PHARMA-LOGIC
THE LOGICAL CHOICE

P-7

April 23, 2007

Licensing Assistance Section
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03033965

Re: License Number 37-30219-01MD

Mail control # 140351

Dear Tom Thompson,

This letter is an attestation of Robert Cole's completion of the requisite 700 hours of didactic and experiential training necessary to attain an Authorized User status. Robert has completed the UAMS/University of New Mexico Authorized User Program, a structured educational program which covers instrumentation, DOT/NRC requirements for handling and shipping of radioactive materials, radiobiology, radiopharmaceuticals, radiation safety, radiation physics, etc. He has obtained over 500 hours of experiental education under my direct preceptor supervision, performing tasks such as receiving packages and preparing shipments, reading survey meters, personnel monitoring dosimetry, dose calibrator constancy/linearity/accuracy, waste management, etc. With this letter is a listing of topics covered and amount of time devoted to each topic. After reviewing each topic, the student is given a chance to ask questions prior to being evaluated on his knowledge and performance of that topic. I have already sent you a copy of his certificate of completion of the course, but I am forwarding to you a copy of the Radiopharmacy Experiential Education Program Workbook so that you can see the comprehensive nature of the program.

Should you have any further questions, please call me at (800) 576-7319.

Sincerely,

Laurie Stallings

Laurie Stallings, PharmD, BCNP
Pharmacy Manager
PharmaLogic Penn Ltd

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140351

NMSS/RGN1 MATERIALS-002

RADIOPHARMACY EXPERIENTIAL EDUCATION PROGRAM WORKBOOK

Kristina M. Wittstrom, RPh, BCNP
Radiopharmacy Education
College of Pharmacy
University of New Mexico Health Sciences Center
Albuquerque, New Mexico

FORWARD

RADIOPHARMACY EXPERIENTIAL EDUCATIONPROGRAM

Radiopharmacy is a specialized pharmacy practice area. The Nuclear Regulatory Commission, the state radiological health agencies and/or state Boards of Pharmacy have established requirements for Authorized Nuclear Pharmacist (ANP) education and training. In addition to the traditional pharmacy education and licensure, the radiopharmacist must complete a minimum of 700 hours of specialized training to become an Authorized Nuclear Pharmacist. ANP education and training consists of two components: a structured didactic educational program (200 hours) and a structured, supervised experience in a radio pharmacy (500 hours).

This program is intended to serve as a structured guide to the supervised experience. It must be used under the supervision of an Authorized Nuclear Pharmacist preceptor who has completed preceptor training. Each area of competency should follow the general progression:

1) Explanation and demonstration of a skill to the student
2) Student practices the skill under close supervision and with preceptor feedback
3) Student becomes responsible for performing the task with the preceptor available for supervision and support.
4) Preceptor assesses the student's level of competency.

Upon completion of the program, the student will achieve a level of overall competency sufficient to independently operate a radiopharmacy.

RADIOPHARMACY EXPERIENTIAL EDUCATION PROGRAM
TABLE OF CONTENTS

STATEMENT OF OBJECTIVES

Upon completion of in the Radiopharmacy Experiential Education Program, the student should be able to:

1. Demonstrate competency in operating and testing instruments routinely used in radiopharmacy practice.
2. Demonstrate competency in preparing, receiving and delivering packages containing radioactive materials.
3. Demonstrate competency in performing and managing routine radiation safety tasks and unanticipated events.
4. Demonstrate competency in preparing and dispensing routine radiopharmaceuticals.
5. Demonstrate competency in performing quality control testing
6. Demonstrate competency in maintaining professional standards of practice for environmental quality assurance.
7. Demonstrate competency in compounding and dispensing radioactive iodine.
8. Describe a typical day in a nuclear medicine department.

INFORMATION FOR PRECEPTORS

1. Review the Radiopharmaceutical Experiential Education Program training modules before the student begins the clerkship. Be prepared to assist the student to complete the module "Orientation to a Radiopharmacy" within the first few days.

2. Each module has a general overview of the tasks to be completed with a "sign-off" space for both the preceptor and the student. All modules must be completed to successfully finish the program. The preceptor signature represents a satisfactory assessment of the student's competency in performing each task.

3. Working with the student, establish a general outline of the clerkship. Modules do not have to be completed in any particular order. A sample schedule has been included for reference.

4. Discuss the preceptor's and the student's expectation of the clerkship. Take the time to be thorough now, so that there are no "surprises" later.

5. The student must be properly instructed and supervised in all procedures. Do not allow the student to perform any tasks for which they have not been trained. The preceptor may delegate training responsibilities to another individual, but the preceptor must make the final competency assessment.

