

出國報告（出國類別：考察）

考察美國消費品安全委員會與相關標準與驗證機構之市場監督管理作法

服務機關：經濟部標準檢驗局

姓名職稱：鍾繼磊科員

派赴國家：美國（華盛頓哥倫比亞特區）

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摘 要

美國為世界最大的商品進口國，其透過完整的大數據分析以及風險評估機制，在有限的人力之下，杜絕不安全商品於國內市場；此外，美國透過法令及行政命令規定讓聯邦機關要採認民間的標準並鼓勵雙方合作，透過多方的溝通尋求一致性的作法，一方面可以讓民間先尋求共識，減少標準及規範與實務上的落差，另一方面也可以減少政府預算支出及提升效率，讓聯邦機關能著重在核心業務上。

本次考察心得及建議如下：

- 一、 強化公私部門間之溝通平臺，提升政府效能。
- 二、 建立完整的市場監督管控系統與風險瞄準系統。
- 三、 持續與美方相關機關(構)保持互動關係
- 四、 建置一站式查詢服務系統

關鍵字：CPSC、NIST、ANSI、UL、商品市場監督、法規機器人、NTTAA、OMB-119

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壹、出國背景與目的

一、背景：

- (一) 美國為世界最大的商品進口國¹，經統計平均每年有 2,400 多萬個貨櫃透過陸運與海運抵達美國邊境，另外每年也有高達 2.5 億個快遞包裹透過空運方式要進口美國²，因此，對於美國每年要對如此龐大的進口商品如何採取有效的監管措施，是值得探討的議題，相關作法亦可作為我國未來商品管理監督機制的借鏡。
- (二) 此外，107 年美國消費品安全委員會（CPSC）曾來臺分享其利用資訊科技有效監管可能違規進入國內市場之商品；另本局 108 年度委託社團法人中華民國品質學會辦理之「六、標準、檢驗及計量管理制度與發展趨勢之研究」計畫，擬蒐集先進國家之標準、檢驗等權責機關運用創新資訊技術（如 IoT 物聯網、AI）或新思維於制度管理之案例與發展趨勢。

二、現況：

目前消費商品安全管理機制主要可分為「前市場管理」與「後市場監督」，世界各國均針對商品安全危害風險程度，採取合適之管理機制：

- (一) 我國依據商品檢驗法對於安全危害風險較高之商品會採逐批檢驗、監視查驗等「前市場管理」方式要求報驗義務人於商品輸入或運出廠場前符合檢驗規定；又基於貿易便捷化及自由化等精神，避免「前市場管理」方式造成商品通關延誤，影響商機，則採驗證登錄及符合性聲明等檢驗方式，如此報驗義務人無須逐批向本局辦理報驗，即可順利將商品流通進入市場；其中針對取得商品驗證登錄證書輸入之商品，本局另依據相關危害性風險因素執行邊境查核，以杜絕不安全商品進口。
- (二) 美國為了監管透過各種管道進口的消費品，以保護消費大眾免於因使用該產品而遭受危害風險，有官方的美國消費品安全委員會（CPSC）

¹ [Leading import countries worldwide in 2017 \(in billion U.S. dollars\)](#)

² 來源：cbp.gov

建置有風險資料庫，運用風險評估方法（RAM）與海關資料庫的訊息共享，可決定在全美 300 多個口岸中、對哪些進口商品執行抽檢，在有限之人力下，利用大數據分析，運用於邊境抽檢，能夠及時攔檢高風險商品並避開較低風險之商品，以避免高風險商品進入國內市場；另有獨立之產品安全驗證機構（如 UL）負責核發相關檢驗標準的測試報告與驗證證書、美國國家標準協會（ANSI）與美國國家標準暨技術研究院（NIST）等提供最新標準與技術供官方與民間依循。

三、目的：為瞭解美國如何利用資訊科技，系統性地建置並分析既有商品風險資訊，再透過跨機關合作，以即時掌握不安全商品之流向與採行適當之處置作為，降低不安全商品對消費者可能造成之危害，爰赴美國考察相關市場監督機制。

貳、行程規劃與考察人員

一、時間：108 年 9 月 2 日~9 月 8 日（含交通時間）

二、考察人員：

本次考察計 4 位：經濟部標準檢驗局鍾繼磊科員、社團法人中華民國品質學會陳文魁博士與蔡宜均研究助理、以及財團法人台灣電子檢驗中心劉尚昇課長。

三、行程規劃：

日期	行程規劃	備註
9 月 2 日(一)	臺北-華盛頓特區（去程）	考察人員各自前往美國會合。
9 月 3 日(二) ~6 日(五)	1. UL（Underwriters Laboratories Inc.） 2. ANSI（American National Standards Institute,美國國家標準協會） 3. NIST（National Institute of Standards and Technology,美國國家標準暨技術研究院） 4. CPSC（U.S. Consumer Product Safety Commission,美國消費品安全委員會）	除前述 4 位外，我國駐美國台北經濟文化代表處之袁鴻麟秘書、蔡智棠秘書亦陪同出席 ANSI 與 NIST。
9 月 7 日(六) ~8 日(日)	華盛頓特區-臺北（返程）	考察人員各自搭機返臺。

參、參訪內容紀要

一、UL (Underwriters Laboratories Inc.)

(一) 機構概述：

保險商實驗室 (Underwriters Laboratories Inc.，簡稱：UL) 是一家獨立的产品安全驗證機構，在美國是第一個也是最大的標準發展組織 (Standards Developing Organization, SDO)，建立許多產品、原料、零件、工具及設備等的標準及測試程序。

UL 成立於 1894 年，總公司在美國的伊利諾州，主要的業務是採用科學方法測試各種材料、裝置、產品及建築物等的安全認證，該等產品或設施是否有危害性，並提供產品危害的調查研究，提供官方或民間參考。

目前 UL 服務區域有 104 個國家，包含臺灣。UL 臺灣成立於 1988 年，是 UL 美國總部第一個在海外設置的授權實驗室。目前 UL 臺灣的服務據點位於臺北，擁有亞太地區先進完備的測試檢驗設備及實驗室，提供亞洲及臺灣市場即時在地的檢測服務。從初設的 40 人團隊，至今十倍多成長，在臺灣服務廠商超過 3,500 家，遍及各消費性及工業類產業，每年平均檢驗 300 種的產品。

(二) 與談人員：

- Karen Grunstra (Senior Government Affairs Specialist).
- Ebonique Padgett-Barker (Senior Trade Associate, Global Government Affairs).

(三) 與談內容摘要：

UL 公司 150 年來致力於商品安全的檢測，尤其是電器安全，服務遍及全世界，本次 UL 分享議題可分為 3 大構面：1. 「標準與符合性評估 (Standards & Conformity Assessment)」的機制；2. 「美國體制-公私部門間的運作模式」；及 3. 「UL 後市場監督與追蹤服務 (Market Surveillance & Follow-up services)」等，以下逐一簡要說明：

1. 「標準與符合性評估」： UL 為美國及加拿大所認可的標準發展組

織(SDO)，在美國，UL 發展出一套標準後，會提交給 ANSI 的審核與調和後，再成為美國國家標準(ANS)；標準可提供創新與商業化的基礎，不僅能創造公益與公平的機制，也能讓市場有相互承認的準則，而標準也能當作品質的一個指標，亦可作為政府部門管理的工具。

根據 NIST 所公布的「符合性評估」機制（如下圖 1³），以標準為基礎，廠商、政府機關或各種機構可根據其 1)需管理的風險程度與 2)所被要求須達成的目標或信心水準，有不同評鑑方式來證明產品或生產程序的符合性；若所需的評鑑方式越嚴格且需經第三方驗證機構測試的話，產品的信任度也會隨之提升。

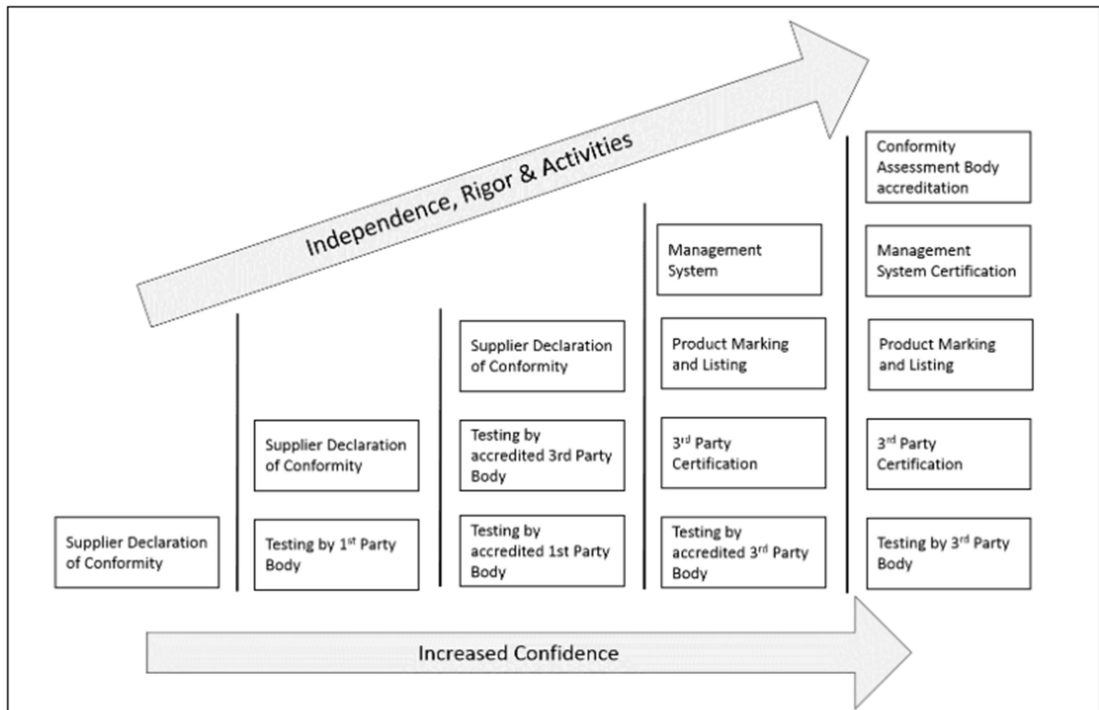


圖 1、符合性評估機制

2. 「美國體制-公私部門間的運作模式」：

(1) 美國體制的運作模式特色包含：(a)政府高度分權、(b)基於市場的需求，綜合私部門與公部門的作法、(c)市場管道與市場接受的要素、(d)運作方式依其行業特性(或對應之聯邦機關)

³ NIST Special NIST Special Publication 2000-02, Conformity Assessment Considerations for Federal Agencies

而定；而聯邦機關依據白宮預算法案（White House Office of Management and Budget (OMB) Circular A-119）及國家技術移轉與促進法（National Technology Transfer and Advancement Act of 1995, NTTAA）須採取民間部門的解決方案（如自願性共通標準、符合性評鑑計畫等），除非有於法不合或其他不切實際的情形發生，才能使用政府的規範。因此，政府只代表一種聲音，而民間的力量才是關鍵。

- (2) 其中 OMB Circular A-119 的目標在於：
- A. 消除制定內部標準的成本；
 - B. 降低政府採購商品與服務的成本；
 - C. 盡量減少為遵守監管單位要求的障礙；
 - D. 提供激勵/機會以建立滿足國家需求的標準；
 - E. 鼓勵美國企業達成長遠的發展；
 - F. 促進政府與民間的效率與競爭；
 - G. 政府並仰賴私部門提供聯邦政府所需的商品與服務。
- (3) UL 亦概述 NIST 在標準制定與發展的角色定位：NIST 是負責實施 NTTAA 的文件標準與符合性評鑑規定，且 NIST 也提供聯邦機關要符合 OMB A-119 所規定的義務時所需的資源，例如在 2018 年 9 月發布了「ABCs of Conformity Assessment」與「Conformity Assessment Considerations for Federal Agencies」供聯邦政府依循，並提供個別利害關係人的參與（如公共論壇、產業公/工會會等）。
- (4) 此次 UL 也分享與多個聯邦機關間(包括聯邦通訊委員會 FCC、職業安全與健康管理局 OSHA、消費品安全委員會 CPSC 與食品藥品監督管理局 FDA 等)的合作案例，UL 與各聯邦機關的合作方式摘述如下：
- A. 與 OSHA（Occupational Safety and Health Administration）合作的國家認可測試實驗室（National Recognized Testing Laboratory, NRTL）計畫：

