

The Regulatory Path To Achieve QMP Requirements

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Learning Objectives

- Understand the differences between licensure and the regulatory approach.
- Learn how the regulatory approach can achieve the goal of requiring use of Qualified Medical Physicists with an appropriate scope of practice.
- Discuss ways of working with regulators to implement regulatory changes.
- Discuss potential draft regulatory language.

Licensure vs. Regulation

- Are they equivalent?

NO!

Licensure

- A technical definition: a license is a government grant of specific legal rights and obligations to the licensee.
- Once a license has been granted, it cannot be restricted or taken away without notice and a hearing, with all the attendant legal rights and appeals.
- If the State proposes to take some action against a licensee, the burden of proof rests with the State.
- Since a license grants a right to do something, it ipso facto limits or prohibits the ability of others to do that same activity.

However...

- Not all states are amenable to licensure
 - Not enough medical physicists
 - Not open to the concept

Licensure is Imperfect

- Board Certification
 - New York: Pass ABR Parts I, II
- Regulations may water down the Legislation
- Local exigencies require departure from the ideal template

Regulation

- This term is being used as short-hand for a comprehensive set of regulations governing the practice of medical physics
 - Credentials
 - Scope of practice
 - Ethics
 - Revocation of privileges

Regulation

- Attempts to use existing radiation control enabling legislation
- Enacted as any other radiation control regulation
- Should not require legislative involvement
 - No formal lobbying
 - Much less expensive

Preparation

- Enabling legislation must allow, and be interpreted to allow, comprehensive registration
- Colorado: (1) (a) The state board of health shall formulate, adopt, and promulgate rules and regulations as provided in subsections (2) and (2.5) of this section which shall cover subject matter relative to radioactive materials, including but not limited to naturally occurring radioactive materials, and other sources of ionizing radiation. The subject matter of such rules and regulations shall include, but not be limited to: Licenses and registration; records, permissible levels of exposure, notification and reports of accidents, technical qualifications of personnel; technical qualifications of mammographers, handling, transportation and storage, waste disposal, posting and labeling of hazardous sources and areas, surveys, monitoring, and financial assurance warranties.
- Interpreted as allowing for comprehensive regulation of MP

Preparation

- Enabling legislation must allow, and be interpreted to allow, comprehensive registration
- Michigan: Sec. 13521. (1) The department shall promulgate rules providing for general or specific licenses or registration, or exemption from licensing or registration, for radioactive materials and other sources of ionizing radiation. The rules shall provide for amendment, suspension, or revocation of licenses. In connection with those rules, **the department may promulgate rules to establish requirements** for record keeping, permissible levels of exposure, notification and reports of accidents, protective measures, **technical qualifications of personnel**, ...
- NOT interpreted as allowing for comprehensive regulation of MP

Lesson

- Establish good, close working relationship with the regulators
- Give advice and CONSTRUCTIVE criticism of radiation control regulations
- Ask them questions
- Be available for consultation
- Help regulators see the importance of QMP

Template

- Growing effort in Colorado since 1999
- Still sub-optimal, but Department is largely supportive
- “‘Registered medical physicist’ (RMP) means an individual who meets the applicable requirements of Appendix 2B and has current Department approval to perform medical physics activities in a designated specialty” (effective 7/1/10)

**PART 2, APPENDIX 2B: REGISTERED MEDICAL PHYSICIST
ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**

Each registered medical physicist shall be an individual who:

28.1 Has provided evidence of:

28.1.1 Current certification in a subfield of medical physics by:

- 2B.1.1.1 The American Board of Medical Physics; or
- 2B.1.1.2 The American Board of Health Physics; or
- 2B.1.1.3 The Canadian College of Medical Physics; or
- 2B.1.1.4 The American Board of Radiology in a radiological physics category; or
- 2B.1.1.5 American Board of Nuclear Medicine Science; or
- 2B.1.1.6 A recognized equivalent specialty board; and

2B.1.2 Written approval from the Department to design shielding or conduct specified medical physics activities as a qualified expert for:

- 2B.1.2.1 Radiography other than radiotherapy, designated QE(R); or
- 2B.1.2.2 Radiation therapy, designated QE(T), with training and experience in the clinical applications of radiation physics to radiation therapy.

