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February 9, 2016

Ms. Sophie Holiday
Health Physicist / ACMUI Coordinator
U.S. Nuclear Regulatory Commission (NRC)
Washington, DC 20555-0001

Re: NRC Training and Experience Requirements for Alpha and Beta Emitters

Dear Members of the Advisory Committee on the Medical Use of Isotopes,

As experienced nuclear pharmacists and experts in the field of radiation safety education and training, we appreciate the opportunity to submit our comments on the training and experience requirements for authorized users of alpha and beta emitters.

It is discouraging to see radiopharmaceuticals with documented clinical impact not used because they are not readily available in physician treatment regimens. For example, Zevalin (Ibritumomab tiuxetan) has been approved for first line therapy against Non-Hodgkin's lymphoma, the seventh most common type of cancer. Xofigo (Radium-223 dichloride) was fast-tracked by the FDA after demonstrating an increased patient life span and pain control in prostate cancer patients. However, the regulatory restrictions on access drive oncologists to use less effective chemotherapy regimens associated with significant side effects and diminished patient outcomes.

These current alpha and beta emitting radiopharmaceuticals, and others under development, are delivered to licensed healthcare sites as patient-ready doses with no additional manipulations needed before patient administration. The needed training and experience for safe handling of these specific drugs does not appear to warrant the full 200 hours of didactic training and 500 hours handling experience.

We recommend that NRC, as part of the current rulemaking, modify the training & experience requirements for authorized users for patient ready alpha and beta emitters to a didactic program which consists of 80 hours of educational material. This will provide a strong foundation for practitioners who wish to become involved in the administration of alpha and beta emitting radiopharmaceuticals. A program such as this would also include enhancements to the distance based didactic education, including specific

requirements for experiential radiation safety hands-on exercises as well as supplemental handling experience for each specific radiopharmaceutical. A representative outline of our consensus for a training program is included as an addendum to this letter.

An addition to the user training requirements, each facility is mandated to have a radioactive materials license and radiation safety officer. With adequate training, radiation safety procedures and guidance documents in place, the risks should be minimal while providing the maximum benefit in patient care.

Sincerely,

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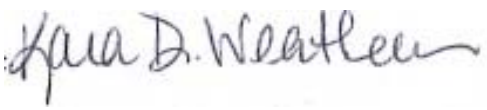

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Authorized User Training for Alpha & Beta Patient Ready Radiopharmaceuticals

Recommendation for ACMUI Subcommittee Report

Developed by:

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Summary of Needs

In that patient access to clinically meaningful therapeutics for treatment of oncologic conditions can be enhanced through better access, it is proposed that individual medical oncologists or urologists be licensed by the NRC or Agreement States for the isotope-specific radiopharmaceutical products. The licensure would consist of

1. Completion of an 80-hour didactic program in basics of radioactive materials handling suitable to alpha/beta emitting products to which access will be granted;

2. Completion of not less than 10 hours of experiential training in radiation safety techniques, protocols, and procedures;

3. Observe/participate in the administration of the specific radiopharmaceutical to not less than 3 patients.

4. Completion of not less than 4 hours of product–specific handling and patient administration techniques including record-keeping and patient counseling as provided by the radiopharmaceutical manufacturer; and

5. Addition to an existent or pending radioactive materials license with restriction in access and use to isotope, form and maximum activity.

Instructional Notes

a. *Suggest restriction to specific radiopharmaceuticals rather than a classification to maximize considerations of patient safety. For example, safe use of Ra-223 is different from safe use of Y-90.*
b. *There is no need for instruction on radiochemistry if use is restricted to patient-ready doses and there is no need for radiolabeling, reconstitution, or preparation of radiopharmaceuticals. Product quality control testing is also not needed.*
c. *Increased didactic and experiential training in radiation safety is recommended to maximize safety of patient and the general public.*
d. *As therapeutic uses do not involve imaging, training on imaging equipment is not needed. Testing and quality assurance of imaging equipment is not needed.*
e. *The requirement of dose calibrators will be variable dependent upon state requirements. Training is included. Instrumentation for contamination wipes and area surveys is included – function, testing, calculations, etc.*
f. *This training does NOT address issues specific to the use and handling of radioiodine products.*

