**INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC) SYSTEM FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

**Title: Discussion Document – Use of Electronic files as Schedule and Related drawings in IECEx system**

**Circulated to: ExTAG – IECEx**

**INTRODUCTION**

At various times the subject of IECEx requirements regarding “Use of Electronic Files” in place of the traditional paper printed drawings has been discussed.

During the ExTAG 2021 Remote Meeting, this issue was brought up and decision taken “Mr Ajay Maira, ExTC, AU has been tasked with preparing a discussion paper (noting that ExTAG WG 03 for IECEx OD 017 needs to be consulted) on the acceptance of electronic files for drawings etc.”

This document has been prepared by Ajay Maira, Certification Manager at Ex Testing and Certification Pty Ltd, Australia, in consultation with other stakeholders. This document is now proposed for further discussions on this subject during the ExTAG Remote Meeting September 2022 as part of WG03 (Revision of OD 017) discussions.

ExTAG Members are requested to note this document and offer comments.

**IECEx Secretariat**

|  |
| --- |
| **Address:**  **IECEx Secretariat**  **Level 33 Australia Square**  **264 George Street**  **Sydney NSW 2000**  **Australia**  **Web:** [**www.iecex.com**](file:///C:\Users\christine.kane\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\christine.kane\AppData\Local\Microsoft\Windows\christine.kane\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Users\horn02\AppData\Local\christine.kane\AppData\Local\Microsoft\christine.kane\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Christine.Kane\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\AppData\Local\jugauthier\AppData\Local\Temp\notesC9812B\www.iecex.com) |

1. **Introduction**

This paper introduces the discussion on the use of ‘Electronic Files as acceptable documentation for Ex compliance’.

The Background section introduces the scope of ‘Documentation’.

The next section shows the development of Documentation and why Electronic Files are being considered necessary.

It then introduces the Risks using Electronic Files, mitigation methods and their application for the laboratory accreditation Standard ISO/IEC 17025, the manufacturer’s quality system requirements Standard ISO/IEC 80079-34, the documentation requirements of IECEx using OD 017, and the documentation requirements of the General Requirements Standard IEC 60079-0

The final section ‘Conclusion’ provides the proposed methodology for the use of ‘Electronic Files’.

It is the intention of this discussion paper that the use of Electronic Files shall be documented in a manner that allows the IECEx and other Ex certification schemes to accept Electronic Files as an alternative to the traditional paper based or pdf documents. It is not proposed to obsolete or discredit the use of the traditional documents.

In this discussion paper, when discussing ‘documentation’, the terms ‘manufacturer’ and ‘applicant’ are used interchangeably.

1. **Background**

Compliance of equipment to the Ex Standards is usually based on:

1. assessment of the ‘product documentation’
2. physical examination of a sample of the product
3. tests conducted on the sample of the product

Based on the above, a test report is prepared that provides information on the compliance with the applicable Ex Standard.

1. The ‘product documentation’ is necessary to record the characteristics of the product in a manner that ‘freezes’ the design. The ‘product documentation’ is then listed in the test report as a ‘scheduled drawing’. Any further changes to the design and hence documentation will then be covered in a ‘document change procedure’.

IECEx OD 017 lists the requirements for product documentation.

It is often the case that the manufacturer / applicant creates a ‘related drawing’ that is used for the detailed manufacture, and a ‘schedule drawing’ that is listed in the report / certificate and enables the conformity of the product with the requirements of the applicable Ex Standards. The ‘related drawing’ must comply with the requirements of the ‘schedule drawing’. This discussion paper is aimed at the ‘schedule drawings’ listed in the report / certificate, but may be extended to ‘related drawings’ as well.

Example of these are:

* An isometric view of an enclosure, with plan, elevation, side views, cross sectional views, with sizes, material, internal construction, encapsulation material and thickness, cable entry provisions
* Printed circuit board assemblies, with documents showing the printed circuit board layouts, material, thickness, layer data, assembled components (including rating, type number), schematic drawings and block diagrams to aid in understanding the product design.

