Quality Control Guidance

Under **Article 166** of the Education Law, Medical Physics is both a title and scope of practice protected profession, which means that only a person licensed under Article 166 can use the title "Professional Medical Physicist" and only such a person may perform the medical physics functions specified in the Education Law. The functions and/or activities described within the Medical Physics' scope of practice may only be performed by a Professional Medical Physicist (PMP) who holds a valid license and current registration. The Medical Physics' "scope of practice" is defined in two separate parts of the Education Law. Education Law **§8702** contains the general scope of practice provisions for Medical Physics, and Education Law **§8701(2)(a) through (d)** contains the scope of practice provisions for the four Medical Physics Specialty Areas.

Education Law §8702 defines the Practice of Medical Physics as follows:

The use and application of accepted principles and protocols of physics in a clinical setting to assure the correct quality, quantity and placement of radiation during the performance of a radiological procedure, so as to protect the patient and other persons from harmful, excessive or misapplied radiation. Such practice shall include, but is not necessarily limited to:

a. radiation beam calibration and characterization;
b. oversight and responsibility for patient radiation dose measurement, calculation and reporting[1];
c. oversight and responsibility for quality control (QC);
d. instrument specification;
e. optimization of image quality;
f. acceptance testing;
g. shielding design;
h. protection analysis on radiation emitting equipment and radio-pharmaceuticals; and
i. consultation with a physician to assure accurate radiation dosage and application to a specific patient.

[1] Examples include, but are not limited to, review of radiation oncology treatment plans and physics chart checks; and, for imaging studies, the estimation of absorbed dose.
Education Law §8701(2)(a) through (d) define the four Medical Physics Specialty Areas as follows:

Diagnostic radiological physics means the branch of medical physics relating to the diagnostic application of radiation, the analysis and interpretation of image quality,

performance measurements and the calibration of equipment associated with the production and use of such radiation, the analysis and interpretation of measurements associated with patient doses and exposures, and the radiation safety aspects associated with the production and use of such radiation.

Medical health physics means the branch of medical physics pertaining to the radiation safety aspects of the use of radiation for both diagnostic and therapeutic purposes, and the use of equipment to perform appropriate radiation measurements.

Medical nuclear physics means the branch of medical physics pertaining to the therapeutic and diagnostic application of radionuclides, excluding those used in sealed sources for therapeutic purposes, the analysis and interpretation of performance measurements associated with radiation imaging equipment and performance oversight of radionuclide calibration equipment associated with the production and use of radionuclides, the analysis and interpretation of measurements and calculations associated with patient organ doses, and the radiation safety aspects associated with the production and use of such radionuclides.

Therapeutic radiological physics or radiation oncology physics means the branch of medical physics relating to the therapeutic application of radiation, the analysis and interpretation of radiation equipment performance measurements and the calibration of equipment associated with the production and use of such radiation, the analysis and interpretation of measurements associated with patient doses, and the radiation safety aspects associated with the production and use of such radiation.

Note: Preparing Draft Reports of any activities related to the Scope of Practice of Medical Physics is not considered the practice of medical physics. However, the PMP must sign and accept responsibility for all reports pertaining to Scope of Practice activities.

Exemptions to Medical Physics License Requirements

As stated in Education Law §8707:

Nothing in Article 166 shall be construed to affect, prevent, or in any manner expand or limit the authority of any person otherwise authorized by law or regulation to practice any function of a medical physicist, or any department or agency authorized by law or regulation to regulate the use of radiation, nor prohibit the repair or calibration of any test equipment used by professional medical physicists by any person otherwise allowed to do so under state or federal law, nor serve to limit radiologic and/or imaging technicians or any individual otherwise authorized by law or regulation from performing

QC measurements or obtaining QC data, nor serve to limit a service engineer in the repair of radiation producing equipment nor an installation engineer in the installation of radiation producing equipment.

The law exempts selected personnel performing specified activities from medical physics license requirements:

Service engineers:

a. Repair or calibration of any test equipment used by professional medical physicists;
b. Repair of radiation producing equipment; and/or
c. Installation of radiation producing equipment.

Quality Control and Service Engineers: Performing QC measurements or obtaining QC data is not among the exempted activities permitted to be performed by a service engineer, given the safety imperative of having an independent, properly trained person (the PMP) double check the service person. However, a service or installation engineer is not prohibited from making any measurements necessary for the repair or installation of radiation producing equipment within the scope of the manufacturer's repair or installation procedures or protocols.

Radiologic technologists or imaging technicians:

a. Performing quality control tests and measurements. Note that licensed Radiologic technologists perform quality control tests under the supervision of a licensed physician or other authorized licensed practitioner as defined in **section 3501 of the NYS Public Health Law**; and/or
b. Obtaining quality control data.

Note: The term "imaging technicians" (used in Article 166 refers to unlicensed technical staff, such as medical physics residents, MR technologists, sonographers and dosimetrists.

Oversight and Responsibility for Quality Control:

The licensed practitioner is responsible for the diagnosis and treatment of the patient.

The PMP is responsible to communicate his or her results, evaluations and recommendations to the licensed practitioner and the facility. The term "facility" refers to the responsible entity or person that holds the NY State Department of Health or

New York State Department of Health and Mental Hygiene registration for x-ray or radiotherapy equipment or license for possession and use of radioactive materials.

Regarding the technical details of the work to be performed, when the QC data is collected by a licensed radiologic technologist (LRT), the PMP communicates clearly with the licensed technologist, as well as with the licensed practitioner, who retains responsibility for the supervision of the LRT. When the QC data is collected by an individual who is not a LRT, (i.e., an "imaging technician"), the PMP communicates clearly with the individual and the facility.

