



Autorizovaná osoba SKTC-125 | Autorizovaná osoba SK05 | Notifikovaná osoba 1358 Authorized Body SKTC-125 | Authorized Body SK05 | Notified Body 1358

REMOTE EVALUATION DUE TO COVID-19 PANDEMIC

RFU-STR-704

Temporary measures for the activities of Notified Bodies in the framework of the restrictions related to the COVID-19 pandemic

Part 1: remote performance of NoBo evaluation activities originally intended to be performed 'on-site' Part 2: amendment of Certificates which have reached their foreseen period of validity

Part 1.

A Risk and Opportunity Analysis for performing Remote Evaluation Activities which relates to

- potential risks & chosen mitigations (see checklist below)

- potential opportunities (e.g. permitting the performance of an AUDIT despite travel prohibition)

ROA-Topics	Option 1 Results permit normal balance of on-site and remote evaluation (Y/N)	Option 2 Results permit reduced on-site evaluation and increased remote evaluation (Y/N)	Option 3 Results permit onsite evaluation to be fully substituted by remote evaluation (Y/N)	Comments
1 Health and Safety Conditions	(Y or N)	(Y or N)	(Y or N)	(text)
2 Travel Restrictions	(Y or N)	(Y or N)	(Y or N)	(text)
3 Data Security and Confidentiality	(Y or N)	(Y or N)	(Y or N)	(text)
4 Validity and Objectivity of the information gathered	(Y or N)	(Y or N)	(Y or N)	(text)
5 Effects of Complexity and Novelty on the effectiveness	(Y or N)	(Y or N)	(Y or N)	(text)
6 Ability and/or Aptitude of client/ evaluated party	(Y or N)	(Y or N)	(Y or N)	(text)
OVERALL RESULT: Only in case of all (Y) in a column, an option may be used. Where no option may be used, the evaluation may not be performed.	all Y above indicate that this option can be used) (at last one N indicates that this option cannot be used)	all Y above indicate that this option can be used) (at last one N indicates that this option cannot be used)	all Y above indicate that this option can be used) (at last one N indicates that this option cannot be used)	

Part 2.

Where a NoBo has been asked by an applicant to use the option to extend the originally foreseen period of validity of a certificate, the Certification Decision check must include in addition to the usual topics also the following requirements:

Requirements for the CERTIFICATION DECISION check	Result	
Are the original and the amended certificates an EC type or design examination	(V or NI)	
certificate issued under TSI LOC&PAS 2011 (and related NOI, PRM and SRT TSIs)?	(Y or N)	
Has the applicant declared a need to extend the originally foreseen period of		
validity due to an unexpected time delay in the project which was caused by	(Y or N)	
Covid-19?		
Is the extension, as requested by the applicant, no longer than 6 Months beyond	(Y or N)	
the original period of validity?		
To act responsively as NoBo: Can you confirm that there is no	(Y or N)	
indication (obtained by NoBo internal staff, from the client or from the public		
domain), which calls in question, that the product actually meets the original		
conformity assessment requirements?		
Is the evaluation reporting and the certification review prepared for the original	(Y or N)	
certificate still available and can be used as evidence for this certification?		

Positive answers (Y) to all above items are needed before providing an extension of the validity.

In order to act with full transparency, the NoBo shall keep the results of the certification decision as records for justifying the certification decision.