Do test Samples have a Identification/Tracking Label?				
Test Procedures and Methods (§5.4)				
Are the specific ExTL test procedures (or equivalent procedures) in place?				
Are the test methods/techniques used to carry out tests in accordance with the ExTL test procedures?				
Are these test methods (if used) recorded and identified with date and revision level?				
Is testing under the control of the ExTL representative?				
If software is used for data processing: - Is it documented; - Validated for accuracy; - - Identified with date and revision levels				
Critical Consumables (§4.6)				
Do procedures exist for the purchase, reception and storage of reagent and laboratory consumable materials relevant for the tests and calibrations?				
Are there records (list) of critical consumables and approved suppliers?				
Are consumables required for the product category under witness testing?				
Do the consumables meet the requirement of the applicable standard(s)?				
Test Results (§5.10)				
Are test results recorded on appropriate and controlled data sheets?				
Do the data sheets contain sufficient information to determine compliance/non compliance with the test standard?				
Are the data sheets signed and dated by the person performing the test?				

File No: _____

Date: _____

	Complies?			Comments/Auditor Notes
	Yes	No	N/A	
Are the data sheets reviewed, countersigned and dated by the ExTL representative witnessing the tests?				
Test Personnel (§5.2)				
Have you noted the names of personnel assigned to perform the required tests?				
Are the personnel performing the tests qualified: - For the tests being performed? - In the use of the test instruments being utilized? - In the use of ExTL test procedures? (provide names)				
Do the personnel: - Have the required training records? - Exhibit knowledge of the tests being performed and the equipment being used?				
<u>Control of Nonconforming Tests or Calibrations (§4.9)</u>				
<u>Corrective Action (§4.11)</u>				
<u>Control of Records (§4.13)</u>				

Readline Version

ANNEX B

OFF-SITE TESTING AGREEMENT

(INFORMATIVE)

This AGREEMENT is made this _____ day of _____, (year) _____, at _____
 _____ between the following parties:

ABC: (Name and address of ExCB) _____; and

XYZ: (Name and address of ExTL) _____; and

MTF/ETF: (Name and address of manufacturer, ~~or~~ end user or third party test facility, referred to as "Test Facility") _____

RECITALS

Whereas Off-Site Testing at ~~the Test Facility Manufacturers' or End User's facility~~ is a (XYZ) procedure for the use of a ~~Test Facility manufacturer's or end user's test facility~~ by (XYZ) staff in accordance with the applicable requirements of:

- a) (XYZ) Operating Procedures, and
- b) The rules of procedure of the IECEx System as stipulated in Operational Documents OD

Pursuant to which personnel from (XYZ) perform the complete tests at the ~~Test Facility (MTF/ETF),~~ using (XYZ) own or ~~Test facility (MTF/ETF)~~ test equipment.

Whereas ~~the Test Facility (MTF/ETF)~~ wishes to participate in the Off-site Testing Program and is prepared to cooperate with and provide the necessary assistance to (XYZ).

Now therefore, for and in consideration of the mutual covenants herein expressed and other lawful and valuable consideration, the parties agree as follows.

1.0 SCOPE

The off-site testing program operated under this Agreement covers the product safety Standards and tests described in **Schedule "A"** to this Agreement.

2.0 OBLIGATIONS OF THE TEST FACILITY (MTF/ETF)

- 2.1 ~~The Test Facility (MTF/ETF)~~ shall demonstrate that the test facility where off-site testing is to be performed, including the power supply and lighting and environmental conditions complies with the relevant requirements of ISO/IEC standard 17025: **2005**, "General requirements for the competence of testing and calibration laboratories".
- 2.2 If the test equipment used is owned by ~~the Test Facility (ETF/MTF), (MTF/ETF)~~ it shall demonstrate that its calibration program complies with the applicable requirements of ISO/IEC standard 17025: **2005**.
- 2.3 ~~The Test Facility (MTF/ETF)~~ shall appoint an appropriate person to be responsible for the test

facility and calibration services, if applicable.

