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PNRI INFORMATION NOTICE 2014-02

REVISED REGULATION: CPR PART 13, "LICENSES FOR MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL"

ADDRESSEES

All PNRI licensees and applicants of unsealed radioactive material license in medical applications.

PURPOSE

The Philippine Nuclear Research Institute (PNRI) is issuing this information notice to inform current license holders and applicants of the publication of the revised Code of PNRI Regulations (CPR) Part 13, "Licenses for Medical Use of Unsealed Radioactive Material", formerly entitled "Licenses for Medical Use of Radiopharmaceuticals", in the Official Gazette Vol. 110 No. 12 on 24 March 2014. The CPR was updated to strengthen regulations and to be consistent with internationally accepted safety standards and regulatory best practices. The PNRI enjoins the recipients to review the revised CPR for applicability to their facilities and to consider actions, as appropriate.

REVISIONS TO THE CPR

The revisions to CPR Part 13 include, among others, the following changes:

I. General Provisions

Section 1 – ***Purpose and Scope***
The scope of this regulation covers licenses authorizing the medical use of unsealed radioactive material in diagnosis including in-vitro clinical and laboratory studies, therapy, and in medical research.

Section 2 – ***Definitions***
The following terminologies have been modified:

- Radiological Health and Safety Officer (RHSO) to Radiation Safety Officer (RSO);
- Assistant Radiological Health and Safety Officer (ARHSO) to Assistant Radiation Safety Officer (ARSO);

- Medical Isotopes Committee (MIC) to Radiation Safety Committee (RSC);
- Bureau of Food and Drugs (BFAD) to Food and Drug Administration (FDA);
- Radiation exposure rate to Radiation dose rate;
- Action levels to Trigger levels;
- Authorized Technologist to Nuclear Medicine Technologist;
- Qualified Expert to Medical Physicist; and
- Retraining to Refresher Course.

The following additional terms used in the document were defined:

- Accident;
- Airborne radioactive material;
- Ambient radiation dose rate;
- Contamination;
- Disused radioactive source;
- In-vitro study;
- Licensee;
- Medical Physicist;
- Radioactive material;
- Radioimmunoassay;
- Source;
- Trigger level; and
- Unsealed radioactive material.

Section 5 – ***Activities Requiring License***

License to transport unsealed radioactive material for medical use may also be granted to an institution, in accordance with CPR Part 4, "Regulations for the Safe Transport of Radioactive Material in the Philippines".

Section 6 – ***Application for a License***

In particular, the proposed radiation safety program should contain procedures addressing each of the areas listed in this section and should be submitted when applying for a license.

Section 8 – ***Terms and Conditions of License***

This section has been shortened to focus on the authority of PNRI to incorporate additional requirements and conditions, as appropriate and necessary. Also, transfer of license or any right granted under such a license must be authorized by PNRI under specific conditions. Under this regulation, the license validity will not anymore be limited to one year but for a period predetermined by PNRI.

II. Administrative Requirements

Section 14 – ***Radiation Safety Program***

The radiation safety program will now be reviewed by the licensee on an annual basis to evaluate its implementation and to incorporate applicable changes in radiation safety procedures and measures.

Section 15 – ***Radiation Safety Officer and Assistant Radiation Safety Officer***

This section stipulates that the Radiation Safety Officer (RSO) is independent from the department to ensure that the RSO has sufficient authority in implementing the

radiation safety program. The specific responsibilities of the RSO are detailed in the corresponding regulatory guide.

Section 16 – ***Radiation Safety Committee (RSC)***
The Radiation Safety Committee is required to review the occupational doses of each personnel and the administration of unsealed radioactive material at least once in every six months.

Section 17 – ***Written Directives***
A written directive by the Authorized User is now required to be made before the administration of any unsealed radioactive material to the patient, regardless if it is for diagnostic or therapeutic purposes.

III. Technical Requirements

Section 18 – ***Unsealed Radioactive Materials for Medical Use***
This section enumerates the type of unsealed radioactive material for activities under which a license pursuant to this regulation may be issued. The limits for the activities of radioactive materials for in vitro clinical and laboratory tests at any given time are also specified in this section.

Section 19 – ***Determination of Dosages of Unsealed Radioactive Material for Medical Use***
The licensee may determine the dosages of radiopharmaceuticals by performing one OR more of the methods specified in this section.

Section 20 – ***Personnel Monitoring***
The processing of personnel monitoring devices should only be done by PNRI, PNRI-licensed or PNRI-recognized dosimetry processor. For future reference, a record of the radiation doses of personnel must be maintained by the licensee.

Section 22 – ***Possession, Use, Calibration and Check of Dose Calibrators***
The procedures for testing the performance of dose calibrator were removed. The detailed description for calibrating the dose calibrator will be provided in the corresponding regulatory guide.

Section 23 – ***Possession, Use and Calibration of Radiation Detection and Measuring Instruments***
A more detailed instrument technical specification will be provided in the regulatory guide.

Section 26 – ***Surveys for Contamination and Ambient Radiation Dose Rate***
In addition to the previous requirements, the survey for removable contamination in isolation rooms after it has been vacated by a patient must also be performed.

