

機械類產品申請先行放行辦法

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Regulations Governing the Application for Prior Release of Mechanical Products

(10 Articles adopted and promulgated in full by Ministerial Order on January 1, 2015.

Articles 2, 3 and 10 amended and promulgated by Ministerial Order on October 21, 2022)

第 1 條	本辦法依職業安全衛生法（以下簡稱本法）第八條第五項規定訂定之。
Article 1	These Regulations are established in accordance with Paragraph 5 of Article 8 of the Occupational Safety and Health Act (the Act).
第 2 條	<p>報驗義務人輸入本法第八條所定應實施型式驗證之機械類產品，有下列情形之一者，得向中央主管機關具結，申請先行放行：</p> <p>一、經型式驗證合格之產品，尚未依法張貼合格標章。</p> <p>二、已申請型式驗證之產品，尚未取得型式驗證合格證明書。</p> <p>三、經型式驗證合格之產品，其為未組裝完成品。</p> <p>四、經型式驗證合格之產品，其為全拆散或半拆散之零組件。</p> <p>五、其他有先行放行之必要，報經中央主管機關核准。</p> <p>依前項第二款規定申請先行放行者，對同一報驗義務人之同一型式產品，以核准一次為限。但有下列情形之一，經中央主管機關核准者，不以一次為限：</p> <p>一、經核准先行放行之待測產品數量不足，致無法完成型式驗證。</p> <p>二、經核准先行放行之產品未具型式代表性，致執行型式驗證有困難。</p> <p>報驗義務人依前項但書規定申請先行放行者，應於原申請案之核准期限屆滿前，檢附受理型式驗證機構出具之說明文件為之，並以一次為限；其核准期限，以原申請案之期限為準。</p>
Article 2	<p>The obligatory applicants who import mechanical products that are subject to the type certification required by Article 8 of the Act may apply to the central competent authority for prior release of their products and present a letter of attestation:</p> <p>1. Products that pass type certification, but the qualification labels have not attached in accordance with related requirements;</p> <p>2. Products of which the applications for type certification have been made, but the certificates of type certification have not yet been issued;</p> <p>3. Products that pass type certification and are not assembled;</p> <p>4. Products that are separated or partly separated components and pass type certification;</p> <p>5. Other situations where prior release is necessary and approved by the</p>

	<p>central competent authority.</p> <p>Permission for a prior release issued in accordance with subparagraph 2 of the preceding paragraph shall be limited to one time only for each obligatory applicant with the same product, except for applications under one of the following conditions approved by the central competent authority.</p> <ol style="list-style-type: none"> 1. The number of samples to be tested that have been permitted for prior release is insufficient, so that the type certification cannot be completed. 2. Products that have been permitted for prior release are not identified as type representative, which makes it difficult to perform type certification. <p>In accordance with the proviso of the preceding paragraph, the obligatory applicants should apply to the central competent authority for prior release of their products before the expiration of the approval period for the original application, and attach the explanatory document that is issued by the body performing the type certification. The application is limited to one time, and the approval period is subject to the period for the original application.</p>
第 3 條	<p>前條機械類產品有下列情形之一者，不得核准先行放行：</p> <ol style="list-style-type: none"> 一、經型式驗證不合格之同一型式產品，未於驗證不合格日起六個月內完成退運、銷燬或拆解至不堪用等必要處置。 二、同一報驗義務人之同一型式產品經中央主管機關核准先行放行，未於核准日起一年內取得型式驗證合格證明書，且未完成退運、銷燬或拆解至不堪用等必要處置。但經核准展延驗證期限者，以該期限屆滿時為準。 三、產品顯有安全顧慮情事。
Article 3	<p>Applications for prior release of products under any of the following circumstances shall be denied:</p> <ol style="list-style-type: none"> 1. If the same type of products were not shipped back, destroyed, disassembled to unusable conditions, or disposed of by other necessary measures within 6 months from the date of the noncompliance notice of type certification. 2. If the same obligatory applicant failed to obtain certificate of type certification for the same type of products within 1 year from the date of prior release notice, and the products were not shipped back, destroyed, disassembled to unusable conditions, or disposed of by other necessary measures. Where extended time is granted for the application for type certification, the extended time limit shall apply.