- i. 透過符合性評鑑機制將私部門相關機構認可為國家測試實驗室，來確定生產的特定產品符合對應的測試標準，並確保這些產品在美國工作場所使用是安全的。
- ii. 藉由此項 NRTL 計畫不僅可以減少政府的人力物力成本，也減輕 OSHA 的市場監督負擔（不用到全美各地檢查），也讓私部門間有良性的競爭以促使共通性標準的發展等好處。
- iii. NRTL 評估機制⁴：
每個受認可的實驗室的檢測標準並不一定是依據全國統一的國家標準（如我國的國家標準），而是依照各個實驗室所制訂的測試標準進行檢測，但至少都必須符合 OSHA 所要求的規範事項，檢測完成後才能標示相關的驗證標章（如 UL mark 或 SGS mark 等），相關的驗證流程如下圖 2：

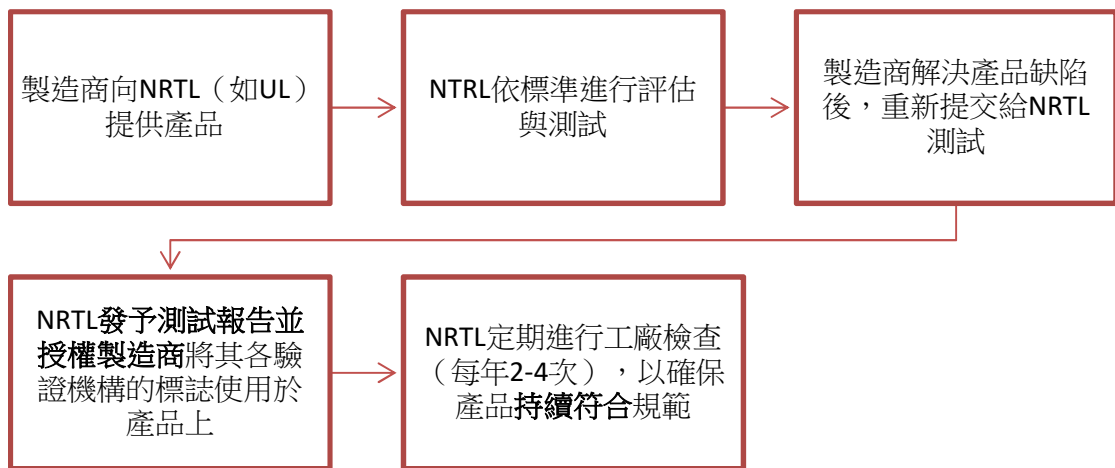


圖 2、NRTL 驗證流程

- B. 與 CPSC 合作：CPSC 與 UL 皆共同致力於商品的安全性以
避免社會大眾因使用商品而遭受傷亡的不合理風險。
 - i. CPSC 參與 UL 許多標準制定的會議，例如有 15 位

⁴ 來源：UL 簡報，本報告翻譯整理

CPSC 的成員參與 UL 的 54 個技術小組，並參加各種 UL 工作小組與技術協調委員會。

- ii. CPSC 也參加 UL 舉辦的消費者諮詢委員會，持續在重大安全議題上進行技術諮詢與協商，並共同對製造商、供應商與相關利害關係人提供標準與技術支援或培訓等，以確保廠商能了解相關法令與技術標準，並依此製造合乎安全的商品提供給消費者使用，雙方合作相當密切。例如 CPSC 與 UL 於 2016 年 9 月在中國大陸召開了電動滑板車安全的標準研討會，並於 2017 年 5 月及 2019 年 9 月分別辦理電池安全與採購商的教育訓練，透過多方面的管道讓製造商、供應商等利害關係人能夠掌握產品安全的資訊。

3. 「UL 後市場監督與追蹤服務 (Market Surveillance & Follow-up services)」：目的是保護 UL 的品牌以及強化公共安全。

(1) UL 的驗證過程及追蹤查核服務⁵(如下圖 3)：

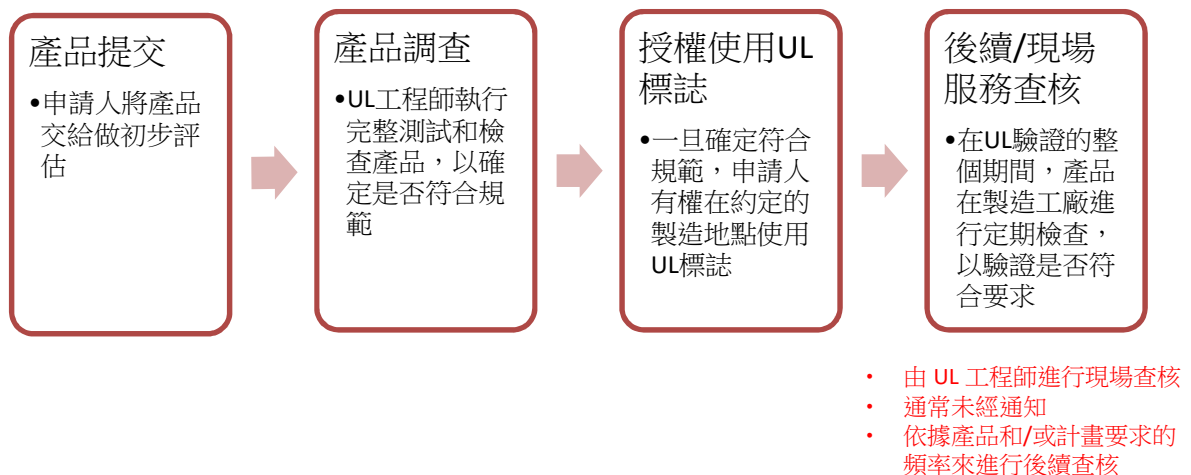


圖 3、UL 的驗證及追蹤查核服務

⁵ 來源：UL 簡報，本報告翻譯整理

(2) 「UL 標誌計畫」：

- UL 根據趨勢和符合規範的資料進行主動式市場監督，以保護其的品牌及標誌。
- UL 每年調查 3,000 起事件/報告，並採取適當的矯正措施，例如發布警訊通知全國消費者。
- UL 透過從市場購買產品並測試商品是否符合安全規範以進行市場調查。因為 CPSC 沒有編列相關額外預算，因此相關經由 UL 驗證的產品均由 UL 自行執行後市場監督，此部分的費用則由廠商負擔（包含在整筆的驗證費用中）。
- 另 UL 與執法單位共同合作去查核是否有冒用 UL 標誌卻未經驗證的產品，這些產品可由執法單位扣押。

(3) UL 執行後市場管理的要訣：

- 所有符合性評鑑方法都需要與有效的市場監督相互搭配才有效果。
- 市場上所販售之合乎標準或規定的產品，需仰賴所有利害關係人-製造商、第三方（如 UL）、政府和消費者的共同努力，但對於消費者的商品安全意識，仍需要多方努力，這部分我國亦同，亦是未來仍要持續努力的方向。
- 在選擇市場監督機制時必須考慮使用一致性方法：自我宣告（Self-declaration）制度會使監管機構（如 CPSC）和製造商在監督市場時帶來更大的障礙（例如：資源、技術專業知識）。但透過第三方驗證可促使符合性評鑑機構來協助監督市場上製造商的產品是否符合相關規定或標準。

4. 案例分享-電動滑板的危機：

電動滑板 (hoverboard) 在多國引起致命火災之後政府方才發布緊急通告，從 2015 年 11 月中旬事件爆發開始，當年 12 月 UL 的技術小組便著手起草電動滑板的安全標準 UL 2272，隔年（2016）年

1 月將標準初稿與主要零售商及 CPSC 共同開會討論，並在 2016 年 2 月就公布全新的電動滑板標準 UL 2272，同時 CPSC 也一併在官方社群網站(twitter)公布相關 UL 2272 訊息讓大眾了解，並於 2016 年 7 月中 CPSC 發布 10 家廠商的商品召回訊息；而 UL 2272 在 2016 年底終於取得 CPSC、ASTM、IEC 等多方共識後，成為電動滑板的共通性標準；對於製造商，UL 亦赴中國工業協會舉辦電池製造商的訓練。目前新加坡也採行 UL 2272 作為該國有關電動個人設備的測試標準供當地國廠商依循。



圖 4、與談人員合影(UL)

二、ANSI (American National Standards Institute)

(一) 機構概述：

1. 美國國家標準協會(American National Standards Institute, ANSI)設立於 1918 年,原名為「美國工程標準委員會」(American Engineering Standards Committee, AESC),於 1969 年改制並更名為 ANSI,現為非官方的標準發展組織,不過卻是美國在 ISO 的官方代表(並非 NIST)。ANSI 不自己訂標準,而是「調和、審核」其他標準發展組織(SDOs)所制定出的標準,ANSI 年度營運資金來自出版品、會員費、各種收費服務計劃和國際標準計劃。

ANSI 代表且服務全球超過 27 萬家企業與組織,以及 3000 萬名專業人士,包括標準發展組織、政府機關、製造商、貿易協會、專業社團、消費者代表、服務業者、實驗室、學術人士、個人...等等。

2. ANSI 的標準活動範圍涵蓋了三大範疇:國際機構(譬如 ISO、IEC、IAF、ILAC...)、外國同儕組織(譬如 BSI、SAC、DIN、ABNTC...)及區域組織(譬如 PASC、COPANT、ESOs、CEN、CENELEC、ETSI...)(詳圖 5⁶),對於我國若與 ANSI 持續維持良好互動,可藉此獲取較多國際參與相關標準活動之機會:

- (1) 國際機構:ANSI 是美國在國際標準化組織 ISO 和國際電工委員會 IEC (International Electrotechnical Commission) 的會員,也是美國在國際認證論壇 IAF (International Accreditation Forum) 與國際實驗室認證聯盟 ILAC (International Laboratory Accreditation Cooperation) 的會員
- (2) 區域組織:ANSI 亦是多個區域性標準組織的會員,包括太平洋標準協會 PASC (Pacific Area Standards Congress)、歐洲標準化委員會 CEN (Comité Européen de Normalisation)、泛美洲標準委員會 COPANT (Pan American Standards Commission)、歐洲電信標準協會 ETSI (European Telecommunications Standards

⁶ 來源 ANSI 簡報

Institute)。

- (3) 外國同儕組織：ANSI 與其他國家的標準組織簽有雙邊協定，包括英國標準協會 bsi (British Standards Institution)、中國標準組織 SAC、德國標準化學會 DIN (Deutsches Institut für Normung e.V.) 等等。



圖 5、ANSI 標準活動範疇

(二) 與談人員：

- Leslie McDermott (Director, International Development)

(三) 與談內容摘要：

1. 再次闡述美國標準化與符合性評鑑的系統機制：

- (1) 如 UL 所述，各種規格標準都是來自市場驅動 (market-driven)，而非由政府主導 (如圖 6)，美國國內的標準制定仍仰賴民間機構與各個利害關係人先自行取得共識後再交由 ANSI 審核與調和，爰此，美國的標準制定方式賦予了民間使用者與各個利害關係人有發聲的機會與更大的授權，而且沒有任何一個政府機關可以對標準有「控制權」，不過每個政府機關可以自行決定採用何種民間標準是符合其政策目標與任務需求。

(2) 而 ANSI 審核標準的準則為：是否有取得共識（consensus）且經大眾評論（public review），並且經審議後回應大眾評論（Consideration of and response to comments），廠商或各個利害關係人以有提出申訴的權利（right to appeal），因此重視開放（openness）、平衡（balance）與是否有正當程序（due process）。

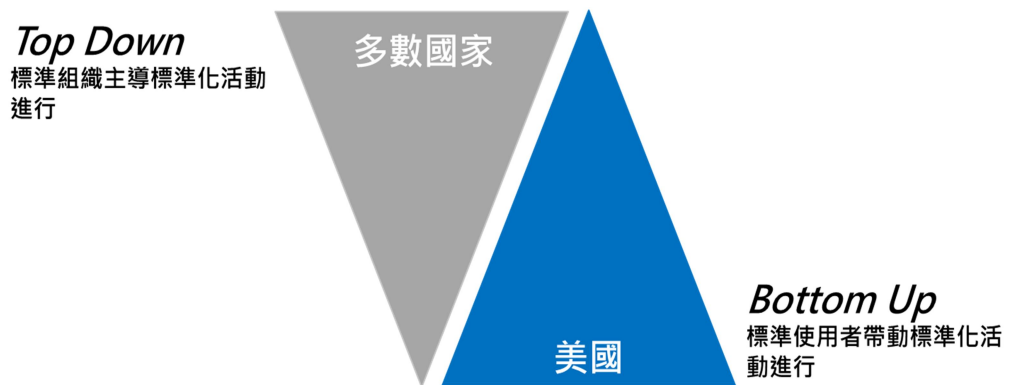


圖 6、美國標準制定程序與他國比較

2. ANSI 做為政府部門與民間部門的橋樑，提供中立的溝通平台：ANSI 既非標準發展組織 SDO (Standards Developing Organizations)，亦不是符合性評鑑組織 CAO (Conformity Assessment Organizations)；ANSI 是負責監督美國有關產品、服務、流程、系統和人員的自願性共識標準之制定。
3. 就美國標準制度而言，其所遵從的原則是：「標準必須兼顧社會與市場的需求，並且不能發展成貿易障礙。」
4. 目前美國國家標準(ANS)的數量高達 1 萬 1,000 件；而經 ANSI 認可的標準發展組織 ASD (Accredited Standards Developers)，目前計有 240 家，包括 UL、ASTM、NFPA、NSF 等等。唯有經 ANSI 認可的 ASD 組織方能提交予 ANSI 以等待核可成為美國國家標準 (American National Standard, ANS)，而並非每家 ASD 組織所開發的標準都會成為待核 ANS。所有 ASD 組織都受到中立第三方 ANSI 的監管，包括例行的 ANS 稽查和認可程序的年度審查。

