Proposal for the Legal Inspection Requirements for UV Disinfection (Sterilization) Appliances

By the Bureau of Standards, Metrology and Inspection (BSMI), Ministry of Economic Affairs (MOEA)

Nowadays, the UV disinfection appliance is popular with consumers for fighting with the pandemic. The radiation emitted from UV disinfection appliance may pose hazards to consumers and the radiation can not be easily detected by consumers. Improper use of UV disinfection appliance may impair vision and cause damage to the skin of consumers. In order to ensure consumer safety, the BSMI plans to regulate UV disinfection appliances. Two alternative conformity assessment procedures are made available for the choice of applicants, i.e. Registration of Product Certification (RPC) or Type-Approved Batch Inspection (TABI).

Proposed date of implementation: 1 May 2023

Scope of covered products:

Description of Commodities	**Inspection Standards(Note)**	**Conformity Assessment Procedures**	**C.C.C. Code (the first 6 digits are the same as HS Code) (For reference)**
UV Disinfection (Sterilization) Appliances (including handheld disinfection light, inspection scope: voltage not exceeding 250 Vac, and not defined as medical device under the "Medical Device Management Act")	1. CNS 60335-1 (2014) 2. CNS 13783-1 (2013) 3. CNS 15592 (2012) 4. CNS 15663 (2013) Section 5 "Marking of Presence" 5. For the product with secondary lithium cells/batteries, requirements in Note 2 shall be meet.	Type Approval Batch Inspection (TABI) Scheme (Module II+III) or Registration of Product Certification (RPC) Scheme	8543.70.99.90.6I

Remarks：

1. The CNS standards are accessible at CNS online service website: www.cnsonline.com.tw. You can preview the content of these standards for free. If you want to download and print, please contact our service counter of Information Center at BSMI.

Tel: +886-2-2341-4772 or +886-2-2343-1994

Fax: +886-2-8192-6746

E-mail: infocenter@bsmi.gov.tw

The two kinds of conformity assessment schemes for the commodities are as follows:

1. Registration of Product Certification (RPC) Scheme (Module II + III)

Under this procedure, domestic manufacturers or importers must have their products type-tested by BSMI designated testing laboratories in advance (Module II) before applying for registration of their products. Manufacturers or importers will also be required to ensure by declaration that all products made at their manufacturing facilities or imported are in conformity with the prototypes submitted for type test at Module II stage, and the declaration procedure is called Module III (conformity-to-type declaration).

The conformity-to-type declaration shall be drawn up by the manufacturer or the authorized local representative, declaring that the mass-produced products comply with the prototype as described in the type-test report.

Products will be allowed to use the Commodity Inspection Mark with the letter 'R' and the identification number given by the BSMI, after they are certified and registered with the BSMI. These products can then clear customs directly without any further inspection if not being sampled by RPC border check procedure. The application fee and annual fee for RPC are both NT$5,000 (about US$170) for each certification, and the RPC certificates are valid for three years. If there are any serial products, an extra NT$3,000 (about US$102) is charged for each application in each certificate.

The fees for type-testing vary by products and depend on the fee schedule of the testing laboratories.

2. Type-approved Batch Inspection (TABI) Scheme

Under this scheme, manufacturers or importers shall have their products type-tested by the BSMI or BSMI designated testing laboratories, and then file an application for type-approval with the BSMI or its branches.

After manufacturers or importers have obtained a type-approval certificate, they are still required to file an application for batch inspection with the BSMI each time before their products arrive at the port of entry. The BSMI will then perform inspection with simplified procedures. Additional samples may be required for further testing if it is deemed necessary. The application fee for a type-approval is NT$3,500, and a type-approval certificate is generally valid for three years.

The fees for type-testing vary by products and depend on the fee schedule of the testing laboratories.

*Further information about the two schemes is also available on the BSMI web site at https://www.bsmi.gov.tw/wSite/lp?ctNode=9768&CtUnit=4132&BaseDSD=7&mp=2

Locations to apply for Type Testing:

The BSMI designated testing laboratories.

Locations to apply for Registration of Product Certification:

The BSMI or its branch offices.

