

Conditions and procedures for granting, maintaining, extending, carrying out, suspending and withdrawing certification

IECEX	
Approval	<p>Certification may be refused if:</p> <ul style="list-style-type: none"> • One of the Essential Health and Safety Regulations (EHSR), as described in the Directive in question, has not been upheld. • One of the points applicable to the various standards involved is not adhered to, and thus does not enable EHSRs to be met. • One of the non-compliance issues found has not been addressed. <p>When a piece of equipment does not pass a test, the manufacturer is asked to make modifications to their equipment. If the manufacturer refuses to make these modifications, the French National Institute for Industrial Environment and Risks (INERIS) will not issue the certification. In the event of a refusal, the manufacturer may appeal this decision through the ad hoc Certification Committee or through the Ministry for Industrial Safety (a plea procedure will be provided). Indeed, the Ministry is tasked with adjudicating on disagreements between Notified Bodies and manufacturers or importers for France (Articles 8 and 13 of Decree 96-1010). The French National Institute for Industrial Environment and Risks (INERIS) will provide a detailed explanation for its rejection.</p>
Rejection	<p>In the event that the results of the ExTL and ExCB tests and examinations (quality audits) are negative, the ExCB will not issue the IECEX certificate of compliance. In the event that the applicant contests a decision affecting them, they may solicit a fresh examination of their application. In this event, they may request that the French National Institute for Industrial Environment and Risks (INERIS) hears their appeal.</p>
Maintenance	<p>The certification remains valid as long as the product has not been subject to any modification. It is the responsibility of the manufacturer to present their product to the French National Institute for Industrial Environment and Risks (INERIS) when any such modifications are made. The applicant must inform the Notified Body of any and all modifications made to the approved product, which must receive fresh approval should said modifications call into question the product's compliance with IEC standards or its stated conditions of use. Where a new approval is necessary, it is delivered in the form of an addendum to the certification for the initial EU-type examination.</p>
Extension	<p>If the manufacturer wishes to modify certified Ex equipment, they must apply to the ExCB that handed down the IECEX certificate of compliance, describing the changes and the measures adopted to ensure continued compliance with the appropriate standard(s). The ExCB will judge whether it is necessary to check that the Ex equipment having been modified remains compliant with the standards. The ExCB will publish a supplementary clause to the certificate authorising the modification. The ExMC will indicate the positioning and the content of the amendment. The ExMC will determine the scale of the change, which may be authorised by using an amendment to the original certificate. An ExCB may determine that a major change requires the issuance of a new certificate. All modifications that the company may wish to make must be subject to a request for the extension or modification of the certificate, in accordance with the rules and procedures set by the IECEX. With regard to modifications pertaining to the types of equipment certified and the quality assurance measures implemented, all modifications which could potentially affect product quality and safety must be indicated, in writing, to the French National Institute for Industrial Environment and Risks (INERIS), which will issue a decision regarding the company's right to use the mark within a period of no more than 30 days.</p>
Reduction	<p>The French National Institute for Industrial Environment and Risks (INERIS) will make all necessary modifications to official certification documents and information destined for use by the public, etc., in order to guarantee that the client has received clear information about the reduction in scope, and that this is specified in a clear manner in such certification documents and information destined for use by the public.</p>
Termination Suspension Withdrawal	<p>A certification may be terminated at the client's request. An IECEX certificate of compliance may be suspended or withdrawn by the ExCB having issued it.</p> <p>The ExCB will issue a notification and explain any such suspension or withdrawal to the manufacturer. When a certification is suspended or withdrawn, the manufacturer may no longer indicate that their Ex equipment is "IECEX certified". Any equipment supplied prior to the withdrawal of the certification will not be affected. When an IECEX certificate of compliance has been withdrawn, the ExCB having issued/withdrawn it shall inform the secretariat of the ExMC as soon as possible. The withdrawal of certificates will be communicated to other ExCBs via a publication in the IECEX bulletin.</p> <p>The French National Institute for Industrial Environment and Risks (INERIS) may also have cause to suspend or withdraw a certificate in the event of non-payment.</p> <p>When a certification is suspended, during the suspension period the applicant may not make any declarations which may mislead another party as to the status of their certification. They shall cease to use the mark of certification on products manufactured after the date on which the suspension notification is issued. During this suspension period:</p> <ul style="list-style-type: none"> <input type="checkbox"/> No IECEX certified product shall be placed on the market. <input type="checkbox"/> Potentially-defective products shall be subject to corrective actions, including recalls where necessary. <p>The French National Institute for Industrial Environment and Risks (INERIS) cannot issue a cancellation of the IECEX mark.</p>
Validity	-
Communication by the French National Institute for Industrial Environment and Risks (INERIS) to the Notifying Authority:	<p>The IECEX is not affected by communications with the Notifying Body. However, when an IECEX certificate of compliance has been withdrawn, the ExCB having issued/withdrawn it shall inform the secretariat of the ExMC as soon as possible.</p>
Communication by the French National Institute for Industrial Environment and Risks (INERIS) to Notified Bodies	<p>The IECEX is not affected by communication with other Notified Bodies. However, the withdrawal of certificates will be communicated to other ExCBs via a publication in the IECEX bulletin.</p>
Contestation of the decision	<p>In the event that a decision is contested, the details of the process are described in procedure PR-0861 "General Rules for the Certification of Products and Services", available via the French National Institute for Industrial Environment and Risks (INERIS) website.</p>