(四) 請 ANSI 協處事項：請 ANSI 推薦我國協作型機器人業者參與 ISO 技術會議 (Activities of ISO/TC299)。

1. 查我國製造之機器人商品規格往往受制於國際規範而不利於廠商出口，若能參與 ISO 相關技術委員會 (TC)，達到我國廠商參與國際標準制定的目的，以利佈局國際市場
2. 另查機器人產品標準隸屬於 ISO/TC 299 Robotics (機器人技術委員會)，然我國非 ISO 會員，無法直接派員參與 ISO 相關會議，往年均由國外標準機構推薦或安排我國專家以非官方模式參加。因 ANSI 為 ISO 會員，擬透過 ANSI 推薦我國專家參與 ISO/TC 299/WG3 相關會議。
3. 經洽 ANSI 表示，海外機構若在美國有分支機構就可加入 ANSI 美國地區的會員，自然就能參與 ISO 專家會議，惟我方無在美國的分支機構，因此目前只能透過 ANSI 或其他組織推薦參與相關標準會議，ANSI 會後也提供本局負責 TC 299 會議主席與行政人員與本局，作為後續洽談。



圖 7、與談人員合影(ANSI)

三、NIST (National Institute of Standards and Technology)

(一) 機構概述：

美國國家標準暨技術研究院 (National Institute of Standards and Technology, 簡寫為 NIST) 的前身為國家標準局 (NBS, 1901 年~1988 年), 是一家量測標準實驗室, 1988 年改為現名, 隸屬於美國商務部 (United States Department of Commerce), 目前約有 2,900 名員工, 主要為科學家、工程師、以及相關技術人員; 此外, 尚有來自國內外 1,800 名的客座科學家與工程師群, 並與國內各領域專家建立合作關係, 以持續在科技創新上維持動能。

目前 NIST 所設置的實驗室有 6 所: 通信技術實驗室 (CTL); 工程實驗室 (EL); 訊息技術實驗室 (ITL); 中子研究中心 (NCNR); 化性實驗室 (MML); 物性實驗室 (PML) 等; 另外還設有 7 個常設委員會: 技術指南制定委員會 (TGDC)、地震災害減少諮詢委員會 (ACEHR)、國家建築安全小組諮詢委員會 (NCST)、訊息安全和隱私諮詢團 (ISPAB)、高級技術參訪委員會 (VCAT)、國家品質獎監督團 (MBNQA)、製造擴展計劃國家諮詢團 (MEPNAB)。

該研究院的使命為: 促進美國的創新和產業競爭力, 推進度量衡、標準、技術以提高經濟安全並改善人民的生活品質。

(二) 與談人員：

- Warren R. Merkel (Chief, Standards Services, Standards Coordination Office)
- Dr. Charles D. Enrich (Group Leader, International Legal Metrology Group, Office of Weights and Measures)

(三) 與談內容摘要：

1. 標準整合辦公室(Standards Coordination Office, SCO)

(1) 採行 4C (Coordinate、Cooperate、Compare、Compete) 的協商方式以建立並推展政府機關的標準化系統

- **Coordinate 協商**: 該辦公室居中協調政府機關的擬採行的標準以及推廣符合性評鑑活動, 以避免重複與簡化標

準。

- **Cooperate 合作**: SCO 鼓勵公私部門合作, 建置標準慣例、法規、規格和自願性的共通標準。爰此, NIST 與 ANSI 即簽有合作備忘錄, 以確保公私部門的合作與夥伴關係, 達到雙向溝通的目的。
- **Compare 比較**: 將民間機構自行研訂的標準與聯邦機關採用或認可的標準進行比較, 並協調聯邦機關採行民間機構使用的標準, 並盡可能鼓勵聯邦機關使用民間機構依共識制定出的標準。
- **Compete 競爭**: SCO 提供政府機關資訊、專業, 以及支持貿易協定, 有助提升美國產業進入市場的競爭能力。

- (2) 標準整合辦公室 SCO 與多個政府與民間機構合作, 在制定標準時可提供技術支援或專業建議, 而不是提供強制性的規定。例如: 因輸入美國的玩具及兒童用品要能符合相關的法令規範, 因此業者需要取得合乎符合性評鑑規定的實驗室所出具的報告及驗證, 有鑑於此, CPSC 與 SCO 合作, 針對玩具(兒童用品) 建立一套完整的實驗室符合性評鑑機制, 以提供業者選取測試實驗室的參考。
- (3) 依據 NTTAA, NIST 與 ANSI 除了有簽訂合作備忘錄, ANSI 的每個標準委員會都有 NIST 的成員, 亦即 NIST 對 ANSI 有實質的影響力, 並提供教育訓練資源。於參訪當天, 就有舉辦多個講座(如圖 8, 當日舉辦的 From Lab to Market 講座), 可窺見 NIST 對於其專業與技術資源相當自豪, 雖為政府單位仍不斷藉由各種交流活動進行意見交換與整合, 也能激盪出不同的創新理念。
- (4) 依據 NIST Organic Act, NIST 主要任務是溝通、整合與提供技術支援, 並不針對個案提供意見。



圖 8、NIST 講座-From Lab to Market

2. 美國度量衡制度（如下圖 9）：

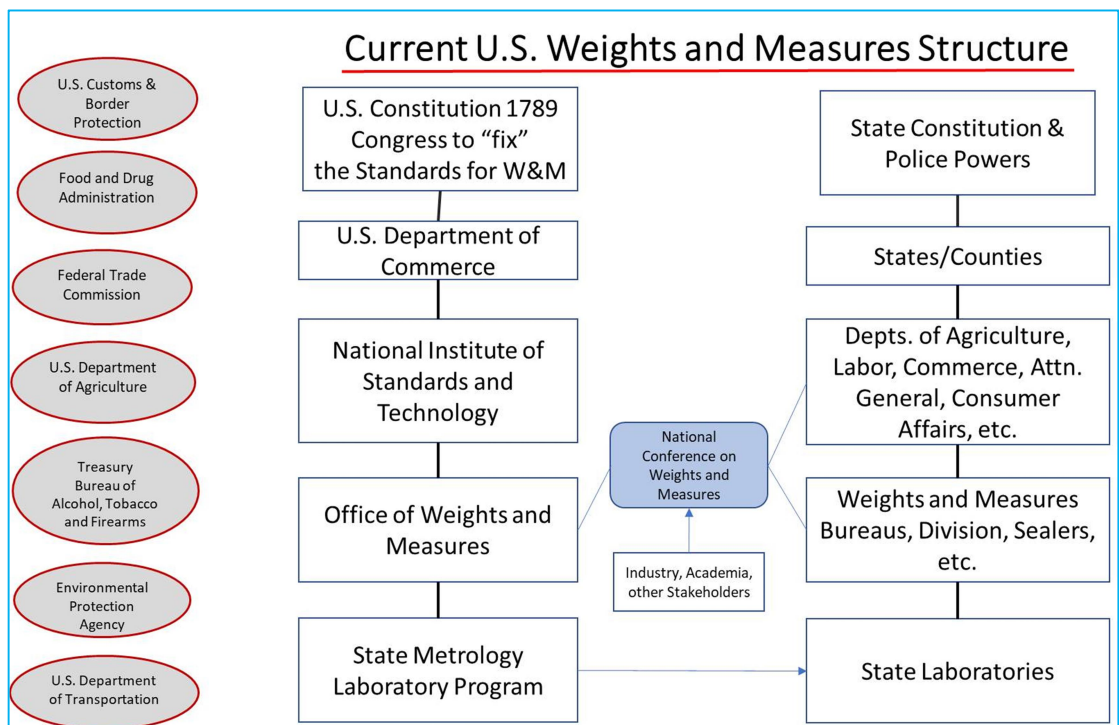


圖 9、美國度量衡制度範疇

(1) 美國聯邦政府並無制定一套度量衡的聯邦法令，惟商務部轄下 NIST 是美國唯一屬於聯邦政府的技術幕僚單位，依據 1987 年所頒定的 NIST Organic Act，除了名稱改變（將國家標準局（National Bureau of Standards）更名為 NIST），也確定其獨立的地位，以建立與維持國家級的計量標準，提供國內計量的

追溯與校正服務，協助產業發展相關度量衡的檢測方法與技術，以及國內度量衡實驗室的承認與認證。

- (2) 另外，依據美國憲法第 1 條 8 款的規定，美國國會有權確認美國國內的度量衡標準⁷，因此 NIST 就須與國會合作以確保各州的度量衡查核方式都能一致。
- (3) 而美國涉及法定計量的政府機關，尚有美國海關暨邊境保護局（U.S. Customs & Border Protection）、農業部（U.S. Department of Agriculture）、交通部（U.S. Department of Transportation）、食品及藥物管理署（Food and Drug Administration）、聯邦貿易委員會（Federal Trade Commission）、菸酒槍砲及爆裂物管理局（Bureau of Alcohol, Tobacco, Firearms and Explosives）、環境保護部（Environmental Protection Agency）等等，因此 NIST 不僅要與國會保持合作，也要協助各行政機關建立法定計量的一致性標準與慣例，並建立標準計量的溯源機制。
- (4) NIST 並非監管機關（NIST is not a regulatory agency），與本局的角色定位不同。因此，NIST 並不參與立法，但是 NIST 負責訂定計量標準、規範或準則，交由全國性計量大會 NCWM（National Conference on Weights and Measures）正式議決通過，然後再推動各州制定州級的計量法令。

⁷ U.S. Constitution Article 1, Section 8, The Congress shall have power to.....fix the Standard of Weights and Measures;

(5) 法定計量實驗室計畫

(Laboratory Metrology

Program)：各州法定計量實驗室是州級計量標準的把關者，以確保各州內市場交易的公平，也提供州內工業界的校正服務。NIST 的計量辦公室

(Office of Weights and Measures, OWM) 建立了一套標準作業程序 (如右圖 10)，

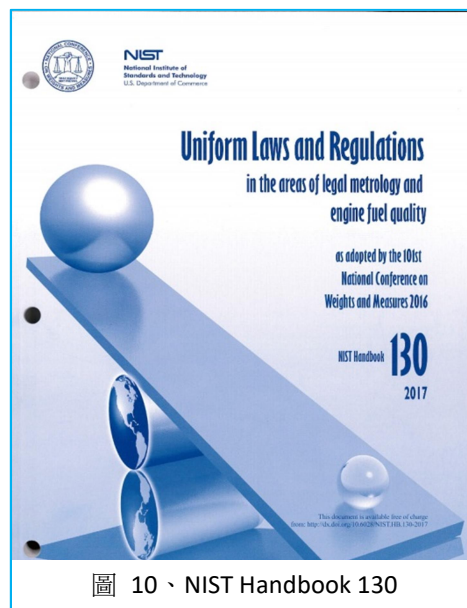


圖 10、NIST Handbook 130

據以評估實驗室的量測能力，評估後再發給計量檢測證書，成為 NIST 認可的州級法定計量實驗室，截至 2017 年 9 月，美國各州經 NIST 認可的法定計量實驗室共有 47 處。NIST 提供統一的衡量標準(機制)、handbook 給各州採用 (例如 NIST Handbook 130、圖 9)，但不是強制性；並提供教育訓練以及召開會議取得各州檢查人員的共識。

(6) 目前美國全國都納入強制管理的計量器具只有加油機和地磅，其餘是否作強制性監管則由各州自行決定，因此美國各州計量執行辦法也不一致。而部分州政府積極推進 IoT 的雲端加油機校正業務，但是絕大多數州政府全數不為所動，資安或相關危害仍是考量的因素之一。



圖 11、與談人員合影(NIST)

四、CPSC (Consumer Product Safety Commission)