Time required for Registration of Product Certification:

Fourteen working days. (This period does not include the time for corrective actions by the applicant due to deficiencies in the documents or samples; another seven working days may be required if additional tests are required.)

Related requirements:

Note 1: The followings are extra requirements in addition to CNS 60335-1 (2014)

Section 7: The additional requirements are as following (Except those that meet the CNS 15592 risk-free category)

1. Non handheld commodities

(1) Product body shall mark

a. Warning sign

UV radiation sign  (IEC 60417-6040:2010-08) shall be used to indicate the UV hazard. The sign shall be shown with black words and yellow background. The position of the sign shall be at light emission place on the outer casing of the commodity.

b. The activation distance (m) of risk-free human body induction protection device

c. Warning words (shall be in Chinese; English for reference only)

(a) The commodity shall be used at the circumstances without human beings, animals and plants. (Low risk commodity do not need to mark this)

(b) Do not look directly into the light source or expose your skin to the light source to avoid visual impairment or damage to skin.

(c) Do not use it as general lighting.

(d) Stop using this product immediately to avoid harming human body when the timer or human body moving sensor of the commodity fails.

(e) The character size of the warning (a) and warning (b) shall be in size over 10 mm in height, and over 10 mm in width.

(2) The precautions in the user manuals shall include the following items:

a. Warning words mentioned above.

b. Read the user manual carefully before usage, and use the product based on the instructions.

c. For fixed and portable UV disinfection (sterilization) light, leave the disinfection area quickly after the light is turned on to avoid exposing to UV rays.

d. If the product is equipped with UV protective glasses, check the glasses before usage to ensure the glasses are in good condition and wear them correctly.

e. Avoid usage by children or those who can't use the product properly.

f. When the human body sensing device and the commodity are designed as separate components, it should have the instructions for appropriate installation and usage.

g. Commodity that can generate ozone during the usage shall add the wordings: before entering the space, it shall be ventilated for more than 30 minutes after usage.

2. Handheld commodities

(1) Product body shall mark

a. Warning sign: Same rules as non handheld products mentioned.

b. Warning words

(a) Do not look directly into the light source to avoid visual impairment. The character size of the warning shall be over 10 mm in height and over 10 mm in width.

(b) Do not use it as general lighting.

(c) Stop using this product immediately to avoid harming human body when the timer of the commodity fails.

(2) The precautions in the user manuals shall include the following items:

a. Read the user manual carefully before usage, and use the product based on the instructions.

b. Stop using this product immediately to avoid harming human body when the timer of the commodity fails.

c. Do not look directly at the light sources or the reflected light because this may cause eye pain or visual impairment. Do not expose the skin directly or indirectly to UV radiation from the light source as it may cause skin irritation or sunburn.

d. If the product is equipped with UV protective glasses, check the glasses before usage to ensure the glasses are in good condition and wear them correctly.

e. Avoid usage by children or those who can't use the product properly.

Section 19: Additional requirements: When the timer or human body motion sensing device of the commodity fails, it should have a protection mechanism to cut off the light source.

Section 21.1: Additional requirements: for protruding lens of the glass components and outer casing outside the luminous body, the impact energy is reduced to 0.35 J. If the luminous body is installed on the ceiling or the luminous body is installed above 2.3m from the ground, it is not necessary to perform the impact test on any protruding lens of the glass components and outer casing outside the luminous body.

Section 25.7: Revised requirements: Power cable shall at least comply with the requirements of CNS 15767-1 "Plugs and receptacles for domestic and similar general use -first- general requirements" or other related national standards for power cable. Power cable shall be covered by polychloroprene. The covering of power cable shall not be inferior to polychloroprene-coated wires (CNS 546 or 60245 IEC 57)

Section 32: Additional requirements: According to the photo-biological safety measurement of CNS15592 for light source and light source system, the risk category of photochemical UV hazard and blue light hazard should be no risk in normal use. However, such requirement does not apply to products equipped with the human body movement sensor, or timer etc., to prevent human body from harm by avoiding exposure or limit the exposure time, and the structure meets the requirements of photo-biological safety.

