SECTION ON NUCLEAR PHARMACY

First Annual Meeting

The Academy of Pharmacy Practice Section on Nuclear Pharmacy will convene on Tuesday, May 17, during the APhA Annual Meeting in New York City. The program for the one-day session includes:

9:00 a.m. BUSINESS MEETING

Presiding: JAMES F COOPER
1. Report of Chairman Pro Tem James F. Cooper
2. Committee Report
   A. Educational Affairs. RONALD J. CALLAGHAN
   B. Regulatory Affairs. J. WILLIAM DIRKSEN
   C. Communications. STANLEY M. SHAW
   D. Program. A. MICHAEL ZIMMER
   E. Nominations
   MICHAEL P. KAVULA, JR.
4. Discussion of Report

10:30 a.m. PLENARY SESSION

Moderator: A. MICHAEL ZIMMER
1. Discussion of Draft Petition for Nuclear Pharmacy Speciality Recognition. Group Leaders
2. Cyclotrons and Radiopharmaceuticals Labeled with Short Lived Nuclides. ALFRED P. WOLF
   EDWARD A. SILVERSTEIN

1:30 p.m. CONTRIBUTED PAPER SESSION

Moderators: KENNETH R. HETZEL and HANK M. CHILTON
1:30 p.m. Nuclear Pharmacy Quality Control with a Multichannel Analyzer.
   R. C. WILLIAMS and H.M. CHILTON
1:40 p.m. Radiochemical Purity: Mini-Radiochromatography or Maxi-Radiochromatography. TOM KAWADA, WALTER WOLF, and
   SAMIR F. BOTROS
1:50 p.m. Evaluation of Factors Involved in Radiolytic Decomposition of Radiopharmaceuticals. C.E. HOTTE, R.D. ICE, and G.L. FLYNN
2:00 p.m. Health Safety Considerations in a Centralized Nuclear Pharmacy.
   D. HOOGLAND, L. WILLIAMS, L. FORSTROM, M. LOKEN
2:10 p.m. Discussion
2:20 p.m. Evaluation of Electrolytically Labeled Versus Tin Labeled Tc-99m Human Serum Albumin. L.R. HENDERSHOTT, R.C CASTON, and
   R.M. DONATI
2:30 p.m. Tc-99m-Diphosphonate Pharmacokinetics. FRANK CASTRONOVO
2:40 p.m. Tc-99m-Stannous Tartrate Complex: A Non-Phosphate Bone Imaging Agent. K.R. HETZEL

2:50 p.m. Clearance, Catabolism and Protein Binding of Tc-99m-Sn-Pyridoxylidine-Glutamate (P.G.) for Biliary Imaging. A. JANSCHOLT, R. STADALNIK, K. KROHN, R. MATOLO, and G. DeNARDO

3:00 p.m. Discussion

3:10 p.m. Ventilation Imaging with Xe-127. H.M. CHILTON

3:20 p.m. Synthesis and Tissue Distribution of 2,5-I-Diodocarnosine. T.S.T. WANG and R.P. SPENCER


3:40 p.m. Influence of Dimercaprol on Tumor Loading of In-111 Bleomycin. G. LEVINE, G. SARTRANO, and S. BOGGS

3:50 p.m. Discussion

The program was assembled under the leadership of Mike Zimmer, Chairman for the Program Committee, with the assistance of Hank Chilton, Phil Hagan, Ken Hetzel and Rodney Ice. Pharmacists can obtain continuing education forms for the APhA Annual Meeting at the APhA Registration Desk.

Invitation to Membership

The Section on Nuclear Pharmacy has been established to serve the needs of practitioners in nuclear pharmacy. The Section exists to serve nuclear pharmacists employed in hospitals, industry or in educational institutions. The strength and accomplishments of the Section are directly related to the support and participation of nuclear pharmacy personnel. Membership is the initial step in giving you the opportunity to share in directing the goals and professional aspects of nuclear pharmacy. An application for membership is enclosed for your convenience. Copies of Pharmacy Practice are also attached to illustrate the monthly communication service provided by the Section on Nuclear Pharmacy.

REGULATORY ACTIVITIES

Advisory Committee on Medical Uses of Isotopes

The Nuclear Regulatory Commission has filed a charter to renew the Advisory Committee for the period February 1, 1977 through February 1, 1979. The Notice was published in the Federal Register, Vol. 42, No. 20, January 31, 1977.

Nominations for new members for two radiological health advisory committees were requested by the FDA in the Federal Register, Vol. 42, No. 43, March 4, 1977. The Medical Radiation Advisory Committee (MRAC) will have two vacancies as of July 1, 1977. According to the Notice in the Federal Register, the need is for candidates with knowledge of ultrasound and computerized tomography in medical diagnosis. Nominations must be received by April 4, 1977.

