Chair Report for the Special Committee on Radiopharmacy

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The practice of radiopharmacy involves the preparation, handling, storage, receiving, dispensing, and disposition of radioactive materials intended for human use, e.g., radiopharmaceuticals.

The Federal Food, Drug and Cosmetic Act states (Section 201) (321) section g, subsection B): "The term 'drug' means articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals."

Radiopharmaceuticals are, therefore, drugs and subject to all rules and regulations of the FDA and state boards of pharmacy as well as to those of the AEC and the state boards of radiological health for their radiological health and safety aspects. One distinguishing feature of radiopharmaceuticals is that they are generally handled in institutional practice and dispensed to a physician, rather than provided directly to the patient.

The radiopharmacist is, therefore, a pharmacist specialized in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of such radiopharmaceuticals.

The class specification in the addendum is a document developed by the staff of the Director of Personnel, County of Los Angeles, subject to the approval of the Civil Service Commission, County of Los Angeles, State of California, after extensive review of several of the radiopharmacy services in operation within the County of Los Angeles Department of Hospitals. It summarizes and exemplifies the job description and responsibilities of a professional pharmacist specialized in radiopharmacy. This committee wishes to stipulate that the present definition and attached class specification defines the professional involved in a professional service, that of providing a radioactive drug and the professional services attached thereto.

No jurisdiction is claimed over individuals or activities in fields other than professional services where professional jurisdictions and legislation does not apply. Neither does this definition preclude a physician, acting under his own full responsibility and liability, to prepare and administer any agent he feels may be helpful to his patient, including radioactive drugs. Neither does the above definition preclude a physician to delegate to any person he chooses to prepare such radioactive pharmaceuticals, inasmuch as he assumes full responsibility and liability for all actions of those persons acting under his direction and supervision. If, however, a radiopharmaceutical is dispensed by a radiopharmacist, then the physician is relieved of legal responsibility for the preparation and dispensing of such drugs and is only responsible and liable for the medical aspects of his practice. We believe that this sharing of responsibilities by both professionals ensures a high efficiency of operation as well as providing the greatest safeguards to the patient.

ADDITIONAL JOB SPECIFICATION LOS ANGELES COUNTY DEPARTMENT OF HOSPITALS

RADIOPHARMACIST

Definition. Provides professional radiopharmacy services to the nuclear medicine and other medical services of a hospital and has immediate charge of the hospital's isotope laboratory.

Classification Standards. Positions allocable to this class apply the established professional principles and practices of pharmacology and nuclear radiation in the preparation, dispensing and control of radiopharmaceuticals used either in producing scans used for imaging, metabolic, or functional studies of internal parts of the body for diagnostic purposes or in the treatment of patients with cancer or other diseases. Positions in this class also perform applied research in developing and testing new or modified radiopharmaceuticals; instruct students, interns, residents and others in the pharmacology of radionuclides; and provide training and supervision to radiopharmacy technicians and technician trainees. Under the general administrative supervision of the head of nuclear medicine services or the head of pharmacy services and the technical supervision of a nuclear medicine physician, positions in this class have full responsibility for the quality and quantity of radiopharmaceuticals produced and for the purchase and control of radionuclides used by the hospital. In addition to established hospital policies and procedures, they work within the framework of the regulations of the Atomic Energy Commission, Food and Drug Administration, and State Department of Public Health governing the use and control of radionuclides.

Examples of Duties

(i) Subjects radioactive substances and reagents to a variety of laboratory procedures involving chemical and electrolytic interactions for the purpose of labeling, or chemically fusing, radioisotopes onto chemical substances and purifying the resulting radiopharmaceutical to eliminate wastes and impurities.

(ii) Assays radiopharmaceuticals at the time of receipt or preparation and again at the time to be dispensed; using mathematics, including calculus, calculates the amount of individual doses based on the half-life of the radiopharmaceutical in relation to the type of procedure required, time of administration, and amount of radioactivity prescribed by the physician.

(iii) Using the above procedures, prepares and dispenses or supervises the preparation of radiopharmaceuticals under radioactive or radiation detection procedures designed to produce images (known as scans) and metabolic or functional studies of the heart, lungs, liver, kidneys, bone structure, etc., for diagnostic scrutiny by the nuclear medicine physician or for the treatment of cancer and other diseases.

(iv) Coordinates the production and dispensing of radiopharmaceuticals with the scheduling of patients for diagnostic or therapeutic procedures so as to maximize the efficient use of time, equipment and materials and to enhance the quality of scans produced.

(v) Reviews and evaluates the quality and value of the radiopharmaceuticals prepared by studying the resulting scans in consultation with nuclear medicine physicians; adjusts procedures to improve quality when possible.

(vi) Conducts pharmacological research in connection with the development of new radiopharmaceutical compounds or new methods for formulating existing compounds for the purpose of exposing the patient to less radiation, expediting the elimination of radioactivity by the patient, producing higher quality scans, or saving time and money; reads professional literature and performs experimental laboratory techniques, includ-
ing animal studies, to determine the chemical interaction of
the proposed components of the drug and to calculate the
likely effects of radiation dosimetry on the patient.

(vii) Prepares formal reports for inclusion in proposals to the
Atomic Energy Commission, Food and Drug Administration,
and the State Department of Public Health required to obtain
approval for testing and use of new radiopharmaceuticals;
reports on research procedures and findings, calculation of
dosimetry and serum levels, and procedures to be used in
preparing the radiopharmaceutical including quality control
procedures.

(viii) Requisitions and supervises the ordering of radionuclides,
reagents, laboratory equipment, and supplies and of other
pharmaceuticals used by the nuclear medicine section.

(ix) Develops and supervises the maintenance of written controls
on the receipt, storage, preparation, administration, and dis-
posal of radionuclides and prepares reports of the circum-
tances and disposition of radioactive materials when spills or
other accidents occur in the isotope laboratory.

(x) Lectures students, residents, interns, isotope technicians, and
isotope technician trainees on radiopharmaceutical charac-
teristics and compounding procedures; provides general
orientation to physicians and others on the policy, proce-
dures, operations, and purpose of the isotope laboratory.

(xi) Attends meetings, conferences and seminars for the purpose
of upgrading professional skills and knowledges and sharing
information on the pharmacological aspects of the field of
nuclear medicine.

(xii) Develops operating, technical, reporting, and safety pro-
dcedures for the conduct of an isotope laboratory and closely
monitors their implementation by technicians and trainees.

(xiii) Supervises technicians and trainees in ordering, preparing,
assaying, and measuring doses of radiopharmaceuticals and
in the maintenance of inventory controls on their receipt,
preparation, administration, and disposal.

(xiv) Participates in the selection of radiopharmacy technicians;
orients and trains new technicians and trains or supervises the
training of technician trainees; plans, assigns and evaluates
the work of subordinates including trainees.

Minimum Requirements. Training and Experience: Completion of
a combination of postgraduate courses and professionally supervised
experience, such as an internship or residency, in the pharmacology of
nuclear medicine equivalent to a Master's degree in radiopharmacy in
an accredited college of pharmacy. License: A license to practice as a
Registered Pharmacist issued by the California State Board of Phar-
macy.

Physical Class.

"2"-Light.