Note 2: Specific information for batteries: For products listed in the above table with secondary lithium cells/batteries, the cells (include the cells in the batteries) shall comply with CNS 15364: 2013, and the battery system shall comply with Section 7.3.8.1 "Vibration" and 7.3.8.2 "Mechanical Shock" of CNS 62133-2: 2018 or related national standards or international standards that are newer than the mentioned standards. The applicants shall provide certificates issued by certification bodies or test reports issued by testing laboratories accredited by Taiwan Accreditation Foundation.

Note 3: The products listed in the table shall not be classified as Class 0 electrical appliances.

Other Inspection Requirements:

1. Above listed products that are imported or domestically manufactured will be subject to mandatory inspection on May 1, 2023. The inspection schemes are dual track. The applicants can choose either TABI or RPC. After the announcement date, the BSMI could accept the application for TABI and RPC. For TABI, the products shall apply for the type approval first and obtain the type approval certificate before the product is imported or released from production premises. If the product complies with the inspection requirements, the product could be sold on the domestic market. For RPC, if the product complies with the inspection requirements, the BSMI will issue the RPC certificate to the applicants.

2. From the date of announcement, those who apply for a certificate to the BSMI shall provide the type test report in accordance with the inspection requirements, the place and the sample indicating "the presence condition of the restricted substances" (Shown in Table 1 and Table 2) and declaration form on "the presence condition of the restricted substances". For those who apply for a certificate to the BSMI between the date of the announcement and the implementation date, the valid duration for certificate will be between May 1, 2023 to April 30, 2026. If the product and inspection requirements don't change, the certificate can be extended once.

3. Locations to apply for product type testing: the BSMI recognized designated laboratories.

4. Locations to apply for TABI or RPC are the BSMI or the branch of the BSMI. The conformity assessment procedure of RPC shall follow the related rules of "Regulations Governing Registration of Product Certification".

5. Locations to apply for Batch-by-Batch Inspection:

   (1) Domestic producers or entrusted producers: the BSMI or the branch of the BSMI with jurisdiction over the production place. If necessary, application for inspection can be made to other BSMI branches.

   (2) Importers or entrusted importers: The BSMI or the branch of the BSMI with jurisdiction over the arriving port of imported goods. If necessary, application for inspection can be made to other BSMI branches.

6. The review period for TABI and RPC of the listed products is 14 working days (the time waiting for the supplementary materials or samples is not counted; for those who take samples, 7 working days will be added after the samples are delivered)

7. The technical documents and attachments for type testing shall follow the rule of "Electrical and Electronic Product Type Approval Regulations".

8. Type testing fees for listed products: Charged based on the laboratory.

9. Related fee for TABI or RPC of listed product shall be in accordance with the "Regulations Governing Fees for Commodity Inspection".

10. The certificate holders of the products shall clearly label “the presence condition of the restricted substances” (Shown in Table 1 and Table 2) on the body, packages, stickers, or user manuals of the products in accordance with Section 5 “Marking of presence” of CNS 15663. Those who use website as a means to announce “the presence condition of the restricted substances” shall also clearly label the website address on the body, packages, stickers or user manuals of the products. In that case, the requirements of Section 5.3 of CNS 15663 regarding the position of labeling are not applicable.

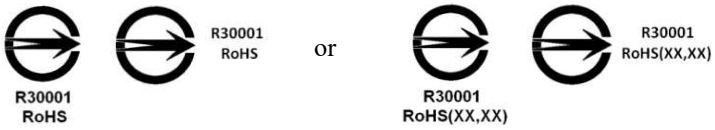
11. The listed products shall label Commodity Inspection Mark as follow:

(1) According to “Regulations Governing the Use of Commodity Inspection Mark”, the Commodity Inspection Mark of listed product for TABI and RPC shall be printed by the certificate holders. The identification number of the Commodity Inspection Mark consists of “A Letter (R or T),” “Designated Code (5 digits)” and “the presence conditions of the restricted substance” (e.g., RoHS or RoHS (XX,XX)).

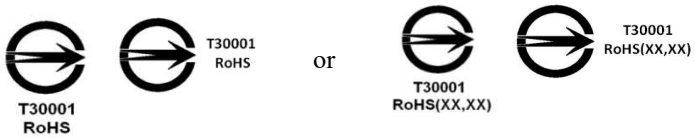
(2) The identification number shall be placed below or right next to the graphic symbol and “the presence conditions of the restricted substance” shall be indicated in the second row.