As a professional licensed under Title VIII of the NYS Education law, it is professional misconduct for a PMP when, "Permitting, aiding or abetting an unlicensed person to perform activities requiring a license," (section 6509(7) of the NYS Education Law), and "delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified, by training, by experience or by licensure, to perform them." (Part 29.1(10) of the Rules of the Board of Regents)

Performing QC measurements or obtaining QC data is to be specified in the facility's QC manual. Such QC data is acquired and maintained under a PMP's overall direction and control, but the PMP's physical presence is not required during all of these activities. Regardless of whether the PMP and the individual(s) acquiring QC data are employed by the same entity, a written agreement or other documentation should be executed by all parties and included in the facility's QC manual to assure QC data is obtained as specified in the QC Manual and that the required level of review by the PMP is maintained. The PMP should be available to deliver training of the personnel who acquire the QC data and address technical questions as needed. Assuring proper calibration, maintenance of the necessary test equipment and availability of necessary supplies should also be specified in the Agreement.

Specifically, the PMP holding the appropriate license in Radiation Oncology Physics, Diagnostic Radiological Physics or Medical Nuclear Physics should be providing general oversight of the technical details of the facility's QC program. The PMP has the responsibility and obligation to contribute to the facility QC Program in Radiation Therapy, Diagnostic Radiology, and Nuclear Medicine by doing the following :

1. Specifying what QC tests are to be performed;
2. Specifying the frequency of each QC test;
3. Specifying the method and procedure to be used for each QC test;
4. Specifying and approving the test equipment to be used for each QC test;
5. Specifying the competence of non-LRT personnel permitted to obtain QC data

6. Specifying the range that would be acceptable for each QC test result and the course of action, should the result be out of that range;
7. Specifying the range of results that would constitute a Critical Failure, and detailing the required steps to be taken in the event of a Critical Failure.
8. Providing selected references to currently accepted standards, such as appropriate regulatory documents, manufacturer's recommendations, accrediting body standards, official American Association of Physicists in Medicine (AAPM) or American College of Radiology (ACR) publications, or articles published in peer-reviewed journals if requested by the licensed practitioner or the facility.
9. Signing the written report. If other personnel performed QC measurements or acquired QC data, include the name(s) and credentials; and
10. Accepting responsibility for the report as if the measurements or QC data were acquired by them.

"Direct and immediate supervision" means the continuous physical presence of the supervisor during the performance of activities that are within the scope of practice of medical physics as defined in **Education Law §§8702 and 8701(2)(a) through (d),** and is only specifically required for limited permittees performing scope of practice activities as required by **section 8706(2)** of the Education law.

In addition to LRTs (who are supervised by a licensed and authorized practitioner), individuals with the following qualifications may acquire QC data **only** under the general oversight of the PMP.

1. Specifically authorized individuals (see note); and
2. Individuals holding a Limited Permit in the appropriate specialty area of Medical Physics.

Note: The PMP should exercise general oversight of individuals other than LRTs authorized by them specifically to aid in the collection of QC data. This authorization is based on the PMP documenting all items listed above in the facility QC manual, along with the qualifications of the individual acquiring the QC data. In addition to exercising general oversight, the PMP must reauthorize any such individual by personally observing them, at recommended intervals of 12 months or less. This reauthorization should document the individual's current, demonstrated competency to perform each QC task for which he or she is authorized. It should be noted that this process only enables the authorized individuals to collect data exclusively for the authorizing PMP and does not constitute an unrestricted authority to collect QC data for other PMP's.

Limited Permits

Education Law §8706(1)(a) and (b) authorizes the Department to issue a limited permit to an individual who has fulfilled all the requirements for a license as a PMP except those relating to examination or experience; or a medical physics student enrolled in a graduate or post-graduate curriculum approved by the Department.

Without exception, individuals practicing medical physics under a limited permit must be under the direct and immediate supervision of a PMP, and only practice in the specialty area of such PMP.

Although obtaining QC data is not within the protected scope of practice for the profession of medical physics, limited permittees may perform QC measurements or acquire QC data under the general oversight of a PMP.

All employers must assure that direct and immediate supervision (for scope of practice activities) and general oversight (for obtaining of QC data) is available when hiring an individual with a limited permit.

Scope of specific Medical Physics Licenses: Examples

An individual with a license in one of the medical physics specialty areas may create and approve a QC Manual within their field. However, an individual may not create or approve a QC manual for another field outside of their specialty area.

For example, only an individual who holds a license in Diagnostic radiological physics may create or approve a QC manual that addresses radiography, fluoroscopy, mammography, CT, MRI or ultrasound imaging. Such a QC manual may address the health and safety aspects of the use of radiation for diagnostic purposes and the use of equipment to perform appropriate radiation measurements.

An individual who holds a license in medical health physics may only create or approve a QC manual that pertains exclusively to “the health and safety aspects of” the use of radiation for diagnostic or therapeutic purposes, and the use of equipment to perform appropriate radiation measurements regarding the health and safety aspects thereof.

Only an individual who holds a license in Therapeutic Radiological Physics or Radiation Oncology Physics may create or authorize a QC manual that pertains to all aspects of this field. An individual who holds a license in Medical Nuclear Physics may create of approve a QC manual for radiopharmaceutical therapy, but not for other areas of radiation oncology, which are beyond their scope of practice.

An individual with a license in medical health physics may perform a radiation shielding design for any specialty area: diagnostic radiological physics, medical health physics, medical nuclear physics, or therapeutic radiological physics or radiation oncology physics. Such an individual may create or authorize only sections of a QC manual that address the health and safety aspects of the use of radiation in radiation oncology, nuclear medicine or diagnostic imaging. An individual with a license in one or more of the medical physics specialty areas may perform radiation shielding design only within his or her licensure specialty area(s).