6. The student and the preceptor should meet daily for about 1 hour to evaluate progress and to address any questions. Be available for discussions.

7. The preceptor and the student should meet weekly for about 2 hours to review the student's weekly progress and to plan the activities for next week. It is recommended that this meeting be held off-site or at a time when distractions are minimized. A form is enclosed for the student's use.

8. A brief E-mail of the student's progress should be sent to the Radiopharmacy Experiential Coordinator each week.

9. Complete the Student Evaluation form. The evaluation should be completed and discussed with the student prior to the end of the clerkship. Evaluations should be mailed to the Radiopharmacy Experiential Coordinator.

10. Any questions or concerns should be discussed with the Radiopharmacy Experiential Coordinator.

Kristina Wittstrom, RPh, BCNP
Radiopharmacy Experiential Coordinator
Radiopharmacy Education
College of Pharmacy
University of New Mexico Health Sciences Center
Albuquerque, NM 87131

505-272-3661
FAX 505-272-4721

RADIOPHARMACY EXPERIENTIAL TRAINING
SUGGESTED TIMELINE

MODULE	MODULE NO.	Hours STUDY TIME	Hours PRACTICE & PERFORM	Hours ASSESSMENT EVALUATION
Orientation to a Radiopharmacy	I	12	8	1
Personnel Monitoring Dosimetry	IV.1	2	5	1
Survey Meters	II.3	4	8	1
Waste Management	IV.4	4	10	1.5
Receiving Packages	III.2	3	10	1.5
Preparing Shipments	III.1	3	10	1.5
Introduction to Radiopharmaceuticals	V.1	6	15	2
Area Wipes and Surveys	IV.2	4	10	2
Emergency Events	IV.3	2	3	1
Dose Calibrator Constancy	II.1.a	2	5	1
Quality Control	V.4	5	15	1.5
Ordering Radiopharmaceuticals	V.6	3	10	2
Dose Calibrator Accuracy	II.1.b	2	3	1
Quality Assurance	V.5	10	20	2
Dose Calibrator Geometry	II.1.c	2	4	1
Dose Calibrator Linearity	II.1.d	2	5	1
Scintillation Detector Calibration	II.2.a	2	10	1.5
Sealed Source Inventory	II.4.a	2	3	1
Sealed Source Leak Testing	II.4.b	3	4	1
Technetium Generators	V.2	5	10	2
Compounding and Dispensing	V.3	14	30	2
Scintillation Detector FWHM	II.2.b	2	4	1
Scintillation Detector Efficiency	II.2.c	2	4	1
Scintillation Detector MDA	II.2.d	2	4	1
Compounding and Dispensing	V.3.	14	30	2
Nuclear Medicine Department	VII	24	15	1.5
Compounding and Dispensing	V.3	14	30	2
Na Iodine handling	VI	10	15	2
	Total Hours	160	300	40

SUGGESTED TRAINING PROCEDURE

I. **Student** reviews information and references applicable to the specific task. Include radioactive materials license commitments, regulations and textbooks as appropriate.

II. **Student and preceptor** discuss the specific task. Discussion should include:

A. The what, why and how of the task
B. A review of the student's understanding of theory applicable to the task
C. The critical steps involved in the task
D. Questions and/or concerns about the task

III. **Preceptor** teaches the student how to perform the task.

Student	Preceptor
Observes preceptor	Demonstrates task
Practices task	Instructs in task performance
Demonstrates task	Observes performance
Demonstrates competency	Assess competency

STUDENT PERFORMANCE & PROGRESS EVALUATION

Name of Student: _____

Name of Preceptor: _____

Experiential Site: _____

Preceptor: Please comment on, and then score, the student's competencies using the scale listed below. It is best to discuss this with the student at the beginning of the clerkship. Complete and sign the evaluation. Discuss the evaluation with the student prior to the last scheduled day of the clerkship.

Upon completion of the clerkship, the student should demonstrate a level of competency with that expected of a licensed nuclear pharmacist.

Levels of Competency

1 Principles discussed only, competency not demonstrated.

2 Student did **not** achieve minimal acceptable level of competency, **unable** to perform adequately even under **close** supervision and **frequent** intervention.

3 Achievement of a level of competency at which the student is able to recognize major principles, and perform under **close** supervision with **frequent** intervention.

4 Achievement of a level of competency at which the student is able to discuss major principles and perform with **minimal** supervision and **infrequent** intervention.

5 Achievement of a level of competency at which the student is able to perform **independently** and without intervention. Has developed competencies adequate for an Authorized Nuclear Pharmacist and consistent with professional radiopharmacy practice.

I. Instrumentation Competency: Assess the student's ability to understand and to effectively use instruments routinely found in a radiopharmacy to measure and detect radioactivity.

Instrumentation Competency Score: (circle one) 1 2 3 4 5

II. Competency in Handling Packages Containing Radioactive Material: Assess the student's ability to safely handle packages containing radioactive materials in compliance with DOT regulations.

DOT Competency Score: (circle one) 1 2 3 4 5

III. Radiation Safety Competency: Assess the student's ability to understand and effectively use good radiation safety techniques with accurate record keeping.

Radiation Safety Competency Score: (circle one) 1 2 3 4 5

IV. Compounding and Dispensing Competency: Assess the student's understanding of compounding, dspensing, quality control and quality assurance procedures with accurate record keeping.

Compounding & Dispensing Competency Score: (circle one) 1 2 3 4 5

V. Overall Assessment: Assess the student's overall understanding and competency in routine tasks performed in a radiopharmacy.

Overall Competency Score: (circle one) 1 2 3 4 5

Date: _____

_____ _____

Signature of Student Signature of Preceptor

INFORMATION FOR STUDENTS

1. Contact the preceptor prior to the starting date of the clerkship by telephone or, preferably make an on-site visit. The student should get information on where and when to report on the first day.

2. Review the Radiopharmacy Experiential Education Program training modules before beginning the clerkship. Be prepared to complete the "Orientation to a Radiopharmacy" module within the first few days.

3. Each module has a general overview of the tasks to be completed with a "sign-off" space for both the preceptor and the student. **All modules must be completed to successfully finish the program.**

   Each module contains self-assessment questions, references and example procedures where appropriate to be used as references. This information should be reviewed before beginning any specific task.

4. Discuss your expectations of the experiential program with your preceptor. Take the time to be thorough now to prevent "surprises" later.

5. Working with the preceptor, establish a general outline of the clerkship. Modules do not have to be completed in any particular order. A sample schedule is included for reference.

6. Keep a log of questions that may arise when the preceptor is not available. Save the questions for discussion later.

7. The student must be properly instructed and supervised in all procedures. Do not accept professional tasks that are inconsistent with training.

8. You should meet with your preceptor daily for about 1 hour to evaluate your progress and to address any questions.

9. A weekly meeting of 2 hours should be scheduled to review the week and plan the next week. A form is enclosed for the student's record.

10. You must send a brief E-mail of your progress to the Radiopharmacy Experiential Coordinator each week.

11. Upon completion of the Radiopharmacy Experiential Education Program you must complete the Student Evaluation of Preceptor form and return it to the Radiopharmaceutical Experiential Coordinator.

12. Any questions or concerns should be discussed with the Radiopharmacy Experiential Coordinator.

Kristina Wittstrom, RPh, BCNP
Radiopharmacy Experiential Coordinator
Radiopharmacy Education
College of Pharmacy
University of New Mexico Health Sciences Center
Albuquerque, NM 87131

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WEEKLY PROGRESS REPORT

STUDENT:_____ PRECEPTOR:_____

WEEK ENDING:_____ PHARMACY LOCATION:_____

Weekly Accomplishments:_____

_____

_____

_____

_____

Goals for Next Week:_____

_____

_____

_____

_____

Questions or comments:_____

_____

_____

_____

Retain copy for your records.

FAX to: Kristina Wittstrom, Radiopharmacy Experiential Coordinator, 505-272-4721

Student's Evaluation of Radiopharmacy Preceptor

Preceptor_____ **Date** _____

Student-Name_____ **Clerkship Dates**_____

The radiopharmacy clerkship, which serves as experiential training for the Pharm.D. candidate, should provide a wide range of activities and experiences where academic knowledge is applied to radiopharmacy practice. The role of a preceptor is to enhance the Pharm.D. candidate's knowledge, skills, and attitudes necessary for the provision of radiopharmacy services.

To assess the performance of a preceptor, feedback from students is important. Please evaluate your preceptor and the clerkship in the following areas: student development, clerkship content, clerkship site resources, and preceptor professionalism.

I. Student Development

Preceptors should cultivate the student learning process through timely, constructive feedback, encouragement of critical thinking, the use of creative learning techniques, and, if applicable, participation in research. How would you characterize your preceptor in the following areas?

