Nuclear Pharmacy, Part II: Nuclear Pharmacy Practice Today

James A. Ponto and Joseph C. Hung

Department of Radiology, University of Iowa Hospitals and Clinics and College of Pharmacy, University of Iowa, Iowa City, Iowa; and Nuclear Medicine, Department of Diagnostic Radiology, Mayo Clinic, Rochester, Minnesota

Objective: Nuclear pharmacy is a specialty within the profession of pharmacy that focuses on the proper use of radiopharmaceuticals. This article reviews various features of contemporary nuclear pharmacy practice. After reading this article the nuclear medicine technologist should be able to: (a) describe nuclear pharmacy training and certification; (b) discuss nuclear pharmacy practice settings; (c) discuss nuclear pharmacy practice activities; (d) list professional organizations; and (e) describe activities associated with job satisfaction. In addition, the reader should be able to discuss regulatory issues of current concern.

Key Words: nuclear pharmacy; professional practice; radiopharmacy

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Nuclear pharmacy (also referred to as radiopharmacy) is the specialty practice of pharmacy that seeks to improve and promote health through the safe and effective use of radioactive drugs for diagnosis and therapy. The history and development of nuclear pharmacy practice have been reviewed previously in this journal (*1*).

Contemporary nuclear pharmacy practice, regardless of practice setting, continues to revolve around the radiopharmaceutical product, especially preparation, quality control testing and dispensing. However, nuclear pharmacists increasingly are becoming involved in patient-focused activities, embracing many of the concepts of pharmaceutical care developed in other areas of pharmacy practice. This article reviews the current state of nuclear pharmacy practice in the US and describes regulatory issues of current concern. Table 1 provides a list of commonly used abbreviations related to nuclear pharmacy.

NUCLEAR PHARMACY TRAINING AND CERTIFICATION

Nuclear pharmacists are specialists who must gain certain knowledge and skills beyond those of general practice pharmacists. To aid educators and to assure compliance with regulations regarding the training of nuclear pharmacists, documents have been prepared that describe the didactic knowledge base and the practice experience components that should be included in a nuclear pharmacy training program. The Section on Nuclear Pharmacy Practice of the American Pharmaceutical Association (APhA) has developed a *Syllabus for Nuclear Pharmacy Training* that details topics for didactic instruction and components for experiential training along with the suggested number of contact hours for each major area of nuclear pharmacy practice (*2*). The American Society of Health-System Pharmacists (ASHP) also has developed standards for residency training in nuclear pharmacy (*3*). These standards include the qualifications of the training site, the nuclear pharmacy service, the program director and preceptors, as well as the qualifications of the applicant. Standards for the residency program itself also are presented, including detailed goal statements and associated educational objectives.

Pharmacists may receive the training necessary to enter the practice of nuclear pharmacy in several ways (*4*,*5*). Nuclear pharmacy training programs have been established in various schools of pharmacy (Table 2). Several these pharmacy schools offer a series of undergraduate elective courses to fulfill the didactic requirement, while practice experience is attained through a nuclear pharmacy within the school or through summer internship programs associated with a licensed nuclear pharmacy. Several schools of pharmacy also offer postgraduate education, such as an MS or PhD degree program in nuclear pharmacy, although some of these postgraduate nuclear pharmacy programs focus on research and do not provide practice training per se.

The estimated 25–30 graduates from college-based nuclear pharmacy training programs, however, are far less than the national demand of $>$ 100 nuclear pharmacists per year (*4*). Hence, other nuclear pharmacy training programs are an important alternative to college-based programs (Table 3). These alternative programs typically provide at least 200 h of didactic coursework (live and/or videotape) to be complemented with at least 500 h of experiential training in a licensed nuclear pharmacy. Currently, the majority of nuclear pharmacists entering the field have received their nuclear pharmacy

For correspondence or reprints contact: James A. Ponto, MS, BCNP, Division of Nuclear Medicine, University of Iowa Hospitals and Clinics, 200 Hawkins Dr., Iowa City, IA 52242; Phone: 319–356–2741; E-mail: james-ponto@uiowa.edu.

