



13 May 2022

(22-3749)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 12 May 2022, is being circulated at the request of the delegation of the Philippines.

Title: Food and Drug Administration Circular 2017-013: Guidelines on the Issuance of Clearance for Customs Release of Radiation Devices

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input type="checkbox"/>	Notified measure published - date:
<input type="checkbox"/>	Notified measure enters into force - date:
<input type="checkbox"/>	Text of final measure available from ¹ :
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input checked="" type="checkbox"/>	Content or scope of notified measure changed and text available from ¹ : Center for Device Regulation, Radiation Health, and Research Food and Drug Administration DEPARTMENT OF HEALTH Contact: (02) 8815-9600 Email: cdrhr@fda.gov.ph ; cdrrhr.rrd@fda.gov.ph ; www.fda.gov.ph https://members.wto.org/crnattachments/2022/TBT/PHL/modification/22_3399_00_e.pdf New deadline for comments (if applicable): 30 days from notification
<input type="checkbox"/>	Interpretive guidance issued and text available from ¹ :
<input type="checkbox"/>	Other:

Description: The proposed Circular aims to align and amend FDA Circular No. 2017-013 with provisions of DOH AO No. 2018-0002 and provide guidelines for medical radiation devices in line with the phased implementation of the AO specified through FDA Circular No. 2021-002 and its amendments.

¹ This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained.