

鐵路使用之產品檢測驗證機構認可及監督管理辦法草案

Draft Regulations Governing the Recognition, Supervision and Management to the Testing and Certification Bodies of Products for Railway Applications

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第一條 本辦法依鐵路法(以下簡稱本法)第十九條之一第三項及規費法第十條第一項規定訂定之。	Article 1 These Regulations are enacted pursuant to Paragraph 3, Article 19-1 of the Railway Act, (hereinafter referred to as the Act) and Paragraph 1, Article 10 of the Charges and Fees Act.
第二條 本辦法用詞，定義如下： 一、指定產品：指交通部依本法第十九條之一第二項規定公告指定之鐵路使用之材料、零組件、設備、軟體、系統或其他構成鐵路之部分。 二、檢測機構：指取得交通部認可，辦理指定產品之檢測業務者。 三、驗證機構：指取得交通部認可，辦理指定產品之驗證業務者。 四、認證機構：指依國際標準組織之標準建立認證制度，並據以實施認證業務，且已簽署國際或區域認證組織相關認證領域相互承認協議之機構。	Article 2 Definitions: (1) Designated products: materials, components, apparatus, software, systems for railway applications, or any other parts that form railways, which designated by the MOTC in accordance with Paragraph 2, Article 19-1 of the Act. (2) Testing body: a body recognized by the MOTC to perform testing operation on designated products. (3) Certification body: a body recognized by the MOTC to perform certification activities for designated products. (4) Accreditation body: a body who have established accreditation system in accordance with the standards of the International Standards Organization, and implement accreditation activities accordingly, and have signed mutual recognition agreements by international or regional accreditation organizations.
第三條 檢測機構之資格條件如下： 一、我國之行政機關(構)、專科以上學校或公益法人。但情況特殊，經交通部公告者，不在此限。 二、取得我國認證機構之認證，符合國際標準 ISO/IEC 17025或國家標準 CNS 17025測試實驗室認	Article 3 The required qualifications for the testing bodies are as follows: (1) Domestic administrative authorities or institutions, schools of college or above, or non-profit juristic persons, except in the case of extraordinary circumstances and publicly announced by the MOTC; (2) Being accredited as a testing

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<p>證規範，認證範圍包含指定產品之檢測程序。</p> <p>三、具備必要之人員、設施、檢測設備與計量追溯性、管理系統，足以辦理指定產品之檢測業務。</p> <p>具備前項資格條件者，得檢附下列資料向交通部申請認可為檢測機構：</p> <p>一、申請表。</p> <p>二、符合前項第一款及第二款資格條件之證明文件。</p> <p>三、辦理指定產品檢測業務之人員職務說明及履歷資料。如實驗室主管、品質負責人、報告簽署人、檢測人員或其他依申請者組織型態及管理系統所配置適任人員。</p> <p>四、地理位置簡圖、機構布置圖及檢測設備配置圖。</p> <p>五、檢測設備規格及計量追溯性之佐證文件。</p> <p>六、標準作業程序書或依其管理系統建立之同等文件。</p>	<p>laboratory to CNS 17025 or ISO/IEC 17025 by domestic accreditation bodies, where the testing procedures of designated products are included in the scope of accreditation; and</p> <p>(3) Possessing necessary personnel, facility, test equipment and metrological traceability, and management system, which are sufficient to handle the testing operation of the designated products. Those who meet the aforementioned qualifications may submit the following documents to the MOTC for recognition as a testing body:</p> <p>(1) Application Form;</p> <p>(2) Documentary proof that the applying body meets the qualifications required in subparagraph 1 and 2 of the preceding paragraph;</p> <p>(3) Function description and resumes of the personnel handling the testing operation on designated products, such as those of the chief of laboratory, the chief of quality assurance, report signatories, and testing personnel, or other competent personnel allocated according to the organization type and the management system of the applying body;</p> <p>(4) Location guide map and layout plan of the body, and allocation drawings of test equipment;</p> <p>(5) The specifications of test equipment and documentary proof of metrological traceability accordingly; and</p> <p>(6) Standard operation procedures (SOP) of testing, or equivalent documentation according to the management system of the body.</p>