TABLE 1
List of Commonly Used Abbreviations

APhA	American Pharmaceutical Association
ASHP	American Society of Health-System Pharmacists
BCNP	Board Certified Nuclear Pharmacist
BPS	Board of Pharmaceutical Specialties
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice
FDA	Food and Drug Administration
FDAMA	Food and Drug Administration Modernization Act
NABP	National Association of Boards of Pharmacy
NANP	National Association of Nuclear Pharmacies
NRC	Nuclear Regulatory Commission
PET	positron emission tomography
PTCB	Pharmacy Technician Certification Board
RDRC	Radioactive Drug Research Committee
SNM	Society of Nuclear Medicine

TABLE 3
Other Nuclear Pharmacy Training Programs*

Nuclear Pharmacy Certificate Programs
- Ohio State University
- Purdue University

Nuclear Pharmacy Residencies
- Medical University of South Carolina
- State University of New York at Buffalo
- US Army

Other Authorized Nuclear Pharmacist Training Programs
- Mallinckrodt Medical (through Nuclear Medicine Associates)
- Syncor International Corporation

*Adapted from Hilliard (*4,5*).

training through certificate or other authorized nuclear pharmacist training programs.

Regardless of the educational approach to training, nuclear pharmacists can demonstrate their competency by gaining certification in nuclear pharmacy. The Board of Pharmaceutical Specialties (BPS) recognized nuclear pharmacy as the first specialty in pharmacy practice in 1978 and has offered certification examinations since 1982. Prerequisites for the certification examination include graduation from an accredited college of pharmacy, valid license to practice pharmacy, and at least 4000 h of nuclear pharmacy training/experience. Successful applicants earn the status of Board Certified Nuclear Pharmacist (BCNP). Recertification, by examination or by satisfactory completion of a BPS-approved continuing education program, is required every 7 y. As of 1999, 431 nuclear pharmacists in the US were BCNPs (*6*).

NUCLEAR PHARMACY PRACTICE SETTINGS

In the early years of nuclear pharmacy, most nuclear pharmacists practiced in institutional settings, primarily academic, tertiary care medical centers where nuclear medicine departments developed. Hospital nuclear pharmacists often have advanced degrees appropriate for participation in the institution's mission of patient care service, teaching and research. In addition to responsibilities for providing radiopharmaceutical products and services and for participating in research, these nuclear pharmacists typically provide formal instruction in nuclear pharmacy topics to resident physicians, pharmacy students, nuclear medicine technology students and others (*7*).

TABLE 2
College-Based Nuclear Pharmacy Programs*

- University of Arkansas
- Butler University
- Duquesne University
- Massachusetts College of Pharmacy
- Mercer University
- University of New Mexico
- University of Oklahoma
- Purdue University
- Medical University of South Carolina
- Temple University
- University of Utah

*Adapted from Hilliard (*4,5*).

Currently, however, the majority of nuclear pharmacists practice in centralized nuclear pharmacies that provide unit doses of radiopharmaceuticals to various hospitals, clinics and offices within a nearby geographic area (*8*). Although a few of these centralized nuclear pharmacies are affiliated with not-for-profit institutions, most are commercial nuclear pharmacies. Of the $>$ 300 commercial nuclear pharmacies in the US today, nearly 65% are members of 1 of 3 major chains (i.e., Syncor, Mallinckrodt, Nycomed/Amersham/MediPhysics) while the remainder are members of small chains (e.g., Central Pharmacy Services Inc., Geodax Technologies Inc.) or are independents (*5,9*). It is estimated that 70%–80% of all radiopharmaceutical doses are dispensed through commercial nuclear pharmacy channels (*8*).

