Nuclear Pharmacy
USA Regulations & Education

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Goal of the Presentation

• Provide an Introduction Only
• Overview of Several Aspects
• Focus on Nuclear Pharmacy Centralized Practice
• Regulations First Followed by Education

Federal Agencies

• Food and Drug Administration (FDA)
  – Radiopharmaceuticals are prescription drugs
• Nuclear Regulatory Commission (NRC)
  – Radiopharmaceuticals are radioactive
• Department of Transportation (DOT)
  – Radioactivity is shipped to nuclear pharmacies and hospitals

Federal Agencies (continued)

• Occupational Safety and Health Administration (OSHA)
  – Concern for the workplace
• Environmental Protection Agency (EPA)
  – Radioactivity is considered as a toxic agent
State Agencies

“Agreement States”

• The state agrees to regulate for the NRC

State Agencies (continued)

State Board of Pharmacy

• Issues a license to a centralized nuclear pharmacy
• Issues a license to the pharmacist
• Regulates the practice of pharmacy
• Centralized nuclear pharmacies are considered “retail pharmacies”

State Agencies (continued)

Centralized Nuclear Pharmacy

• Licensed by the NRC or Agreement State
• Licensed by the State Board of Pharmacy

Food and Drug Administration

• Regulates the Manufacture, Sale and Distribution of New Drugs
  – Radiopharmaceuticals are new drugs
• Requires a Drug Establishment (manufacturer) to Register with the FDA
  – The manufacturer must operate under guidelines called Current Good Manufacturing Practices (cGMP)
  – Guidelines require considerable quality assurance and assessment for products
Food and Drug Administration
(continued)

• A Centralized Nuclear Pharmacy is Exempt from cGMP if it:
  – Conforms to Local Laws Regulating Practice
  – Dispenses prescription drugs on prescription to a practitioner licensed to administer the drugs.

Nuclear Regulatory Commission

• Created to Regulate the Use of Byproduct Material
  – Radioactivity made in a reactor and fission products
  – Authority does not include cyclotrons
• Regulations of the NRC are Published in the Federal Register
  – Title 10, Chapter 1, Code of Federal Regulations (10CFR) in several parts

Nuclear Regulatory Commission
(continued)

• Part 19 Notices, Instructions and Reports to Workers: Inspections
• Part 20 Standards for Protection Against Radiation
• Part 30 Rules of General Applicability to Domestic Licensing of Byproduct Material
• Part 32 Specific Domestic License to Manufacture or Transfer Certain Items Containing Byproduct Material
• Part 35 Medical Use of Byproduct Material

Part 19 Notices, Instructions and Reports

• Designed to Inform Occupational Personnel of their “Rights”
• Brief Examples
  – Availability of documents such as Part 19 and 20
  – Type and use of radioactivity
  – Radiation health effects
  – Procedures to minimize exposure
  – Purpose and function of protective devices
  – Emergency procedures
  – Radiation dose records
Part 20 Standards for Radiation Protection

• Contains Information that Covers Almost Every Aspect of Protection
• Many Precautions and Procedures in a Nuclear Pharmacy are Directly Related to Part 20
• Only Highlights will be Presented

Occupational Radiation Dose

• Maximum Permissible Dose (MPD) Designed to:
  – Prevent serious radiation induced acute and chronic deterministic effects
  – Limit the risk of stochastic effects to a reasonable level
• Acute and Chronic Deterministic Effects
  – Conditions that will not occur below a certain radiation dose

Occupational Radiation Dose (continued)

• Stochastic Effects/Concerns are Primarily the Induction of Cancer and Possibility of Genetic Effects. The MPD allowed is designed based upon a conservative approach to this risk.
• The Concept of As Low As Reasonably Achievable (ALARA) is Used to Reduce Risk Further

Maximum Permissible Dose (MDP)

• Whole Body 5 REM/Year Total Effective Dose Equivalent
• Extremities 50 REM/Year
• Lens of Eye 15 REM/Year
• Dose to Embryo/Fetus Over Nine Months is 0.5 REM in a Declared Pregnant Woman
Part 20 Additional Examples

• Personnel Monitoring
• Instrumentation
• Surveys for Contamination
• Signs/Posting
• Labeling
• Opening and Receiving Packages
• Waste Disposal
• Records
• Notification of Incidents

Part 30 Rules of General Applicability to Domestic Licensing

• Covers All Types of Activities
• List Exemptions
• Describes the Two Types of Licenses
  – General
  – Specific
• Describes Requirements for Issuance of a Specific License

Part 32 Specific Domestic Licenses to Manufacture or Transfer

• A Centralized Nuclear Pharmacy Operates Under a Specific License
• Requirements for Labeling, Instrumentation and More Specified
• Designation of an Authorized Nuclear Pharmacists is Described
• Responsibilities
• Training
• State Board Pharmacy License
• Equipment and Procedures

Part 35 Medical Use of Byproduct Material

• Describes Requirements and Provisions for Medical Use and Issuance of Specific License Authorizing Medical Use
• Many Aspects Relevant to Nuclear Pharmacy
• Larger Component Involves Rules Governing Physicians
  – Training
  – Experience
Part 35 Medical Use of Byproduct Material (continued)

- Nuclear Pharmacists
  - Dose calibrator calibration
  - Calibration of survey instruments
  - Measurement of radiopharmaceutical doses
  - Labels and more items

