

機械設備器具監督管理辦法(民國 103 年 12 月 22 日發布)

Regulations Governing the Surveillance of Machinery, Equipment and Tools (2014.12.22
Announced)

第一章 總則	
Chapter I General Provisions	
第 1 條	本辦法依職業安全衛生法（以下簡稱本法）第七條第四項及第八條第五項規定訂定之。
Article 1	These Regulations are established in accordance with Paragraph 4, Article 7 and Paragraph 5, Article 8 of the Occupational Safety and Health Act (the Act).
第 2 條	本辦法用詞，定義如下： 一、產品監督：指對本法第七條第一項、第三項或第八條第一項所定產品，於生產廠場或倉儲場所，執行取樣檢驗、查核產銷紀錄完整性及製造階段產品安全規格一致性。 二、市場查驗：指對本法第七條第一項、第三項或第八條第一項所定產品，執行其於經銷、生產、倉儲、勞動、營業之場所或其他場所之產品檢驗或調查。
Article 2	The terms and vocabulary used in these Regulations shall be defined as follows: 1. Product surveillance: for products specified in Paragraph 1 or 3, Article 7 or Paragraph 1, Article 8 of the Act, to perform inspection of sampled products, check completeness of production and distribution records and ensure consistency of safety specifications at the manufacturing stage at the production premises or warehouses. 2. Market checks: for products specified in Paragraph 1 or 3, Article 7 or Paragraph 1, Article 8 of the Act, to perform product inspection or investigation at places of distribution, production premises, warehouses, working areas, business sites or other places.
第 3 條	製造者、輸入者、供應者及前條第二款所列場所負責人（以下簡稱受查驗者）受查驗、調查、檢驗或封存時，非有正當理由，不得規避、妨礙或拒絕。
Article 3	Manufacturers, importers, suppliers and the responsible persons of places mentioned in subparagraph 2 of the preceding Article (hereinafter referred to as the person subject to inspection) shall not evade, impede or refuse the checks, investigation, inspection or seal of products without justified reasons.
第 4 條	中央主管機關、勞動檢查機構及本法第八條第一項之型式驗證機構，得依業務需要，執行產品之購樣、取樣之檢驗或調查。 中央主管機關執行前項產品購樣、取樣之市場查驗業務，得依本法第五十二條規

	定委託專業團體辦理。
Article 4	<p>The central competent authority, labor inspection bodies and type certification bodies mentioned in Paragraph 1, Article 8 of the Act may inspect or investigate purchased or sampled products, if it is so required in order to carry out their activities.</p> <p>The central competent authority may commission, in accordance with Article 52 of the Act, professional groups to purchase or sample products from the market required for market checks.</p>
第二章 產品監督	
Chapter II Product Surveillance	
第 5 條	<p>型式驗證機構每年度應依據發證產品之風險等級，訂定執行計畫。前項執行計畫，包括型式驗證合格產品之工廠製程與產銷紀錄之查核及取樣檢驗。</p> <p>第一項之產品風險等級，得依據廠商或其型式驗證合格產品之違規紀錄、事故發生率、購樣或取樣檢驗不合格紀錄、工廠品保模式或產地等風險因素區分之。</p>
Article 5	<p>The type certification body shall have an annual implementation plan based on the risk level of the products it certifies.</p> <p>The implementation plan mentioned in the preceding paragraph shall cover the factory's production processes of type-certified products, checks of production and distribution records and sampling inspection.</p> <p>The risk level of products mentioned in the first paragraph may be determined by factors such as the violation records of the manufacturer or type-certified products, occurrences of incidents, noncompliance records of purchased or sampled products, quality assurance of factories, or place of origin.</p>
第 6 條	<p>型式驗證機構監督驗證合格產品，應依產品類別，指派適當專業人員於產品之生產廠場或倉儲場所執行下列事項。但製程監督之執行地點，以生產廠場為限：</p> <p>一、產品實體監督：包括取樣檢驗及查核產品之產銷資料。</p> <p>二、製程監督：包括對生產廠場有關原物料、零組件之管理，及半成品、成品之檢測，檢視生產廠場之產製品與原型式驗證合格品，應持續維持安全規格之一致性。</p> <p>前項監督，型式驗證機構應製作產品監督紀錄，並妥存備查。</p>
Article 6	<p>To monitor type-certified products, the type certification body shall assign professionals to perform the following tasks at the production premises or warehouses of the products, whereas surveillance of production processes shall only be carried out at the production premises:</p> <p>1. Surveillance on products: including sampling inspection and checking of the production and distribution records.</p>