A few nuclear pharmacists are employed in other settings, such as academia, industry or government. Overall, of the estimated 900–1000 nuclear pharmacists in the US, approximately 850 work in commercial nuclear pharmacy facilities (*8*), approximately 75 work in institutional nuclear pharmacies (*5*), and the remainder work in other settings.

NUCLEAR PHARMACY PRACTICE

Nuclear Pharmacy Practice Domains

The practice of nuclear pharmacy is composed of several domains related to the provision of nuclear pharmacy services. These domains, determined by formal task analyses, serve as the basic structure for the APhA's *Nuclear Pharmacy Practice Guidelines* (*5,10*). The *Guidelines* include lists of tasks and their related knowledge statements for each domain. Briefly, the 9 general domains and their primary tasks are:

1. *Procurement* includes the ordering, receipt, storage and inventory control of radiopharmaceuticals, ancillary drugs, supplies and related materials.

2. *Compounding* includes generator elution, kit reconstitution, preparation of products not commercially available, and other radiolabeling procedures.
3. *Quality assurance* includes functional checks of instruments, equipment and devices and determination of radiopharmaceutical quality and purity (e.g., radionuclidic purity, radiochemical purity, chemical purity, particle size, sterility, apyrogenicity, etc.).
4. *Dispensing* includes the filling of prescription orders by preparing bulk vials or individual patient doses for delivery to the user.
5. *Distribution* includes the packaging, labeling and transport of radiopharmaceuticals to the user.
6. *Health and safety* includes radiation protection practices and proper handling of hazardous chemicals and biological specimens.
7. *Provision of information and consultation* includes communicating radiopharmaceutical-related information to others; this information may be of general applicability (e.g., teaching), of organizational value (e.g., policies and procedures), or of pertinence to the care of specific patients.
8. *Monitoring patient outcome* includes a variety of activities that help assure optimal outcomes for individual patients, such as assuring that patients receive proper preparation before radiopharmaceutical administration, and assuring that clinical problems (e.g., drug interactions) are prevented or recognized, investigated and rectified.
9. *Research and development* includes laboratory testing of new radiopharmaceuticals, new compounding procedures, or new quality control methods, and participation in clinical trials of radiopharmaceuticals.

Recent evolution of nuclear pharmacy practice has emphasized advancements in activities associated with Domains 7 and 8. Several examples of current efforts in these areas are highlighted in the following subsections.

Pharmaceutical Care. Pharmaceutical care has become an important component of general pharmacy practice. It can be defined as a practice in which the pharmacist takes responsibility for a patient's drug therapy needs for the purpose of positive patient outcomes. On the surface, the specialty of nuclear pharmacy, which deals primarily with diagnostic radiopharmaceuticals, may appear to fall outside the precepts of pharmaceutical care. However, when viewed more broadly, many activities routinely performed by nuclear pharmacists directly or indirectly contribute to positive patient outcomes (*7*).

Drug Interventions and Interactions. Increasingly, nuclear medicine procedures use pharmacological interventions, such as dipyridamole or adenosine for myocardial perfusion studies, sincalide or morphine for hepatobiliary studies, and captopril or furosemide for renal studies. Nuclear pharmacists help develop protocols for the drug intervention procedure, provide information on dosing, storage, adverse reactions, contraindications, etc., and assist in selecting the optimal drug when several similar drugs are available. Nuclear pharmacists evaluate the patient for interfering drugs before a procedure (e.g., theophylline before a pharmacological stress myocardial perfusion study) or trouble-shoot scans with unexpected biodistribution (*11*).

Radiation Protection. Nuclear pharmacists provide a variety of information needed for patient-specific care. Applying the new release criteria, recently issued by the NRC (*12–14*) and adopted by many agreement states, nuclear pharmacists provide patient-specific calculations and radiation protection recommendations for patients treated with therapeutic radiopharmaceuticals. In situations involving pregnancy (e.g., a perfusion lung scan requested for a pregnant woman), nuclear pharmacists provide dosimetry estimates for the fetus/embryo and explain radiation-induced effects to the patient and family. In situations involving lactating patients, nuclear pharmacists provide recommendations for interrupting infant breast-feeding.

