NOTIFICATION

Addendum

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

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

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| **Reason for Addendum:** |
| [ ] | Comment period changed - date:  |
| [ ] | Notified measure adopted - date:  |
| [ ] | Notified measure published - date:  |
| [ ] | Notified measure enters into force - date:  |
| [ ] | Text of final measure available from[[1]](#footnote-1):  |
| [ ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [X] | Content or scope of notified measure changed and text available from1: Center for Device Regulation, Radiation Health, and ResearchFood and Drug AdministrationDEPARTMENT OF HEALTHContact: (02) 8815-9600Email: cdrrhr@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 |
| [ ] | Interpretive guidance issued and text available from1:  |
| [ ] | 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.

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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. [↑](#footnote-ref-1)