因應疫情採行遠端查核作業規定

Measures of remote audit to cope with COVID-19 pandemic

一、 適用對象:

1. Applicable to:

依交通部「車輛型式安全審驗管理辦法」及「電動輔助自行車及電動自行車型式安全 審驗管理辦法」相關規定應採或得採實地查核辦理者,包括:

According to the requirement of "Vehicle Safety Type Approval Management Regulations" and "Electric power-auxiliary bicycle and electric bicycle type approval management regulations" by Ministry of Transportation and Communications (MOTC), the on-site audit which shall be conducted, or could be conducted, including the category of applicants as below:

- (一)已取得國外政府同項目認可之檢測機構首次申請認可者。
- 1.1 For the first application for technical service accreditation, which has been accredited for the same test item by the foreign authority.
- (二)檢測機構申請新增或變更檢測項目認可依規定應辦理實地評鑑者。
- 1.2 For extension or modification of technical service accreditation, which on-site assessment shall be conducted according to the requirement.
- (三)檢測機構申請監測實驗室評鑑(含首次評鑑及已通過之監測實驗室新增項目等)依規定應辦理實地評鑑者。
- 1.3 Technical services apply for witnessed laboratory assessment (including first application and extension), which on-site assessment shall be conducted according to the requirement.
- (四)符合交通部 110 年 5 月 14 日交路字第 1090035791 號函規定耐久性能測試驗證設備、場地及程序實地查核得採視訊查核者。
- 1.4 Comply with the requirement by Letter of Ministry of Transportation and Communications (MOTC) 1090035791 dated 14th May 2021, which the on-site assessment for Durability Test Equipment, site and procedure could be conducted by remote audit.
- (五)應辦理監督評鑑之檢測機構及監測實驗室。
- 1.5 Technical service and witnessed laboratory which supervising audit shall be conducted-to.
- (六)應辦理品質一致性現場核驗之申請者。
- 1.6 The applicants which on-site COP verification shall be conducted-to.

二、 辦理方式

- 2. Application process:
- (一)符合適用對象之申請者得檢附相關申請文件提出遠端查核申請,經本中心初步審查後聯繫安排遠端查核作業。
- 2.1 The suitable applicants shall provide related application documents and make application for remote audit. After initial document confirmation, VSCC will contact the applicants for the arrangement of remote audit.
- (二)雙方簽署遠端查核資訊安全及保密性協議書。
- 2.2 Sign the agreement for security and confidentiality for remote audit transmission.
- (三)遠端查核過程應就申請者品質管理系統相關文件紀錄與現場進行查核,申請者應於遠端查核過程充分展示其符合性。惟現場如受視訊相關軟硬體設備、使用環境...等因素影響,得採申請者補充提供相關文件資料、照片、影片或電話說明等輔助方式進行,必要時予以記錄列為下次實地查核追查事項。
- 2.3 The documentation and facility related to the quality management system shall be verified during the remote audit, and the applicants shall sufficiently demonstrate it can comply with the requirement during the remote audit. If there is difficulty of the facility by the reasons such as the device of video software and hardware, environment...etc., the applicants to provide related supplement documents, pictures, video or explanation by telephone afterwards could be accepted. If necessary, it will be recorded and be the follow up item for next on-site audit.
- (四)遠端查核所需時間以原訂實地查核時間為原則,如因時差、連線品質...等因素影響, 得分段進行。
- 2.4 The time of remote audit is the same as the duration of on-site audit in principle; however, the time of audit may be divided if remote audit was influenced by the reasons such as time difference, the quality of internet connection...etc.

三、 辦理結果及後續處置

- 3. Audit result and follow up measures:
- (一)遠端查核結果符合規定者,本中心依規定出具報告或紀錄,並加註係以遠端查核方式 辦理。若查有不合格之情事,依實地查核不合格相關規定續為處置。
- 3.1 VSCC will issue the report or record if the results of remote audit comply with all the requirement and it will be remarked the audit was conducted by remote audit.

 If there is non-conformity found during remote audit, the further actions shall be conducted according to the related requirement of non-conformity by on-site audit.

(二)申請者未能配合遠端查核者,依下列處置:

- 3.2 Measures for applicants fail to conduct remote audit:
 - 1. 無故未能配合遠端查核者,屬適用對象(一)至(四)之申請者,不受理其申請;屬 適用對象(五)及(六)之申請者,依不合格相關規定續為處置。
 - 3.2.1 If the applicant fails to conduct remote audit, the new application will be rejected for the applicants of category of No.1.1~1.4. For the applicants No.1.5~1.6, the further actions shall be conducted according to the related requirement of non-conformity.
 - 2. 申請者雖配合遠端查核,但因故未能充分配合遠端查核或有刻意誤導或隱瞞情事,得採限期補充提供說明及相關資料、限期改善後重新查核或終止查核等方式辦理,並得視情形依不合格相關規定處置。
 - 3.2.2 Even the applicant is able to conduct remote audit, but if the applicant can't fully fulfill the requirement of remote audit, mislead or conceal, the actions will be conducted such as request to provide the additional explanation information with related documents within the request period, re-audit after making improvement within the request period or terminating the audit, the further actions will be conducted by the related requirement of non-conformity depending on the situations.

(三)疫情獲得有效控制後之配套措施:

- 3.3 Measures after the COVID-19 pandemic is under effective control:
 - 1. 屬已取得國外政府同項目認可之檢測機構首次申請認可、申請監測實驗室首次 評鑑者及符合交通部 110 年 5 月 14 日交路字第 1090035791 號函規定耐久性能 測試驗證設備、場地及程序實地查核得採視訊查核者,應於疫情獲得有效控制 後儘速辦理實地監督查核。
 - 3.3.1 For the first application for technical service accreditation, which has been accredited for the same test item by the foreign authority, for the first application for witnessed laboratory assessment and comply with the requirement by Letter of Ministry of Transportation and Communications (MOTC) 1090035791 dated 14th May 2021, which mentioned that the on-site assessment for Durability Test Equipment, site and procedure could be conducted by remote audit, on-site supervision audit shall be conducted as soon as the COVID-19 pandemic is under effective control.
 - 2. 屬檢測機構申請新增或變更檢測項目認可及監測實驗室新增項目依規定應辦 理實地評鑑者、應辦理監督評鑑之檢測機構及監測實驗室及辦理品質一致性現 場核驗之申請者,應於疫情獲得有效控制後依其監督查核週期辦理實地監督查 核。惟前述對象位於大陸地區者,應於疫情獲得有效控制後儘速辦理實地監督 查核。
 - 3.3.2 For extension or modification of technical service accreditation and witnessed laboratory assessment which shall be conducted on-site assessment according to the requirement, the applicants of technical service and witnessed laboratory which shall be conducted supervising audit and the applicants shall be conducted on-site COP verification, on-site supervision audit shall be conducted according to their supervision audit period after the COVID-19 pandemic is under effective control. However, for the applicant located in Mainland China, on-site supervision audit shall be conducted as soon as the COVID-19 pandemic is under effective control.
 - 3. 疫情獲得有效控制後,已提出遠端查核申請但未備齊申請文件之案件,應辦理 實地查核。
 - 3.3.3 After the COVID-19 pandemic is under effective control, on-site audit shall be conducted if the application for remote audit has been submitted but the application documents do not yet fulfill the requirement.

(The measures are made in Chinese, which shall prevail in case of any discrepancy between the English translation and the Chinese original.)