	<p>2. Surveillance on production processes: including the management of raw materials and components, inspection and testing of semi-finished and final products, verification of consistency in safety specifications of products at the production premises with type-certified products. The type certification body shall make product surveillance records of the surveillance mentioned in the preceding paragraph and maintain them properly.</p>
第 7 條	<p>型式驗證機構執行取樣檢驗，應就最新生產批次之型式驗證合格產品，隨機選取其中主型式或系列型式產品，現場比對各該型式試驗報告及技術資料。</p> <p>型式驗證機構依產品現場比對結果，認有必要時，得進行現場測試或攜回測試，並作成紀錄。</p>
Article 7	<p>The type certification body shall sample products from the most recent batch of type-certified products, including the main type and series of type, and compare on site with the information listed in the type test reports and technical files.</p> <p>Where the type certification body considers it necessary, it may perform testing on site or take back the sampled products for further testing based on the findings of the on-site comparison, and make records.</p>
第 8 條	<p>型式驗證機構辦理前二條之製程監督，有下列情形之一者，應於現場取樣，並攜回測試。但產品有不易攜回者，不在此限：</p> <p>一、監督地點無測試設備。</p> <p>二、經現場比對或測試，有不相符情事。</p> <p>三、其他認有疑義，須再測試釐清。</p>
Article 8	<p>Under any of the following circumstances, the type certification body shall sample products on site and take them back for testing when it performs surveillance on production processes, except where it is not easy to take back the products:</p> <ol style="list-style-type: none"> 1. Where there are no testing facilities at the surveillance place; 2. Where there are discrepancies as a result of the on-site comparison or testing; or 3. Where there are doubts requiring further clarifications.
第 9 條	<p>型式驗證機構辦理驗證合格產品之監督作業，認其產品之產銷資料不符規定者，應通知受查驗者限期改正，並將其列為後續加強監督之對象。</p>
Article 9	<p>Where the type certification body determines noncompliance of the production and distribution records during the surveillance on type-certified products, it shall notify the person subject to inspection to take corrective actions within a certain time limit and put it on the list of prioritized surveillance.</p>

第 10 條	<p>型式驗證機構對於型式驗證合格產品購樣或取樣檢驗，確認其不符安全標準者，應通報中央主管機關廢止該型號產品之型式驗證合格證明書，並通知相關業者限期回收產品。</p> <p>前項回收期限屆滿後，型式驗證機構應辦理市場查核，追蹤確認其回收情形。</p>
Article 10	<p>Where the type certification body confirms that the purchased or sampled type-certified products do not comply with the safety standards, it shall report to the central competent authority for rescinding the certificate of type-certification of the products and notify relevant parties to recall the products within a certain time limit.</p> <p>The type certification body shall conduct market checks to follow up the status of recall after the time limit expires.</p>
第 11 條	<p>製造者或輸入者對於完成安全資訊申報網站登錄或取得型式驗證合格之產品，應建立產品之產製日期、型式、規格、數量、出廠日期、銷售對象、客戶抱怨處理紀錄及客戶服務紀錄等產銷資料，並保存相關技術文件，供中央主管機關或勞動檢查機構不定期查核。</p>
Article 11	<p>For products registered at the Safety Information Reporting Website or granted certificates of type certification, manufacturers or importers shall have production and distribution documents concerning such products, such as dates of manufacture, types, specifications, quantities, dates of shipment, clients, complaints records and service records, and maintain related technical files for non-periodic checks by the central competent authority or labor inspection bodies.</p>
第 三 章 市場查驗	
Chapter III Market Checks	
第 12 條	<p>中央主管機關或勞動檢查機構，得因下列事由之一者，辦理市場查驗：</p> <p>一、檢舉人、工作者或勞工團體反映。</p> <p>二、產品發生災害事故，致有損害工作者生命、身體、健康或財產之虞。</p> <p>三、依據其他資訊來源認有查驗之必要。</p>
Article 12	<p>The central competent authority or labor inspection body may conduct market checks as a result of any of the following reasons:</p> <ol style="list-style-type: none"> 1. Accusations made by informants, workers or labor groups, 2. Disasters or incidents caused by products that are likely to damage the life, body, health or properties of workers, or <p>Other information resources indicating that the conduction of market checks is considered necessary.</p>
第 13 條	<p>產品市場查驗之查驗項目如下：</p> <p>一、產品符合本法第七條第一項及第三項規定。</p> <p>二、產品符合本法第八條第一項規定。</p>