(一) 機構概述：

美國消費品安全委員會 (U.S. Consumer Product Safety Commission) 成立於 1972 年，是美國政府的一個獨立機構，並不隸屬聯邦政府任何部門或機構，但是必須向國會和總統報告。

CPSC 設置有 5 名委員，由總統提名並經參議院通過任用，任期是七年，其中一人則擔任主席。CPSC 委員們的主要職責是為 CPSC 制定政策。

CPSC 在創立之初，預算金額僅 350 萬美元，至 2008 年國會通過了消費品安全改進法 (Consumer Product Safety Improvement Act, CPSIA) 後，CPSC 的預算逐年提高，截至目前員工約 500 人，年度預算達 1.27 億美元。

(二) 與談人員：

- Richard W. O'BRIEN (Director, Office of International Programs)
- Sylvia C. Chen (Program Manager for East Asia and Pacific)
- Sabrina Keller (Deputy Director, Office of Import Surveillance)
- Shelby Mathis (Small Business Ombudsman)
- Will Cusey (Deputy Small Business Ombudsman)

(三) 與談內容摘要：

1. 美國消費品安全架構概況

(1) CPSC 負責規範製造和銷售的消費商品超過 15,000 種，從包括各類嬰幼兒用品、家電等，其他「任何不是為消費者生產或出售，或供消費者消費、使用的商品」都不在 CPSC 管轄範圍，例如酒精、槍砲與爆裂物歸屬美國菸酒槍砲及爆裂物管理局 (BATFE)；食品歸屬美國農業部 (USDA) 或聯邦食品與藥品管理局 (FDA)；殺蟲劑歸屬美國環保署 (EPA)、固定地點遊樂場活動遊樂設施則歸各州政府管轄。

(2) 在 2007 與 2008 年，美國國會特別關切大量召回的「兒童玩具(含有鉛漆)」與「嬰兒床」，因此在 2008 年美國國會通過了

消費品安全改進法（CPSIA, Consumer Product Safety Improvement ACT），要求制訂消費品安全標準和兒童商品的其他安全要求，並對 CPSC 重新授權，讓 CPSC 整個組織與職權更為現代化，如前述簡介，CPSC 能有更多預算致力於強化消費品安全的監督。

(3) 在消費品安全改進法中，有許多特別針對兒童產品的規定，因此 CPSC 特別針對兒童產品需要有兒童產品證書(CPC)；兒童產品以外的則列屬一般用途產品，相較於兒童產品則有不同的規定，不過皆須在進口或進入市場前要完成相關檢測程序並取得證明文件：

- 兒童產品證書 CPC（Children’s Product Certificate）：此類產品的進口商或製造商必須要有經驗證且被 CPSC 認可的第三方實驗室⁸驗證檢測並取得證明。此外，兒童商品應在**產品及外包裝**上貼附永久性的標籤，標籤上的資訊包括製造商名稱、製造地點、製造日期、生產履歷及其他辨識資訊以供後續追蹤查核。
- 一般符合性證明 GCC(General Certificate of Conformity)：CPSC 要求美國製造商或進口商提出「合理檢測計畫 RTP (Reasonable Testing Program)」⁹，該計畫是由業者依據每種產品的檢測結果或檢測計畫後自行發出，並不需要第三方的檢測。
- 前述的證明上應包含有產品的資訊、所引述的法規、進口商或製造商資訊、聯絡資訊、生產日期與地點、檢測的日期與地點等等，若是兒童用品則需要有第三方實驗室的資訊。

2. 進口監測辦公室（Office of Import Surveillance）

(1) 成立來源：在 2008 年美國國會通過了消費品安全改進法

⁸ www.cpsc.gov/testing

⁹ www.cpsc.gov/generaluse

(CPSIA)，賦予 CPSC 有別以往的職權以更貼近現實的管理方式；因此，CPSC 成立了進口監測辦公室（前身為進口處 Import Division），並依據消費品安全改進法（CPSIA）的第 222 節，制定了風險評估方法（RAM, Risk Assessment Methodology），並規定使用自動商業環境（ACE, Automated Commercial Environment）與單一窗口的國際貿易數據系統（ITDS, International Trade Data System）來評估進口的商品，搭配與美國海關（CBP）合作來負責監管進口的消費性商品。

(2) CPSC 的瞄準方法(Targeting Methodologies)有 3 種主要方式：

- 國際貿易數據系統(International Trade Data System, ITDS) 風險評估方法 (Risk Assessment Methodology, RAM)
- 美國海關及邊境保護局的商業目標搜尋和分析中心 (Commercial Targeting and Analysis Center, CTAC)
- 現場查核。

而被瞄準的目標商品會依據以下各種因素，再由前述 RAM 系統計算後給予評分與分級，以判定可能具有高風險的違規商品，各種判斷因素包括有：

- 進口商、外國製造商、供應鏈中的相關業者、
- 公司違規紀錄
- 產品曾被召回的歷史紀錄、
- 產品既有的風險、
- 新進廠商或是新產品、
- 海關的進口關稅表 (Harmonized Tariff Schedule)、
- 情資通報、
- 商品數量、
- 機關的政策方向與重點項目等等。

(3) 「風險評估方法 (Risk Assessment Methodology, RAM)」：自 2010 年開始試行，經過多年的運行後，到了 2017 年才有完整的產品分析系統。該系統每 5 分鐘自海關接收資訊，由系統

自動計算風險評分供現場查核人員做為應取樣的商品參考（但並非系統判定出現「紅燈」的都要查驗，現場查核人員會依據經驗判定是否要抽驗）。利用 RAM 的風險計算將進口商品作優先排序，可提升進口監測檢測的效率，並可讓合乎規範的商品能順利進口。

(4) 商業目標瞄準和分析中心 (CTAC, Commercial Targeting and Analysis Center) 位在華盛頓哥倫比亞特區的美國海關及邊境保護局，由美國海關、CPSC 以及其他 10 位負責進口安全的相關機構人員（如 FDA 等）組成，該中心有全國入港的數據與貨物清單，有助於 CPSC 搜尋目標。

(5) 進口商品查核流程（如圖 12）：

在商品抵港並運往指定的倉庫 (Bonded Warehouse) 後，CPSC 的查核人員會針對被鎖定要查核的目標，現場查核人員會先利用配發的 X 光線螢光分析儀 (X-ray fluorescence analyzer) 作含鉛量與塗料的初步篩檢（如圖 13、14）、傅里葉變換紅外光譜儀 (Fourier Transform Infrared Spectrometer) 檢測磷苯二甲酸酯、小物件檢查等等，並初步檢查是否有商品檢測證明與商品標籤。

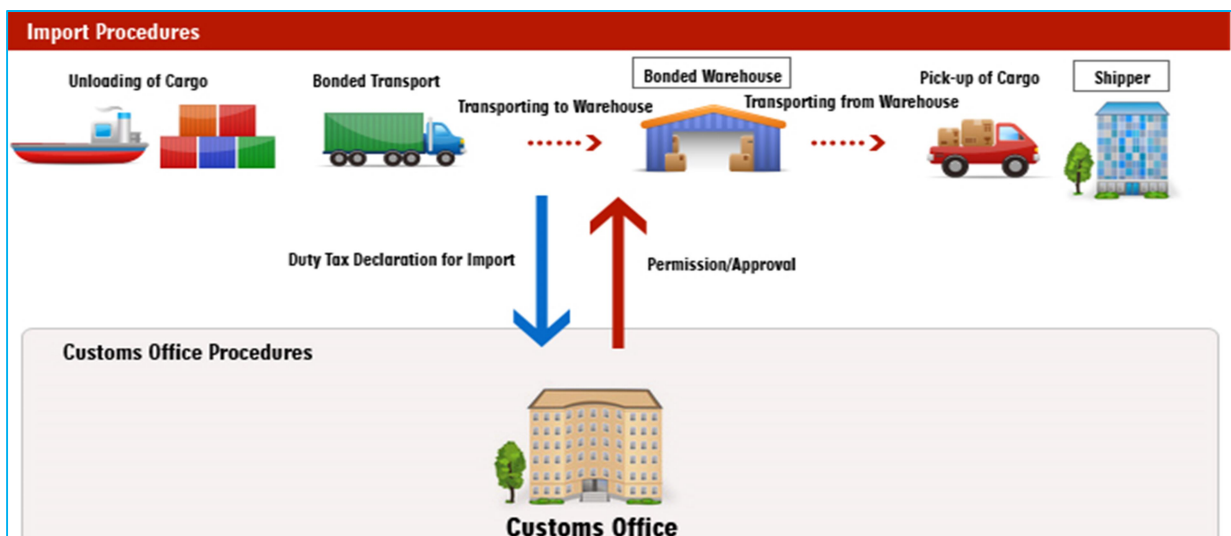


圖 12、美國進口商品查核流程

查核結果若都符合則放行；但經初步檢查結果有不符合者，查核人員會有條件放行或封存該批進口的商品，並將取樣商品送回 CPSC 總部的實驗室執行複驗，在複驗結果出來前，業者不能將被查封的商品銷售或運出倉庫，CPSC 會不定時派員檢查商品存置狀況，若業者在正式結果出來前擅自將商品運出倉庫或銷售，CPSC 會予以罰鍰處分。



圖 13、X 光線螢光分析儀



圖 14、X 光線螢光分析儀進行初步檢測

3. 網路查核與物聯網 (Internet of Things, IoT) 議題：

- (1) 為確保召回的商品不會再持續於網路上販售，CPSC 的網路監管小組 (Internet Surveillance Unit, ISU) 會執行網路市場檢查。ISU 也與主要的網路平臺保持合作以移除具有危害風險且不符合檢驗規範的商品於網路上販售。
- (2) 現行許多商品具有連網功能，可以透過網路接收與傳輸使用資訊，如果運用得宜，IoT 應可提升消費安全，例如即時偵測並通報即預警有關產品的風險與危害，以保護消費者；然而 IoT 仍有潛在風險而肇生新的危害，包括透過遠端遙控或更改軟體設定使產品安全功能失效等問題。

(3) 因此，CPSC 也開始從多方面著手來因應物聯網可能產生的新興危害風險，除了與相關聯邦機關及國內外業者合作，也持續與國內外相關的標準發展組織（如 UL）參與研究有關物聯網的標準開發與制定的工作。

4. 法規機器人（Regulatory Robot）：

(1) 建置目的：提供廠商一套完整的法規與相關產品規範的查詢/諮詢系統，實際查詢方式請參閱附錄 3。

(2) 建置過程與訣竅：

- 歸納：先整理出 CPSC 目前有的 200 多種強制規定；並且整理出近年來業者常問的問題（FAQs）。
- 彙整商品：將 CPSC 監管的 1 萬 5,000 多種商品分類歸納成 9 個大類（如下圖 15），把最常被問到的商品項目放在最前方。
- 店訪：實際到各賣場去確認商品的實際名稱、而且會陳列在哪個分類架上，而不是直接用官方所用的學名或標準使用的名稱。
- 內部資料庫應用：利用 RAM 系統資料庫中容易出現的商品名稱，當作法規機器人的搜尋比對資料。
- 4 個月完成整個「法規機器人」的架構與內容，3 個月建置完成網站，另用 3 月執行內部測試。

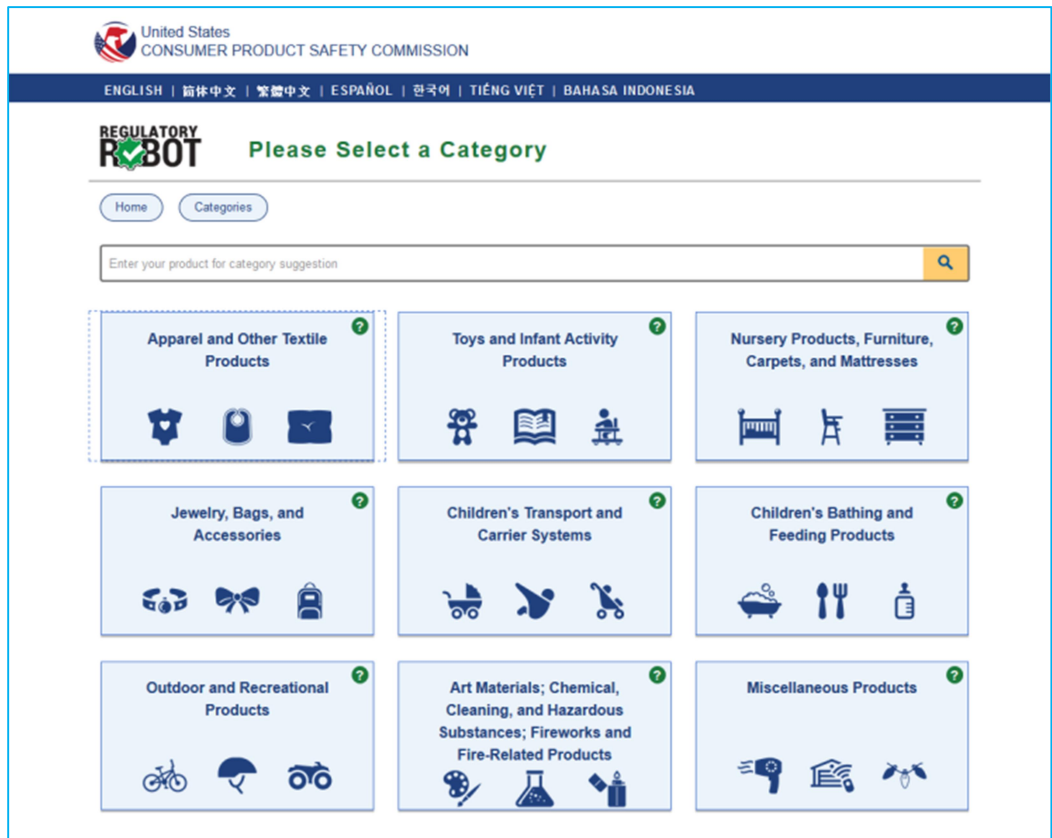


圖 15、法規機器人商品分類



圖 16、與談人員合影(CPSC)

