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PNRI REGULATORY BULLETIN No. 18-01

**TRANSITORY MEASURES FOR THE DESIGNATION OF MEDICAL
PHYSICIST IN NUCLEAR MEDICINE FACILITIES**

ADDRESSEES

The addressee shall be all PNRI license holders for the medical use of unsealed radioactive material in Nuclear Medicine.

PURPOSE

This Bulletin is issued to provide guidance to the abovementioned licensees to address issues related to the implementation of the medical physicist requirement provided in Section 40 of CPR Part 13, "Licenses for Medical Use of Unsealed Radioactive Material" published in the Official Gazette on March 24, 2014. It is expected that all PNRI licensees will review this Bulletin and consider appropriate actions in order to ensure strict compliance with the PNRI regulations.

DESCRIPTION OF CIRCUMSTANCES

Over the past decade, we have witnessed a growing number of nuclear medicine facilities in the country with many remarkable technological developments of the equipment, including hybrid imaging systems, many of which have also been integrated in existing facilities. However, the use of such technical advancements is accompanied by a considerable amount of radiological risk to the patients and workers and therefore, demands for more competent and well-trained personnel to ensure safe and effective patient diagnosis, treatment and management and well-maintained equipment, among others. Medical physicists have been recognized as vital health professionals with important responsibilities related to the quality and safety of applications of ionizing radiation in medicine.

The PNRI has acknowledged that the services of medical physicists must be made available in the clinical environment such as in radiation therapy and nuclear medicine. While the role of medical physicists has long been established in radiation therapy, its corresponding role in medical imaging is often underestimated. Many nuclear medicine centers integrate modern and highly technical equipment into their facilities without access to experts for medical

physics support. As a result, the existing mechanism for safety may no longer be adequate to meet the needs of modern radiation medicine in terms of quality and safety.

Currently, there are 65 nuclear medicine facilities in the country and only a few have designated a medical physicist in their facility. The PNRI is aware of the present situation in the country, where there is an insufficient number of adequately trained medical physicists to address the needs of medical imaging and therapy, specifically in the application of unsealed radioactive materials. Although various meetings with stakeholders and interested parties have been organized in the past to resolve this problem, there are still some difficulties to implement this requirement, owing to the fact that medical physicists are also being shared with other areas in medical physics such as radiotherapy and diagnostic radiology. The resolution to this problem must be realistic, attainable, and mutually agreed upon to ensure appropriate implementation.

DISCUSSIONS

CPR Part 13 requires the designation of a medical physicist who met the education and training requirements stipulated in Section 40 of the said Part. This requirement is further established in the International Atomic Energy Agency (IAEA) Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards which was adopted by the PNRI in 2015, describing, in brief, three key roles of medical physicists in equipment calibration, quality assurance and dosimetry. The medical physicist is responsible for these activities and his or her direct involvement increases with equipment and activities involving higher complexity and with higher radiation risk.

All PNRI licensees in nuclear medicine must ensure that the provisions of the applicable Parts and Sections of the Code of PNRI Regulations and the conditions of their licenses are satisfactorily addressed to avoid unnecessary disruption of authorized activities. While these requirements may typically be well below the levels needed for good clinical practice, the minimum standards covered by the national regulations must be complied with by all licensees. To determine the degree of involvement of medical physicists in a nuclear medicine facility, the PNRI recommends the use of the guidelines set forth by the IAEA in its Human Health Reports No. 15, *Medical Physics Staffing Needs in Diagnostic Imaging and Radionuclide Therapy: An Activity Based Approach* (IAEA, 2018).

The PNRI recognizes that the shortage of medical physicists in the country today poses a serious problem in the implementation of the requirement introduced by CPR Part 13 in 2014 and as a result, many existing nuclear medicine facilities are unable to hire a medical physicist in their facilities. As a transitory measure, the PNRI would accept medical physicist/s to be named in the application for license renewal or new application under the conditions that they are preparing to comply with the one-year relevant fulltime training and work experience requirement in radiation protection, radiation dosimetry, quality assurance and

quality control, and equipment management. During their training period they should work under the responsibility of a clinically qualified nuclear medicine medical physicist recognized by the PNRI for being listed in other nuclear medicine license.

REQUIRED ACTION BY THE LICENSEES

If the licensee is unable to designate a medical physicist who met the training requirements in Section 40 of CPR Part 13, the licensee shall submit a letter to the PNRI that clearly states its commitment to comply with the requirements, including detailed action plans, strategies and timeline of activities, within the approved period of time. This letter of commitment shall be submitted to the PNRI upon application for license renewal or new application subject to the review and approval by PNRI.

If, however, the licensee/applicant finds it unnecessary to designate a medical physicist as required in Section 40 of CPR Part 13 based on their current activities, the licensee shall submit a letter to the PNRI that clearly states its justification for exemption from the requirements subject to the evaluation and approval by PNRI.

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