PNRI Administrative Order No. 03
Series of 2020

AMENDMENT TO THE CPR PART 13, "LICENSES FOR MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL, Rev. 2"

***WHEREAS*,** pursuant to the authority under Republic Act No. 2067: "Science Act of 1958", as amended, and Republic Act No. 5207, "Atomic Energy Regulatory and Liability Act of 1968", as amended, the Philippine Nuclear Research Institute (hereinafter referred to as PNRI) establishes and issues regulations and orders with regards to atomic energy facilities and materials for the protection of the health and safety of the workers and for the general public; and for this purpose the regulations are established in the Code of PNRI Regulations (CPR);

WHEREAS, pursuant to Section 4(m) of Republic Act No. 5207, as amended, the PNRI has the authority to issue, amend and revoke such regulations and orders as may be necessary or proper to carry out the purposes and provisions of the Act;

***WHEREAS*,** the PNRI recognizes the need to amend the corresponding provisions on specific requirements stipulated in the following sections: Section 2. Definitions (gg), Section 14. Radiation Safety Program (a), Section 19. Determination of Dosages of Unsealed Radioactive Material for Medical Use and Permissible Mo-99 Concentration, Section 20. Personnel Monitoring (f), Section 22. Possession, Use, Calibration, and Check of Dose Calibrators, (b)(e), Section 32. Control of Airborne Radioactive Materials (a)(d) and Section 34. Waste Management and Disposal of Radioactive Materials (c) of CPR Part 13, "Licenses for Medical Use of Unsealed Radioactive Material", Rev. 2 to address issues that have arisen on regulatory inspections to ensure compliance of licensees with the law and the PNRI regulations;

***WHEREAS*,** in view of this issuance, the aforementioned provisions on the specific requirements of the CPR Part 13 are hereby superseded;

NOW, THEREFORE, pursuant to the authority of PNRI as mandated under Section 4(m) of R.A. No. 5207, as amended, the CPR Part 13, "Licenses for Medical Use of Unsealed Radioactive Material", Rev. 2is hereby amended:

1. To include the definition of bioassay in Section 2:

Section 2. Definitions.

(gg) **"Bioassay"** means any procedure used to determine the nature, activity, location, or retention of radionuclides in the body by direct (in vivo) measurement or by in vitro analysis of material excreted or otherwise removed from the body.

2. To specify the requirements in the radiation safety program in Section 14:

Section 14. Radiation Safety Program.

(a) Each applicant or licensee shall develop, document, and implement a radiation safety program containing the following elements:
   (1) Organization, duties and responsibilities of Radiation Safety Committee
   (2) Designation of a Qualified Radiation Protection Officer (RPO) and Assistant Radiation Protection Officer (ARPO)
   (3) Duties and responsibilities of the RPO
   (4) ALARA Program
   (5) Personnel Monitoring Program
   (6) Training Program
   (7) Procedure for ordering, receiving and opening of packages containing radioactive material
   (8) Procedure for keeping records of radiopharmaceutical use and dosages
   (9) Procedure for developing, maintaining, and implementing written directives
   (10) QA/QC of the proposed nuclear medicine imaging and non-imaging equipment
   (11) Rules for safe use of radiopharmaceuticals
   (12) Procedure for leak testing of sealed sources
   (13) Procedure for radiation area monitoring
   (14) Procedure for minimization of contamination and/or spill
   (15) Procedure for monitoring, calculating, and controlling airborne concentrations, including procedure for performance testing of fume hood
   (16) Radiation safety procedure during Radionuclide Therapy
   (17) Procedure for hospital care and handling of radioactive patients, including procedure for release of patients after Radionuclide Therapy
   (18) Radiation safety precautions and instructions for patients
   (19) Procedure for calibration of instruments
   (20) Procedure for radioactive waste disposal and decay-in storage
   (21) Procedure for safe handling of dead persons that contain unsealed radioactive material
   (22) Emergency Plan

3. To include the Permissible Mo-99 Concentration in Section 19:

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

(a) The licensee shall determine and record the activity of each dosage of unsealed radioactive material before medical use.
   (1) For unit dose, the determination shall be made by direct measurement of radioactivity or a decay correction based on the activity or activity concentration as determined by the manufacturer or PET radioactive drug producer.
   (2) For multi-dose, the determination shall be made by direct measurement of radioactivity, by mathematical calculations, or a combination of volumetric measurements and mathematical calculations based on the measurement made by the manufacturer or PET radioactive drug producer.

