

Republic of the Philippines
Department of Science and Technology



PHILIPPINE NUCLEAR RESEARCH INSTITUTE

12 July 2022

PNRI INFORMATION NOTICE 2022-03

Publication of PNRI Administrative Order No. 01, Series of 2022: “Criteria for the Acceptability of Imaging Equipment Used in Nuclear Medicine”

ADDRESSEES

All PNRI licensees and applicants of license for the medical use of unsealed sources in nuclear medicine

PURPOSE

The Philippine Nuclear Research Institute (PNRI) is issuing this Information Notice to inform current license holders and applicants of the publication of the PNRI Administrative Order No. 01, Series of 2022, “Criteria for the Acceptability of Imaging Equipment Used in Nuclear Medicine” in the Official Gazette Vol. 118 No. 26 on 27 June 2022. This Administrative Order establishes the criteria for the acceptability of nuclear medicine imaging equipment which shall be complied with as a requirement for licensing in accordance with the Code of PNRI Regulations Part 13, “Licenses for Medical Use of Unsealed Radioactive Material”, Rev. 02.

DISCUSSION

Nuclear medicine relies heavily on the accurate, reproducible performance of its instrumentation. Its quality control is thus considered an essential component of optimized radiation protection by ensuring that the instrumentation provides the best possible diagnostic information while the dose which the patient receives is kept to a minimum – ALARA principle.

CPR Part 3, “Standards for Protection Against Radiation”, Rev. 02 and CPR Part 13 provide for the establishment of a comprehensive quality assurance program for all nuclear medicine imaging equipment, including measurements and verification of physical

parameters, and to implement corrective actions if measured values are outside established tolerance limits. In compliance with this requirement, all equipment used in nuclear medicine for imaging purposes must be subject to internal quality control. At the technical level, each imaging equipment is required to undergo an acceptance test when it is put into service (and, if necessary, after major modifications) and regular performance tests afterwards. This serves to ensure the proper functioning of the equipment, and to detect, without delay, any deviations from the desired or reference values during its operation.

The PNRI Administrative Order establishes the acceptability criteria for the acceptance and performance of nuclear medicine imaging equipment, including gamma camera, SPECT and SPECT/CT scanner, and PET and PET/CT scanner. The acceptability criteria define key parameters expressed as tolerance limits which indicates the minimum requirements of safe performance of the equipment. Such criteria have to be achieved during the acceptance testing, before the instrument is put into clinical use and at regular intervals throughout the lifetime of the equipment. The AO covers the tolerance limits for relevant test parameters identified for each of the equipment, but it does not specify the procedures and their respective frequencies, which are available in the referenced standards and guidelines.

To verify that the criteria for acceptability are being met, the licensee shall appoint a competent person or persons. The person(s) appointed should be a Medical Physicist or have similar standing, whose role will include signing and attesting the test results to establish compliance. Who performs the tests in practice is a matter for local arrangements and may vary with the circumstances, subject to the approval of the PNRI. When test results are found to be outside the tolerance limits, the equipment shall be taken out of service and appropriate corrective action must be performed immediately until it is restored to satisfactory performance. A record shall be maintained of the performance tests and the maintenance carried out on the equipment, and of failures and causes of unsatisfactory performance with details of their repair, for a period specified in the regulations.

The PNRI Administrative Order No. 01, Series of 2022, "Criteria for the Acceptability of Imaging Equipment Used in Nuclear Medicine" is now available and can be downloaded from the PNRI website (www.pnri.dost.gov.ph).

REQUIRED LICENSEE RESPONSE

All current holders of Radioactive Material License in nuclear medicine are directed to review the AO and to update the Quality Control Program of nuclear medicine imaging instrumentation, as appropriate and applicable, to reflect the changes and additional requirements necessary for compliance.

CONTACT

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

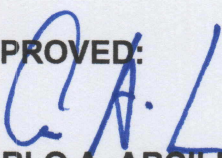

TERESITA G. DE JESUS

Head, Regulations and Standards Development Section
Nuclear Regulatory Division
Philippine Nuclear Research Institute
Tel. No. 8929-6011 to 19 local 227

ENGR. ALAN M. BORRAS, MPM

Chief, Nuclear Regulatory Division
Philippine Nuclear Research Institute
Tel. No. 8920-8796

APPROVED:


CARLO A. ARCILLA, Ph.D.
Director 

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