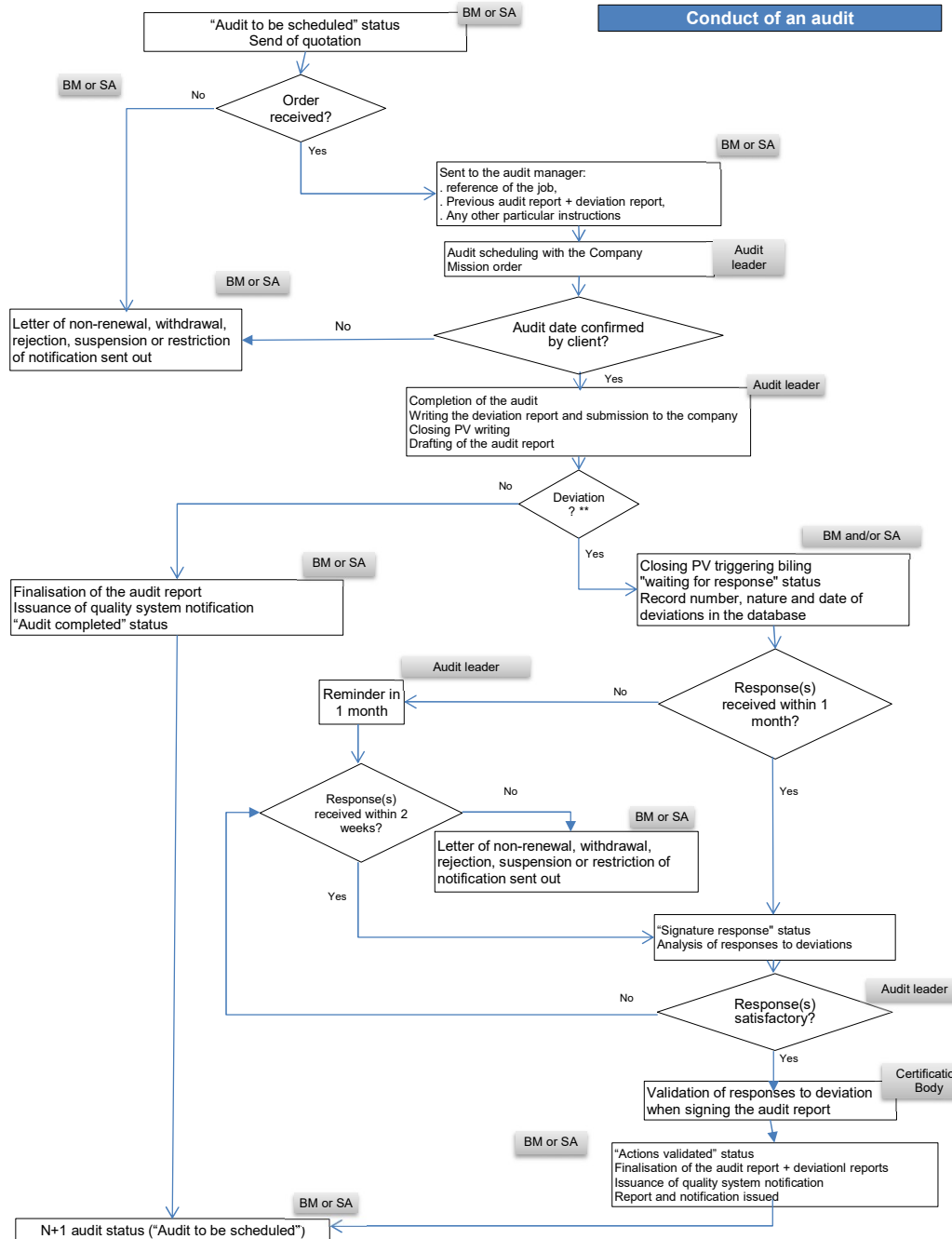
Reference document: OD 209 (current version on the IECEX website)