This discussion paper focuses on the format of ‘product documentation’ – how should the product documentation be provided, and how will it be controlled in a manner that suffices the responsibility of the manufacturer (applicant), the test laboratory that provides the compliance test report, and the responsibility of the Ex certifying schemes.

1. and c) regarding sample examination and tests conducted using laboratory test equipment are not discussed in this paper.
2. **Documentation – Traditional and the Future**

Level i):

In the early parts of the last century, documents submitted by the manufacturer to the Ex laboratory were hand drawn drawings, sent by post or by hand, with ammonia printers and photocopiers used to generate duplicates that would be held in the records of the Ex laboratory.

Often a rubber ink stamp would be applied to the copy returned to the manufacturer signifying that this document had been used during the compliance assessment.

The test report would list the document by title, drawing number, revision number and date to provide traceability between the report and the actual drawing used for the assessment.

Level ii):

With the advent of fax machines, transmission of documents became faster, but a layer of risk was added – how sure is the Ex laboratory that the document sent by fax is indeed the correct copy of the original?

Ex laboratories generally mitigated this risk by keeping a stamped version of the documentation received in their records, and sending a copy of the stamped documents back to the manufacturer.

Level iii):

With the advent of computers, the hand sketched drawings were replaced by the same drawing information now in a computer file that could be readily viewed and printed. In this era, either the paper printed copy of the electronic file was sent to the Ex laboratory for the compliance assessment, or the electronic file itself was transmitted by emails etc. This could be in the form of photos, scan data, or pdf files.

However, it is noted that the design was still in the ‘head of the designers’, and the electronic file was only a method of documenting the design for the compliance assessment.

Another layer of risk was added – how sure is the Ex laboratory that the document sent is indeed the correct copy of the electronic file?

Ex laboratories generally mitigated this risk by keeping a printed version of the drawing in their records, stamping a copy, and sending the stamped copy back to the manufacturer.

Often an electronic scan (pdf) of the stamped drawing was used for the secure storage.

Level iv):

We are now in the era where the electronic file is made by the CAD (computer aided design) software. In this case, the CAD software itself is the method by which the design is created. The electronic design files are able to be read by machines that manufacture the parts of the product. Often text pages are added to the CAD files to indicate the material, heat treatment etc. Also, quite often, additional electronic documents such as word files or pdf files indicate the bills of materials, fasteners used, encapsulation details etc.

All these electronic files require suitable Readers to decode the information for understanding the product and to conduct measurements.

In this case, printed copies of the original CAD / PCB drawings are ‘created’ by using the print facilities of the CAD / PCB design software.

Under Level iv) the following risks were identified as listed in section 4 below.

1. **Additional risks to be navigated when using Electronic Files:**
2. How sure is the Ex laboratory that the Electronic File sent by the manufacturer is indeed the correct one being used to certify the product?
3. Is the Electronic File complete? For example, the Electronic File may be missing a pcb layer information and the Ex laboratory may not have taken that into consideration during the compliance assessment.
4. Is the Electronic File being read by the correct Electronic File Reader? Often the version of the CAD / PCB design software will be revised quite often and hence the older version Reader may not be able to read all of the information in the Electronic File.
5. Are sufficient test records being prepared to document the compliance information obtained from the Electronic File?
6. Does the Ex laboratory have the technical expertise and capability in reading the Electronic Files? Often the training requirements for using the CAD / PCB software may be quite extensive, and the Ex laboratory staff may not have trained their staff, specially as the manufacturers may choose CAD / PCB software that may not be the same one that the Ex laboratory had trained its staff on.

We have not discussed intellectual property safeguards in this discussion paper. It is assumed that the manufacturer has established the necessary non-disclosure agreements with the Ex laboratory such that they are able to confidently provide the complete Electronic Files without holding back information.