2B.2 Or, as an alternative to fully satisfying 2B.1, is approved by the Department as a provisional registered medical physicist to assist a registered medical physicist with assigned activities of specified duration, having provided to the Department:

- 2B.2.1 An application that includes the name and signature of each registered medical physicist for whom the applicant will be working under supervision; and
- 2B.2.2 Evidence that all training and experience requirements are met to become certified as prescribed by 2B.1.1, but full certification has not yet been received.

Scope of Practice - Dx

6.5.5 Each fluoroscopic x-ray system shall have written quality control and quality assurance procedures.

6.6.5.1 The quality control and quality assurance procedures shall be consistent with 6.3.5 and shall follow:

- (1) Specifications of the manufacturer; and
- (2) Specifications of a registered medical physicist; and/or
- (3) Standards of an appropriate nationally recognized organization.

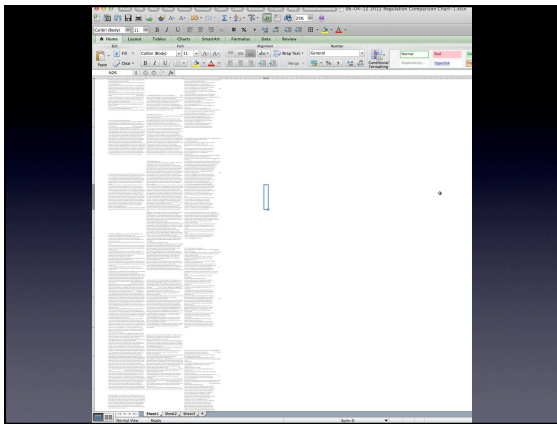
6.5.5.2 Systems shall be evaluated periodically by a registered medical physicist in accordance with standards and protocols published by nationally recognized organizations (for example, AAPM Report 4 and AAPM Report 74), unless the registered medical physicist determines that a particular recommendation of such report is not warranted for the clinical tasks for which the equipment will be used.

TX Scope of Practice - Dx

- (I) The diagnostic radiological physics specialty serves the following:
 - (A) providing evidence that imaging equipment meets specific applications and regulations of radiation safety and performance standards required by accrediting and regulatory agencies;
 - (B) acceptance testing or monitoring diagnostic imaging equipment;
 - (C) evaluating policies and procedures pertaining to radiation and its safe and appropriate application in imaging procedures;
 - (D) providing consultation in development and maintenance of a quality control program;
 - (E) measurement and characterization of radiation from diagnostic equipment;
 - (F) specification of instrumentation to be used in the practice of diagnostic radiological physics;
 - (G) providing consultation on patient or personnel radiation dose (effective dose equivalent, fetal dose equivalent, specific organ dose, deterministic, etc.) and the associated risk; and
 - (H) protective shielding design and evaluation of a diagnostic imaging facility.
- (I) conducting performance evaluations of medical radiological and fluoroscopic imaging systems, which include the following physical tests and assessments:
 - (i) kVp scale (kVp) and timer accuracy;
 - (ii) exposure reproducibility;
 - (iii) exposure range; e.g. source to image distance (SID) collimation; (iv) entrance skin exposure and exposure rate;
 - (v) beam quality;
 - (vi) image quality.

Other States - Dx

- NJ: "Fluoroscopic X-ray Systems (4) The registrant of a facility or responsible person at the facility shall have a qualified medical physicist perform periodic measurement of AKR for both typical and maximum values"
- OH: "After initial evaluations of fluoroscopic equipment have been performed, the test and evaluations in paragraph (D)(2) of this rule shall be performed by a radiation expert annually within periods not to exceed fourteen months."



Scope of Practice - Tx

24.5 Registered Medical Physicist Support.	
24.5.1	In a facility having a therapeutic radiation machine, the Registered Medical Physicist shall perform the following:
24.5.1.1	Full calibration(s) required by 24.7.16 and 24.8.19;
24.5.1.2	Protection surveys required by 24.4.1;
24.5.1.3	Supervision and review of dosimetry;
24.5.1.4	Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
24.5.1.5	Surveys of residual radioactivity required by 24.8.17;
24.5.1.6	General supervision of quality assurance, including establishing written procedures and reviewing quality assurance checks as required by 24.7.17 and 24.8.20.
24.5.1.7	Consultation with the authorized user in treatment planning, as needed; and
24.5.1.8	Calculations/assessments regarding a reportable medical event.
24.5.2	The Registered Medical Physicist shall be available for problems or emergencies consistent with the procedure specified pursuant to 24.3.7.