Significant Events Nuclear Pharmacies

- Concept of shared nuclear pharmacy services established and evaluated by Tom Gnau in 1969
- Establishment of other central radiopharmacies
  - University of Washington by David Allen
  - University of Tennessee by James Cooper
  - University of Nebraska by J. William Dirksen
- First centralized radiopharmacy licensed by a state board of pharmacy and the AEC
  - University of New Mexico by Richard Keesee in 1971-72

Significant Events Commercial Centralized Radiopharmacies

- University of Tennessee College of Pharmacy by James Cooper
- University of Utah Medical Center Intermountain Radiopharmacy by Bill Baker
- Nuclear Pharmacy, Incorporated by Robert Sanchez and Richard Sakasitz
- Pharmatopes, Incorporated by Mark Hebner and Monty Fu
- Texatopes, Incorporated by Nunzio Desants and Larry Oliver
- Pharmaco Nuclear, Incorporated by Richard Keesee and David Hurwitz

Significant Events Education

- M.S. degree in radiopharmacy by Manuel Tubis and Walter Wolf in 1969
- Establishment of first professional degree programs in schools of pharmacy in early seventies
- Establishment of in-house training program by Syncor, International
- Short course post-graduate training programs developed.
Current Educational Focus

• Didactic training for recognition as an authorized nuclear pharmacist or authorized user on a license
• Didactic training for first professional degree students and post-degree professionals
• Directed to meet the needs of commercial centralized nuclear pharmacies
• Limited education of M.S. degree and almost no Ph.D. pharmacist training

Professional Services Emphasized in Training

• Directed by "Nuclear Pharmacy Practice Guidelines"
• General domains in the guidelines
  – Procurement
  – Compounding
  – Quality assurance
  – Dispensing
  – Distribution
  – Health and safety
  – Provision of information and consultation
  – Monitoring patient outcome

Education Programs

• First professional degree students
  – Single course
  – Series of courses
• Residency
• Graduate degree program
• Company conducted short course
• School of pharmacy short course
• Short course for physician/pharmacist

Single Course

• Available in a school of pharmacy
• Often taught by staff from a centralized nuclear pharmacy
• Introduction useful for recruiting
• Lecture or advanced clerkship format
Series of Courses

- Elective series available to first professional degree pharmacy students
- Ranges from seven to ten credits
- Requires staffing, equipment and laboratory space
- Problems
- Competitive with other electives
- Student may not elect to practice nuclear

Series of Courses

- Positive aspects
- Reasonable pace of learning
- Repetition and reinforcement
- Well-informed student
- Large numbers can be trained
- Clinical experience through an advanced clerkship
- With practice experience recognition can be attained from regulatory agencies at graduation

Residency in Nuclear Pharmacy

- Didactic training and clinical experience in a medical environment
- Requires considerable commitment from supervisory person and other staff
- One year for a person with a general pharmacy practice residency

Residency in Nuclear Pharmacy

- Positive aspects
- In-depth understanding of radiopharmaceutical care
- Skills to serve as an integral member of the health care team
- Advanced level of knowledge
- Basic, clinical and evaluative research
- Didactic and experiential teaching
M.S. Degree

- Requires 1.5-2.0 years to complete
- Requires faculty and facilities dedicated to training and research
- Expensive on a per student basis
- Positive aspects
  - In-depth knowledge and research
  - Expanded employment opportunities

Short Course

- Originally designed for licensed pharmacists wishing to redirect their career
- Developed to meet the needs of centralized nuclear pharmacies
- Positive aspects
  - Large numbers can be trained as needed
  - Relaxed admission requirements compared to advanced degree
  - Fees paid by corporation
  - Selection of trainee by geographical area

Short Course (continued)

- Risks to the trainee and corporation
  - Trainee may be limited in knowledge of the practice of nuclear pharmacy
  - Intensive training may be required

The Ohio State University
College of Pharmacy
Nuclear Pharmacy Certificate Program

- George Hinkle, Director Established in 1996
- Five consecutive weeks at the Ohio State
  - University for 200 hours didactic material and practice
  - Based on the nuclear pharmacy practice guidelines and NRC published requirements for authorized nuclear pharmacists
### Nuclear Pharmacy Online

**University of New Mexico and University of Arkansas for Medical Sciences**

- Nicki Hilliard, Director
- Established in 2001
- Does not require on-campus training
- Program designed to cover 200 hours at approximately 20 hours per week
- Based on the APhA syllabus for nuclear pharmacy training and the NRC requirements for authorized user training

### Nuclear Pharmacy Certificate Program

**Purdue University School of Pharmacy**

- Steve Piepenbrink, Director
- Established in 1988
- Distance learning and two-weeks on-campus components
- Provides over 200 hours of didactic lecture and laboratory training
- Training program based on nuclear pharmacy practice guidelines

**Nuclear Pharmacy Certificate Program**

- Designed to provide traditional educational student-centered problem-based learning
- Staffing by nuclear pharmacists with preceptor at practice sites
- Local preceptor responsible for experiential training material
- Assessment by timed or proctored exams
- ACPE continuing education awarded

**Nuclear Pharmacy Certificate Program**

- Training satisfies NRC requirements for authorized nuclear pharmacist or authorized user on a license
- Fundamentals presented on videotape and reinforced on campus
- Staffing by nuclear pharmacists, radiochemists and health physics personnel
- Assessment by examinations administered by pharmacy preceptor and on-campus
- ACPE credit for continuing education
The Good News

- Educational programs have developed and changed as the practice has changed
- Nuclear medicine and patient's have benefited greatly from nuclear pharmacy services
- Nuclear pharmacy has matured as a specialty practice