It is the opinion of the author of this discussion paper that Level iv) (using CAD / PCB software for design and manufacture) is the norm now. It allows creation of complex modern designs and aids quicker development of the product, lesser costly errors in the mismatch of parts and faulty assembly. It is the present and foreseeable future for product design and manufacture.

The results obtained by interrogating the CAD / PCB file for dimensional measurements, thickness of the materials specially where curved surfaces are involved, interference, gaps, specially where the assembly of the parts allows relative movement, are much superior to those possible by reading paper documents.

Similarly for printed circuit boards, distances between tracks and components are read with much greater accuracy using PCB electronic files. Interrogation using the appropriate software results in lesser errors, specially where complex electronic assemblies are being considered.

1. **Navigating the risk requirements of using CAD / PCB electronic files**
2. How sure is the Ex laboratory that the Electronic File sent by the manufacturer is indeed the correct one being used to certify the product?

Electronic files may be identified by the file name, date of creation. Unfortunately, these can be manipulated quite easily.

They also may be identified by file size, file extension, but invariably even by creating copies, the file size can change.

The proposed methodology (see Conclusion ii)) is to create an accompanying pdf drawing that contains the traditional title block, name of the manufacturer, document name and title, with revision history showing the revision number and date, with approval information. This drawing should list the Electronic document File name with date of creation (or version number).

This pdf drawing will be listed in the test report, and will be held on file. It may also be returned to the manufacturer with a ‘stamp’.

The Ex laboratory will hold the above pdf drawing and also the Electronic File in their secure electronic data storage.

If ever a check is to be made regarding the identicality of the Electronic File held by the Ex laboratory and any other file that claims to be the correct version, there are several easily available data comparison programs that will compare the data in the two versions and provide visual information of the changes in the data, if found.

1. Is the Electronic File complete? For example, the Electronic gerber file may be missing a pcb layer information and the Ex laboratory may not have taken that into consideration during the compliance assessment.

The proposed methodology (see Conclusion iii)) is to provide a pdf drawing (with title block etc as discussed earlier) that would depict, as an example for PCB drawings, all the pcb layers so that the Ex laboratory can check that the same and complete information is provided in the Electronic File using the appropriate Reader. Similarly, for mechanical drawings, an isometric view, plans, elevations, critical cross sections may be created that would allow the Electronic File information to be confirmed. Overall dimensions may be placed on this drawing to allow validation of the same from the CAD / PCB file interrogation.

It is satisfactory if the pdf drawing were a series of screen shots obtained when reading the Electronic File with its native application program that would serve the purpose that the pdf drawing is traceable to the Electronic File.

It is quite expected that the pdf document discussed in a) providing the filename information may also provide the necessary information as discussed in b).

1. Is the Electronic File being read by the correct Electronic File Reader? Often the version of the CAD / PCB design software will be revised quite often and hence the older version Reader may not be able to read all of the information in the Electronic File.

The proposed methodology (see Conclusion iv)) is to provide sufficient information of the Electronic File design software (with revision number) being used, with a recommendation of the Electronic File Readers (with revision number) to be used.

The above methodology, in combination with the information required to address the risk discussed in b) above, will minimise this risk.

It is quite expected that the pdf document discussed in a) providing the filename information may also provide the necessary information as discussed in b) and c).

1. Are sufficient test records being prepared to document the compliance information obtained from the Electronic Files in a manner sufficient to meet the traceability requirements for measurements?

The proposed methodology (see Conclusion v)) is to prepare comprehensive test records based on the measurements of the software interrogation of the Electronic File and list all the results that provide the compliance information.

Examples would be listing the maximum flamepath gap in a spigot joint, or the minimum creepage measurement across a current limiting resistor mounted on a printed circuit board. The test record would contain information regarding the Electronic File that was interrogated, the Reader used, date, name of technical staff etc as required under IEC 17025 requirements.

1. Does the Ex laboratory have the technical expertise and capability in reading the Electronic Files? Often the training requirements for using the CAD / PCB software may be quite extensive, and the Ex laboratory staff may not have trained their staff, specially as the manufacturers may choose CAD / PCB software that may not be the same one that the Ex laboratory has trained its staff on.