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<p>第四條 驗證機構之資格條件如下：</p> <p>一、我國之行政機關（構）、專科以上學校或公益法人。但情況特殊，經交通部公告者，不在此限。</p> <p>二、取得我國認證機構之認證，符合國際標準 ISO/IEC 17065 或國家標準 CNS 17065 相關領域之產品驗證機構認證規範，認證範圍包含指定產品之驗證基準。</p> <p>三、具備辦理指定產品驗證業務之適任性、公正性之管理與維護機制及固定辦公處所，組織架構健全且財務穩定。</p> <p>四、設有與指定產品驗證業務相關之檢測實驗室或可取得適當之外部資源，應符合 ISO/IEC 17025 或 CNS 17025 相關領域之測試實驗室認證規範。</p>	<p>Article 4</p> <p>The required qualifications for the certification bodies are as follows:</p> <p>(1) Domestic administrative authorities or institutions, schools of college or above, or non-profit juristic persons, except in the case of extraordinary circumstances and publicly announced by the MOTC.</p> <p>(2) Being accredited as a product certification body to CNS 17065 or ISO/IEC 17065 by domestic accreditation bodies, where the certification criteria for the designated products are included in the scope of accreditation;</p> <p>(3) Possessing competence to perform certification activities of designated products, management and maintaining mechanism for impartial, and fixed place for business, with a sound organization structure and good financial infrastructure; and</p> <p>(4) Having established testing laboratories related to the testing operation on the designated products, or obtaining appropriate external resources, which all shall comply with accreditation specifications for testing laboratory to CNS 17025 or ISO/IEC 17025.</p>

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<p>具備前項資格條件者，得檢附下列資料向交通部申請認可為驗證機構：</p> <ol style="list-style-type: none"> 一、申請表。 二、符合前項第一款及第二款資格條件之證明文件。 三、驗證過程中負責評估、審查、作成驗證決定之人員職務說明及履歷資料。 四、品質手冊、品質文件系統架構及一覽表或依其管理系統建立之同等文件。 五、公正性之管理與維護機制說明。 六、地理位置簡圖及機構布置圖。 七、組織架構及業務功能之說明。 八、具備穩定財務之說明及證明文件。 九、辦理評估所需資源一覽表，含自設檢測實驗室及可取得之外部資源，以及確保可信賴性之說明。 	<p>Those who meet the aforementioned qualifications may submit the following documents to the MOTC for recognition as a certification body:</p> <ol style="list-style-type: none"> (1) Application form; (2) Documentary proof that the applying body meet the qualifications required in subparagraph 1 and 2 of the preceding paragraph; (3) Function description and resumes of the personnel, who are responsible for evaluation, review and certification decision in the process; (4) Quality manual, system structure and overview list for quality documents, or equivalent documentation according to its management system; (5) Description of management and maintaining mechanism for impartial; (6) Location guide map and layout plan of the body; (7) Description of the organization and functions; (8) Description of stable finances and supporting documentation; and (9) List of resources required for the evaluation, including self-established testing laboratories and available external resources, as well as description of ensuring confidence.
<p>第五條 第三條第二項及前條第二項情形，申請文件不完備者，經交通部通知限期補正，屆期未補正或補正不完備者，不予受理。</p> <p>前項通知，交通部應逐項列出須補正之事項或文件，一次通知申請者於收到通知之次日起三十日內補正。</p>	<p>Article 5</p> <p>In the case of Article 3, Paragraph 2 and Paragraph 2 of the preceding article, where the application documents are deemed incomplete, if the application are not fully supplemented after the applicant receiving notice from the MOTC to undertake corrective action within a prescribed period of time, their applications shall be dismissed.</p> <p>For the aforementioned notice, the MOTC shall list matters or documents to be supplemented by items, notifying the applicant to make a supplement within THIRTY (30) days after receiving the notice.</p>

