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# Nuclear Pharmacy, Part I: Emergence of the Specialty of Nuclear Pharmacy

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**Objective:** Nuclear pharmacy was the first formally recognized area in pharmacy designated as a specialty practice. The events leading to nuclear pharmacy specialty recognition are described in this article. After reading this article the nuclear medicine technologist or nuclear pharmacist should be able to: (a) describe the status of nuclear pharmacy before recognition as a specialty practice; (b) describe the events that stimulated pharmacists to organize a professional unit to meet the needs of nuclear pharmacists; and (c) identify the steps by which nuclear pharmacists become board certified in nuclear pharmacy.

**Key Words:** nuclear pharmacy; specialty recognition; board certification

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Today the services supplied by nuclear pharmacists are accepted as routinely as are those of a staff pharmacist in any hospital. Radiopharmaceuticals as unit doses arrive on time containing the right amount of radioactivity prepared for individual patients. Radioactive products that are used infrequently now are available the same day. Radioactive waste is minimized in the clinic as the syringes used 1 d are removed and replaced with new radiopharmaceuticals the next day. The required space is minimal for preparing and dispensing radiopharmaceuticals. Clinical paperwork to satisfy the NRC or Agreement State regulations is minimal. Person-rem doses are reduced, achieving required as low as reasonably achievable (ALARA) radiation levels (1). Today information on products, drugs used in interventional procedures, and drugs that may interfere with the biodistribution of a radiopharmaceutical is just a local telephone call away. In larger medical centers, the nuclear pharmacist may assist in clinical trials or research associated with investigational radiopharmaceuticals. The nuclear pharmacist may take an active role in teaching nuclear medicine technologists and/or nuclear medicine residents.

These services and others that are taken for granted today

hardly existed less than 30 y ago. The term nuclear pharmacy did not exist while the terminology radiopharmacist and radiopharmacy were in the process of becoming formalized. Radiopharmacists (nuclear pharmacists) were few. Many had advanced degrees, such as doctorates, obtained from training programs that did not focus on radiopharmaceuticals. However, they saw the need to apply their pharmacy expertise to the development of radiopharmaceuticals and to the provision of professional pharmacy services. There were few radiopharmaceuticals and many were raw radiochemical products, as compared to today's refined and efficacious drugs. Many of the early products were shipped in final form and required long half-lives to cover shipping times. Those radionuclides with short half-lives were prepared in-house and required considerable skill.

## EARLY LEADERS

While few pharmacists were involved, it was not due to a lack of encouragement by individuals such as William H. Briner and John E. Christian. Briner had started the National Institutes of Health (NIH) Radiopharmacy in 1958. He had been developing procedures for radiopharmaceutical services by pharmacists and encouraging pharmacy involvement through training and in publications. In a 1960 publication (2) Briner wrote:

To assure oneself at the outset that certain radioactive products administered to patients are in fact pharmaceutical entities, one needs only to consult the current revision of the U.S. Pharmacopoeia. In the fifteenth revision of this compendium, there appear several monographs outlining specifications for radiopharmaceutical products, which were in sufficiently wide use to warrant inclusion in this volume at the time it became official on December 15, 1955.

If products such as those under consideration are pharmaceutical in nature, why, then, are not more pharmacists actively engaged in the purchasing, storing, compounding, assaying and dispensing of these materials.

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In 1968 Briner (3) stated:

Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established.

It is tragic indeed that most hospital pharmacists have no concept of either the meaning of the significance of this rather simple statement of concern shown by a federal regulatory agency for the safety of an ever-increasing number of patients in American hospitals.

Their meaning for pharmacists should be crystal clear—when the property of radioactivity is introduced into a compound by some artificial means, as in a nuclear reactor, serious consideration must be directed to the question of whether or not the resultant material is of a pharmaceutical quality compatible with its safe use in human subjects.

The obvious question posed by this statement is, who shall assess the pharmaceutical quality of a radioactive product.

Does it not seem reasonable, then, to suggest that pharmacists ought to be competent to make judgments concerning the pharmaceutical aspects of radiopharmaceutical products?

Even before Briner's activities John E. Christian, at Purdue University, had encouraged pharmacists to be involved with radiopharmaceuticals and radiotracer studies, both through research and hospital pharmacy services. In 1948 (4) Christian stated:

Pharmacy, as a profession, is chiefly the application of all branches of science to the production of medicinals and medicinal products, and since radioactive isotopes are applicable to all branches of science, isotopes have particular application in the various divisions of the pharmaceutical profession. In view of these facts, the pharmaceutical profession should be quick to awaken to the unique opportunities afforded.

Radioactive isotopes when used for therapeutic and diagnostic purposes are in the true sense of the word drugs and are so classified and regulated under Section 505 of the Federal Food, Drug, and Cosmetic Act. . . . It is desirable that in the future a greater number of individuals interested in pharmaceutical research and the welfare of pharmacy make use of this tool.