(3) The size of the Mark is not fixed and can be applied proportionally on a prominent location of the products. The Mark shall use materials that are not easily altered, and the content shall be in a clearly identifiable and inerasable form affixed permanently to the product.

(4) For RPC scheme, the examples of the Commodity Inspection Mark are listed below:



(5) For TABI scheme, the examples of the Commodity Inspection Mark are listed below:



(6) “RoHS” indicates the content of restricted substance(s), other than exemptions stated in CNS 15663, does not exceed the reference percentage value of presence condition.

“ RoHS(XX,XX)” indicates the content of restricted substance(s) (element XX, element XX, …), other than exemptions stated in CNS 15663, exceeds the reference percentage value of presence condition.

Restricted substances state in Annex A of CNS 15663: Pb, Cd, Hg, Cr^{+6}, PBB, and PBDE.

Examples:

- RoHS (Pb) indicates that the percentage content of Pb in certain parts of the commodity exceeds the reference percentage value specified in Annex A to CNS 15663.
- RoHS (Cd, Cr^{+6}, PBB) indicates that the percentage content of Cd, Cr^{+6}, and PBB in certain parts of the commodity exceeds the respective reference percentage value specified in Annex A to CNS 15663.

12. When the applicants obtain the TABI or RPC certificate of the listed product, the applicants shall follow the article 4 of the “Regulations Governing the Use of Commodity Inspection Mark” to self print product Commodity Inspection Mark and label the mark at obvious place on the product body. If the applicants obtain the RPC certificate before May 1, 2023, the certificate holders can self print Commodity Inspection Mark and label the mark at obvious place on the product body.

13. The inspection standards for the listed commodities are subject to the version specified in this announcement. If there is an additional (revised) version, the BSMI will make an announcement for the implementation date.

14. C.C.C. Code listed in the table is used for reference only. The products listed in the table shall still complete the inspection procedures before entering into the market even though their C.C.C. Code is determined differently by the Customs Administration, Ministry of Finance, or Bureau of Foreign Trade, Ministry of Economic Affairs.

15. The import regulation code for the listed products is C02.

16. Commodities with combined features or multifunctional products shall comply with the respective inspection standards and the applicable modules under the RPC scheme.

Table 1. Example of markings for the presence conditions of the restricted substances exceeds the reference percentage value of presence conditions

Equipment name: UV Disinfection Appliances, Type designation：XXX						
Unit	Restricted substances and its chemical symbols					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr^{+6})	Polybrominated Biphenyls (PBB)	Polybrominated Diphenyl Ethers (PBDE)
Circuit Board	Exceeding 0.1 wt %	○	○	○	○	○
Outer Casing	○	○	○	○	○	○
Switches	—	○	○	○	○	○
Power Cable	○	○	○	○	○	○
Lamp Assembly	○	○	Exceeding 0.01 wt %	○	○	Exceeding 0.1 wt %

Note 1: "Exceeding 0.1 wt %" and "exceeding 0.01 wt %" indicate that the percentage content of the restricted substance exceeds the reference percentage value of presence condition.

Note 2: "○" indicates that the percentage content of the restricted substance does not exceed the percentage of reference value of presence.

Note 3: The "–" indicates that the restricted substance corresponds to the exemption.

Table 2. Example of markings for the content of the restricted substances other than exemption do not exceed the reference percentage value of presence condition

Equipment name: UV Disinfection Appliances, Model：YYY						
Unit	Restricted substances and its chemical symbols					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr^{+6})	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Circuit Board	○	○	○	○	○	○
Outer Casing	○	○	○	○	○	○
Switches	–	○	○	○	○	○
Power Cable	○	○	○	○	○	○
Lamp Assembly	○	○	○	○	○	○

Note 1: "○" indicates that the percentage content of the restricted substance does not exceed the percentage of reference value of presence.

Note 2: The "–" indicates that the restricted substance corresponds to the exemption.

Note *The 1st "name and model" row can be omitted if the position of "the markings for the presence conditions" shows clearly to specify the corresponding commodity.

*Multiple models could be shown together in the same field if "the markings for the presence conditions" can be applied to multiple models.