The proposed methodology (see Conclusion vi)) is for the Ex laboratories to develop sufficient skills and expertise in the use of the Electronic File Reader software to allow an independent review of the design and to interrogate the Electronic File for the Ex compliance determination.

It is understood that the proficiency of the manufacturer to use the software program for creation of the design to be superior to the skills and experience of the Ex laboratory. Therefore while it is expected that the Ex laboratory would be discussing with the manufacturer to understand the various information that depicts the product, the Ex laboratory shall require to ensure that their independence and impartiality is not placed at risk by being influenced by the manufacturer.

1. **ISO/IEC 17025 Requirements pertinent to this Discussion Paper**

|  |  |  |
| --- | --- | --- |
| ISO/IEC 17025:2018  Clause # | Requirement | Application using this methodology |
| 6.2 Personnel | “The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.” | As provided in Conclusion vi) the Ex laboratory requires to develop sufficient skills and expertise in the Electronic File software to allow an independent review of the design and to interrogate the CAD design for the Ex compliance determination. Optionally, to establish and implement procedures that allow the Ex laboratory to use the skills and knowledge of the manufacturer without compromising independence of the assessment. |
| 6.4 Equipment | “The laboratory shall have access to equipment (including … software..) that is required for the correct performance of laboratory activities and that can influence the results.” | As provided in Conclusion iv) the pdf drawing provides the Ex laboratory information to review their resources prior to accepting the job. |
| 6.4 Equipment | “Records shall be retained … that include the following, where applicable:  a) the identity of equipment, including software and firmware version; | As provided in Conclusion v) the test record prepared will list this information. |
| 7.1 Review of requests, tenders and contracts | “the laboratory has the capability and resources to meet the requirements;” | As provided in Conclusion iv) and vi), the pdf file with information on the Electronic File design software (with revision number) will allow the Ex laboratory to review their resources and capabilities during the contract review process |
| 7.11 Control of data and information management | “Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the shelf software, they shall be authorized, documented and validated before implementation…  Note 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated” | As provided in Conclusion iii) overall dimensions placed on this pdf drawing will allow validation of the same from the Electronic File interrogation. |

1. **ISO/IEC 80079-34 Requirements pertinent to this Discussion Paper**

|  |  |  |
| --- | --- | --- |
| ISO/IEC 80079-34:2018  Clause # | Requirement | Application using this methodology |
| 3.8 schedule drawing | “Drawing or document listed in the certificate or test report” | As provided in Conclusion ii) the methodology of using the pdf drawing allows it to be listed in the certificate and test report |
| 3.10 technical documentation | “documentation that enables the conformity of the product with the requirements of the  standard(s) to be assessed  (Note: It covers the design, manufacture and operation of the product and can contain:  – a general description;  – design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;  – descriptions and explanations necessary for the understanding of drawings and layouts and the operation of  the product;  – a list of the standards referred to in the certificate, applied in full or in part, and descriptions of the solutions  adopted to meet the requirements of the standards;  – results of design calculations made, examinations carried out, risk assessment etc.;  – test reports” | ‘Documentation’ in this Clause is interpreted as ‘including electronic file’.  As provided in Conclusion i) this will now include not just CAD / PCB files, but also excel files, word files, pdf files that will provide the information listed in this Clause.  Pdf files as discussed in Conclusion ii) and iii) would be required to complete the information provided in the electronic file of Conclusion i). |
| 7.5.3 Control of documented Information | “there shall be a documented system that refers all related drawings to the relevant  schedule drawings” | The word “drawings” had been interpreted as similar to “documents”.  It is then appropriate to consider electronic files as ‘related drawings’.  Based on the discussion at Conclusion i) these files will need to be controlled in conjunction with Conclusion ii) |