In 1950 (5) Christian stated:

The hospital pharmacists should be prepared to provide information and assistance and take the initiative in the establishment of facilities and know how for utilization of these materials in medical practice and in medical research.

In conclusion, one might logically again ask, "What can the hospital pharmacist contribute to the radioisotope program in the hospital?" The answer—(1) Be authoritatively informed on the basic principles, applications, methods of obtaining, facilities necessary, means of control, and sources of information of radioactive isotopes used in medical practice. (2) Encourage the hospital administration to look into the possibilities of establishing necessary facilities for isotope utilization. (3) Take active interest in and/or assist in the radioisotope program of the institution.

In 1964 (6) Christian identified the responsibilities and contributions that pharmacists could make with regard to the area of radioisotope medications. His response was directed to community pharmacists, manufacturing pharmacist and hospital pharmacists. He concluded:

The advancement and increased prestige of any profession is only possible through the application, without undue hesitation, of extra special effort in the realm of new responsibilities. The dispensing of radiopharmaceuticals is the responsibility of the pharmacist and the challenge to assume this responsibility should be accepted—right now!

Christian was responsible for the first monographs on radiopharmaceuticals published in 1955 in the 15th revision of the US Pharmacopoeia (USP). Furthermore, in 1947 he initiated courses in the School of Pharmacy at Purdue University that provided fundamental concepts of nuclear physics, instrumentation and applications of radiotracer methodology applicable to research in pharmacy and the life sciences. Several early leaders in nuclear pharmacy received advanced degrees under Christian. Briner also trained several individuals at the NIH radiopharmacy who contributed significantly to the development of nuclear pharmacy.

#### MOTIVATING FORCES

By the early 1970s several factors influenced the emergence of nuclear pharmacy as a specialty practice in pharmacy. An informal network of nuclear pharmacists began to emerge at national meetings. In the beginning, nuclear pharmacists were registered pharmacists, who, because of special requests in nuclear medicine clinics, helped clinicians with their radiopharmaceutical problems. In general there were no formal training programs or specialty practice areas. Pharmacists interested in radiopharmaceuticals received their training on the job, in a related area such as health physics or radiological health, or by teaching themselves, such as through attending symposia or professional meetings associated with nuclear medicine. Pharmacists became acquainted with each other and often met together after the symposia. These open meetings served as the "critical mass" of personnel interested in nuclear pharmacy sufficient to organize and draw attention to their needs as a group. Another motivating force was the establishment of the first formal education leading to the master of science degree in radiopharmacy at the University of Southern California in 1969

by Walter Wolf and Manuel Tubis. Before that, training had been provided in programs that did not specifically focus on the provision of radiopharmaceutical services by pharmacists (Table 1). In 1972, both schools of pharmacy at the University of New Mexico and at Purdue University established training programs that allowed first professional degree pharmacy students, as well as advanced degree students, to prepare to enter the field of nuclear pharmacy. Nuclear pharmacy also was being emphasized at the University of Alberta School of Pharmacy and the University of Michigan in the early 1970s. The combined growth of nuclear medicine and nuclear pharmacy in the late 1960s and early 1970s led to the need for additional personnel trained to provide nuclear pharmacy services. To meet the need, the scope and competency levels of nuclear pharmacists were developed and published to encourage schools of pharmacy to train nuclear pharmacists (7–9).

In addition to the evolution of formalized education, interest in establishing nuclear pharmacy as a specialty was stimulated by the creation of a task force by the American Pharmaceutical Association (APhA) to develop a mechanism for recognizing specialties in pharmacy and for certifying specialists. The report of the task force, published in 1974, listed several criteria that made it obvious that nuclear pharmacy was an area that would merit recognition as a specialty. For example, nuclear pharmacy required a special knowledge base. The functions of a nuclear pharmacist were clearly beyond the range of functions performed by a general practitioner. Education and training programs existed to prepare pharmacists to practice in the specialty.

#### THE SECTION ON NUCLEAR PHARMACY

The opportunity to become a recognized specialty was just one motivating factor among several for nuclear pharmacy to develop as a specialty. The desire of practitioners and educators to communicate and stimulate professional development was another motivation. In addition, regulatory issues and pending

**TABLE 1**  
**Early Education Programs**

Tracer methodology courses developed at Purdue University in 1947 by John E. Christian
Radioisotope course for pharmacists in 1955 by Philadelphia College of Pharmacy and Philadelphia Hospital Pharmacists
Six 2-h sessions offered by the Oregon Society of Hospital Pharmacists in 1958
"Radioisotopes in Modern Pharmaceutical Practice," a series of lectures by Manuel Tubis, University of Southern California, 1960
"Basic Radiological Health for Pharmacists," cosponsored by the PHS and ASHP in 1963
Radiological training grants: North Dakota State University, 1963 Temple University, 1963 University of Arkansas, 1964 Purdue University, 1964

legislation that could adversely affect nuclear pharmacy services were factors. There was a need to more clearly identify nuclear pharmacy practice as services varied from one site to another. A questionnaire was developed to ascertain the interest in a formal organization for nuclear pharmacy and to determine the professional organization to petition. The questionnaire was distributed to individuals identified previously through a network used for the distribution of a newsletter. Based on the consensus gained from the questionnaire, it was determined that the APhA would be the most appropriate organization.