肆、出國心得及建議

一、強化公私部門間之溝通平臺，提升政府效能

美國聯邦與各級政府遵照 OMB-119 公告及《國家技術移轉與促進法》(National Technology Transfer and Advance Act ,NTTAA)，讓民間與政府間的交流與溝通相對頻繁，由下往上(bottom-up)的發展機制相較於多數國家，更能夠由市場機制快速地發展出適合且共通性的標準或運作模式，政府並未有過多的干涉與限制，讓各種標準發展組織(SDO)與驗證機構(如 UL)能蓬勃發展，政府則透過技術支援或專案合作計畫與民間組織交流，不僅可提升效率，也能減少政府預算支出。

二、建立完整的市場監督管控系統與風險瞄準系統

標準局針對輸入之應施檢驗商品，會依商品特性決定不同的抽批數，例如採監視查驗的玩具商品經連續 10 批逐批查驗符合者，則採每批 50% 之隨機抽批查驗方式檢驗¹⁰；另外對取得商品驗證登錄證書之輸入商品，會依據相關危害風險性與後市場監督結果反饋至前市場，於邊境採取一般抽批、加強抽批與逐批查核。

然而，美國對於商品的管理是著重其「安全性」與「可能危害性」，管理重點在商品實質安全，與我國商品檢驗法所重視「程序性合法」而非商品實質安全有所不同。CPSC 與海關建立資訊交換的合作關係，藉由內部的風險評估機制 (RAM)，利用大數據分析有效地找出具高風險危害的進口商品再予以抽驗，就能避免高風險商品流入國內市場以保障消費者安全。

另一方面，歐盟亦然：對於進口到歐盟區各國的商品是沒有前市場管理，所以其後市場監督方面相當程度仰賴廠商的「自制與自主管理」，如商品於進入市場後發現有危害性，經通報後，歐盟得依商品瑕疵所引發的風險，藉由風險評估機制(risk assessment)，針對不同個案採行適當

¹⁰ 依「玩具商品檢驗作業規定」第四點規定，凡同一報驗申請書報驗同一商品分類號列且未超過 100 項之玩具商品，經同一商品分類號列連續十批逐批查驗符合規定者，採每批 50%機率之隨機抽批查驗方式檢驗，未抽中批採書面核放；再經連續 50 批查驗符合規定，且近一年內無不合格紀錄者，改採每批 20%機率之隨機抽批查驗方式檢驗，未抽中批採書面核放；且該次報驗紀錄列入簡化報驗規定之批數累計。

處置措施，並即時更新商品風險資料庫，有效降低商品風險與保障消費者使用安全。

概略來看，我國對於商品的市場監督人力仍著重於程序違規而非商品實質安全。因此，若為更著重商品實質安全，可仿效 CPSC 或歐盟先建立完整的商品風險評估資料庫，有一致性的標準與完整的資料庫可供業者或市場監督人員遵循，有了完整的資料庫再藉由系統分析計算商品的危害性與風險程度，則可作為相關商品處置作為的依循，並減少人為主觀的判定商品風險與危害性，與國際作法接軌，讓我國商品監督機制趨於完備。

三、持續與美方相關機關(構)保持互動關係

這次透過拜訪美國官方或非官方組織，可建立雙方的溝通窗口，一方面能透過持續交流而逐步調整我國的商品監管機制，也透過非官方組織（如 ANSI）讓我國持續參與國際組織以提升能見度與參與率，亦可提供國內產業與國際接軌的管道。

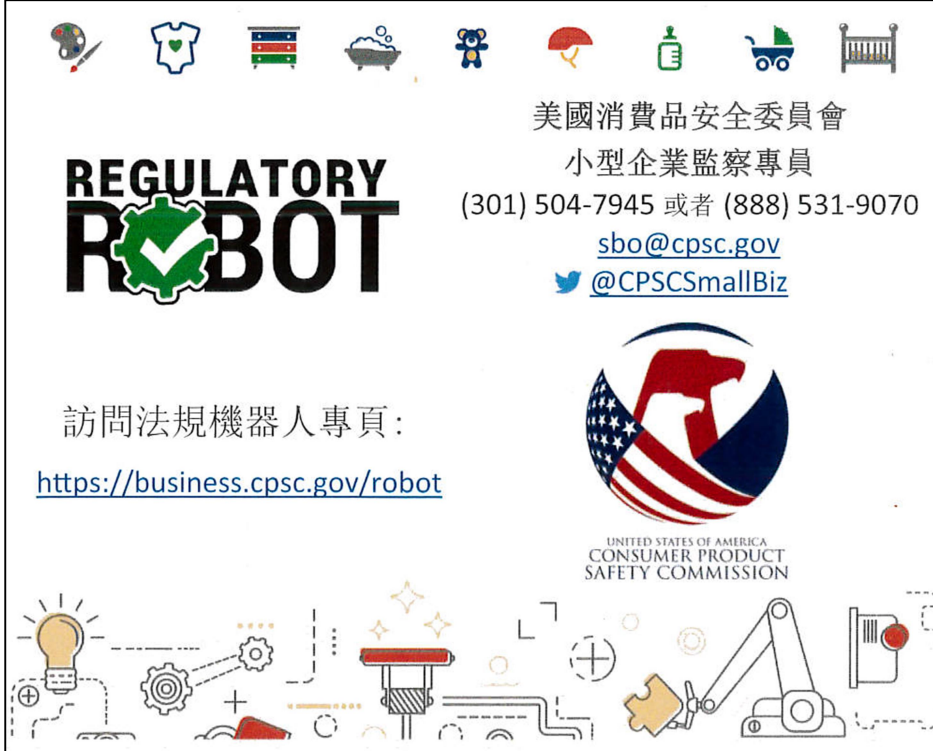
四、建置一站式查詢服務系統

本局檢驗制度共有 4 種（逐批檢驗、監視查驗、驗證登錄與符合性聲明），公告列為應施檢驗商品的種類也高達 1200 種以上，且持續增加中，對於業者而言過於複雜，建議可以仿效 CPSC 的法規機器人(Regulatory Robot)，將業者常問的問題（FAQs）與相關法令規範整合後，透過互動式選單，提供業者單一便捷的檢索方式，可減少政府針對類似重複事件耗費過多人力處理，以提升政府效能。

附錄

一、Regulatory Robot 網站簡介

Regulatory Robot 網站：<https://business.cpsc.gov/robot>、或者可掃描 QR code¹¹。



美國消費品安全委員會
小型企業監察專員
(301) 504-7945 或者 (888) 531-9070
sbo@cpsc.gov
[@CPSCSmallBiz](https://twitter.com/CPSCSmallBiz)

訪問法規機器人專頁：
<https://business.cpsc.gov/robot>

UNITED STATES OF AMERICA
CONSUMER PRODUCT
SAFETY COMMISSION

The banner features a row of icons at the top representing various consumer products: a paint palette, a t-shirt, a flag, a bathtub, a teddy bear, an umbrella, a baby bottle, a shopping cart, and a crib. The central text provides contact information for the CPSC Small Business Office. Below the text is a circular logo with an American flag motif and a stylized robot head. At the bottom, there is a decorative border with icons of a lightbulb, gears, a robot arm, and other mechanical elements.



從哪兒入手？
在這兒掃描。



服裝和其他紡織品 	玩具和嬰兒活動產品 	幼兒護理產品、家具、地毯和床墊 
首飾、包和配件 	兒童輸送和攜帶系統 	兒童沐浴和膳食產品 
戶外和娛樂產品 	藝術材料：化學、清潔和有害物質；煙花和與火相關的產品 	各種產品 

The block contains a QR code and a grid of nine category cards. Each card has a title, a question mark icon, and several product icons. The categories are: Clothing and Textiles, Toys and Infant Activity Products, Child Care Products, Furniture, Carpets and Mattresses, Jewelry, Bags and Accessories, Child Transport and Carrying Systems, Child Bathing and Feeding Products, Outdoor and Recreation Products, Art Materials, and Miscellaneous Products.

¹¹ CPSC 自製小卡，有提供網頁與 QR code

- 目前共有 7 種語言，廠商可依據慣用語選擇，並且可隨時切換語言。
- 在第 1 步驟會請廠商給予查詢的標題，並接受使用條款後，即可繼續查詢。
- CPSC 不會保存報告的副本，因此廠商每次查詢後要隨時存檔。



United States
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歡迎使用美國消費品安全委員會的法規機器人！

首頁

機器人將引導您了解我們的規定，幫助您了解可能適用於您的產品的重要的產品安全規定。在繼續之前，您必須先確認您已經審閱並同意了法規機器人使用條款和條件。

機器人向您提供公共信息，並不產生任何權利或義務。機器人僅用於引導，並基於每個用戶的輸入。機器人並不提供法律建議，也不會取代或者替代製造商遵守所有適用的美國消費品安全委員會規定的義務。

第1步：請為您自己的記錄放上一個標題。 [“為什麼要給我的報告加標題？”](#)

test

第2步：我承認我已經審核並同意 [法規機器人的使用條款和條件](#)

同意並繼續



- 選擇產品類別（目前有 9 大類別，以兒童用品居多）。
- 亦可在搜尋框中輸入商品名稱，系統會建議類別。
- 每個大類右上角的「？」會列出每個類別中的產品。
- 此例選擇玩具和嬰兒產品

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REGULATORY ROBOT 請選擇一個類別

首頁 分類

輸入您的產品的類別建議

<p>服裝和其他紡織品</p>	<p>玩具和嬰兒活動產品</p>	<p>幼兒護理產品、家具、地毯和床墊</p>
<p>首飾、包和配件</p>	<p>兒童輸送和攜帶系統</p>	<p>兒童沐浴和餵食產品</p>
<p>戶外和娛樂產品</p>	<p>藝術材料；化學、清潔和有害物質；煙花和與火相關的產品</p>	<p>各種產品</p>

- 選擇「兒童玩具」類別後，再選擇細項商品。
- 並選擇是否屬於小量商品的製造商(小批量製造商定義如下圖)

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REGULATORY ROBOT 兒童玩具

首頁 分類 玩具和嬰兒活動產品

您有資格成為 **小批量製造商** 嗎？

是
 不是

哪個子類最能代表您的產品？（選擇一個）

- 兒童玩具 ?
- 兒童讀物 ?
- 嬰兒搖椅 ?
- 嬰兒鞦韆 ?
- 嬰兒學步車 ?
- 固定活動中心 ?
- 牙膠、安撫奶嘴和安撫奶嘴/牙膠鐘
- 遊樂場設備 ?