Conditions and procedures for granting, maintaining, extending, carrying out, suspending and withdrawing certification

	ATEX (Directive 2014/34/EU)	EXPLO (Directive 2014/28/EU)	PYRO (Directive 2013/29/EU)	Machines (Directive 2006/42/EC)
Approval	<p>The decision to certify a product and the notification of a manufacturer's production management system are the purview of the French National Institute for Industrial Environment and Risks (INERIS) certifier for the certification area in question.</p> <p>The initial certification of a product is issued based on the results of an EU-type examination carried out at the French National Institute for Industrial Environment and Risks (INERIS), which looks at all the technical documents supplied by the manufacturer and the results of all examinations and tests carried out to demonstrate the compliance of the product in question with the Directive's Essential Health and Safety Requirements (EHSR).</p> <p>The French National Institute for Industrial Environment and Risks (INERIS) makes information available to other Notified Bodies concerning the outcome of the EU-type examination certifications, as well as the list of notified bodies.</p>			
Rejection	<p>Certification may be refused if:</p> <ul style="list-style-type: none"> • One of the Essential Health and Safety Regulations (EHSR), as described in the Directive in question, has not been upheld. • One of the non-compliance issues found has not been addressed. <p>When a piece of equipment does not pass a test, the client is forewarned and given two options:</p> <ul style="list-style-type: none"> - Either the applicant makes a modification to their product, - or the applicant downgrades the scope of certification applied for. <p>If the applicant decides to take neither of these two options, the certification is rejected.</p> <p>In the event of a refusal, the manufacturer may appeal this decision through the ad hoc Certification Committee or through the Ministry for Industrial Safety (a plea procedure will be provided). Indeed, the Ministry is tasked with adjudicating on disagreements between Notified Bodies and manufacturers or importers for France (Articles 8 and 13 of Decree 96-1010). The French National Institute for Industrial Environment and Risks (INERIS) will provide a detailed explanation for its rejection.</p>			
Maintenance	<p>The certification is maintained if the equipment has not been subject to any modification not authorised in the certification file. It is the responsibility of the manufacturer to present their product to the Notified Body when any such modification is made to the equipment.</p> <p>The manufacturer of a product which the French National Institute for Industrial Environment and Risks (INERIS) has certified, in accordance with the directive, must inform the latter of "all modifications to the product in question". These "modifications" must receive new approval where they have the potential to call into question compliance with the EHSRs or the product's stated conditions of use.</p> <p>When an EU-type examination certificate reaches the end of its validity period, and upon the request of a manufacturer, the French National Institute for Industrial Environment and Risks (INERIS) will examine the impact of any developments in harmonised standards and will carry out a compliance study based on new standards if they have been updated.</p> <p>A supplement to the certification is issued in accordance with the new standards.</p> <p>In the event of an absence of changes to the standards, a supplementary approval is issued, extending the CE examination certificate by 5 years.</p>			
Extension	<p>The manufacturer may further develop a certified product. However, the modifications made must be submitted to a Notified Body. In this event, the French National Institute for Industrial Environment and Risks (INERIS) takes over the certification procedure. Tests already carried out during the original certification are re-run only if the development has the potential to affect the results. If compliance with the EHSRs is established, a new approval is issued in the form of a new version of the EU-type examination certificate, supplemented by an index number.</p> <p>The manufacturer may further develop a certified product. However, the modifications made must be submitted to a Notified Body. In this event, the French National Institute for Industrial Environment and Risks (INERIS) takes over the certification procedure. Tests already carried out during the original certification are re-run only if the development has the potential to affect the results. If compliance with the EHSRs is established, a new approval is issued in the form of a new version of the CE-type examination certificate.</p>			
Reduction	<p>Not applicable to the CE marking framework (only the administration or European commission may impose a reduction). The French National Institute for Industrial Environment and Risks (INERIS) will then make all necessary modifications to official certification documents and information destined for use by the public, etc., in order to guarantee that the client has received clear information about the reduction in scope, and that this is specified in a clear manner in such certification documents and information destined for use by the public.</p>			