1. **IECEx requirements OD 017 Requirements pertinent to this Discussion Paper**

|  |  |  |
| --- | --- | --- |
| IECEx OD 017:2019  Clause # | Requirement | Application using this methodology |
| 1, 2 | “The drawings and other documentation provided to demonstrate explosion protection  conformity of the product”  “..are a definitive specification of the product that  has been certified” | Use of the Electronic File fits this definition as it is not listed in the certificate but linked to the pdf schedule drawing.  The Electronic File is used for detailed manufacture |
| 4.1 General requirements | All drawings should be identified by: drawing number, revision number, date of revision, title  and name of the design authority in whose drawing record system the drawing is recorded  (with relationship to the manufacturer if different). | As provided in Conclusion i) the pdf of an electronic file is not possible.  However, by using the methodology of Conclusion ii) to reference the Electronic File, it is then possible to provide all the details listed in this Clause of OD 017 in the document of Conclusion ii). |

1. **IEC 60079-0 General Requirements**

|  |  |  |
| --- | --- | --- |
| IEC 60079-0:2017  Clause # | Requirement | Application using this methodology |
| 3.74 related drawing | Drawing or document not listed in the certificate but linked to the schedule drawing, and used for example, for detailed manufacture of component parts | Use of the Electronic File of Conclusion i) fits this definition as it is not listed in the certificate but linked to the pdf schedule drawing.  The Electronic File is used for detailed manufacture |
| 3.76 schedule drawing | Drawing or document listed in the certificate or test report | As provided in Conclusion ii) the methodology of using the pdf drawing allows it to be listed in the certificate and test report |
| 24 Documentation | The manufacturer shall prepare documentation that details the explosion safety aspects of the equipment necessary to determine compliance with this Standard and any other applicable explosion safety standards. | As provided in Conclusions ii) and iii) the preparation of the Electronic File together with the accompanying pdf drawing will be used to determine compliance with the Ex Standard. |

1. **Conclusion**

This discussion paper has suggested a solution for the use of electronic files by the following methodology:

1. The electronic file (or folder) provided by the manufacturer shall have a name and date of creation (version number can be used, if more convenient). This shall be held securely by the Ex laboratory. This may be considered as a ‘related drawing’ as per IEC 60079-0
2. An accompanying pdf drawing (with the traditional title block, name of the manufacturer, document name and title, with revision number and date etc) shall be created by the manufacturer. This drawing should list the above electronic document file name with date of creation (or version number). This pdf drawing will be considered as a ‘schedule drawing’ as per IEC 60079-0, will be listed in the test report, and will be held securely by the Ex laboratory. It may also be returned to the manufacturer with a ‘stamp’.
3. A further pdf drawing will be created that would depict sufficient information of the electronic file such that it can be checked that the information is consistent with that in the electronic file. (Example: for mechanical drawings, a 3-D isometric drawing, plans, elevations, critical cross sections may be shown. For printed circuit boards, all the pcb layers would be depicted). This pdf drawing will be considered as a ‘schedule drawing’ as per IEC 60079-0, will be listed in the test report, and will be held securely by the Ex laboratory. It may also be returned to the manufacturer with a ‘stamp’. It is allowed that this drawing may be amalgamated with ii).
4. Another pdf drawing will be provided with sufficient information on the Electronic File design software (with version number) and recommended Reader that pertains to the electronic file of i) above. It is allowed that this drawing may be amalgamated with ii).
5. Test records prepared by the Ex laboratory recording the measurements based on use of the electronic file will list the electronic file (with revision number) being applied, and the electronic file Readers (with revision number). (Examples: dimensional measurements by interrogating CAD file or pcb / Gerber files with Autodesk / Gerberview).
6. The Ex laboratory shall establish competency of their staff to read and interrogate the electronic files with suitable software. Optionally to establish and implement procedures that allow the Ex laboratory to use the skills and knowledge of the manufacturer without compromising assessment independence.

This document is being circulated to generate comments and views, and the final presentation will be made at the 2022 Annual meeting of the ExTAG.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*