合格的小批量製造商可以通過網路申請機制免於兒童產品的某些第三方檢測規定的約束。為了獲得這種豁免，合格的小批量生產商必須在美國消費品安全委員會登記並確證以下情況：
從上一年起銷售所有消費品的總收入為 115.109 萬美元或更少；以及他們製造的“適用產品”不超過 7500 件。“適用產品”指的是由小批量生產商生產的消費品，在前一年製造的這種產品不超過 7500 件（即用於申請 2019 年資格的 2018 年製造的同一產品數量。）

- 用戶依據指示回答一系列產品的問題（特徵等）
- 最後產出報告



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兒童玩具

首頁

分類

玩具和嬰兒活動產品

兒童玩具

您孩子的玩具屬於下面的一種嗎？（選擇一個）

- 遊戲帳篷
- 撥浪鼓
- 其它玩具

您孩子的玩具是否具有以下特徵？（如果不確定，請考慮選擇可能適用的所有項目。）

- 產生聲音
- 木
- 折疊機製或者合頁
- 兒童騎乘能力
- 電子產品/電池
- 發射投射物
- 填充
- 小輪子、輪胎或軸
- 磁鐵冰箱貼
- 氣球、彈子或者小球
- 繩索、皮帶或者鬆緊帶
- 可以拖拉的玩具
- 塗料或者類似表面塗層
- 以上都不是

生成定制的最終報告

- 產出最後的報告供用戶下載/列印，並且還是可轉換成其他語言。
- 提供產品的檢驗規定、實驗室供用戶參考。
- 報告有為一的 URL，可以透過電子郵件分享。


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二、國家技術移轉與促進法(NTTAA)

於 1996 年 3 月 7 日成為法律的《國家技術移轉與促進法》(第 104-113 號公共法),要求所有聯邦機關盡可能使用民間機構所制定的自願性與共識的標準,而不是以政府部門制定的單一標準為依據。更重要的是,該法令包括了多個條款以鼓勵聯邦機關與私部門共同合作以制定標準,這些由民間標準制定機構制定出的標準不僅有助於提高政府的效率和效能,而且可以增強美國在全球市場上的領先地位。以下為該法令的全文:

National Technology Transfer and Advancement Act

SECTION 1. SHORT TITLE.

This Act may be cited as the 'National Technology Transfer and Advancement Act of 1995'.

SEC. 2. FINDINGS.

The Congress finds the following:

- (1) Bringing technology and industrial innovation to the marketplace is central to the economic, environmental, and social well-being of the people of the United States.
- (2) The Federal Government can help United States business to speed the development of new products and processes by entering into cooperative research and development agreements which make available the assistance of Federal laboratories to the private sector, but the commercialization of technology and industrial innovation in the United States depends upon actions by business.
- (3) The commercialization of technology and industrial innovation in the United States will be enhanced if companies, in return for reasonable compensation to the Federal Government, can more easily obtain exclusive licenses to inventions which develop as a result of cooperative research with scientists employed by Federal laboratories.

SEC. 3. USE OF FEDERAL TECHNOLOGY.

Subparagraph (B) of section 11(e)(7) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710(e)(7)(B)) is amended to read as follows:

'(B) A transfer shall be made by any Federal agency under subparagraph (A), for any fiscal year, only if the amount so transferred by that agency (as determined under such subparagraph) would exceed \$10,000.'

SEC. 4. TITLE TO INTELLECTUAL PROPERTY ARISING FROM COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

Subsection (b) of section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)) is amended to read as follows:

`(b) ENUMERATED AUTHORITY- (1) Under an agreement entered into pursuant to subsection (a)(1), the laboratory may grant, or agree to grant in advance, to a collaborating party patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, for reasonable compensation when appropriate. The laboratory shall ensure, through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement or, if there is more than one collaborating party, that the collaborating parties are offered the option to hold licensing rights that collectively encompass the rights that would be held under such an exclusive license by one party. In consideration for the Government's contribution under the agreement, grants under this paragraph shall be subject to the following explicit conditions:

`(A) A nonexclusive, nontransferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of section 552(b)(4) of title 5, United States Code, or which would be considered as such if it had been obtained from a non-Federal party.

`(B) If a laboratory assigns title or grants an exclusive license to such an invention, the Government shall retain the right--

`(i) to require the collaborating party to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive license to use the invention in the applicant's licensed field of use, on terms that are reasonable under the circumstances; or

`(ii) if the collaborating party fails to grant such a license, to grant the license itself.

`(C) The Government may exercise its right retained under subparagraph (B) only in exceptional circumstances and only if the Government determines that--

`(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the collaborating party;

`(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the collaborating party; or

`(iii) the collaborating party has failed to comply with an agreement containing provisions described in subsection (c)(4)(B).

This determination is subject to administrative appeal and judicial review under section 203(2) of title 35, United States Code.

`(2) Under agreements entered into pursuant to subsection (a)(1), the laboratory shall ensure that a collaborating party may retain title to any invention made solely by its employee in exchange for normally granting the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

`(3) Under an agreement entered into pursuant to subsection (a)(1), a laboratory may--

`(A) accept, retain, and use funds, personnel, services, and property from a collaborating party and provide personnel, services, and property to a collaborating party;

`(B) use funds received from a collaborating party in accordance with subparagraph (A) to hire personnel to carry out the agreement who will not be subject to full-time-equivalent restrictions of the agency;

`(C) to the extent consistent with any applicable agency requirements or standards of conduct, permit an employee or former employee of the laboratory to participate in an effort to commercialize an invention made by the employee or former employee while in the employment or service of the Government; and

`(D) waive, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party.

`(4) A collaborating party in an exclusive license in any invention made under an agreement entered into pursuant to subsection (a)(1) shall have the right of enforcement under chapter 29 of title 35, United States Code.

`(5) A Government-owned, contractor-operated laboratory that enters into a cooperative research and development agreement pursuant to subsection (a)(1) may use or obligate royalties or other income accruing to the laboratory under such agreement with respect to any invention only--

`(A) for payments to inventors;

`(B) for purposes described in clauses (i), (ii), (iii), and (iv) of section 14(a)(1)(B); and

`(C) for scientific research and development consistent with the research and development missions and objectives of the laboratory.'.

SEC. 5. DISTRIBUTION OF INCOME FROM INTELLECTUAL PROPERTY RECEIVED BY FEDERAL LABORATORIES.

Section 14 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710c) is amended--

(1) by amending subsection (a)(1) to read as follows:

`(1) Except as provided in paragraphs (2) and (4), any royalties or other payments received by a Federal agency from the licensing and assignment of inventions under agreements entered into by Federal laboratories under section 12, and from the licensing of inventions of Federal laboratories under section 207 of title 35, United States Code, or under any other provision of law, shall be retained by the laboratory which produced the invention and shall be disposed of as follows: `(A)(i) The head of the agency or laboratory, or such individual's designee, shall pay each year the first \$2,000, and thereafter at least 15 percent, of the royalties or other payments to the inventor or coinventors.

`(ii) An agency or laboratory may provide appropriate incentives, from royalties, or other payments, to laboratory employees who are not an inventor of such inventions but who substantially increased the technical value of such inventions.

`(iii) The agency or laboratory shall retain the royalties and other payments received from an invention until the agency or laboratory makes payments to employees of a laboratory under clause (i) or (ii).

`(B) The balance of the royalties or other payments shall be transferred by the agency to its laboratories, with the majority share of the royalties or other payments from any invention going to the laboratory where the invention occurred. The royalties or other payments so transferred to any laboratory may be used or obligated by that laboratory during the fiscal year in which they are received or during the succeeding fiscal year--

`(i) to reward scientific, engineering, and technical employees of the laboratory, including developers of sensitive or classified technology, regardless of whether the technology has commercial applications;

`(ii) to further scientific exchange among the laboratories of the agency;

`(iii) for education and training of employees consistent with the research and development missions and objectives of the agency or laboratory, and for other activities that increase the potential for transfer of the technology of the laboratories of the agency; `(iv) for payment of expenses incidental to the administration and licensing of intellectual property by the agency or laboratory with respect to inventions made at that laboratory, including the fees or other costs for the services of other agencies, persons, or organizations for intellectual property management and licensing services; or

`(v) for scientific research and development consistent with the research and development missions and objectives of the laboratory.

(C) All royalties or other payments retained by the agency or laboratory after payments have been made pursuant to subparagraphs (A) and (B) that is unobligated and unexpended at the end of the second fiscal year succeeding the fiscal year in which the royalties and other payments were received shall be paid into the Treasury.

(2) in subsection (a)(2)--

(A) by inserting 'or other payments' after 'royalties'; and (B) by striking 'for the purposes described in clauses (i) through (iv) of paragraph (1)(B) during that fiscal year or the succeeding fiscal year' and inserting in lieu thereof 'under paragraph (1)(B)';

(3) in subsection (a)(3), by striking '\$100,000' both places it appears and inserting '\$150,000';

(4) in subsection (a)(4)--

(A) by striking 'income' each place it appears and inserting in lieu thereof 'payments'; (B) by striking 'the payment of royalties to inventors' in the first sentence thereof and inserting in lieu thereof 'payments to inventors';

(C) by striking 'clause (i) of paragraph (1)(B)' and inserting in lieu thereof 'clause (iv) of paragraph (1)(B)';

(D) by striking 'payment of the royalties,' in the second sentence thereof and inserting in lieu thereof 'offsetting the payments to inventors,'; and

(E) by striking 'clauses (i) through (iv) of'; and(5) by amending paragraph (1) of subsection (b) to read as follows: '(1) by a contractor, grantee, or participant, or an employee of a contractor, grantee, or participant, in an agreement or other arrangement with the agency, or'.

SEC. 6. EMPLOYEE ACTIVITIES.

Section 15(a) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710d(a)) is amended--T (1) by striking 'the right of ownership to an invention under this Act' and inserting in lieu thereof 'ownership of or the right of ownership to an invention made by a Federal employee'; andT (2) by inserting 'obtain or' after 'the Government, to'.

SEC. 7. AMENDMENT TO BAYH-DOLE ACT.

Section 210(e) of title 35, United States Code, is amended by striking ', as amended by the Federal Technology Transfer Act of 1986,'.

SEC. 8. NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY ACT AMENDMENTS.

The National Institute of Standards and Technology Act (15 U.S.C. 271 et seq.) is amended--

(1) in section 10(a)--(A) by striking 'nine' and inserting in lieu thereof '15'; and

(B) by striking 'five' and inserting in lieu thereof '10'; (2) in section 15--

(A) by striking 'Pay Act of 1945; and' and inserting in lieu thereof 'Pay Act of 1945;';
and

(B) by inserting `; and (h) the provision of transportation services for employees of the Institute between the facilities of the Institute and nearby public transportation, notwithstanding section 1344 of title 31, United States Code' after `interests of the Government'; and (3) in section 19--

(A) by inserting `, subject to the availability of appropriations,' after `post-doctoral fellowship program'; and

(B) by striking `nor more than forty' and inserting in lieu thereof `nor more than 60'.

SEC. 9. RESEARCH EQUIPMENT.

Section 11(i) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710(i)) is amended by inserting `loan, lease, or' before `give'.

SEC. 10. PERSONNEL.

The personnel management demonstration project established under section 10 of the National Bureau of Standards Authorization Act for Fiscal Year 1987 (15 U.S.C. 275 note) is extended indefinitely.

SEC. 11. FASTENER QUALITY ACT AMENDMENTS.

[section not included here]

SEC. 12. STANDARDS CONFORMITY.

(a) USE OF STANDARDS- Section 2(b) of the National Institute of Standards and Technology Act (15 U.S.C. 272(b)) is amended--

(1) in paragraph (2), by striking `, including comparing standards' and all that follows through `Federal Government';

(2) by redesignating paragraphs (3) through (11) as paragraphs (4) through (12), respectively; and

(3) by inserting after paragraph (2) the following new paragraph:

`(3) to compare standards used in scientific investigations, engineering, manufacturing, commerce, industry, and educational institutions with the standards adopted or recognized by the Federal Government and to coordinate the use by Federal agencies of private sector standards, emphasizing where possible the use of standards developed by private, consensus organizations;'

(b) CONFORMITY ASSESSMENT ACTIVITIES- Section 2(b) of the National Institute of Standards and Technology Act (15 U.S.C. 272(b)) is amended--

(1) by striking `and' at the end of paragraph (11), as so redesignated by subsection (a)(2) of this section;

(2) by striking the period at the end of paragraph (12), as so redesignated by subsection (a)(2) of this section, and inserting in lieu thereof `; and'; and

(3) by adding at the end the following new paragraph:

`(13) to coordinate Federal, State, and local technical standards activities and conformity assessment activities, with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures.'.

(c) TRANSMITTAL OF PLAN TO CONGRESS- The National Institute of Standards and Technology shall, within 90 days after the date of enactment of this Act, transmit to the Congress a plan for implementing the amendments made by this section.

(d) UTILIZATION OF CONSENSUS TECHNICAL STANDARDS BY FEDERAL AGENCIES; REPORTS - (1) IN GENERAL- Except as provided in paragraph (3) of this subsection, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.

(2) CONSULTATION; PARTICIPATION- In carrying out paragraph (1) of this subsection, Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards.

(3) EXCEPTION- If compliance with paragraph (1) of this subsection is inconsistent with applicable law or otherwise impractical, a Federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of each such agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards. Each year, beginning with fiscal year 1997, the Office of Management and Budget shall transmit to Congress and its committees a report summarizing all explanations received in the preceding year under this paragraph.