Section 27 – ***Release of Patients after Radionuclide Therapy***
A radionuclide therapy patient can only be released if the total effective dose equivalent (TEDE) to any other individual from exposure to the patient is not likely to exceed 3 mSv. A written instruction and other pertinent information on actions recommended to maintain doses to other individual ALARA must be provided if the TEDE to any other individual is likely to exceed 1 mSv.

Section 28 – ***Safety Precautions in Handling Radioactive Patients***
This section requires that patients administered with diagnostic levels of radioactive material should be surveyed before being discharged. A patient administered with therapeutic dose and cannot be released under Section 27 must be confined in an isolation room with an appropriate radiation warning sign. The licensee must also address the control of patients and visitors in these areas.

Section 31 – ***Quality Assurance (QA) Program of Nuclear Medicine Equipment***
PNRI now requires that all nuclear medicine imaging and non-imaging equipment be subject to quality assurance program to ensure proper operating conditions and performance characteristics. A guide on quality assurance program based on the IAEA safety guides is provided in the corresponding guidance document.

Section 32 – ***Control of Airborne Radioactive Materials***
This section stipulates that the licensee should use controls to minimize airborne radioactivity in rooms where radioactive gases or aerosols are employed. Preventive maintenance must be established to ensure that the fumehood is maintained in an operable condition. The number of room air changes and face velocity of the laboratory fumehood are no longer specified in the regulation, but recommended values will be given in the regulatory guide.

Section 33 – ***Surveys of Packages Containing Radioactive Material on Receipt***
This is a new requirement. The licensee must have written procedures for the safe receipt/acceptance and opening of packages containing radioactive material, and ensure that these procedures are followed by the designated personnel.

Section 34 – ***Waste Management and Disposal of Radioactive Materials***
Used Mo-99/Tc-99m generators must be returned to the supplier/manufacturer if the generators are not decayed in storage for 60 days. This is an additional requirement to the existing radioactive waste management program.

Section 35 – ***Transport of Radioactive Materials***
Transport requirements must conform to the provisions of CPR Part 4.

VI. Training and Experience Requirements

Section 37 – ***Radiation Safety Officer (RSO) and Assistant Radiation Safety Officer (ARSO)***
To become an RSO, PNRI requires that the individual must have completed 200 hours of training courses and at least 1 year of relevant fulltime experience on radiation safety in the use of radioactive materials in nuclear medicine.

Section 38 – ***Authorized User***
The new requirement includes a certification by a medical specialty board, a 200-hour PNRI-approved radiation safety training, and at least 2 years of relevant clinical training and experience.

Section 39 – **Medical Physicist**
The new regulation requires Nuclear Medicine departments to designate a Medical Physicist whose degree of involvement is determined by the complexity of the

procedures and associated risks in the licensed facility. A more detailed description of the roles and responsibilities of the Medical Physicist is provided in the regulatory guide.

Section 40 – **Nuclear Medicine Technologist**
In addition to 6 months of relevant work experience, a 200-hour training on nuclear safety is a prerequisite to become a nuclear medicine technologist.

IV. Recordkeeping

The required records are self-explanatory. It is important to note, however, that the licensee is required to retain these records for 2 years subject to inspection by PNRI, except for the annual performance evaluation of nuclear medicine equipment which is required to be maintained for at least 5 years. A clear distinction must be made among quantities entered on these records and the units of measure must be in accordance with the measurements required by the regulation.

V. Reports and Notifications

Notifying PNRI of incidents or medical events which may have caused or threaten to cause an exposure of over 50 mSv must be done within 24 hours by any fast means of communication.

VI. Inspection and Enforcement

The PNRI Administrative Order No. 02, Series of 2011, “Regulatory Criteria for Determining Severity of Violation(s)” complements and expands the information stipulated in this chapter addressing the measures adopted by PNRI for its inspection and enforcement program. The licensee is therefore required to review in detail the information set forth in this document in order to aid their respective organizations in implementing an effective regulatory compliance monitoring program.

VII. Effectivity

Facilities previously licensed are given 2 years to fully comply with the new provisions and requirements in this revised CPR. However, new applications will be evaluated in accordance with the requirements of this CPR.

DISCUSSION

PNRI has been implementing a prescriptive regulatory approach wherein specific regulatory criteria and procedures were defined for strict compliance. However, recent developments from international regulatory practices recommended a more flexible approach towards meeting regulatory objectives. In line with this effort, PNRI has been updating its regulations which include this revised CPR Part 13.

PNRI believes that the implementation of this new approach demonstrates a high degree of confidence in its licensees, thereby giving them opportunity to take responsibility for their own decisions and attitudes towards safety within their facilities. For new applicants/licensees, it may be prudent to implement the procedures as recommended by PNRI, whereas licensees with more experience in radiation safety may revise procedures based on their own prior experience and expert judgment, consistent with the safety objectives. It is expected that this new regulatory approach will help both the licensees and the PNRI achieve more cost-effective compliance solutions.

In general, the requirements stipulated in the revised CPR Part 13 are commensurate with the degree of complexity of procedures and associated risks. A regulatory guidance document will be available in support of this revised CPR.

The CPR Part 13 Rev. 02 is now available and can be downloaded from the PNRI website (www.pnri.dost.gov.ph).

REQUIRED LICENSEE RESPONSE

The licensee is expected to direct all nuclear medicine staff to review the revised regulation and to make necessary revisions in its radiation safety program, as appropriate and applicable, to reflect the changes and additional requirements necessary for compliance.

CONTACT

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