	3. If there are safety concerns.
第 4 條	報驗義務人向中央主管機關申請先行放行時，應填具申請書，並檢附相關文件及佐證資料；其有第二條第二項但書所定情形者，並應檢附核准函。
Article 4	The obligatory applicant shall make an application for prior release to the central competent authority by submitting a completed application form together with related documents. The approval letter from the central competent authority mentioned in paragraph 2 of Article 2 shall also be provided, where applicable.
第 5 條	中央主管機關核准先行放行者，應發給輸入先行放行通知書，並副知驗證機構；未核准者，應將其理由告知申請人。 前項輸入先行放行之通知，中央主管機關應以電子訊息傳送海關憑辦輸入通關放行。
Article 5	Where prior release is approved, the central competent authority shall issue a prior-release notice and send a copy to authorized certification bodies. Where prior release is not approved, reasons of the decision shall be made known to the applicant. The central competent authority shall transmit the preceding prior-release notice electronically to the customs for customs clearance.
第 6 條	先行放行之產品符合型式驗證規定前，不得運出產品之設置或儲存地點，亦不得啟用或移轉於第三人。 前項產品，報驗義務人應於中央主管機關指定期間內，依法張貼合格標章、取得型式驗證合格證明書或組裝完成等，並將執行情形通報中央主管機關。 前二項之處理情形，中央主管機關得委託驗證機構至該產品之設置或儲存地點，進行必要之查核及追蹤。 第一項產品之設置或儲存地點擬變更者，報驗義務人應報請中央主管機關核准後，始得為之。
Article 6	Prior-released products shall not transported to places outside of the installed or storage locations before they are type certified, neither shall them be put into service nor the ownership be transferred to a third party. The obligatory applicant are required to put up the qualification label, obtain certificate of type certification or complete the assembly of the prior-released products mentioned in the preceding paragraph, and report to the central competent authority within the specified time limit. The central competent authority may commission authorized certification bodies to perform the necessary audits or surveillance to verify completion of the obligations mentioned in the preceding two paragraphs

	<p>at locations where the prior-released products are installed or stored. The obligatory applicant shall apply for approval from the central competent authority in order to change the locations of installation or storage of prior-released products mentioned in paragraph 1 of this Article.</p>
第 7 條	<p>機械類產品未能於指定期間內依法張貼合格標章、取得型式驗證合格證明書或組裝完成者，報驗義務人得向中央主管機關申請展延。 前項展延期限不得逾六個月，並以一次為限。</p>
Article 7	<p>Where the obligatory applicant is not able to put up the qualification label, obtain certificate of type certification or complete the assembly of the prior-released products within the specified time limit, an extension of the time limit may be filed with the central competent authority. The extension of time limit mentioned in the preceding paragraph shall not exceed 6 month and be limited to one time only.</p>
第 8 條	<p>經具結先行放行之產品，申請型式驗證不合格者，除法令另有規定外，報驗義務人應於驗證不合格日起六個月內辦理退運、銷燬或拆解至不堪用等必要處置。</p>
Article 8	<p>Where the prior-released products under attestation do not pass type certification, they shall be shipped back, destroyed, dissembled to unusable conditions or disposed of with other necessary measures by the obligatory applicant within 6 months from the date of noncompliance notice.</p>
第 9 條	<p>本辦法所定之各種書表格式，由中央主管機關定之。</p>
Article 9	<p>Forms specified by these Regulations shall be stipulated by the central competent authority.</p>
第 10 條	<p>本辦法自中華民國一百零四年一月一日施行。 本辦法修正條文，自發布日施行。</p>
Article 10	<p>These Regulations shall take effect on January 1, 2015. The amended articles of these Regulations come into effect on the day of promulgation.</p>