A. *Feedback*

1. Provided timely feedback regarding my performance.

Always				Never
5	4	3	2	1

2. Gave constructive feedback for improving my performance.

Always				Never
5	4	3	2	1

B. *Critical Thinking and Integration of Prior Knowledge*

3. Encouraged independent problem solving.

Always				Never
5	4	3	2	1

4. Enhanced my ability to recognize radiation safety issues.

Yes, significantly				No, not at all
5	4	3	2	1

5. Required me to use evidence and data to support my answers.

Always				Never
5	4	3	2	1

6. Identified gaps/weaknesses in my knowledge base and worked with me to correct them.

Excellent				Poor
5	4	3	2	1

7. Allowed me to progressively accept more responsibility.

Yes, significantly				No, not at all
5	4	3	2	1

8. Respected me for my knowledge and skills.

Yes, significantly				No, not at all
5	4	3	2	1

C. *Communication Skills*

9. Encouraged me to use and develop strategies to effectively elicit information from others.

Yes, significantly				No, not at all
5	4	3	2	1

10. Encouraged me to use terminology appropriate to the people to whom I was speaking.

Always				Never
5	4	3	2	1

11. Encouraged me to ask questions.

Always				Never	Not Applicable
5	4	3	2	1	

D. *Creative Learning Techniques*

12. Fostered an environment in which I was able to cooperate and learn from others (e.g. physicians, technologists, and other health care professionals).

Yes, significantly				No, not at all	Not applicable
5	4	3	2	1	

Comments for preceptor development:

II. Clerkship Content

Experiential clerkships are to be structured with clear expectations and a fair grading system. Clerkship assignments should compliment the on-site learning experience. Please evaluate the following:

13. Expectations and objectives were clearly defined at the beginning of the clerkship.

Strongly Agree				Strongly Disagree
5	4	3	2	1

14. The preceptor worked with me to develop time management skills for completing activities and assignments during the clerkship.

Strongly Agree				Strongly Disagree
5	4	3	2	1

15. The assignments complimented the clerkship content.

Strongly Agree				Strongly Disagree
5	4	3	2	1

16. The evaluation system used for this clerkship adequately measured my performance.

Strongly Agree				Strongly Disagree
5	4	3	2	1

Comments for clerkship content:

III. Clerkship Site Resources

The physical layout, support staff, and educational materials available on premises must facilitate, and not impede, the educational process.

Please evaluate the following:

17. The physical layout of the clerkship site, including noise, lighting, space and temperature, was conducive to my educational experience.

Strongly Agree				Strongly Disagree	Not applicable
5	4	3	2	1	

18. The staff and other health care professionals at the clerkship site enhanced my educational experience.

Strongly Agree				Strongly Disagree	Not applicable
5	4	3	2	1	

19. The resource materials available met my needs for the clerkship.

Strongly Agree				Strongly Disagree	Not applicable
5	4	3	2	1	

Comments for clerkship site resources:

IV. Preceptor's Professionalism

The preceptor should exemplify professional behavior in all aspects of their practice. The preceptor's attitudes and professional interactions should excite students about the practice of pharmacy. How would you characterize the preceptor in each of the following dimensions?

20. Ability to promote pharmacy in a positive light.

Excellent				Poor
5	4	3	2	1

21. Encouraged me to participate in professional activities (e.g. professional organizations, seminars, etc.).

Often				Seldom
5	4	3	2	1

22. Accessibility for students to ask questions and seek guidance.

Readily Accessible				Never Accessible
5	4	3	2	1

23. Interacted with students in an appropriate and professional manner.

Strongly Agree				Strongly Disagree
5	4	3	2	1

Comments for preceptor's professionalism:

V. Preceptor's Skills Inventory

In some clinical settings, preceptors physically assess patients for their response to drug therapies. All preceptors should possess good communication and interaction skills. Please evaluate the preceptor on the following:

A.. *Communications Skills*

24. Ability to explain.

Excellent				Poor
5	4	3	2	1

B. *Health Care Provider Interactions*

25. Ability to practice in an appropriate and professional manner with other health care personnel.

Excellent				Poor
5	4	3	2	1

26. Encouraged me to respond to drug-related questions and provide additional information or education to other health care providers when appropriate.

Always				Never	Not Applicable
5	4	3	2	1	

D. Skills and Knowledge

27. Overall knowledge and skill of the preceptor.

Excellent				Poor
5	4	3	2	1

28. Overall rating as a preceptor.

Excellent				Poor
5	4	3	2	1

Comments for preceptor's skills inventory:

We would also appreciate any feedback from you regarding the usefulness of this preceptor evaluation form. Please feel free to include any comments you may have in the space below.

Thank you for your time in completing this important evaluation.

PLEASE FEEL FREE TO COMMENT ON ANY OTHER ASPECT OF THE CLERKSHIP.