Revocation of Privileges

2.9.2 The Department shall periodically review and audit:
2.9.2.4 The performance of each qualified expert and/or registered medical physicist, in particular:
(1) Adequacy of shielding evaluations; and
(2) Competency in performing activities in accordance with these regulations.
2.9.6 The Department may deny, withdraw, limit or qualify its approval of any person to perform activities upon determining that such action is necessary in order to prevent undue hazard to health and safety, or for other reasonable cause.

- While not stated explicitly (yet), current practice is to review questionable cases with a number of trusted RMPs.
- The burden of proof is on the registrant to prove its case if someone makes a claim against the individual.

Ethics

- Not currently explicitly addressed in Colorado regulation
- Cases of questionable situations have been brought to the attention of a small group of RMPs (with anonymity preserved) for advice

CRCPD

- Conference of Radiation Control Program Directors
- Write Suggested State Regulations (SSR)

Part ZZ

- Part Z is a new section dealing with credentials
- Part ZZ is that part of Z dealing with QMP
- In DRAFT FORM
- Following are only as suggested by AAPM liaisons, and have not been accepted by CRCPD

PART ZZ REGISTRATION REQUIREMENTS FOR QUALIFIED MEDICAL PHYSICISTS (QMP)

Sec. ZZ.1 - Purpose and Scope. This Part provides for the approval and registration of Qualified Medical Physicists (QMP). Specifically, this Section:

- a. Establishes standards and procedures to be applied by the Agency for approving individuals as a QMP; and
- b. Establishes standards and procedures to be applied by the Agency when withdrawing its approval of a QMP.

Sec. ZZ.2 - Certification/Education/Experience Requirements. An individual shall be considered to be a QMP to practice one or more of the subfields of Medical Physics if that individual is certified in that subfield by any one of the following:

- i. The American Board of Radiology
- ii. The American Board of Medical Physics
- iii. The American Board of Health Physics
- iv. The American Board of Science in Nuclear Medicine
- v. The Canadian College of Physics in Medicine

Grandfather

- i. Individuals that have, prior to the effective date of these regulations, performed the functions of a QMP under an existing state rule or regulation, and have maintained the active status of any required licensure, approval or certification, within 3 years from date of enactment may continue to perform the functions of a QMP, or
- ii. Individuals that do not meet the requirements specified in ZZ.2.b in one of the subfields, must meet the requirements of section ZZ.2.b. of this section within 5 years from date of enactment of the regulation in order to practice as a QMP.

Sec.ZZ.4 - Suspension and Revocation of Registration

- a. The Agency may act to suspend or revoke an individual's registration as an approved medical physicist and/or therapeutic radiological physicist and remove the individual's name from the record of approval for any one or a combination of the following causes: ...

- i. Misrepresentations on application
- ii. Evading or violating an Agency regulation or order
- iii. Significant or repeated incompetence
- iv. Providing false or misleading information to the Agency
- v. Signing for an evaluation not performed or overseen
- vi. Failing to repay educational loan
- vii. Failing to meet child support orders

b. If, based upon any of the grounds in subsection (a) of this Section, the Agency determines that action is necessary to suspend or revoke the registration of an approved QMP and to remove the individual's name from the record of approved individuals, the Agency shall first notify the individual of the reason for its action and the proposed length of a suspension or revocation and shall provide an opportunity for a hearing in accordance with (cite appropriate Administrative Proceedings citation). An opportunity for a hearing shall be provided before the Agency takes final action to suspend or revoke an individual's registration.

National Registry of Medical Physicists

- The national registry is NOT equivalent to the regulatory approach
- The national registry is a tool that can be used by states in support of both regulation and licensure approaches
- It is merely a list of individuals who are certified by one of the identified boards

Licensure	Component	Regulation

What's Next?

- Late 2012: Develop model regulatory language
 - Based on existing regulations and licensure model language
- Work with CRCPD for incorporation into SSRs
- Establish list of physicists within each state to interact regularly with regulatory authorities
- Assist states to the degree desired to incorporate model into regulations

Conclusion

- Ideal licensure is the gold standard
- Ideal licensure may not be achievable for a number of reasons
- Some states will likely never have licensure
- Regulatory approach is an appropriate alternative