	<p>三、產品之安全標示或驗證合格標章之樣式及張貼方式，與法令規定相符。</p> <p>四、違規產品經通知限期改正，是否如期改正。</p> <p>五、違規產品經通知限期回收，是否如期回收。</p> <p>六、產品之資料登錄或型式驗證合格經註銷、廢止或撤銷者，是否有違法產製運出廠場、輸入、租賃、供應或設置等情事。</p> <p>中央主管機關或勞動檢查機構於市場查驗時，得通知受查驗者提供驗證合格證明、測試報告、技術文件、測試樣品或其他相關佐證資料，以供查驗。</p>
Article 13	<p>The following items shall be included in market checks:</p> <ol style="list-style-type: none"> 1. Compliance of the product with the requirements of Paragraphs 1 and 3, Article 7, 2. Compliance of the product with the requirements of Paragraph 1, Article 8, 3. Compliance of the safety labels or certification labels, in terms of their patterns and manners of posting, with the requirements specified in the regulations, 4. Completion of corrective actions within the specified time limit for violating products, 5. Recall of violating products within the specified time limit, and 6. Violations of laws by manufacturing and shipping out of the production premises, importing, renting, supplying or installing products of which the registered information or type-certified qualification is cancelled, rescinded or withdrawn. <p>The central competent authority or labor inspection body may notify the person subject to inspection to provide certificate of type certification, test reports, technical files, testing samples or other supporting documents during market checks.</p>
第 14 條	<p>查驗人員執行市場查驗時，應向受查驗者出示識別證，並說明查驗依據及目的。</p> <p>執行市場查驗時，受查驗者或其指派人員應在場陪同。</p> <p>查驗人員執行市場查驗後，應作成查驗紀錄，並由受查驗者於查驗紀錄表簽名或蓋章。</p>
Article 14	<p>The inspector performing market checks shall present identification documents to the person subject to inspection and explain the basis and reasons of the checks.</p> <p>The person subject to inspection shall be present or assign representative to accompany the inspector during market checks.</p> <p>The inspector shall make inspection records after completing market checks and have the person subject to inspection sign or seal stamps on the</p>

