

構造規格特殊產品安全評估報告及檢驗辦法(民國 103 年 11 月 21 日發布)

Regulations Governing the Safety Assessment Report and Inspection of Products with Special Structures (2014.11.21 Announced)

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, Article 8 of the Occupational Safety and Health Act (the Act).
第 2 條	本法第八條第三項所稱產品構造規格特殊，指產品之構造、性能或防護之設計、工法、技術、材料或其他安全機構性能有別於常規，致驗證有困難之情況。
Article 2	Products that are mentioned in Paragraph 3, Article 8 of the Act as having special structural specifications shall mean those of which the specifications are different from normal specifications in terms of the structure, performance, design, engineering methods, technology, materials of safeguard devices or the performance of other safety mechanisms, which lead to difficulties in certification.
第 3 條	<p>報驗義務人對於前條產品擬採用適當檢驗方式者，應檢附產品安全評估報告及相關資料，向中央主管機關申請核准。</p> <p>前項產品安全評估報告及相關資料如下：</p> <p>一、產品基本資料：包括產品之型錄、名稱、外觀圖及貨品分類號列等圖件資料。</p> <p>二、安全評估資料：包括採取國際間常用之風險評估方法，完成該產品之安全評估、危害分析或風險評估，併同危險對策，彙集成冊。</p> <p>三、產品擬採檢驗方式之建議及其與中央主管機關所定型式驗證實施程序，及安全標準之差異性說明。</p> <p>四、該產品具有國內外獨立第三者驗證機構依據建議檢驗方式完成驗證測試者，檢附有效期限內之合格證明文件。</p> <p>五、其他經中央主管機關認有必要之符合性評鑑程序資料或技術文件。</p>
Article 3	<p>The obligatory applicant shall apply to the central competent authority for approval by submitting product safety assessment reports and other related documents if he intends to use other appropriate methods to inspect products with special structural specifications.</p> <p>The product safety assessment report and other related documents shall include the followings:</p> <p>1. Basic information of the product: including product catalog, product name, illustrations of the appearance of the product, product classification code, etc.</p> <p>2. Safety assessment documents: including the adoption of risk assessment methods widely used by international communities, completion of safety</p>

	<p>assessment, risk analyses or risk evaluation of the product, and recommended practices for responding to hazards, all of which shall be compiled in a document.</p> <p>3. Recommended inspection methods for the product and implementing procedures for type certification decided with the central competent authority, as well as explanations for deviations from the safety standards.</p> <p>4. Valid certificates issued by domestic or foreign third-party certification bodies against the recommended inspection methods.</p> <p>5. Other conformity assessment procedure documents or technical files as deemed necessary by the central competent authority.</p>
第 4 條	<p>中央主管機關審查前條申請案時，得邀請學者專家提供意見或委託專業團體辦理，並得通知報驗義務人到場說明。</p> <p>前項審查未通過者，中央主管機關應以書面說明不予核准理由，復知申請人。</p>
Article 4	<p>The central competent authority may invite experts to provide comments when reviewing the applications mentioned in the preceding Article or commission professional groups to process the review of such applications. It may also inform the obligatory applicant to explain in person.</p> <p>The central competent authority shall inform the applicant in written of reasons of disapproval if the application does not pass the review mentioned in the preceding paragraph.</p>
第 5 條	<p>經核准採用適當檢驗方式驗證者，其他與申請案同一型式之產品，均得比照辦理型式驗證，無須重複申請。</p> <p>前項核准採用適當檢驗方式驗證之產品，俟中央主管機關對其定有型式驗證實施程序及安全標準時，報驗義務人即應依各該規定辦理，不得再沿用前項之檢驗方式為之。</p>
Article 5	<p>Where approval is granted to the use of appropriate inspection methods for certification, the type certification of products with the same type may be conducted accordingly without having to make another application. For products that are granted to use appropriate inspection methods as mentioned in the preceding paragraph, the obligatory applicant shall follow the required procedures as soon as related implementing procedures for type certification and safety standards are announced by the central competent authority. The appropriate inspection methods mentioned in the preceding paragraph shall no longer be used.</p>
第 6 條	<p>報驗義務人以詐欺、虛偽不實或其他不當方式取得核准採適當檢驗方式者，中央</p>

	主管機關應予追繳相關驗證合格證明書及撤銷合格標章；其有涉及刑責者，另移送司法機關依法處理。
Article 6	Where the approval of appropriate inspection methods is obtained by fraudulent, deceptive or other inappropriate means, the central competent authority shall recall related product certificates and withdraw the certification labels. Where criminal charges are involved, the cases shall be forwarded to judicial organizations for processing.
第 7 條	本辦法所定各種書表格式，由中央主管機關定之。
Article 7	The forms of documents mentioned in these Regulations shall be prescribed by the central competent authority.
第 8 條	本辦法自中華民國一百零四年一月一日施行。
Article 8	These Regulations shall take effect on January 1, 2015.