A proposed rule was published in the Federal Register, Vol. 42, No. 42, March 3, 1977 by the Nuclear Regulatory Commission. A part of the summary states "The Nuclear Regulatory Commission has under consideration an amendment to its regulations in 10 CFR Part, "Human Uses of Byproduct
Material." The amendment would require a medical institution to be licensed for byproduct material used in the institution, rather than the individual physician using the byproduct material. This would be accomplished by limiting the granting of individual physician licenses under part 35.12 to a physician or group of physicians in private practice in an office outside the institution. The amendment under consideration includes comments on procedures to be followed to allow delivery of nuclear medicine services at small medical institutions or clinics. Written comments or suggestions for consideration should be sent by April 18, 1977.

\[99m\text{Tc}-\text{HSA PREPARATION}\]

The November, 1976 issue of Pharmacy Practice focused attention on problems in the preparation of \(^{99m}\text{Tc}-\text{HSA}\) as described in a recent journal article. "Accumulation of daughter \(^{99}\text{Tc}\) in \(^{99m}\text{Mo}-^{99m}\text{Tc}\) generator systems may adversely affect the preparation of certain \(^{99m}\text{Tc}\) radiopharmaceuticals, according to a recent study (J Nucl Med 17:704, 1976). In a study of the effect of "carrier" technetium on the radiochemical purity of \(^{99m}\text{Tc}\)-human serum albumin, varying amounts of \(^{99}\text{Tc}\) were added to a commercially available electrolytic kit. The maximum amount of \(^{99}\text{Tc}\) that could be added to such a kit and still maintain radiochemical purity above 90\% was about 3 x 10^{15} atoms. When kits containing 10^{16} \(^{99}\text{Tc}\) atoms were electrolyzed for the conventional 42 seconds, the radiochemical purity was only 50.8\%. However, when the electrolysis time was varied, it was found that electrolysis for 80 seconds yielded a product with greater than 90\% radiochemical purity.

Four solutions to the observed \(^{99}\text{Tc}\) carrier problem are suggested by the authors, all of which limit the amount of \(^{99}\text{Tc}\) added to a kit:

1. When preparing \(^{99}\text{Tc}-\text{HSA}\), avoid using the initial eluate from \(^{99m}\text{Mo}-\text{Tc}\) generators.
2. If the initial eluate is used, the maximum recommended volume should be calculated.
3. Pre-elute the generator to remove the accumulated \(^{99}\text{Tc}\) atoms.
4. Electrolyze the \(^{99m}\text{Tc}-\text{HSA}\) kit for 80 seconds, which will obviate the carrier problem under the worst possible conditions. Note, however, that possibility of colloid formation could limit this approach."

NCRP REPORT

NCRP Report No. 48, Radiation Protection for Medical and Allied Health Personnel may be helpful in providing information about the possible effects and safe levels of radiation to individuals involved in the use of radiation in the healing arts. The report is designed to answer questions concerning radiation and radiation protection practices. The report includes sections on biological considerations, radioactive nuclides, the morgue, and disposal of radioactive waste. Appendices cover additional topics of interest. Information on the NCRP Report No. 48 may be obtained by writing: NCRP Publications, P.O. Box 30175, Washington, DC 20014.
Nuclear pharmacists interested in views concerning the merits of the formation of an American Board of Nuclear Medicine Science should consult recent issues of Applied Radiology. The proposal was described in an editorial by Ibrahim B. Syed, ScD, in the September-October, 1976, issue. Objections to the proposal were voiced by E. Ulric Buddemeyer, ScD, as an editorial in the January-February, 1977, issue.

EDUCATION

U.S.C.

The University of Southern California Radiopharmacy Program will offer an advanced course in radiopharmacy entitled "Inter-Regional Training Course on the Preparation, Control and Utilization of Radiopharmaceuticals" on July 18-August 12, 1977. The course is intended to provide advanced training to pharmacy educators, practicing radiopharmacists as well as others interested in advanced knowledge of radiopharmacy. Tuition costs range between $1300-1500. Application deadline is April 15. For information contact:

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E.R. Squibb and Sons, Inc.