2.4 ~~The Test Facility (MTF/ETF)~~ shall assist (XYZ) personnel in the preparation for and conduct of tests by providing the services described in **Schedule “B”**

~~2.5 (TF) agrees to provide adequate power supply in case of Long term testing and/or Heating tests The conditions are those defined in OD 24~~

~~2.5.2.6 The Test facility (MTF/ETF) agrees to compensate (XYZ) pursuant to agreed upon (XYZ) quotations for services and expenses in connection with the provisions of this Agreement.~~

3.0 OBLIGATIONS OF (XYZ)

3.1 Maintain complete and full responsibility for all testing carried out at ~~the Test Facility(MTF/ETF) facility~~ and for the integrity and completeness of the test results.

3.2 Prepare the required test report.

3.3 Perform the activities outlined in Section 4 of this Agreement.

3.4 Maintain all required documentation related to activities carried out under this Agreement.

4.0 QUALIFICATION ASSESSMENT AND CONTINUED VERIFICATION OF COMPETENCE

4.1 Prior to conducting tests under the Off-site Testing Program, (XYZ) will conduct an initial assessment of ~~the Test Facility (ETF/MTF) test facility~~ to verify compliance with the relevant requirements of ISO/IEC standard 17025: 2005.

4.2 At each visit to ~~the Test Facility (MTF/ETF) test facility~~ under this program, (XYZ) will validate the initial assessment results to ensure the ongoing suitability of the facility and the competence of ~~the Test Facility (MTF/ETF)~~ personnel to perform the role assigned to them under Clause 2.4 above.

5.0 CONFIDENTIALITY

Although proprietary documents, material and information which come to the attention of (XYZ) in the course of performing services under this Agreement shall be regarded as confidential, ~~the Test Facility (MTF/ETF)~~ acknowledges and agrees that (XYZ) is obligated to disclose such information to other third parties in accordance with the relevant rules and requirements of:

- (Name of accreditation body/Bodies under which XYZ is accredited) , and
- The IECEx System.

6.0 MISCELLANEOUS TERMS AND CONDITIONS

6.1 This Agreement shall continue in effect as long as both parties jointly agree to and abide by its terms and conditions.

6.2 This Agreement is subject to cancellation by either party upon giving a written notice to the party.

6.3 This Agreement, including the Schedules referenced herein shall be executed in duplicate, each of which shall be considered to be an original.

On behalf of the Test Facility(MTF/ETF)

On behalf of (XYZ)

Name: _____

Name: _____

Title: _____

Title: _____

Signature: _____

Signature: _____

On behalf of (ABC)

Name: _____

Title: _____

Signature: _____

Redline Version

Schedule A

The standards and tests listed below are covered under this Agreement

TEST STANDARD	TESTS

Redline Version

SCHEDULE B

| ~~The Test Facility (MTF/ETF)~~ agrees to assist (XYZ) in conducting the Off-site Testing Program by providing the following services:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

Redline Version

ANNEX C
WITNESS TESTING AGREEMENT
 (INFORMATIVE)

This AGREEMENT is made this _____ day of _____, (year) _____, at _____
 _____ between the following parties:

ABC: (Name and address of ExCB) _____; and

XYZ: (Name and address of ExTL) _____; and

Test Facility MTF/ETF: (Name and address of manufacturer, ~~or~~ end user ~~or third party~~)

RECITALS

Whereas Witness Testing at ~~the Test Facility~~ ~~Manufacturer's or End User's facility~~ is a (XYZ) procedure for the use of a ~~Test Facility~~ ~~manufacturer's or end user's test facility~~ by (XYZ) staff in accordance with the applicable requirements of:

- a) (XYZ) Operating Procedures, and
- b) The rules of procedure of the IECEx System as stipulated in Operational Documents OD _____

Pursuant to which personnel from (XYZ) observe ("witness") all tests carried out at the ~~Test Facility~~ ~~(MTF/ETF)~~ using ~~Test Facility~~ ~~(MTF/ETF)~~ test equipment and personnel.

Whereas ~~the Test Facility~~ ~~(MTF/ETF)~~ wishes to participate in the Witness Testing Program and is prepared to cooperate with and provide the necessary assistance to (XYZ).

Now therefore, for and in consideration of the mutual covenants herein expressed and other lawful and valuable consideration, the parties agree as follows.

1.0 SCOPE

The Witness Testing Program operated under this Agreement covers the product safety Standards and tests described in **Schedule "A"** to this Agreement.