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<p>第六條 交通部受理第三條第二項及第四條第二項申請後辦理書面審查，必要時得派員赴現場勘查，經審查通過者，由交通部核發認可文件。</p> <p>依前項審查未符規定，經交通部通知限期改善並申請複審，屆期未申請複審或經複審仍未符規定者，不予認可。</p> <p>前項通知，交通部應逐項列出未符規定事項，一次通知申請者於通知送達之次日起六十日內改善完成並向交通部申請複審。</p> <p>經複審仍未符規定者，申請者於不予認可通知送達之次日起九十日後，始得重新提出申請。</p>	<p>Article 6</p> <p>Where an application as described in Paragraph 2, Article 3 and Paragraph 2, Article 4 is received by the MOTC, the MOTC shall conduct document review, with onsite survey when necessary, and a document of recognition will be issued by the MOTC after the application passes review.</p> <p>If an application does not fulfill requirements of the regulations herein according to the aforementioned review, the MOTC shall notify the applicant to undertake corrective action within a prescribed period of time and apply for a second review; in case of failure to apply for a second review by the given deadline or failure of the second review, the recognition shall not be granted.</p> <p>For the aforementioned notice, the MOTC shall list matters or documents to be corrected by items, notifying the applicant to complete the improvement and apply for a second review within SIXTY (60) days after receiving the notice.</p> <p>If the application does not meet the requirements after the second review, the applicant may re-apply after NINETY (90) days from the following day to the date of receiving the notice for recognition not granted.</p>
<p>第七條 檢測機構或驗證機構之認可有效期間為自取得認可之日起三年；有效期間屆滿之日前九十日內，得向交通部申請展延，每次展延期間為三年。</p> <p>展延之申請、審查及核發展延認可文件，準用第三條至前條規定。</p>	<p>Article 7</p> <p>The recognition of a testing body or a certification body has a validity period of three years, beginning on the day of recognition granted. Within NINETY (90) days prior to expiration, the recognized body may apply for renewal, each renewal period shall be THREE (3) years.</p> <p>The provisions from Article 3 to the preceding article shall apply mutatis mutandis to the application for renewal, review, and document issued for recognition renewal.</p>

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<p>第八條 檢測機構或驗證機構擬增列認可範圍時，準用第三條至第四條之規定，應檢具申請書及相關資料向交通部申請認可並重新核發認可文件。</p> <p>檢測機構或驗證機構經認證機構減列認證範圍時，應即停止辦理受影響業務，並於認證範圍減列生效之次日起三十日內檢具申請書向交通部申請變更範圍及重新核發認可文件。</p> <p>因增列或減列認可範圍，交通部重新核發之認可文件，其有效期限與原認可文件相同。</p> <p>第九條 檢測機構依第三條第二項第二款、第四款至第六款或驗證機構依第四條第二項第二款、第四款至第九款所定資料有異動情形時，應於異動發生之次日起三十日內檢附相關資料向交通部申請異動記載；未經審查核准前，不得辦理指定產品之檢測或驗證業務。</p>	<p>Article 8</p> <p>Where the testing body or the certification body applying for expansion of the scope of recognition, the provisions of Article 3 to 4 shall apply mutatis mutandis, and the body shall apply to the MOTC for recognition and re-issuing the document of recognition.</p> <p>Where the scope of accreditation of the testing body or the certification body has been reduced by the accreditation body, the testing body or certification body shall immediately stop performing the activities relating to the affected area, and apply to the MOTC within THIRTY (30) days from the following day to the effective date of reduction of the scope of accreditation. For expansion or reduction of the scope of recognition, the validity period of documents re-issued by the MOTC shall be identical with that of the original documents.</p> <p>Article 9</p> <p>In case of alternation of the document contents prescribed in Subparagraph 2, 4 to 6 of Paragraph 2, Article 3 for the testing body, or in Subparagraph 2, 4 to 9 of Paragraph 2, Article 4 for the certification body respectively, the body shall, within THIRTY (30) days from the following day to the date of alternation, apply to the MOTC by submitting related documents for change of registration. The testing operation or certification activities on the designated products shall not be conducted before review and approval of the changes is granted.</p>
<p>第十條 檢測機構依第三條第二項第三款或驗證機構依第四條第二項第三款所定人員有出缺、增補或任免之異動者，應於異動發生之次日起三十日內，檢附異動人員資料報請交通部備查。</p>	<p>Article 10</p> <p>Where there are changes in the personnel prescribed in Subparagraph 3 of Paragraph 2, Article 3 for the testing body, or in Subparagraph 3 of Paragraph 2, Article 4 for the certification body respectively, as a result of resignation, recruitment or employment, the body shall, within</p>

