



# **Suspension and Cancellation of IECEx Certificate of Conformity**

## **Expectations of actions to be undertaken by ExCBs**

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International  
Electrotechnical  
Commission



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# Overview of process

## Current relevant documents of the IECEx system

- Rules of procedure IECEx 02 Ed. 5.2
- Operational document IECEx OD 009 Ed. 3.0
- Operational document IECEx OD 025 Ed. 3.0
- Operational document IECEx OD 011-1
- Operational document IECEx OD 011-2
- Guide IECEx 01D



## Overview of process

Change (suspension or cancellation) may be request by :

- Manufacturer / Holder
- Certification body
  
- General requirements are given in the document  
Rules of procedure IECEx 02 Ed. 5.2 e.g. Clause 9.11
  
- In addition, specific guidance relative to suspensions following surveillance of manufacturer (QAR) can be found in :
  - Operational document IECEx OD 009 Ed. 3.0 Section 4
  - Operational document IECEx OD 025 Ed. 3.0 Clause 6.8.1 +.2



# Overview of process

## Reasons for suspension or cancelation of CoC : (IECEX 02 § 9.11)

- the holder requests cancellation or suspension (eg. manufacturer may no longer manufacture the product or during relocation of premises)
- CoC is used in a misleading way



# Overview of process

## Reasons for suspension or cancelation of CoC :

*(IECEX 02 § 9.11)*

- the Ex equipment no longer corresponds to the design of the certified equipment, or the QAR no longer adequately covers the relevant Ex equipment
- the manufacturer's quality system and associated quality plan no longer provides adequate confidence that Ex equipment will be produced in conformity with the design of the certified equipment



# Overview of process

## Reasons for cancelation of CoC :

*(IECEX 02 § 9.11)*

- CoC has been issued in error
- the assessment by an ExTL has been found to be deficient
- the equipment design cannot be considered as explosion protected

An ExCB may also decide to cancel a CoC if the manufacturer has not improved satisfactory corrective actions after suspension.



# Overview of process

## Obligations of ExCB :

- Advise the applicant / manufacturer of intended action and agree on a date of the cancellation or suspension being effective
- Notify as soon as possible the IECEx Secretariat to reset the status to “Suspended” or “Cancelled”
- Notification to Secretariat shall include
  - the reason for suspension or cancellation + effective date
  - information about impact on Ex equipment supplied prior to the cancellation/suspension of the certificate (for example, not affected and need not be withdrawn from the market or from the field)





# Overview of process

## Obligations of ExCB :

- Give due notice to the manufacturer of such suspension or cancellation and state the reason(s)
- Inform manufacturer that the Ex equipment shall not be anymore described as "IECEx certified", nor affix the IECEx Conformity Mark



## Information to be contained in CoCs

- After due notification by ExCB, IECEx Secretariat changes the status of CoC to “Suspended” or “Cancelled”
- An explanatory paragraph is added to the “Equipment” field of the CoC, including :
  - Actual date of suspension/cancellation
  - Body to be contacted for details (applicant and/or ExCB)
  - Impact on previous supplied products
- CoC “**suspended**” can be restored to “Current” (once the reasons of suspensions are resolved)
- CoC “**cancelled**” CANNOT be restored to “Current”



# Information to be contained in CoCs

## Example of suspended Certificate



## IECEX Certificate of Conformity

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Certificate No:

Issue No: 0

Date of Issue:

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**Schedule**

**EQUIPMENT:**  
*Equipment and systems covered by this certificate are as follows:*

**NOTE:** *This Certificate is suspended from **16th July 2016** at the request of the issuing IECEx Certification Body (ExCB). Products produced or installed prior to this date are NOT affected by this suspension. Any comments or questions may be directed to the ExCB.*



# Information to be contained in CoCs

## Example of cancelled Certificate



## IECEx Certificate of Conformity

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Certificate No:

Issue No: 0

Date of Issue:

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**Schedule**

**EQUIPMENT:**  
*Equipment and systems covered by this certificate are as follows:*

**Note:** *This Certificate is cancelled as of 12 November 2013 at the request of the Applicant. This cancellation does not affect products previously purchased or installed. Any questions should be directed to the Applicant or the ExCB.*



## Impact on product previously supplied and in the field

According to IECEx 02 § 9.11 :

*“Equipment already supplied prior to the suspension or cancellation of the certificate is generally not affected by this change of certificate status.”*

However, an analysis of the impact on products previously supplied is necessary to determine which case applies :

- No impact to products already supplied prior to date of suspension/cancellation (eg. Suspension because of premises relocation)
- Products provided prior to the date of suspension/cancellation (may be limited to a batch of products) may require withdrawal from the market or other corrective action to ensure compliance : products considered as non-conforming.