2.0 OBLIGATIONS & RESPONSIBILITIES OF THE TEST FACILITY (MTF/ETF)

- 2.1 Demonstrate that the test facility where witness testing is performed complies with the requirements of following applicable elements of ISO/IEC standard 17025: ~~2005~~, "General requirements for the competence of testing and calibration laboratories".
- 2.2 Possess the appropriate test equipment required to perform the tests specified in the standard(s) covered under Schedule A of this Agreement.
- 2.3 Have a calibration program that complies with the applicable requirements of ISO/IEC standard 17025: ~~2005~~.
- 2.4 Have technical staff with the necessary skills, training and hands on experience (minimum

three years) to perform the required tests.

- 2.5 Appoint an appropriate person to be responsible for the test facility and calibration services.
- 2.6 Assist (XYZ) personnel in the preparation for and conduct of tests by providing the services described in Schedule "B".
- 2.7 Ensure that all tests are carried out in accordance with the following:
 - a) The applicable technical requirements,
 - b) The test plan provided by (XYZ),
 - c) Any additional work instructions provided by (XYZ), using the test report forms required and supplied by (XYZ).
 - e)d) The TF can demonstrate, in case of Long term testing and/or Heating tests that the power supply conditions are appropriate Conditions are those defined in OD 24
- 2.8 Prepare and sign the required test reports using the relevant test report forms provided by (XYZ).
- 2.9 Compensate (XYZ) pursuant to agreed upon (XYZ) quotations for services and expenses in connection with the provisions of this Agreement.

3.0 OBLIGATIONS & RESPONSIBILITIES OF (XYZ)

- 3.1 Maintain complete and full responsibility for all testing carried out at the Test Facility(MTF/ETF) facility and for the integrity and completeness of the test results.
- 3.2 Provide the Test Facility (MTF/ETF) with the test plan and any additional work instructions required.
- 3.3 Check the test set-up for completeness and adequacy and verify the suitability of the Power supply based on evidences provided by (TF) Conditions are those defined in OD 24.
- 3.4 Verify the suitability and accuracy of test equipment used.
- 3.5 Verify proper calibration of test equipment before use.
- 3.6 Supervise, check and witness all critical aspects of the tests and the final data acquisition and conduct its validation where necessary.
- 3.7 Review and sign the accepted test report.
- 3.8 Perform the activities outlined in Section 4 of this Agreement.
- 3.9 Maintain all required documentation related to activities carried out under this Agreement.

4.0 QUALIFICATION ASSESSMENT AND CONTINUED VERIFICATION OF COMPLIANCE

- 4.1 Prior to conducting tests under the Witness Testing Program (XYZ) will conduct an initial assessment of the Test Facility (ETF/MTF) test facility to verify compliance with the relevant requirements of ISO/IEC standard 17025: 2005.
- 4.2 At each visit to the Test Facility (MTF/ETF) test facility under this program, (XYZ) will validate the initial assessment results to ensure the ongoing suitability of the facility and the competence of the Test Facility (MTF/ETF) personnel to perform the role assigned to them.

5.0 CONFIDENTIALITY

Although proprietary documents, material and information which come to the attention of (XYZ) in the course of performing services under this Agreement shall be regarded as confidential, (MTF/ETF) acknowledges and agrees that (XYZ) is obligated to disclose such information to other third parties in accordance with the relevant rules and requirements of:

- a) (Name of accreditation body/Bodies under which XYZ is accredited),
- b) The IECEX System

6.0 MISCELLANEOUS TERMS AND CONDITIONS

- 6.1 This Agreement shall continue in effect as long as both parties jointly agree to and abide by its terms and conditions.
- 6.2 This Agreement is subject to cancellation by either party upon giving a written notice to the party.
- 6.3 This Agreement, including the Schedules referenced herein shall be executed in triplicates, each of which shall be considered to be an original.

On behalf of Test Facility(MTF/ETF)

Name: _____

Title: _____

Signature: _____

On behalf of (XYZ)

Name: _____

Title: _____

Signature: _____

On behalf of (ABC)

Name: _____

Title: _____

Signature: _____

Schedule A

The standards and tests listed below are covered under this Agreement

TEST STANDARD	TESTS

Redline Version

SCHEDULE B

| ~~The Test Facility (MTF/ETF)~~ agrees to assist (XYZ) in conducting the Off-site Testing Program by providing the following services:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

Redline Version