(3) The licensee shall ensure that the administered dose is within the prescribed range or within ±20 percent of the prescribed dose, as applicable.

(b) For the use of Molybdenum-99/Technetium-99m, the licensee shall:
(1) Measure the Molybdenum-99 concentration in each eluate or extract when using Molybdenum-99/Technetium-99m generators for preparing a Technetium-99m radiopharmaceutical.
(2) Ensure to not administer to humans a radiopharmaceutical containing more than 150 Bq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of molybdenum-99 per mCi of technetium-99m).
(3) Keep the records for two (2) years of each measurement that includes the measured activity of the Technetium-99m and Molybdenum-99, the ratio of the measured activities, the time and date of the measurement, and the name of the individual who made the measurement for each elution or extraction of Technetium-99m.

(c) The licensee shall keep a record of the measurements required by this section in accordance with Section 43 of CPR Part 13.

4. To include (f) in Section 20:

Section 20. Personnel Monitoring

(f) The licensee shall develop bioassay procedures, for all personnel handling unsealed radioiodine, and shall submit to PNRI as part of the Radiation Safety Program. The bioassay testing shall be conducted at least quarterly, or as specified in the approved Radiation Safety Program in accordance with Section 14 of CPR Part 13.

5. To amend the provision stated in Section 22 (b) and (e):

Section 22. Possession, Use, Calibration, and Check of Dose Calibrators.

(b) A licensee shall:
(1) Test each dose calibrator for constancy with a dedicated check source upon its installation and daily before use. Testing shall be done on a frequently used setting with a sealed source, long-lived radionuclide with an activity of at least 2 MBq;
(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources of different energies, one low and one high energy, whose activities the manufacturer has determined to be within 5 percent of its stated activity; these sealed sources shall have an activity of at least 2 MBq;
(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between 0.4 MBq and the highest dose that will be dispensed; and
(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be

used. The licensee shall keep a record of this test for the duration of use of the dose calibrator.

(e) The licensee shall maintain a record of each test for two years in accordance with Section 45 of CPR Part 13, unless otherwise directed by PNRI.

6. To amend the provisions stated in Section 32 (a) and (d) and include additional requirements as Section 32 (e) and (f):

Section 32. Control of Airborne Radioactive Materials.

(a) The licensee that operates a laboratory where radioactive aerosols or gases may be produced or handled shall install, maintain, and use a dedicated nuclear medicine fume hood to provide a mechanical means to cause all air from the laboratory to flow toward the hood with a face velocity sufficient both to prevent dispersal of radioactive substances from inside the hood and to exhaust the contaminated air to the outside through appropriate filters. The fumehood shall:
   (1) Be in a negative pressure room;
   (2) Be located in a closed laboratory so that no air current can adversely affect its proper function;
   (3) Be constructed using corrosion-resistant, non-porous, non-combustible materials such as stainless steel or special composite or polymer materials;
   (4) Have an average face velocity of 125-200 fpm and a minimum face velocity of 100 fpm to ensure that no radioactive material contaminant would escape;
   (5) Have an average of four (4) to twelve (12) air changes per hour;
   (6) Have an exhaust stack with an appropriate filter system;
   (7) Be properly maintained for longer usage and to achieve the purpose of an efficient operation; and
   (8) Be tested and certified for performance by the Radiation Protection Officer (RPO) or a qualified individual at least once a year.

(d) The licensee shall conduct fume hood performance test at least semi-annually. Performance test includes, but is not limited to, measurements of average face velocity and determination of room air changes per hour.

(e) The licensee shall conduct fume hood maintenance annually. Fume hood maintenance includes, but is not limited to, cleaning, mechanical and lighting checks and change of filters (as necessary).

(f) The records of these tests shall be kept in accordance with Section 48 of the CPR Part 13 and shall be made available during inspection.

7. To amend the provision stated in Section 34 (c):

Section 34. Waste Management and Disposal of Radioactive Materials.

(c) The licensee shall return to the supplier all disused sealed sources and generators, following the provisions specified in CPR Part 4.

Published in Volume 117, No. 9 of the Official Gazette dated 1 March 2021

This order shall take effect fifteen (15) days after its publication in the Official Gazette.

APPROVED:

CARLO A ARCILLA, Ph.D.
Director

Date: 27 November 2020