



12 August 2024

(24-5649)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>PHILIPPINES</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> DR. VALERIANO V. TIMBANG, JR. OIC-Director IV Center for Device Regulation, Radiation Health and Research Food and Drug Administration DEPARTMENT OF HEALTH Email: <a href="mailto:cdrhr@fda.gov.ph">cdrhr@fda.gov.ph</a> ; <a href="mailto:cdrhr.rrd@fda.gov.ph">cdrhr.rrd@fda.gov.ph</a> ; <a href="mailto:BPS@dti.gov.ph">BPS@dti.gov.ph</a> ; <a href="mailto:BPS.SMD@dti.gov.ph">BPS.SMD@dti.gov.ph</a> <a href="http://www.fda.gov.ph">www.fda.gov.ph</a> <b>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:</b>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> - Apparatus based on the use of X-rays, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus: (HS code(s): 90221); Radiation protection (ICS code(s): 13.280)
<b>5. Title, number of pages and language(s) of the notified document:</b> Amendment to Administrative Order (AO) 2013-0031 entitled "Requirements for the Operation of Therapeutic X-ray Facility Utilizing Medical Linear Accelerators"; (8 page(s), in English)
<b>6. Description of content:</b> Upon review of the implementation of the A.O. No. 2013-0031, many therapeutic x-ray facilities were not able to comply with the manpower requirements. Additionally, several dedicated radiation generators used in radiotherapy were also made available over the past years. Hence, in order to ensure compliance with the manpower requirement and to keep abreast with the emerging technologies, current provisions of A.O. 2013-0031 shall be made.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> This amendment aims to address the non-compliance of most therapeutic x-ray facilities with the manpower requirements. This also aims to accommodate dedicated radiation generators that are not yet included in the current regulation.
<b>8. Relevant documents:</b>

DOH Administrative Order No. 2013-0013 or the Requirements for the Operation of Therapeutic X-ray Facility Utilizing Medical Linear Accelerators	
<b>9.</b>	<b>Proposed date of adoption:</b> Q1 of 2025 <b>Proposed date of entry into force:</b> 15 days after the publication
<b>10.</b>	<b>Final date for comments:</b> 60 days from notification
<b>11.</b>	<b>Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b>  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 1200 Tel: (632) 751 4700; (632) 7913128 Email: <a href="mailto:bps@dti.gov.ph">bps@dti.gov.ph</a> Website: <a href="http://www.bps.dti.gov.ph">http://www.bps.dti.gov.ph</a> <a href="https://members.wto.org/crnattachments/2024/TBT/PHL/24_05203_00_e.pdf">https://members.wto.org/crnattachments/2024/TBT/PHL/24_05203_00_e.pdf</a>