** (4) EXPENSES OF GOVERNMENT PERSONNEL. - Section 5946 of title 5, United States Code, shall not apply with respect to any activity of an employee of a Federal agency or department that is determined by the head of that agency or department as being an activity undertaken in carrying out this subsection.

(5) DEFINITION OF TECHNICAL STANDARDS- As used in this subsection, the term `technical standards' means performance-based or design-specific technical specifications and related management systems practices.

SEC. 13. SENSE OF CONGRESS.

It is the sense of the Congress that the Malcolm Baldrige National Quality Award program offers substantial benefits to United States industry, and that all funds

appropriated for such program should be spent in support of the goals of the program. Speaker of the House of Representatives. Vice President of the United States and President of the Senate.

三、OMB-119 公告

由白宮的管理及預算辦公室 (OMB) 於 2016 年 1 月修訂的 OMB-119 公告，闡明制定了有關聯邦機關使用和制訂自願性共通標準以及符合性評鑑活動的政策方向。1995 年的《國家技術移轉與促進法》確立了政府與民間機構制定標準間的活動，並授權國家標準與技術研究院 (NIST) 協調各機構的符合性評鑑活動。而 OMB 在 2016 年修訂了 OMB-119 公告，使公告的用語與 1995 年《國家技術轉讓和進步法》保持一致，提供各聯邦機關在執行符合性評鑑活動時一套準則。

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT : Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.

Revised OMB Circular A-119 establishes policies on Federal use and development of voluntary consensus standards and on conformity assessment activities. Pub. L. 104-113, the "National Technology Transfer and Advancement Act of 1995," codified existing policies in A-119, established reporting requirements, and authorized the National Institute of Standards and Technology to coordinate conformity assessment activities of the agencies. OMB is issuing this revision of the Circular in order to make the terminology of the Circular consistent with the National Technology Transfer and Advancement Act of 1995, to issue guidance to the agencies on making their reports to OMB, to direct the Secretary of Commerce to issue policy guidance for conformity assessment, and to make changes for clarity.

BACKGROUND

1. What Is The Purpose Of This Circular?

This Circular establishes policies to improve the internal management of the Executive Branch. Consistent with Section 12(d) of P.L. 104-113, the "National Technology Transfer and Advancement Act of 1995" (hereinafter "the Act"), this Circular directs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. It also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the Act. The policies in this Circular are intended to reduce to a minimum the reliance by agencies on government-unique standards. These

policies do not create the bases for discrimination in agency procurement or regulatory activities among standards developed in the private sector, whether or not they are developed by voluntary consensus standards bodies. Consistent with Section 12(b) of the Act, this Circular directs the Secretary of Commerce to issue guidance to the agencies in order to coordinate conformity assessment activities. This Circular replaces OMB Circular No. A-119, dated October 20, 1993.

2. What Are The Goals Of The Government In Using Voluntary Consensus Standards?

Many voluntary consensus standards are appropriate or adaptable for the Government's purposes. The use of such standards, whenever practicable and appropriate, is intended to achieve the following goals:

- a. Eliminate the cost to the Government of developing its own standards and decrease the cost of goods procured and the burden of complying with agency regulation.
- b. Provide incentives and opportunities to establish standards that serve national needs.
- c. Encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards.
- d. Further the policy of reliance upon the private sector to supply Government needs for goods and services.

WHAT DEFINITIONS OF STANDARDS

3. What Is A Standard?

- a. The term "standard," or "technical standard" as cited in the Act, includes all of the following:
 - (1) Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices.
 - (2) The definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength.
- b. The term "standard" does not include the following:
 - (1) Professional standards of personal conduct.
 - (2) Institutional codes of ethics
- c. "Performance standard" is a standard as defined above that states requirements in terms of required results with criteria for verifying compliance but without stating the methods for achieving required results. A performance standard may define the functional requirements for the item, operational requirements, and/or interface and interchangeability characteristics. A performance standard may be viewed in juxtaposition to a prescriptive

standard which may specify design requirements, such as materials to be used, how a requirement is to be achieved, or how an item is to be fabricated or constructed.

d. "Non-government standard" is a standard as defined above that is in the form of a standardization document developed by a private sector association, organization or technical society which plans, develops, establishes or coordinates standards, specifications, handbooks, or related documents.

4. What Are Voluntary, Consensus Standards?

a. For purposes of this policy, "voluntary consensus standards" are standards developed or adopted by voluntary consensus standards bodies, both domestic and international. These standards include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties. For purposes of this Circular, "technical standards that are developed or adopted by voluntary consensus standard bodies" is an equivalent term.

(1) "Voluntary consensus standards bodies" are domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. For purposes of this Circular, "voluntary, private sector, consensus standards bodies," as cited in Act, is an equivalent term. The Act and the Circular encourage the participation of federal representatives in these bodies to increase the likelihood that the standards they develop will meet both public and private sector needs. A voluntary consensus standards body is defined by the following attributes:

(i) Openness.

(ii) Balance of interest.

(iii) Due process.

(vi) An appeals process.

(v) Consensus, which is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

b. Other types of standards, which are distinct from voluntary consensus standards, are the following:

(1) "Non-consensus standards," "Industry standards," "Company standards," or "de facto standards," which are developed in the private sector but not in the full consensus process.

(2) "Government-unique standards," which are developed by the government for its own uses.

(3) Standards mandated by law, such as those contained in the United States Pharmacopeia and the National Formulary, as referenced in 21 U.S.C. 351.

POLICY

5. Who Does This Policy Apply To?

This Circular applies to all agencies and agency employees who use standards and participate in voluntary consensus standards activities, domestic and international, except for activities carried out pursuant to treaties. "Agency" means any executive department, independent commission, board, bureau, office, agency, Government-owned or controlled corporation or other establishment of the Federal Government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding the use of voluntary consensus standards. It does not include the legislative or judicial branches of the Federal Government.

6. What Is The Policy For Federal Use Of Standards?

All federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical. In these circumstances, your agency must submit a report describing the reason(s) for its use of government-unique standards in lieu of voluntary consensus standards to the Office of Management and Budget (OMB) through the National Institute of Standards and Technology (NIST).

a. When must my agency use voluntary consensus standards?

Your agency must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical. In all cases, your agency has the discretion to decline to use existing voluntary consensus standards if your agency determines that such standards are inconsistent with applicable law or otherwise impractical.

(1) "Use" means incorporation of a standard in whole, in part, or by reference for procurement purposes, and the inclusion of a standard in whole, in part, or by reference in regulation(s).

(2) "Impractical" includes circumstances in which such use would fail to serve the agency's program needs; would be infeasible; would be inadequate, ineffectual, inefficient, or inconsistent with agency mission; or would impose more burdens, or would be less useful, than the use of another standard.

b. What must my agency do when such use is determined by my agency to be inconsistent with applicable law or otherwise impractical?

The head of your agency must transmit to the Office of Management and Budget (OMB), through the National Institute of Standards and Technology (NIST), an explanation of the reason(s) for using government-unique standards in lieu of voluntary consensus standards. For more information on reporting, see section 9.

c. How does this policy affect my agency's regulatory authorities and responsibilities?

This policy does not preempt or restrict agencies' authorities and responsibilities to make regulatory decisions authorized by statute. Such regulatory authorities and responsibilities include determining the level of acceptable risk; setting the level of protection; and balancing risk, cost, and availability of technology in establishing regulatory standards. However, to determine whether established regulatory limits or targets have been met, agencies should use voluntary consensus standards for test methods, sampling procedures, or protocols.

d. How does this policy affect my agency's procurement authority?

This policy does not preempt or restrict agencies' authorities and responsibilities to identify the capabilities that they need to obtain through procurements. Rather, this policy limits an agency's authority to pursue an identified capability through reliance on a government-unique standard when a voluntary consensus standard exists (see Section 6a).

e. What are the goals of agency use of voluntary consensus standards?

Agencies should recognize the positive contribution of standards development and related activities. When properly conducted, standards development can increase productivity and efficiency in Government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment.

f. What considerations should my agency make when it is considering using a standard?

When considering using a standard, your agency should take full account of the effect of using the standard on the economy, and of applicable federal laws and policies, including laws and regulations relating to antitrust, national security, small business, product safety, environment, metrication, technology development, and conflicts of interest. Your agency should also recognize that use of standards, if improperly conducted, can suppress free and fair competition; impede innovation and technical progress; exclude safer or less expensive products; or otherwise adversely affect trade, commerce, health, or safety. If your agency is proposing to incorporate a standard into a proposed or final rulemaking, your agency must

comply with the "Principles of Regulation" (enumerated in Section 1(b)) and with the other analytical requirements of Executive Order 12866, "Regulatory Planning and Review."

g. Does this policy establish a preference between consensus and non-consensus standards that are developed in the private sector?

This policy does not establish a preference among standards developed in the private sector. Specifically, agencies that promulgate regulations referencing non-consensus standards developed in the private sector are not required to report on these actions, and agencies that procure products or services based on non-consensus standards are not required to report on such procurements. For example, this policy allows agencies to select a non-consensus standard developed in the private sector as a means of establishing testing methods in a regulation and to choose among commercial-off-the-shelf products, regardless of whether the underlying standards are developed by voluntary consensus standards bodies or not.

h. Does this policy establish a preference between domestic and international voluntary consensus standards?

This policy does not establish a preference between domestic and international voluntary consensus standards. However, in the interests of promoting trade and implementing the provisions of international treaty agreements, your agency should consider international standards in procurement and regulatory applications.

i. Should my agency give preference to performance standards?

In using voluntary consensus standards, your agency should give preference to performance standards when such standards may reasonably be used in lieu of prescriptive standards.

j. How should my agency reference voluntary consensus standards?

Your agency should reference voluntary consensus standards, along with sources of availability, in appropriate publications, regulatory orders, and related internal documents. In regulations, the reference must include the date of issuance. For all other uses, your agency must determine the most appropriate form of reference, which may exclude the date of issuance as long as users are elsewhere directed to the latest issue. If a voluntary standard is used and published in an agency document, your agency must observe and protect the rights of the copyright holder and any other similar obligations.

k. What if no voluntary consensus standard exists?

In cases where no voluntary consensus standards exist, an agency may use government-unique standards (in addition to other standards, see Section 6g) and is not

required to file a report on its use of government-unique standards. As explained above (see Section 6a), an agency may use government-unique standards in lieu of voluntary consensus standards if the use of such standards would be inconsistent with applicable law or otherwise impractical; in such cases, the agency must file a report under Section 9a regarding its use of government-unique standards.

I. How may my agency identify voluntary consensus standards?

Your agency may identify voluntary consensus standards through databases of standards maintained by the National Institute of Standards and Technology (NIST), or by other organizations including voluntary consensus standards bodies, other federal agencies, or standards publishing companies.

7. What Is The Policy For Federal Participation In Voluntary Consensus Standards Bodies?

Agencies must consult with voluntary consensus standards bodies, both domestic and international, and must participate with such bodies in the development of voluntary consensus standards when consultation and participation is in the public interest and is compatible with their missions, authorities, priorities, and budget resources.

a. What are the purposes of agency participation?

Agency representatives should participate in voluntary consensus standards activities in order to accomplish the following purposes:

- (1) Eliminate the necessity for development or maintenance of separate Government-unique standards.
- (2) Further such national goals and objectives as increased use of the metric system of measurement; use of environmentally sound and energy efficient materials, products, systems, services, or practices; and improvement of public health and safety.

b. What are the general principles that apply to agency support?

Agency support provided to a voluntary consensus standards activity must be limited to that which clearly furthers agency and departmental missions, authorities, priorities, and is consistent with budget resources. Agency support must not be contingent upon the outcome of the standards activity. Normally, the total amount of federal support should be no greater than that of other participants in that activity, except when it is in the direct and predominant interest of the Government to develop or revise a standard, and its timely development or revision appears unlikely in the absence of such support.

c. What forms of support may my agency provide?

The form of agency support, may include the following:

- (1) Direct financial support; e.g., grants, memberships, and contracts.
- (2) Administrative support; e.g., travel costs, hosting of meetings, and secretarial functions.
- (3) Technical support; e.g., cooperative testing for standards evaluation and participation of agency personnel in the activities of voluntary consensus standards bodies.
- (4) Joint planning with voluntary consensus standards bodies to promote the identification and development of needed standards
- (5) Participation of agency personnel.

d. Must agency participants be authorized?