	inspection records.
第 15 條	<p>中央主管機關或勞動檢查機構執行市場查驗時，發現疑有違規之產品，應進行調查。</p> <p>前項調查之方式如下：</p> <p>一、向受查驗者或相關業者查詢，並得要求其提供相關佐證資料。</p> <p>二、於第二條第二款所列之場所進行調查，並得對可疑產品取樣檢驗，或請受查驗者提供與疑有違規產品同型式之產品送驗。</p> <p>三、必要時，得封存疑有違規產品，並於受查驗者填具進貨證明及保管書後，將產品交其具結保管或運存指定處所。</p>
Article 15	<p>The central competent authority or the labor inspection body shall investigate on products that are likely to violate related regulations when it performs market checks.</p> <p>The means of investigation shall be:</p> <ol style="list-style-type: none"> 1. To make inquiry to the person subject to inspection or related persons and request for supply of relevant supporting documents, 2. To investigate at the site mentioned in subparagraph 2, Article 2 and sample products that are likely to violate related regulations for inspection, or ask the person subject to inspection to provide products that are of the same type with suspect products for testing, and 3. To seal products that are likely to violate regulations, where necessary, and put the products in the custody of the person subject to inspection or deliver the products to designated places after the person subject to inspection draws up proof documents or affidavit concerning the status of these sealed products.
第 16 條	<p>查驗人員執行前條之調查時，應於調查現場或運存指定處所，作成訪談紀錄，並將受查驗者之陳述意見，列入紀錄。</p> <p>受查驗者將疑有違規產品運存指定處所時，應保留退運文件備查。</p> <p>中央主管機關、勞動檢查機構及本法第八條第一項之型式驗證機構為前條之調查，遇有規避、妨礙或拒絕情事，得依個案請求警察機關派員協助之。</p>
Article 16	<p>The inspector when performing the investigation mentioned in the preceding Article shall make interview records on the site of investigation or designated places where the products are stored. Comments or explanations made by the person subject to inspection shall be noted in the records.</p> <p>The person subject to inspection shall keep shipment-return documents for later checks when delivering products likely to violate regulations to designated places for storage.</p> <p>The central competent authority, labor inspection body and type</p>

	certification body mentioned in Paragraph 1, Article 8 of the Act may request assistance from the police on a case-by-case basis when situations such as evasion, impediment or refusal of investigation occur.
第 17 條	查驗人員執行市場查驗，受查驗者或其指派人員無正當理由，不得規避、妨礙或拒絕。
Article 17	The person subject to inspection or the designated representative shall not evade, impede or refuse market checks without justified reasons.
第 18 條	受查驗者無正當理由，有規避、妨礙或拒絕查驗之情事，查驗人員應將查驗情形作成紀錄。 前項紀錄，應記載下列事項： 一、受查驗者之名稱、事務所或營業所，及負責人或代表人之姓名、出生年月日、性別、身分證統一號碼及住居所。 二、規避、妨礙或拒絕查驗之事由及經過。 三、查驗之單位、人員、時間及地點。 四、其他採證所需之必要事項。 前項第一款之受查驗者相關資料不明時，查驗人員得向有關機關查詢後，補列之。
Article 18	The inspector shall make records on market checks if the person subject to inspection evade, impede or refuse checks without justified reasons. The records mentioned in the preceding paragraph shall include the following items: 1. Name, office or business place of the person subject to inspection, and the name, date of birth, gender, personal identification number and address of domicile of the responsible person or representative, 2. Reasons of evasion, impediment or refusal of checks and the whole course of the situation, 3. The body and person performing checks, and the time and place of checks, 4. Other items for collecting evidence. Where the information on the person subject to inspection is not available, the inspector may make inquiry to related government agencies and record it at a later time.
第 19 條	中央主管機關或勞動檢查機構執行領有型式驗證合格證明書產品之市場查驗，發現有檢驗不合格之情形者，應通知原型式驗證機構追蹤調查不合格原因及製作訪談紀錄，並依相關規定辦理。
Article 19	The central competent authority or labor inspection body findings noncompliant products during market checks of type-certified products shall inform the type certification body that issue the certificate to investigate reasons of noncompliance, make interview reports and process the case in accordance with related requirements.

