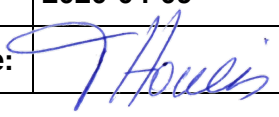
ExNB	Co-ordination of Notified Bodies Directive 2014/34/EU of the European Parliament and of the Council (ATEX) *Equipment and protective systems intended for use in potentially explosive atmosphere*	Clarification Sheet N° ExNB/CS/017

Status:	Step*5.2.1	Initial proposal by	Ineris and Dekra BV	Date:	2020-02-10
	Step 5.2.2	Final Draft		Date:	2020-02-10
	Step 5.2.3				2020-04-09

Step refers to ExNB Rules

Authorised by Chairman:	Mr. Houeix	Date:	2020-04-09
Date of application:	2020-04-09	Signature:	

Question regarding how to deal with Organizations holding an ATEX Quality Assurance Notification due to Extraordinary Circumstances

Description of situation:

Due to Extraordinary Circumstances like travel restriction, it is sometime impossible to perform On-going Surveillance and Follow-up at the Manufacturing Site as originally scheduled.

What it is authorised to do in order to act a Notified Body?

Answer:

For Notified Bodies that have issued an ATEX Quality Assurance Notification in accordance with Annex IV and/or VII to organizations (e.g. manufacturers) located in countries / regions / areas impacted by an Extraordinary Circumstances, where travel to that area is restricted, the requirements of 1.1 and 1.2 shall apply.

Subject:	Directive, 2014/34/EU Article No.	
	Directive, ESR No.	
	Directive, Module Annex No.	Annex IV and VII
	Standard, No.	

This ExNB Interpretation/Clarification Sheet has the sole purpose of clarifying the application of the EN Standards and/or of the requirements of Directive 2014/34/EU and related documents. It does not in any way change the content of the standards and/or of the requirements. It remains valid until an official answer is received from the European Commission of the relevant standardization bodies.

1. Scheduled surveillance audits – Postponed for up to 6 months

The scheduled surveillance audits of organizations holding an ATEX Quality Assurance Notification in accordance with Annex IV and/or VII may be postponed for a maximum period not exceeding 6 months on the strict provisions of:

1. That there are no outstanding non-conformances; and
2. That the Notified Body is not aware of any complaints or concerns that could give rise to the Notified Body questioning the on-going compliance of the organization covered by the an ATEX Quality Assurance Notification in accordance with Annex IV and/or VII, with the requirements of Directive 2014/34/EU, associated EN ISO/IEC 80079-34.

2. Scheduled surveillance audits

Where clause 1 is not met or for periods beyond 6 months or for the processing of scope extensions, that normally require a site visit, the following provisions apply:

1. The use of video communication maybe considered for closing out issues raised during a previous site audit visit associated with the scope of certification.
2. Video communication may be used to gather the objective evidence required to demonstrate a manufacturer's compliance with the requirements of EN ISO/IEC 80079-34 to enable the surveillance or re-assessment factory audit to be conducted as required by Directive 2014/34/EU. The Notified Body shall determine the applicability and use of this method.
3. Video Communication may be used to gather the objective evidence required to demonstrate a manufacturer's compliance with the requirements of EN ISO/IEC 80079-34 when processing an application for an "up issue" of the certification scope. The Notified Body shall determine the applicability and use of this method.
4. The Notified Body may require the organization / manufacturer to provide results of the organization's previously conducted internal audit for the Notified Body to review and gather sufficient evidence that the requirements of EN ISO/IEC 80079-34 continue to be met. The Notified Body may also require the organization / manufacturer to conduct an internal audit under the instruction of the Notified Body. Organizations / manufacturers may also be audited by other third-party Ex auditing

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companies for the purpose of national accreditation schemes. These audit results should also be assessed where they exist.

The main point to stress is that even during situations arising from Extraordinary Circumstances, including Events; it is not acceptable for a Notified Bodies to simply do nothing, as they are responsible to exercise some level of surveillance over the organisations to which they have issued an ATEX Quality Assurance Notification in accordance with Annex IV and/or VII.

3. Extending validity of or Issuing a new notification based on re-assessment in compliance following clause 1 and/or clause 2:

For the issue of the notification is in a re-assessment stage, the following provisions apply:

1. in compliance with clause 1, the notification validity may be extended with a maximum of 6 months.
2. in compliance with clause 2, a new issue of the notification may be issued following the normal follow-up procedures.

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