Termination Suspension Withdrawal	<p>The certificate may be terminated at the client's request.</p> <p>When, over the course of a compliance check carried out following the issuance of a certificate, the French National Institute for Industrial Environment and Risks (INERIS) observes that a product is no longer compliant, it will invite the manufacturer to take appropriate corrective measures and will suspend or withdraw the certificate if necessary.</p> <p>Where these corrective measures are not taken or do not have the required effect, the French National Institute for Industrial Environment and Risks (INERIS) will impose restrictions, or suspend or withdraw the certificate depending on the circumstances.</p> <p>The French National Institute for Industrial Environment and Risks (INERIS) may also have cause to suspend or withdraw an existing certificate at the request of the French government, in particular a request issued by the Ministry for Industrial Safety.</p>			
Validity	<p>A temporary suspension or limitation of the EU-type examination certificate may be issued by the French National Institute for Industrial Environment and Risks (INERIS).</p> <p>EU-type examinations do not currently carry any time limit.</p> <p>However, the notification of the manufacturer's production quality system carries a duration of validity that depends on the module (C, D, E, F or G) of the Directive.</p> <p>EU-type examinations do not currently carry any time limit.</p> <p>However, the notification of the manufacturer's production quality system carries a duration of validity that depends on the module (C, D, E, F or G) of the Directive.</p> <p>EU-type examinations do not currently carry any time limit.</p> <p>However, the notification of the manufacturer's production quality system carries a duration of validity that depends on the module (D, E, or H) of the Directive.</p> <p>A temporary suspension or limitation of the EU-type examination certificate may be issued by the French National Institute for Industrial Environment and Risks (INERIS).</p> <p>The applicant must inform the French National Institute for Industrial Environment and Risks (INERIS) of all approved type modifications. The French National Institute for Industrial Environment and Risks (INERIS) will examine these modifications, and will either confirm the validity of the EU-type examination certificate, or will issue a new one in cases where the modifications could call into question compliance with Essential Health and Safety Requirements or the type's stated conditions of use.</p> <p>When an EU-type examination certificate reaches the end of its validity period, and upon the request of a manufacturer, the French National Institute for Industrial Environment and Risks (INERIS) will examine the impact of any developments in harmonised standards and will carry out a compliance study based on new standards if they have been updated.</p> <p>A supplement to the certification is issued in accordance with the new standards.</p> <p>In the event of an absence of changes to the standards, a supplementary approval is issued, extending the EU-type examination certificate by 5 years.</p> <p>In the event that the EU-type examination certificate is not renewed, the manufacturer must cease market sale of the machine in question. The French National Institute for Industrial Environment and Risks (INERIS) will withdraw certificates that are no longer valid.</p> <p>A temporary suspension or limitation of the EU-type examination certificate may be issued by the French National Institute for Industrial Environment and Risks (INERIS).</p>			
Communication by the French National Institute for Industrial Environment and Risks (INERIS) to the Notifying Authority	<p>The French National Institute for Industrial Environment and Risks (INERIS) communicates the following elements to the Notifying Authority:</p> <ol style="list-style-type: none"> The rejection, restriction, suspension or withdrawal of a certificate and notification; The circumstances affecting the scope and the conditions of their notification and their accreditation; The requests for information received from market monitoring authorities regarding evaluation and compliance activities; <p>These elements (a, b and c) are communicated during meetings of 'Explosives' certification committees in the fields involved.</p> <p>d) Upon request, compliance assessment activities carried out as part of their notification and accreditation procedures, as well as all other activities carried out, including cross-national subcontracting activities.</p>			
Communication by the French National Institute for Industrial Environment and Risks (INERIS) to Notified Bodies	<p>The French National Institute for Industrial Environment and Risks (INERIS) will supply relevant information (rejection, restriction, withdrawal, etc.) to other Notified Bodies carrying out similar compliance assessment activities covering the same products.</p>			
Contestation of the decision	<p>In the event that a decision is contested, the details of the process are described in procedure PR-0861 "General Rules for the Certification of Products and Services", available via the French National Institute for Industrial Environment and Risks (INERIS) website.</p>			