第 四 章 不 合 格 品 處 理	
Chapter IV Processing of Noncompliant Products	
第 20 條	<p>中央主管機關、勞動檢查機構及本法第八條第一項之型式驗證機構對於檢驗不符合安全標準之產品，應列入追蹤處理，並向製造者、輸入者或供應者進行調查及製作訪談紀錄。</p> <p>前項之機關(構)認定前項產品涉有不安全情形者，應製作不安全產品通知文件，載明法令依據、通知事由、產品名稱、型號、製造(輸入)日期及製造(輸入)廠商等事項，並附佐證照片。</p> <p>勞動檢查機構或型式驗證機構，應將前二項之調查資料、訪談紀錄及不安全產品通知文件，送中央主管機關。</p> <p>中央主管機關接獲前項調查資料、訪談紀錄及不安全產品通知文件時，應依法處理並予以保存。</p>
Article 20	<p>The central competent authority, labor inspection body and typecertification body mentioned in Paragraph 1, Article 8 of the Act shall follow up products not in compliance with safety standards, and carry out investigations to the manufacturer, importer or supplier and make interview reports.</p> <p>For products mentioned in the preceding paragraph that are considered not safe, the organization or body mentioned in the preceding paragraph shall prepare a notification document stating the basis of regulations, reasons of notification, name of products, type, date of manufacture/import and name of manufacturer/importer, with supporting photos.</p> <p>The labor inspection body or type certification body shall sent the investigation documents, interview reports and notifications of unsafe products mentioned in the preceding two paragraphs to the central competent authority.</p> <p>The central competent authority shall process and keep the investigation documents, interview reports and notifications of unsafe products mentioned in the preceding paragraph in accordance with related regulations.</p>
第 21 條	<p>受查驗者無正當理由規避、妨礙或拒絕調查者，查驗人員應作成紀錄，送中央主管機關、勞動檢查機構及本法第八條第一項之型式驗證機構依法處理。</p> <p>前項紀錄，應記載事項準用第十八條第二項及第三項之規定。</p>
Article 21	<p>Where the person subject to inspection evade, impede or refuse investigation without justified reasons, the inspector shall make a record and sent it to the central competent authority, labor inspection body or type certification body mentioned in Paragraph 1, Article 8 of the Act</p>

	<p>to process in accordance with related regulations.</p> <p>The provisions of Paragraphs 2 and 3 of Article 18 shall apply mutandis mutatis to the content of the record mentioned in the preceding paragraph.</p>
第 22 條	<p>中央主管機關對於購樣或取樣檢驗不符合安全標準，而有危害工作者安全之虞之產品，得請海關實施邊境抽驗。</p>
Article 22	<p>The central competent authority may request assistance from the Customs to perform border inspection of products that do not comply with safety standards during purchased or sampled inspection and are likely to pose hazards to the safety of workers.</p>
第 23 條	<p>報驗義務人對於檢驗不合格之產品，不能改正使其符合安全標準者，應於接獲不合格通知書後六個月內，辦理退運、銷毀、拆解致不堪使用或為其他必要之處置。報驗義務人對於產品進行前項之必要處置時，應向中央主管機關申請拆封或核准自行拆封，中央主管機關、勞動檢查機構及本法第八條第一項之型式驗證機構並應派員到場監督。</p> <p>報驗義務人辦理第一項產品之退運時，應於退運後三個月內，檢附復運出口報單副本等相關文件，向中央主管機關申請銷案或核符關務退運資料後銷案。</p>
Article 23	<p>If the products that fail inspection cannot be further modified to meet the safety standards, the obligatory applicant shall return the shipment, destroy or disassemble the products, or adopt other necessary measures within six months after receiving an a notice of noncompliance.</p> <p>When actions mentioned in the preceding paragraph are taken to dispose of products, the obligatory applicant shall apply to the central competent authority for opening the seal, or may open the seal themselves, after obtaining an approval from, and under the supervision of, the central competent authority, labor inspection body and type certification body mentioned in Paragraph 1, Article 8 of the Act.</p> <p>For products that are to be returned as mentioned in the first paragraph, the obligatory applicant shall report to the central competent authority to close the case by providing documents related to export or crosschecking the information on returned shipment with the Customs within three months after the products are returned.</p>
第 24 條	<p>報驗義務人對於檢驗不合格產品之測試樣品，應於接獲不合格通知書之日起三個月內領回。逾期未領回者，中央主管機關、勞動檢查機構及本法第八條第一項之型式驗證機構得予銷毀、拆解致不堪使用或為其他必要之處置。</p> <p>中央主管機關、勞動檢查機構及本法第八條第一項之型式驗證機構辦理前項測試樣品之銷毀、拆解致不堪使用或為其他必要之處置所生費用，應由報驗義務人負擔。</p>
Article 24	<p>Sampled products that fail inspection shall be taken back by the obligatory</p>