Agency employees who, at Government expense, participate in standards activities of voluntary consensus standards bodies on behalf of the agency must do so as specifically authorized agency representatives. Agency support for, and participation by agency personnel in, voluntary consensus standards bodies must be in compliance with applicable laws and regulations. For example, agency support is subject to legal and budgetary authority and availability of funds. Similarly, participation by agency employees (whether or not on behalf of the agency) in the activities of voluntary consensus standards bodies is subject to the laws and regulations that apply to participation by federal employees in the activities of outside organizations. While we anticipate that participation in a committee that is developing a standard would generally not raise significant issues, participation as an officer, director, or trustee of an organization would raise more significant issues. An agency should involve its agency ethics officer, as appropriate, before authorizing support for or participation in a voluntary consensus standards body

e. Does agency participation indicate endorsement of any decisions reached by voluntary consensus standards bodies?

Agency participation in voluntary consensus standards bodies does not necessarily connote agency agreement with, or endorsement of, decisions reached by such organizations.

f. Do agency representatives participate equally with other members?

Agency representatives serving as members of voluntary consensus standards bodies should participate actively and on an equal basis with other members, consistent with the procedures of those bodies, particularly in matters such as establishing priorities, developing procedures for preparing, reviewing, and approving standards, and developing or adopting new standards. Active participation includes full involvement in discussions and technical debates, registering of opinions and, if selected, serving as chairpersons or in other official capacities. Agency representatives may vote, in accordance with the procedures of the voluntary consensus standards body, at each stage of the standards development process unless prohibited from doing so by law or their agencies.

g. Are there any limitations on participation by agency representatives?

In order to maintain the independence of voluntary consensus standards bodies, agency representatives must refrain from involvement in the internal management of such organizations (e.g., selection of salaried officers and employees, establishment of staff salaries, and administrative policies). Agency representatives must not dominate such bodies, and in any case are bound by voluntary consensus standards bodies' rules and procedures, including those regarding domination of proceedings by any individual. Regardless, such agency employees must avoid the practice or the appearance of undue influence relating to their agency representation and activities in voluntary consensus standards bodies

h. Are there any limits on the number of federal participants in voluntary consensus standards bodies?

The number of individual agency participants in a given voluntary standards activity should be kept to the minimum required for effective representation of the various program, technical, or other concerns of federal agencies.

i. Is there anything else agency representatives should know?

This Circular does not provide guidance concerning the internal operating procedures that may be applicable to voluntary consensus standards bodies because of their relationships to agencies under this Circular. Agencies should, however, carefully consider what laws or rules may apply in a particular instance because of these relationships. For example, these relationships may involve the Federal Advisory Committee Act, as amended (5 U.S.C. App. I), or a provision of an authorizing statute for a particular agency.

j. What if a voluntary consensus standards body is likely to develop an acceptable, needed standard in a timely fashion?

If a voluntary consensus standards body is in the process of developing or adopting a voluntary consensus standard that would likely be lawful and practical for an agency to use, and would likely be developed or adopted on a timely basis, an agency should not be developing its own government-unique standard and instead should be participating in the activities of the voluntary consensus standards body.

8. What Is The Policy On Conformity Assessment?

Section 12(b) of the Act requires NIST to coordinate Federal, State, and local standards activities and conformity assessment activities with private sector standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and

promulgation of conformity assessment requirements and measures. To ensure effective coordination, the Secretary of Commerce must issue guidance to the agencies.

MANAGEMENT AND REPORTING OF STANDARDS USE

9. What Is My Agency Required to Report?

a. As required by the Act, your agency must report to NIST, no later than December 31 of each year, the decisions by your agency in the previous fiscal year to use government-unique standards in lieu of voluntary consensus standards. If no voluntary consensus standard exists, your agency does not need to report its use of government-unique standards. (In addition, an agency is not required to report on its use of other standards. See Section 6g.) Your agency must include an explanation of the reason(s) why use of such voluntary consensus standard would be inconsistent with applicable law or otherwise impractical, as described in Sections 11b(2), 12a(3), and 12b(2) of this Circular. Your agency must report in accordance with format instructions issued by NIST.

b. Your agency must report to NIST, no later than December 31 of each year, information on the nature and extent of agency participation in the development and use of voluntary consensus standards from the previous fiscal year. Your agency must report in accordance with format instructions issued by NIST. Such reporting must include the following:

- (1) The number of voluntary consensus standards bodies in which there is agency participation, as well as the number of agency employees participating.
- (2) The number of voluntary consensus standards the agency has used since the last report, based on the procedures set forth in sections 11 and 12 of this Circular.
- (3) Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review under section 15b(7) of this Circular.
- (4) An evaluation of the effectiveness of this policy and recommendations for any changes.

c. No later than the following January 31, NIST must transmit to OMB a summary report of the information received.

10. How Does My Agency Manage And Report Its Development and Use Of Standards?

Your agency must establish a process to identify, manage, and review your agency's development and use of standards. At minimum, your agency must have the ability to (1) report to OMB through NIST on the agency's use of government-unique standards in lieu of voluntary consensus standards, along with an explanation of the reasons for such non-usage, as described in section 9a, and (2) report on your agency's participation in the development

and use of voluntary consensus standards, as described in section 9b. This policy establishes two ways, category based reporting and transaction based reporting, for agencies to manage and report their use of standards. Your agency must report all uses of standards in one or both ways.

11. What Are The Procedures For Reporting My Agency's Use Of Standards In Regulations?

Your agency should use transaction based reporting if your agency issues regulations that use or reference standards. If your agency is issuing or revising a regulation that contains a standard, your agency must follow these procedures:

a. Publish a request for comment within the preamble of a Notice of Proposed Rulemaking (NPRM) or Interim Final Rule (IFR). Such request must provide the appropriate information, as follows:

- (1) When your agency is proposing to use a voluntary consensus standard, provide a statement which identifies such standard.
- (2) When your agency is proposing to use a government-unique standard in lieu of a voluntary consensus standard, provide a statement which identifies such standards and provides a preliminary explanation for the proposed use of a government-unique standard in lieu of a voluntary consensus standard.
- (3) When your agency is proposing to use a government-unique standard, and no voluntary consensus standard has been identified, a statement to that effect and an invitation to identify any such standard and to explain why such standard should be used.

b. Publish a discussion in the preamble of a Final Rulemaking that restates the statement in the NPRM or IFR, acknowledges and summarizes any comments received and responds to them, and explains the agency's final decision. This discussion must provide the appropriate information, as follows:

- (1) When a voluntary consensus standard is being used, provide a statement that identifies such standard and any alternative voluntary consensus standards which have been identified.
- (2) When a government-unique standard is being used in lieu of a voluntary consensus standard, provide a statement that identifies the standards and explains why using the voluntary consensus standard would be inconsistent with applicable law or otherwise impractical. Such explanation must be transmitted in accordance with the requirements of Section 9a.
- (3) When a government-unique standard is being used, and no voluntary consensus standard has been identified, provide a statement to that effect.

12. What Are The Procedures For Reporting My Agency's Use Of Standards In Procurements?

To identify, manage, and review the standards used in your agency's procurements, your agency must either report on a categorical basis or on a transaction basis.

a. How does my agency report the use of standards in procurements on a categorical basis?

Your agency must report on a category basis when your agency identifies, manages, and reviews the use of standards by group or category. Category based reporting is especially useful when your agency either conducts large procurements or large numbers of procurements using government-unique standards, or is involved in long-term procurement contracts which require replacement parts based on government-unique standards. To report use of government-unique standards on a categorical basis, your agency must:

- (1) Maintain a centralized standards management system that identifies how your agency uses both government-unique and voluntary consensus standards.
- (2) Systematically review your agency's use of government-unique standards for conversion to voluntary consensus standards.
- (3) Maintain records on the groups or categories in which your agency uses government-unique standards in lieu of voluntary consensus standards, including an explanation of the reasons for such use, which must be transmitted according to Section 9a.
- (4) Enable potential offerors to suggest voluntary consensus standards that can replace government-unique standards.

b. How does my agency report the use of standards in procurements on a transaction basis?

Your agency should report on a transaction basis when your agency identifies, manages, and reviews the use of standards on a transaction basis rather than a category basis. Transaction based reporting is especially useful when your agency conducts procurement mostly through commercial products and services, but is occasionally involved in a procurement involving government-unique standards. To report use of government-unique standards on a transaction basis, your agency must follow the following procedures:

- (1) In each solicitation which references government-unique standards, the solicitation must:
 - (i) Identify such standards.
 - (ii) Provide potential offerors an opportunity to suggest alternative voluntary consensus standards that meet the agency's requirements.

- (2) If such suggestions are made and the agency decides to use government-unique standards in lieu of voluntary consensus standards, the agency must explain in its report to

OMB as described in Section 9a why using such voluntary consensus standards is inconsistent with applicable law or otherwise impractical.

c. For those solicitations that are for commercial-off-the-shelf products (COTS), or for products or services that rely on voluntary consensus standards or non-consensus standards developed in the private sector, or for products that otherwise do not rely on government-unique standards, the requirements in this section do not apply.

AGENCY RESPONSIBILITIES

13. What Are The Responsibilities Of The Secretary Of Commerce?

The Secretary of Commerce:

- a. Coordinates and fosters executive branch implementation of this Circular and, as appropriate, provides administrative guidance to assist agencies in implementing this Circular including guidance on identifying voluntary consensus standards bodies and voluntary consensus standards.
- b. Sponsors and supports the Interagency Committee on Standards Policy (ICSP), chaired by the National Institute of Standards and Technology, which considers agency views and advises the Secretary and agency heads on the Circular.
- c. Reports to the Director of OMB concerning the implementation of the policy provisions of this Circular.
- d. Establishes procedures for agencies to use when developing directories described in Section 15b(5) and establish procedures to make these directories available to the public.
- e. Issues guidance to the agencies to improve coordination on conformity assessment in accordance with section 8.

14. What Are The Responsibilities Of The Heads Of Agencies?

The Heads of Agencies:

- a. Implement the policies of this Circular in accordance with procedures described.
- b. Ensure agency compliance with the policies of the Circular.
- c. In the case of an agency with significant interest in the use of standards, designate a senior level official as the Standards Executive who will be responsible for the agency's implementation of this Circular and who will represent the agency on the ICSP.
- d. Transmit the annual report prepared by the Agency Standards Executive as described in Sections 9 and 15b(6).

15. What Are The Responsibilities Of Agency Standards Executives?

An Agency Standards Executive:

a. Promotes the following goals:

- (1) Effective use of agency resources and participation.
- (2) The development of agency positions that are in the public interest and that do not conflict with each other.
- (3) The development of agency positions that are consistent with administration policy.
- (4) The development of agency technical and policy positions that are clearly defined and known in advance to all federal participants on a given committee.

b. Coordinates his or her agency's participation in voluntary consensus standards bodies by:

- (1) Establishing procedures to ensure that agency representatives who participate in voluntary consensus standards bodies will, to the extent possible, ascertain the views of the agency on matters of paramount interest and will, at a minimum, express views that are not inconsistent or in conflict with established agency views.
- (2) To the extent possible, ensuring that the agency's participation in voluntary consensus standards bodies is consistent with agency missions, authorities, priorities, and budget resources.
- (3) Ensuring, when two or more agencies participate in a given voluntary consensus standards activity, that they coordinate their views on matters of paramount importance so as to present, whenever feasible, a single, unified position and, where not feasible, a mutual recognition of differences.
- (4) Cooperating with the Secretary in carrying out his or her responsibilities under this Circular.
- (5) Consulting with the Secretary, as necessary, in the development and issuance of internal agency procedures and guidance implementing this Circular, including the development and implementation of an agency-wide directory identifying agency employees participating in voluntary consensus standards bodies and the identification of voluntary consensus standards bodies.
- (6) Preparing, as described in Section 9, a report on uses of government-unique standards in lieu of voluntary consensus standards and a report on the status of agency standards policy activities.
- (7) Establishing a process for ongoing review of the agency's use of standards for purposes of updating such use.
- (8) Coordinating with appropriate agency offices (e.g., budget and legal offices) to ensure that effective processes exist for the review of proposed agency support for, and participation in, voluntary consensus standards bodies, so that agency support and participation will comply with applicable laws and regulations.

SUPPLEMENTARY INFORMATION

16. When Will This Circular Be Reviewed?

This Circular will be reviewed for effectiveness by the OMB three years from the date of issuance.

17. What Is The Legal Effect Of This Circular?

Authority for this Circular is based on 31 U.S.C. 1111, which gives OMB broad authority to establish policies for the improved management of the Executive Branch. This Circular is intended to implement Section 12(d) of P.L. 104-113 and to establish policies that will improve the internal management of the Executive Branch. This Circular is not intended to create delay in the administrative process, provide new grounds for judicial review, or create new rights or benefits, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, or its officers or employees.

18. Do You Have Further Questions?

For information concerning this Circular, contact the Office of Management and Budget, Office of Information and Regulatory Affairs: Telephone 202/395-3785.