French National Institute for Industrial Environment and Risks (INERIS) SIL (Safety Integrity Level)	
Approval	<p>Carried out by the French National Institute for Industrial Environment and Risks (INERIS) when proof of compliance documents are available and the relevant testing and examinations have been carried out and deemed compliant.</p> <p>The notification of the quality management system is carried out based on documentary evaluation or an audit of the company.</p>
Rejection	<p>Certification may be refused if:</p> <ul style="list-style-type: none"> - One of the requirements described in the French National Institute for Industrial Environment and Risks (INERIS) SIL reference document and its associated procedures are not upheld, - One of the non-compliance issues found has not been addressed. <p>The details of the reason for rejection are provided to the manufacturer by the Notified Body. An appeal procedure will be provided, available upon demand.</p>
Maintenance	<p>The certification is maintained if the equipment has not been subject to any modification not authorised in the certification file. It is the responsibility of the manufacturer to present their product to the Notified Body when any such modification is made to the equipment.</p> <p>The manufacturer of a product which the French National Institute for Industrial Environment and Risks (INERIS) has certified, in accordance with the directive, must inform the latter of "all modifications to the product in question". These "modifications" must receive new approval where they have the potential to call into question compliance with the EHSRs or the product's stated conditions of use.</p>
Extension	<p>The manufacturer may further develop a certified product. However, the modifications made must be submitted to a Notified Body. In this event, the French National Institute for Industrial Environment and Risks (INERIS) takes over the certification procedure. Tests already carried out during the original certification are re-run only if the development has the potential to affect the results. If compliance with the EHSRs is established, a new approval is issued in the form of a new version of the CE-type examination certificate.</p>
Reduction	-
Termination Suspension Withdrawal	<p>The certificate may be terminated at the client's request.</p> <p>When, over the course of a compliance check carried out following the issuance of a certificate, the French National Institute for Industrial Environment and Risks (INERIS) observes that a product is no longer compliant, it will invite the manufacturer to take appropriate corrective measures and will suspend or withdraw the certificate if necessary. Where these corrective measures are not taken or do not have the required effect, the French National Institute for Industrial Environment and Risks (INERIS) will impose restrictions, or suspend or withdraw the certificate depending on the circumstances.</p> <p>The French National Institute for Industrial Environment and Risks (INERIS) may also have cause to suspend or withdraw an existing certificate at the request of the French government, in particular a request issued by the Ministry for Industrial Safety.</p>
Validity	-
Communication by the French National Institute for Industrial Environment and Risks (INERIS) to the Notifying Authority:	-
Communication by the French National Institute for Industrial Environment and Risks (INERIS) to Notified Bodies	-
Contestation of the decision	<p>In the event that a decision is contested, the details of the process are described in procedure PR-0861 "General Rules for the Certification of Products and Services", available via the French National Institute for Industrial Environment and Risks (INERIS) website.</p>