Leaders in the APhA were contacted and agreed to sponsor the first formal gathering of nuclear pharmacists. Thus, on August 8, 1974, a session entitled "Nuclear Pharmacy '74" was held at the APhA annual meeting in Chicago. Meeting topics, such as clinical nuclear pharmacy, regulatory matters and nuclear pharmacy health physics, served as a catalyst to identify and resolve problems common to nuclear pharmacists. The meeting was a success and stimulated further consideration of the need to establish a formal organization. A petition was generated requesting the APhA to form a Section on Nuclear Pharmacy in the Academy of General Practice (currently the Academy of Pharmacy Practice and Management). The board of trustees of the APhA approved the petition in San Francisco on April 23, 1975. The Section on Nuclear Pharmacy was born. As the first major action item as an organized group, the section presented expert testimony to the FDA Advisory Committee in Washington, DC on April 24 regarding radiopharmaceuticals. In 1981, the APhA recognized the founders of the Section on Nuclear Pharmacy.

At the outset, the section identified certain objectives: to provide a mechanism whereby section members could make their training available to other pharmacists; to provide a forum wherein the special problems and interests of nuclear pharmacists could be discussed; to serve as a means for planning and executing sessions and workshops of interest to nuclear pharmacists; and to provide a mechanism to express the views and needs of nuclear pharmacists to the APhA membership. A committee structure was developed to aid elected leaders in addressing the many issues confronting the section.

One of the first major issues confronting the section was the need to develop guidelines describing the responsibilities of a nuclear pharmacist and differentiating a nuclear pharmacist from a pharmacist. Practice sites, responsibilities and training varied considerably among early practitioners. The guidelines were developed using a committee that conducted a task analysis of the practice of nuclear pharmacy. The committee wrote *Nuclear Pharmacy Practice Standards*, which was validated and accepted by the Section on Nuclear Pharmacy in 1978. This document became the basis for developing a petition to the Board of Pharmaceutical Specialties (BPS) for recognition as a specialty practice. The board approved the petition in 1978. Nuclear pharmacy had become the first formally recognized pharmacy specialty practice in the US and the world. In addition, nuclear pharmacy established the process by which other pharmacy specialties would be recognized.

## BOARD CERTIFICATION

The BPS appointed a Council on Nuclear Pharmacy to develop the procedures necessary to award board certification in nuclear pharmacy. The council was asked to establish knowledge areas, determine requirements for eligibility, prepare an examination and, ultimately, administer an examination and set scores for passing. The development of the nuclear pharmacy specialty certification examination (NUSPEX) has been described in depth previously (10). The exam was based on the official criteria for recognition as a specialty and the *Nuclear Pharmacy Practice Standards*, developed by the Section on Nuclear Pharmacy. The exam discriminated between the competencies of nuclear pharmacy specialists and those of general practitioners. Sets of 343 tasks, or practice behaviors, for nuclear pharmacists were identified. Development of an exam was initiated in September 1980, and included behavior amplification for each task, examination specification development, item (question) writing and review, developing a demonstration exam, presetting passing scores, and the final editing and assembly. The demonstration exam was given to nuclear pharmacists and general practitioners to demonstrate the ability of the exam to discriminate and to test the exam. The process used in preparing the demonstration exam was repeated for the first actual examination for board certification in nuclear pharmacy (BCNP), taken by 72 pharmacists on April 24, 1982. The BPS officially designated 63 as BCNPs on August 25, 1982. In 1998 there were more than 430 BCNPs in the US.

## CURRENT STATUS

From the small number of pharmacists serving nuclear medicine in the early 1970s, the specialty has grown to more

than 1,000 nuclear pharmacists located today in hospitals or centralized commercial nuclear pharmacies. Several centralized nuclear pharmacy corporations exist as well as many independent nuclear pharmacies. Dedicated nuclear pharmacy service for PET is a rapidly expanding area, as well. The services and benefits to patients and personnel in nuclear medicine have come into existence as a result of the vision, dedication and efforts of a few individuals that realized the importance of pharmacy involvement in radiopharmaceuticals. Twenty-five years after the official formation of the Section on Nuclear Pharmacy, it is appropriate to recognize the efforts of these individuals by documenting the events leading to the emergence of the specialty of nuclear pharmacy.

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