Indirect Clinical Services. Nuclear pharmacists also provide several indirect clinical services that benefit patients in general. They provide literature reviews or in-service presentations on selected nuclear medicine/radiopharmacy topics. They assist in developing institutional guidelines for the use of radiopharmaceuticals and related drugs. They are involved in formulating special radiopharmaceutical products or dosage forms needed for special procedures. They conduct drug use evaluations or drug use reviews. Nuclear pharmacists also serve on radiation safety committees and radioactive drug research committees (RDRCs).

Commercial Nuclear Pharmacists versus Hospital Nuclear Pharmacists

Although it is recognized that not all nuclear pharmacists perform all of the activities described above, each of these activities is performed by some nuclear pharmacists. In general, nuclear pharmacists working in commercial settings have emphasized drug product-related services and cost savings to customers (*8*) whereas nuclear pharmacists working in hospitals have promoted their value-added contributions to clinical care activities, teaching and research (*7,15*). These distinguishing activities are becoming less apparent, however, as nuclear pharmacists in commercial settings are increasingly becoming more involved in clinical, teaching and research activities, while hospital nuclear pharmacists are increasingly concerned with cost containment measures and budgetary restrictions.

PROFESSIONAL ORGANIZATIONS

Presently, the professional ''home'' for nuclear pharmacists is the Section on Nuclear Pharmacy Practice of the APhA. The APhA, which is the national society of pharmacists, was founded in 1852 and is the first established and largest professional association of pharmacists in the US. Its Section on Nuclear Pharmacy Practice was established in 1975 and has grown to well over 300 members. Section activities include provision of continuing education programs at the APhA annual meeting, maintenance of nuclear pharmacy practice guidelines and other professional practice documents, monitoring of and response to regulatory matters, and assorted other work by various committees. ''The Nuclear Pharmacy'' home page, the unofficial web site for the section, is provided by Nicki Hilliard at the University of Arkansas (*5*).

Many nuclear pharmacists are also members of the Society of Nuclear Medicine (SNM) and its Radiopharmaceutical Science Council. Although this multidisciplinary organization promotes nuclear medicine in general, much of its educational programming and various activities are of interest to nuclear pharmacists. Another organization composed of nuclear pharmacists is the National Association of Nuclear Pharmacies (NANP). The focus of this group is promoting interactions with state boards of pharmacy, especially educational efforts vis-à-vis state regulations and inspections of nuclear pharmacies.

REGULATORY ISSUES

Regulation of nuclear pharmacy practice is quite complex. This is due largely to the dichotomous nature of radiopharmaceuticals, which are viewed as both radioactive materials and as drug products.

Nuclear Regulatory Commission

The NRC has the responsibility for licensing and otherwise regulating the possession, use and transfer of by-product materials, including radiopharmaceuticals. However, because the NRC has authority to regulate byproduct materials only, individual states are responsible for regulating accelerator-produced radionuclides in a manner similar to their regulation of x-ray machines. In addition, the NRC has entered into agreements with about 30 states, referred to as Agreement States, whereby authority to control byproduct materials has been transferred to the analogous state agencies. Hence, under the current regulatory scheme, the NRC regulates byproduct materials only in nonagreement states, the nonagreement states regulate x-ray machines and accelerator-produced materials only, and agreement states regulate all radioactive materials and x-ray machines.

Most institutional nuclear medicine facilities are licensed and regulated under Title 10 of the Code of Federal Regulations (CFR) Part 35, Medical Use of Byproduct Material (*16*) or the state equivalent. Because of their distributive functions, however, commercial nuclear pharmacies are licensed and regulated under 10 CFR Part 32, Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material, specifically 10 CFR 32.72, ''Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35'' (*17*), or the state equivalent.