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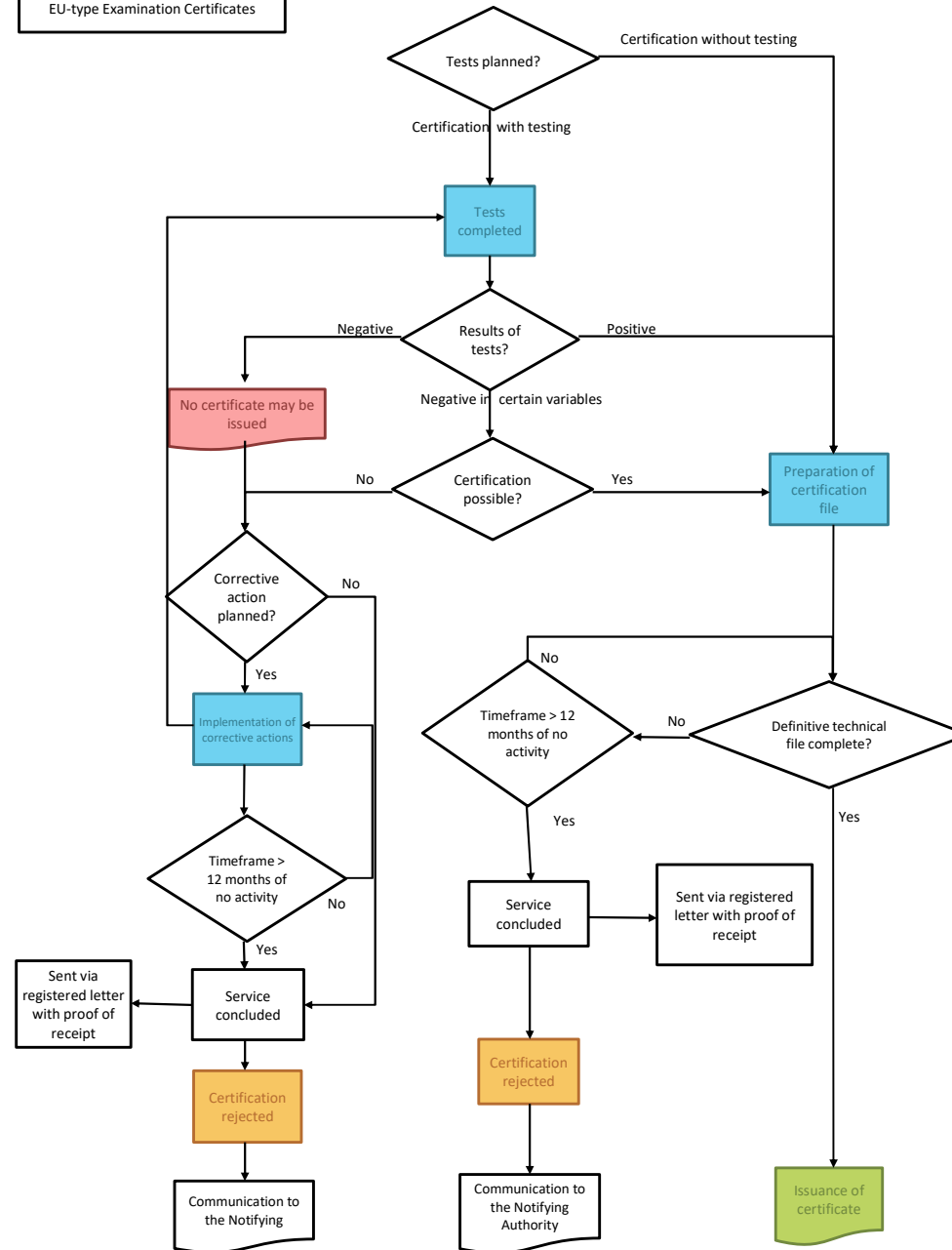


* Before notification end date or 1 year elapsed date (audit follow up).

** pertains only to NC and observations.

Case no. 1

EU-type Examination Certificates



Case no. 2

General product verification
Compliance with type
Individual verification