	<p>applicant within three months after receiving the notice of noncompliance. Where the sampled products are not taken back by the obligatory applicant after three months, the central competent authority, labor inspection body and type certification body mentioned in Paragraph 1, Article 8 of the Act may destroy the products, disassemble the products to unusable status or take necessary actions.</p> <p>The fees evolved from actions taken by the central competent authority, labor inspection body and type certification body mentioned in Paragraph 1, Article 8 of the Act to destroy the products, disassemble the products to unusable status or other necessary dispositions shall be borne by the obligatory applicant.</p>
<p>第 五 章 退 運 及 銷 燬</p>	
<p>Chapter V Return Shipment and Destruction</p>	
<p>第 25 條</p>	<p>報驗義務人對於輸入或產製之產品，因檢驗不合格而退運或銷燬時，應依下列規定辦理：</p> <p>一、退運：退運後三個月內，檢附復運出口報單副本等相關文件，向中央主管機關申請銷案或核符關務退運資料後銷案。</p> <p>二、銷燬：檢附銷燬計畫，向中央主管機關提出申請，完成銷燬程序，辦理銷案。</p>
<p>Article 25</p>	<p>The obligatory applicant shall observe the following requirements for imported or manufactured products that need to be returned or destroyed because they fail inspection:</p> <p>1. Return shipment: to provide the central competent authority with copies of export related documents to close the case or crosscheck information on return shipment with the Customs to close the case within three months after the products are returned.</p> <p>2. Destruction: to apply to the central competent authority by presenting a destruction plan, destroy products and request for closing the case.</p>
<p>第 26 條</p>	<p>中央主管機關受理前條第二款銷燬之申請，應審查銷燬計畫內容，包括報驗案號、品名、規格、數量、銷燬地點、銷燬方式及後續廢棄物處理等資料。</p> <p>中央主管機關經審核通過前項銷燬計畫者，得自行派員或委託其他機關(構)監燬，並以拍照或重點錄影方式存證；其銷燬過程與銷燬計畫有不符之情事者，應停止銷燬，並由中央主管機關通知報驗義務人改正後，另行銷燬。</p>
<p>Article 26</p>	<p>When accepting applications for destroying products as mentioned in subparagraph 2 of the preceding Article, the central competent authority shall review the content of destruction plan, including serial number of the application, name of products, specifications, quantities, place of destruction, means of destruction and subsequent disposition of wastes, etc.</p>

	The central competent authority approves the destruction plan mentioned in the preceding paragraph may dispatch personnel or commission other organizations/bodies to witness the destruction and take photos or video recording the critical processes for documentation. Where the process of destruction does not comply with that stated in the destruction plan, destruction shall be stopped and carried out at a later time after correction is made by the obligatory applicant upon receipt of notice from the central competent authority.
第 27 條	監燬人員應於銷燬完成時，確認銷燬產品已不堪使用，並於銷燬紀錄簽註查核情形及銷燬完成日期等相關事項，送中央主管機關銷案，並將相關文件影本留存備查。
Article 27	The personnel witnesses the destruction shall confirm that the products are destroyed to unusable status after completion of the destruction and note down the checks and date of destruction on the destruction report, which shall be sent to the central competent authority for closing the case. A copy of the destruction report and related documents shall be kept for subsequent checks.
第 六 章 附 則	
Chapter VI Others	
第 28 條	本辦法自中華民國一百零四年一月一日施行。
Article 28	These Regulations shall take effect on January 1, 2015.