Since 1994, the NRC has recognized certain practitioners as authorized nuclear pharmacists. An authorized nuclear pharmacist is a pharmacist who either is currently board certified as a nuclear pharmacist by the BPS or has completed a structured educational program as described in Table 4 (*18,19*). Also in 1994, the NRC revised its previous rule that restricted the use of radiopharmaceuticals to those for which the FDA had accepted an Investigational New Drug (IND) exemption or an approved New Drug Application (NDA). Since this revision, authorized nuclear pharmacists have been allowed to prepare radiopharmaceuticals using radionuclide generators and reagent kits in a manner other than in accordance with the manufacturer's instructions and to compound radiopharmaceuticals in accordance with state law (*18*).

TABLE 4
Training Program Requirements for an Authorized Nuclear Pharmacist (*18,19*)

700 h in a structured educational program consisting of both:

(1) Didactic training in the following areas:
- Radiation physics and instrumentation
- Radiation protection
- Mathematics pertaining to the use and measurement of radioactivity
- Chemistry of byproduct material for medical use
- Radiation biology, and

(2) Supervised experience in a nuclear pharmacy involving:
- Shipping, receiving and performing related radiation surveys
- Using and performing checks for proper operation of dose calibrators, survey meters and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
- Calculating, assaying and safely preparing dosages for patients or human research subjects
- Using administrative controls to avoid mistakes in the administration of byproduct material
- Using procedures to prevent or minimize contamination and using proper decontamination procedures.

Obtain written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

State Boards of Pharmacy

The regulation of nuclear pharmacy practice, being highly technical and specialized, has presented a rather unique challenge to the state boards of pharmacy. The National Association of Boards of Pharmacy (NABP) has assumed a leadership role in assisting individual state boards with guidance in this area. Since 1977, as part of its ''Model State Pharmacy Act and Model Rules,'' the NABP has published *Model Regulations for Nuclear Pharmacy*. This document was developed and is maintained through timely revisions in consultation with the FDA, the NRC, pharmacy professional organizations, and individual practicing nuclear pharmacists (*20*). Although variable, most state boards of pharmacy tend to follow, in large part, these NABP model regulations when developing their own regulations.

In most states, nuclear pharmacy facilities must be licensed by the Board of Pharmacy as a retail pharmacy or as a nuclear pharmacy. In some cases, hospital nuclear pharmacies may be licensed as institutional pharmacies. The pharmacy practice regulations in most states require that a ''qualified nuclear pharmacist'' be present during hours of operation. Requirements for recognition as a ''qualified nuclear pharmacist'' are generally similar to those for an ''authorized nuclear pharmacist.'' In at least one state, Florida, nuclear pharmacists are issued a special nuclear pharmacist license, separate from and in addition to a standard pharmacist license.

Another regulatory issue facing nuclear pharmacy practice involves pharmacy technicians (i.e., individuals who perform nonjudgmental tasks under the supervision of a licensed pharmacist). State boards of pharmacy increasingly are enacting guidelines or regulations concerning pharmacy technicians, such as training requirements, certification examinations and registration. Current training programs for pharmacy technicians do not address the specialized needs of technicians working in nuclear pharmacies. On the other hand, nuclear medicine technologists who are trained to work in nuclear pharmacies are not prepared to take the national Pharmacy Technician Certification Board (PTCB) examination. In an initial attempt to proactively confront this issue, an ad hoc committee of APhA's Section on Nuclear Pharmacy Practice recently drafted ''Proposed Guidelines for Nuclear Pharmacy Technician Training Programs'' (*5*). This document includes objectives, competencies and training guidelines appropriate for technicians working in nuclear pharmacies.

Food and Drug Administration

A traditional aspect of pharmacy practice always has been the compounding of noncommercially available or otherwise special drug products for individual patients on the receipt of a physician's prescription order. This practice activity was recently the subject of federal regulation in the FDA Modernization Act of 1997 (FDAMA) (*21,22*). Section 127 of FDAMA describes the application of federal law to pharmacy compounding and mandates the establishment of FDA regulations to implement the section. Of special note is an applicability clause that states that this section does not apply to radiopharmaceuticals or compounded PET drugs.