Authorized User Didactic Training to Administer

Patient- Ready Alpha / Beta Emitting Radiopharmaceuticals

Block I: Nuclear Physics & Instrumentation: 25 hours

I. Structure and Properties of Atoms
II. Radiation and Radioactive Decay
III. Production of Radionuclides
IV. Interaction of Radiation with Matter
V. Gas-Filled Detectors
VI. Scintillation Counters
VII. Personnel Monitoring Devices

Block II: Radiation Biology: 20 hours

I. Physical Effects of Radiation
II. Chemical effects of Radiation
III. Cellular Effects of Radiation
IV. Biological Effects of High Dose Radiation
V. Biological Effects of Low Dose Radiation
VI. Therapeutic Application of Particulate Radiation

Block III: Regulations and Radiation Protection: 25 hours

I. Characteristics of Ionizing Radiation
II. Definitions of Radiation Measurement
III. Principles of Radiation Protection
IV. Personnel Monitoring & Safety Precautions
V. Regulatory Agencies
VI. Documentation and Regulatory Reporting
VII. Sealed Reference Sources
VIII. Area Monitoring
IX. Waste Management & Disposal
X. Packages containing Radioactivity

Block IV: Mathematics Pertaining to Use & Measurement of Radioactivity: 10 hours

Includes fundamental calculations: decay equation, half-value layers, exposure calculations, instrumentation needs.

Note: The traditional Radiochemistry material is not included here as the intended Authorized User will not be mixing, radiolabeling, or preparing patient doses. All radiopharmaceuticals will be received in patient-specific, ready-to-inject unit dose form.

Name of Trainee (Please print)

Assignments

	Operator	Supervisor
1. Use basic operational functions of GM meters.	_____	_____
2. Use basic operational functions of dose calibrator.	_____	_____
3. Perform area wipe test for contamination.	_____	_____
4. Perform regulatory performance checks of SCA / MCA	_____	_____
5. Perform area-monitoring (surveys) for contamination.	_____	_____
6. Perform decontamination procedure in a contaminated area.	_____	_____
7. Dispose of radioactive waste and radioactive labels.	_____	_____
8. Radioactive materials package check-in procedure.	_____	_____
9. Determine appropriate patient-specific dose/ dose volume for ordering and administering radiopharmaceutical doses.	_____	_____
10. Know regulatory requirements for, and how to arrange for, calibration of survey meters.	_____	_____
11. Perform regulatory requirements for dose calibrator performance. (If applicable)	_____	_____
12. Take appropriate steps to ensure that the right patient receives	_____	_____
the right drug, in the right dosage, at the right time, via the right route of administration	_____	_____
13. Interpret radioactive material license, applications, amendments.	_____	_____
14. Locate applicable state/federal regulations for handling radioactive materials	_____	_____
15. Demonstrate the proper selection, placement and handling of radiation dosimetry devices.	_____	_____
16. Compile and maintain appropriate documentation to meet regulatory requirements	_____	_____

Name of Supervisor *Signature* *Date*

_____

Licensed Facility Name

_____

Mailing Address

_____

City, State Zip

Date(s) of Training

Biographical Information

Nicki L. Hilliard, PharmD, MHSA, BCNP, FAPhA

Dr. Hilliard was the manager and radiation safety officer in a nuclear pharmacy for 7 years before coming to UAMS to start a nuclear pharmacy education program. In the past 30 years she has taught thousands of authorized users both at the University and through the Nuclear Education Online program. Among her numerous awards she has received the William H. Briner Distinguished Achievement in Nuclear Pharmacy Practice and the American College of Nuclear Medicine Personal Mentor of the Year.

Kara D. Weatherman, PharmD, BCNP, FAPhA

Dr. Weatherman is a Board Certified Nuclear Pharmacist, with experience in both operational and clinical aspects of nuclear pharmacy practice prior to moving to academia as a member of the nuclear pharmacy program at Purdue University College of Pharmacy in 1998. Through her faculty appointment and as Director of Nuclear Pharmacy Programs at the College, she has focused on the development and implementation of various authorized user training programs, both via live and distance based education. In addition, she coordinates Purdue's continuing education program in nuclear pharmacy and maintains a research program in areas relating to nuclear pharmacy practice.

Kristina Wittstrom PhD, RPh, BCNP, FAPhA

As a Board Certified Nuclear Pharmacist since 1983, Dr. Wittstrom has extensive experience in operating a nuclear pharmacy both as manager and RSO. Her nuclear experience combined with a doctorate in adult education supports nuclear science education at the University of New Mexico in the classroom, the dispensing pharmacy and in the online environment.