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<p>第十一條 檢測機構或驗證機構之檢測報告、審查紀錄、驗證文件及相關技術文件應詳實記載，並至少保存十年。但其他法令規定較長保存期限者，從其規定。</p>	<p>THIRTY (30) days from the following day to the date of changes, report to the MOTC with information of the personnel for reference.</p> <p>Article 11 The test reports, review records, certification documents and relevant technical documents shall be recorded correctly and in detail, and shall be preserved for TEN (10) years at least. Nonetheless, if the period of preservation is otherwise prescribed in other laws and regulations, the longer shall apply.</p>
<p>第十二條 交通部應對檢測機構或驗證機構辦理每年業務定期查核及不定期督導；檢測機構或驗證機構無正當理由者，不得規避、妨礙或拒絕。</p> <p>依前項查核或督導發現有缺失之情形者，應依交通部通知限期改善。</p> <p>第十三條 交通部為辦理鐵路監督事項、行車事故或異常事件調查，得向檢測機構或驗證機構調閱認可範圍相關業務文件或資料；檢測機構或驗證機構無正當理由者，不得規避、妨礙或拒絕。</p>	<p>Article 12 The MOTC shall conduct periodic checks on the annual operation of the testing bodies and the certification bodies, and non-periodic supervision as well. The bodies shall not evade, impede or refuse the checks or supervision without justified reasons. If there is non-conformity found by the aforementioned checks or supervision, the bodies shall make improvement by the deadline noticed by the MOTC</p> <p>Article 13 The MOTC may, in order for the supervision on railways, and investigation into accidents and abnormal events, access documents and information of the operation and activities related to the scope of recognition of the testing bodies and the certification bodies. The bodies shall not evade, impede or refuse without justified reasons.</p>

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<p>第十四條 檢測機構或驗證機構有下列情事之一者，交通部得令其暫停辦理全部或部分認可範圍之業務，並限期改善：</p> <p>一、檢測機構或驗證機構之人員出缺未補實，致不符合第三條第一項第三款或第四條第一項第三款所定資格條件。</p> <p>二、經認證機構暫停其認證資格。</p> <p>三、驗證機構對其驗證之產品疏於追查。</p> <p>四、經交通部通知限期提供資料，無正當理由屆期未提供。</p> <p>五、於交通部辦理定期查核、不定期督導時，無正當理由未配合辦理，或有缺失之情形未依限期改善。</p> <p>六、有申訴、陳情或爭議案件時，無正當理由未配合辦理。</p> <p>前項情形經改善，並經交通部確認符合者，始予恢復辦理業務。</p>	<p>Article 14</p> <p>Under any of the following circumstances, the MOTC may order the testing body or the certification body to stop performing all or part of the operation or activities of the scope of recognition, and request that correction actions be taken within a certain time limit:</p> <p>(1) Where the testing body or the certification body does not fill in a vacant position of the personnel and violates the requirements set out in Subparagraph 3, Paragraph 1 of Article 3 or Subparagraph 3, Paragraph 1 of Article 4 respectively;</p> <p>(2) Where the accreditation by the accreditation body has been suspended;</p> <p>(3) The certification body fails to surveillance the certified products;</p> <p>(4) Not providing the necessary information requested by the MOTC within the requested period without justified reasons;</p> <p>(5) Refusing to be periodically checked or supervised by the MOTC without justified reasons, or in the event of defects that cannot be rectified in a timely manner; or</p> <p>(6) Not assisting in processing appeals, complaints or disputes without justified reason.</p> <p>The operation or activities shall be resumed only after the aforementioned situations are improved and confirmed by the MOTC to be in compliance with related requirements.</p>
<p>第十五條 檢測機構或驗證機構有下列情事之一者，交通部得撤銷或廢止其認可：</p> <p>一、主動申請終止認可。</p> <p>二、經認證機構撤銷或廢止其認證資格。</p> <p>三、喪失辦理業務能力或有礙公正有效辦理業務。</p> <p>四、執行認可範圍之業務違反利益</p>	<p>Article 15</p> <p>Under any of the following circumstances, the MOTC may withdraw or abolish the recognition granted to the testing body or the certification body:</p> <p>(1) Where the body applies for terminating the recognition;</p> <p>(2) Where the accreditation is withdrawn or revoked by the accreditation body;</p> <p>(3) Where the body loses the ability to</p>

