WORLD TRADE ORGANIZATION

G/TBT/N/PHL/295

11 November 2022

(22-8447)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** PHILIPPINES **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** DR. SAMUEL A. ZACATE Director General Food and Drug Administration DEPARTMENT OF HEALTH **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** MARIA CECILIA C. MATIENZO Director IV Center for Device Regulation, Radiation Health, and Research Food and Drug Administration DEPARTMENT OF HEALTH Contact: (02) 8815-9600 Email: cdrrhr@fda.gov.ph; cdrrhr.rrd@fda.gov.ph; www.fda.gov.ph
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Radiation protection (ICS code(s): 13.280)
5.	**Title, number of pages and language(s) of the notified document:** Guidelines on the Conduct of Regulatory Inspections for Radiation Facilities; (34 page(s), in English)
6.	**Description of content:** FDA aims to operationalize and supplement the provisions of DOH AO No. No. 2020-0035 providing for a rationalized process for the conduct of regulatory inspections for radiation facilities. This FDA Circular is issued to revoke the FDA Circular No. 2020-035 and provide uniform guidelines on the conduct of regulatory inspections for radiation facilities under the jurisdiction of the FDA.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** This Circular aims to outline guidelines on the conduct of regulatory inspections for radiation facilities with alternative modes and approaches using digital means to the conduct of such in line with the graded approach established through DOH AO No. 2020-0035.

8.	**Relevant documents:** • DOH Administrative Order No. 2020-0035 or the Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorizations • FDA Circular No. 2020-035 or "Interim Guidelines for the Conduct of Licensing Inspection for Radiation Facilities"
9.	**Proposed date of adoption:** 1st Quarter of 2023 **Proposed date of entry into force:** 15 days after publication
10.	**Final date for comments:** 60 days from notification
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Mr. Neil P. Catajay Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati City Philippines Tel: (632) 751 4700; (632) 7913128 Email: bps@dti.gov.ph Website: http://www.bps.dti.gov.ph https://www.fda.gov.ph/wp-content/uploads/2022/11/Draft-for-Comments_CDRRHR_November-2022.pdf https://members.wto.org/crnattachments/2022/TBT/PHL/22_7732_00_e.pdf