23 March 2021

#### **PNRI INFORMATION NOTICE 2021-02**

PNRI ADMINISTRATIVE ORDER NO. 03, SERIES OF 2020: AMENDMENT TO THE CPR PART 13, "LICENSES FOR MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL, Rev. 2"

#### **ADDRESSEES**

All PNRI license holders for the use of unsealed radioactive material.

#### **PURPOSE**

This Information Notice is issued to inform all concerned PNRI licensees on the publication of PNRI Administrative Order (AO) No. 03, Series of 2020, entitled "Amendment to the CPR Part 13, "Licenses for Medical Use of Unsealed Radioactive Material, Rev. 2" in the Official Gazette Vol. 117 No. 9 on 1 March 2021. The Administrative Order was developed to impose additional requirements to address issues related to the implementation of CPR Part 13.

### **DESCRIPTION OF CIRCUMSTANCES**

The PNRI published in the Official Gazette the CPR Part 13, "Licenses for Medical Use of Unsealed Radioactive Material, Rev. 2" on March 24, 2014 under Volume 110, No. 12. During the implementation of the regulations, various feedback and recommendations were received from the PNRI inspectors and evaluators on some areas that should have been included or revised. Upon several meetings and discussions of the regulatory staff, the PNRI recognizes the need to amend the corresponding provisions on specific requirements stipulated in the following sections:

- Section 2. Definitions The term "bioassay" was defined and added in this Section.
- Section 14. (a) Radiation Safety Program This Section provides a detailed requirements for the radiation safety program for implementation of the licensees.

 Section 19. Determination of Dosages of Unsealed Radioactive Material for Medical Use and Permissible Mo-99 Concentration

This Section specifies the requirements for the Mo-99 concentration and the prescribed dose range for administration.

Section 20. (f) Personnel Monitoring

This Section requires the conduct of bioassay testing for all workers handling unsealed radioiodine.

- Section 22 (b)(e) Possession, Use, Calibration, and Check of Dose Calibrators
   The procedures and the requirements such as the activity and energy of the sealed sources for the performance testing of dose calibrator were provided in this Section.
- Section 32. (a)(d)(e)(f) Control of Airborne Radioactive Materials
   The requirements for the fume hood, performance testing and preventive maintenance were stipulated in this Section. The number of room air changes and face velocity of the laboratory fume hood were specified.
- Section 34. (c) Waste Management and Disposal of Radioactive Materials of the CPR Part 13, "Licenses for Medical Use of Unsealed Radioactive Material", Rev. 2.

This section requires the licensees to return to supplier all disused sealed sources and generators. This is an additional requirement to the existing radioactive waste management program.

#### DISCUSSION

The PNRI Administrative Order No. 03, Series of 2020, "Amendment to the CPR Part 13, "Licenses for Medical Use of Unsealed Radioactive Material, Rev. 2" was published in the Official Gazette Vol. 117 No. 9 on 1 March 2021 and took effect fifteen (15) days thereafter. The provisions of this order are applicable to all addressees.

The PNRI AO is now available and can be downloaded from the PNRI website. (www.pnri.dost.gov.ph).

## **REQUIRED LICENSEE RESPONSE**

The licensee is required to comply with the amendments as provided under the said PNRI Administrative Order.

# CONTACT

If you have any question about the information in this notice, please contact:

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APPROVED

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