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<p>迴避或保密義務原則。</p> <p>五、逾越認可範圍或怠於辦理業務。</p> <p>六、無正當理由而為差別待遇。</p> <p>七、未依第八條規定申請增列或減列認可範圍，或未經認可前擅自辦理檢測或驗證業務。</p> <p>八、未依前條規定於限期內完成改善並經交通部認定符合者，而逕自恢復業務。</p> <p>九、簽署報告或核發證明文件有虛偽不實之情事。</p> <p>十、接受認可範圍之業務利害關係者餽贈財物、飲宴應酬或請託關說，或假借職務上之權力、方法、機會圖本人或第三人不正之利益，情節重大。</p> <p>十一、其他違反法令規定，情節重大。</p> <p>經交通部撤銷或廢止其認可者，應於撤銷或廢止之次日起三十日內，將受理案件之完整文件及檔案移交至交通部指定機構，無正當理由者，不得規避、妨礙或拒絕。</p>	<p>perform operation or activities, or is unable to maintain impartiality to perform the operation or activities effectively;</p> <p>(4) Where the principles of avoidance of conflict of interest or observance of confidentiality are violated during the operation or activities of the scope of recognition;</p> <p>(5) Where the body performs operation or activities beyond the scope of recognition or in a manner of tardiness,</p> <p>(6) Discrimination without justified reasons;</p> <p>(7) Where the application for expansion or reduction of the scope of recognition is not made in accordance with Article 8, or conducting the operation or activities before the recognition is granted;</p> <p>(8) Where corrective actions are not taken within the specified time limit in accordance with the preceding article and resuming conduction of the operation or activities before confirmation by the MOTC of compliance;</p> <p>(9) Where fraudulence is found for the report signatory or issuance of certificate;</p> <p>(10) Where the body accepts gratuities such as monetary or material gifts, meals or other entertainment, or of instances of entreaties or lobbying from interested parties in the operation or activities of the scope of recognition, or take advantage of their powers, procedures or opportunities to seek illegitimate gain for itself or third parties and the violations are significant; or</p> <p>(11) Where the violations against other laws and regulations are significant.</p> <p>The one whose recognition has been withdrawn or abolished by the MOTC shall, within THIRTY (30) days from the following day to the date of withdrawal or abolishment, transfer the complete documents and files of the</p>

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<p>檢測機構或驗證機構之認可經撤銷或廢止者，自撤銷或廢止之次日起三年內不得重新申請認可。但依第一項第一款主動申請終止認可，其情形特殊並經交通部同意者，不在此限。</p> <p>第十六條 檢測機構或驗證機構之認可範圍及有效期間，交通部應公告並公開於資訊網路；異動時，亦同。</p> <p>第十七條 檢測機構或驗證機構經撤銷或廢止認可時，交通部得協調其他檢測機構或驗證機構，配合接收保管原認可範圍之業務相關文件及檔案。</p>	<p>cases to the agency designated by the MOTC. The one shall not evade, impede or refuse without justified reasons.</p> <p>The one whose recognition is withdrawn or abolished shall not, within THREE(3) years from the following day to the date of withdrawal or abolishment, apply for recognition, except where recognition is terminated as a result of application made by the body in accordance with Subparagraph 1 of Paragraph 1 hereof, and the case of extraordinary circumstances is approved by the MOTC.</p> <p>Article 16 The scope of recognition and validity period of the testing body or the certification body shall be publicly announced by the MOTC and publish on the World Wide Web. The same process shall apply in the event of any changes.</p> <p>Article 17 Where the recognition of a testing body or a certification body has been withdrawn or abolished, the MOTC may coordinate with other testing bodies or certification bodies to receive and preserve relevant documents and files of the operation and activities of the original scope of recognition.</p>
<p>第十八條 申請認可為檢測機構或驗證機構者，應繳納審查費每件新臺幣一萬二千元；向交通部申請認可、展延或增列認可範圍時繳納。展延及增列認可範圍依性質得併案申請者，以一件計收之。</p>	<p>Article 18 To apply for recognition as a testing body or a certification body shall pay the review fee of NT\$12,000; review fee shall be paid at the time when apply to the MOTC for recognition, renewal of recognition or expansion of the scope of recognition. Where the renewal of recognition or expansion of the scope of recognition can be filed together according to their nature, the applications may be treated as one application case.</p>

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<p>為應申請者需要，有赴國外辦理審查、勘查、查核或督導之必要時，除前項費用外，交通部派員出國之差旅費另依國外出差旅費報支要點所定各項費用基準計收。</p> <p>第十九條 第三條至第十條、第十二條至第十四條、第十六條至前條所定交通部之事項，交通部得委任所屬機關執行之；其委任事項及法規依據，應公告及刊登行政院公報。</p> <p>第二十條 本辦法自發布日施行。</p>	<p>At the request of the applicant, for any review, survey, checks and supervision conducted abroad, in addition to the aforementioned fee, expenses for the MOTC to send personnel abroad shall be collected in accordance with the Directions for the Overseas Travel Allowance Disbursement.</p> <p>Article 19 The MOTC may delegate its subordinate authorities to perform matters of the MOTC prescribed in Article 3 to 10, Article 12 to 14, and from Article 16 to the proceeding article; The matter delegated and the legal basis for such delegation shall be publicly announced and published in Executive Yuan Gazette.</p> <p>Article 20 These Regulations shall be effective upon the day of promulgation.</p>