## Impact on product previously supplied and in the field

- According to clause 8.3 of ISO/IEC 80079-34 (control of non-conforming products), the risk analysis is to be performed by the manufacturer.
- Support of ExCB may be requested (for complementary assessment, expertise or performance of specific additional tests to demonstrate safety of supplied product).
- The analysis shall conclude on :
  - The degree of risk
  - The appropriate action to be taken by the manufacturer



## Impact on product previously supplied and in the field

If there is a safety issue with product previously supplied the manufacturer shall :

- Inform the customer and ExCBs involved, and if necessary instigate product recall
- Place notice in appropriate publications providing recommended action to be taken where it is not possible to trace the unsafe, nonconforming product (e.g. product supplied via a distributor, or for high volume products such as cable glands)
- Maintain records
- If relevant, provide notification to Regulatory Authorities



## Follow-up of actions by the ExCB

After suspension, ExCB is intended to :

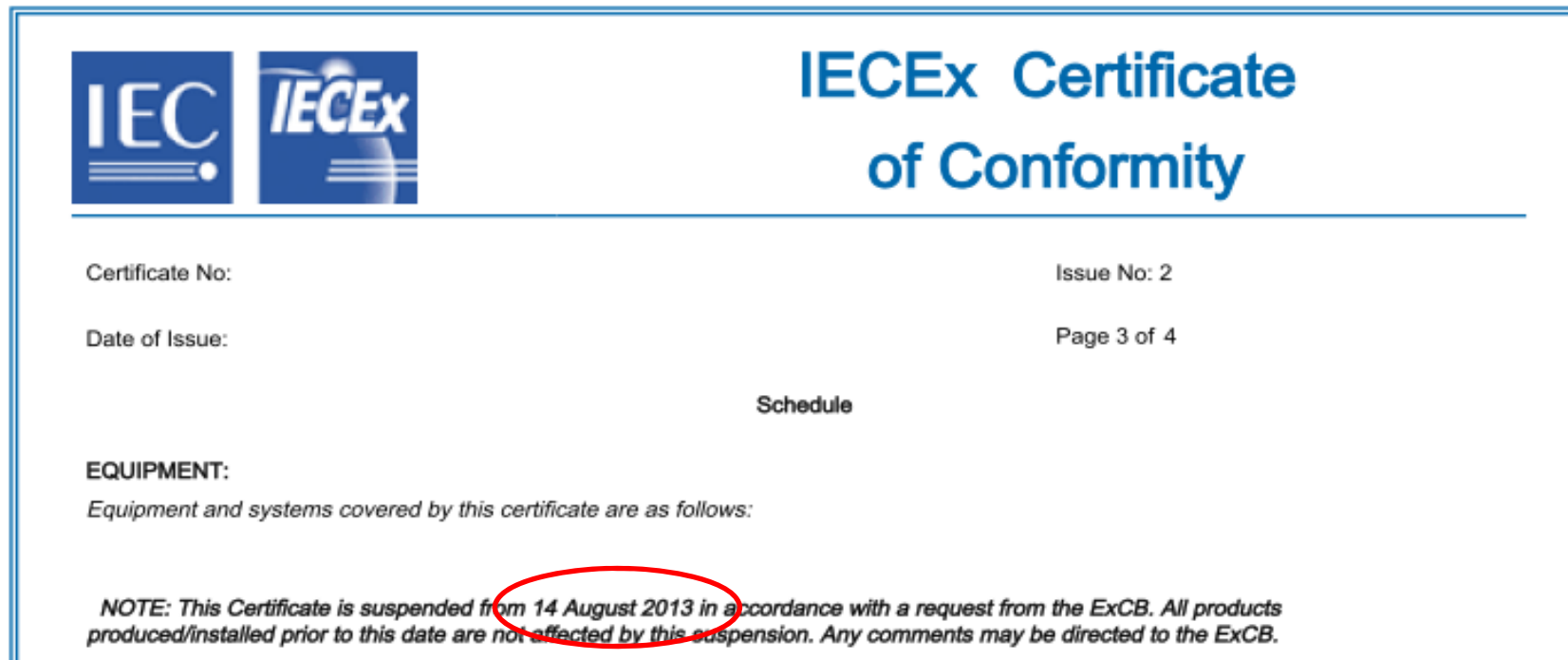
- Define with manufacturer / holder the necessary actions to implement
- Define a timeframe (recommended not greater than 12 months) to implement the corrective actions
- Check that the concerned Ex Products are not anymore described as "IECEx certified" on the manufacturer / holder documentation and marketing material, eg website
- Ensure the follow-up of any expected corrective actions required





# Follow-up of actions by the ExCB

**Remind** : suspension of Certificate should only be considered as a short term issue



Example of “old” suspended Certificate that should already have been cancelled.



## Information on Special Task Group led by Andy Smith, CSA

- ExMC WG1 has decided during last IECEx operational meetings (May 2016) to establish a Special Task Group
- Convener : Andy Smith, CSA
- Expect to develop guidelines on the steps and processes that ExCBs should undertake when the situation arises for the need of an IECEx CoC to be suspended or cancelled
- Guidelines intended to ensure that all ExCBs operate in a consistent manner
- First draft already prepared by Andy Smith and sent to the group



## Information on Special Task Group led by Andy Smith, CSA

Discussions currently includes (not limited to) the following issues :

- Details about processes for status changes including expected timeframe
- Actions to be taken
- Communication to parties and information content
- Investigation methods of non-conforming products
- Involvement of surveillance authorities

Group meeting held last Sunday in Umhlanga to discuss the proposal