Because of its exclusion in FDAMA, compounding of non-PET radiopharmaceuticals apparently still falls under the FDA's ''Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment'' (*23*). These criteria are useful in differentiating activities, including compounding of radiopharmaceuticals, that are considered to be state-regulated practice of pharmacy versus those that are considered to be drug manufacturing.

PET radiopharmaceuticals are included in a separate section of FDAMA, Section 121, which mandates the establishment of appropriate procedures for the approval of PET radiopharmaceuticals and appropriate current good manufacturing practice (CGMP) requirements for such PET drugs. This section also mandates that any relevant differences between not-for-profit institutions that compound the drugs for their own patients and commercial manufacturers of the drugs must be considered in establishing such approval procedures and CGMP requirements. At the time of this writing, the FDA is in the process of drafting regulations for PET radiopharmaceuticals.

JOB SATISFACTION

Limited survey data and anecdotal reports suggest that nuclear pharmacists generally are satisfied with their jobs. Nuclear pharmacist base salaries and fringe benefits reflect market value for pharmacists in general, and are commensurate with compensation packages of non-nuclear pharmacists practicing in retail pharmacies and hospitals (*24*). In situations requiring special expertise, such as compounding PET radiopharmaceuticals, salaries may be substantially higher.

Distributive activities (i.e., procurement, compounding, quality control, dispensing and distribution) and radiation safety remain fundamental to nuclear pharmacy practice. Compared to these activities, however, nuclear pharmacists derive greater satisfaction from performing clinical activities (*24*). Nuclear pharmacists' preference for more cognitive responsibilities and desire for increased time providing clinical activities (*7,24*) are consistent with the evolutionary changes occurring in nuclear pharmacy practice.

Nuclear pharmacists tend to have personality characteristics reflecting a high degree of task orientation (i.e., concern about completing a job, solving problems, working persistently, and doing the best job possible) (*24*). This orientation is consistent with attitudes mentioned above and is a major driving force for advancements in nuclear pharmacy practice. This orientation is also consistent with the finding that board-certified nuclear pharmacists derive substantially more satisfaction from feelings of self-recognition and acceptance (e.g., self-esteem, self-worth, professional confidence) than from recognition and acceptance from employers and others (*25*).

Not all nuclear pharmacists, however, are happy with their jobs. Turnover of nuclear pharmacists, especially in commercial nuclear pharmacies, may reflect that the personality orientation of some individuals does not match workplace requirements (*24*). For instance, some nuclear pharmacists may become disillusioned from spending large amounts of time performing mundane tasks and complying with burdensome regulatory requirements. Another factor contributing to nuclear pharmacist turnover is their nontraditional work schedule. Many nuclear pharmacists, for example, start work at about 2 am to provide delivery of radiopharmaceutical doses to client hospitals before 8 am. At least one commercial nuclear pharmacy is open 24 h a day.

THE FUTURE

Over the past several decades, nuclear pharmacy has evolved to become a recognized and valuable specialty in the profession of pharmacy. We predict that nuclear pharmacy will remain a strong specialty for many years to come. Commercial nuclear pharmacies will continue to thrive, but hospital nuclear pharmacies will still exist in some institutions where teaching and research are prominent. However, the distinguishing activities in these settings will tend to disappear as nuclear pharmacists in centralized settings increasingly embrace pharmaceutical care activities. These activities will become especially important with new radiopharmaceuticals, many of which will be sophisticated, possibly patient-specific, biologicals intended for therapy. This shift in practice emphasis will be complemented by increased use of nuclear pharmacy technicians and robotics for routine radiopharmaceutical preparation and dispensing. In addition, as PET technology becomes increasingly available and accepted, there will be a corresponding demand for nuclear pharmacists with PET expertise (*26*).

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