E.R. Squibb and Sons, Inc. is offering a series of seminars in nuclear medicine. Three four-day seminars will be conducted, without charge to participants, in 14 cities during 1977. In Vivo and In Vitro procedures will be presented through lectures and laboratory workshops. Seminars will be held March 15-18, Memphis; March 29-April 1, Portland Maine; April 12-15, Los Angeles; April 19-22, St. Petersburg; April 26-29, Denver; May 3-6, Piscataway; May 3-6, New Orleans; May 9-12, Omaha; July 11-14, Louisville; September 19-22, Detroit; September 27-30, Albany; October 25-28, Williamsburg; November 1-4, Piscataway; November 1-4, San Francisco. Information may be obtained from Daniel J. Murphy, Jr., Technical Customer Service Manager, E.R. Squibb and Sons, Inc, P.O. Box 4000, Princeton, NJ 08540.
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NUCLEAR PHARMACY HIGHLIGHTED IN NEW PHARMACY PUBLICATION

The October 1976 issue of U.S. Pharmacist, the newly launched pharmacy publication, carried the first in a series of articles on nuclear pharmacy authored by University of Michigan PhD candidate Harriet L. Behm and Dr. Rodney D. Ice, University of Oklahoma College of Pharmacy dean and chairperson-elect of the APP Section on Nuclear Pharmacy. The article provides a broad overview of nuclear pharmacy, with sections on types of nuclear pharmacies, responsibilities of a nuclear pharmacist, nuclear pharmacy operation, and quality control of pharmaceuticals. Dispensing and record keeping are discussed, as well as equipment necessary for the operation of a nuclear pharmacy, and regulations affecting nuclear pharmacy practice are briefly summarized. The article is a good introduction to the practice of nuclear pharmacy.

STATE NUCLEAR PHARMACY REGS GETTING INCREASED ATTENTION

The increasing number of states who are drafting regulations applying to nuclear pharmacy practice again became evident at the District 1 meeting of the National Association of Boards of Pharmacy and the American Association of Colleges of Pharmacy held November 7 in Hyannis, Mass. A panel consisting of Massachusetts Board of Pharmacy president Ethel Pierce, Ronald Callahan and Frank Castronovo of the Massachusetts College of Pharmacy, Northeastern University's Clifford Hotte, and Al Velucci of Massachusetts Nuclear, Inc. presented an overview of nuclear pharmacy, discussed the experiences of a number of states in their attempts to regulate the practice, and pointed out specific problems related to the current Massachusetts effort.

According to panel member Ronald Callahan, "The goal of the panel participants was to present as much information as possible to members of state boards of pharmacy so that in drafting regulations, a significant impact from practitioners would be realized. Callahan suggests that all nuclear pharmacists should become involved in such efforts in their own areas "to insure that reasonable regulations are passed in other states".

The APP Section on Nuclear Pharmacy's Regulatory Affairs Committee has also offered assistance to state boards considering the promulgation of such regulations.

SECTION MEMBERS ARE BUSY ON THE SPEAKING CIRCUIT

Besides the participation in the District 1 NABP-AACP meeting described above, APP Section on Nuclear Pharmacy members took an active part in the programs at other such meetings: Jack Coupal, Gordon Born and Stanley Shaw at the District 4 meeting in Lexington, Kentucky, October 14-16; Rodney D. Ice (Section chairman-elect) at the District 6 meeting in Hot Springs, Arkansas, October 11; and William J. Baker at the District 8 meeting in Salt Lake City on October 25.

DID YOU MISS THESE RECENT ARTICLES ON RADIOPHARMACY?

In a recent editorial (J Nucl Med 17:865, 1976), William C. Eckleman set forth guidelines for the determination of radiochemical purity of new radiopharmaceuticals "to bring uniformity to the articles on new radiopharmaceuticals published in the Journal".

Another article of possible interest to nuclear pharmacists is the report of an investigation by J. E. Furchner and G. A. Drake, "Comparative Metabolism of Radioisotopes in Mammals--XI Retention of 115Sn in the Mouse, Rat, Monkey and Dog" (Journal of Health Physics 31:219-224, 1976).
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HOSPITAL ACCREDITATION MANUAL The 1976 edition of the Accreditation Manual for Hospitals (April, 1976, pp. 117-120) contains considerable information of interest to nuclear pharmacists, according to APP Section on Nuclear Pharmacy member Ronald J. Callahan. Radiopharmacist Callahan cites the following excerpts as examples:

1. The Director of Nuclear Medicine shall ensure that proper radiation safety principles and practices are observed and that all technical personnel are qualified for the duties performed through documented formal training and on-the-job experience. Appropriate credentials shall be required for any pharmacist involved in the preparation of radiopharmaceuticals.

2. All nuclear medicine personnel should participate in in-service education programs, as well as outside workshops and professional society meetings.

3. Facilities shall be provided for the safe preparation, storage, and disposal of radioactive materials so that radiation levels in all areas are as low as practicable and do not exceed accepted standards.

4. All radioactive materials, reagents, and standards shall be prepared, stored, and checked at a defined interval to be determined by the Director (of Nuclear Medicine) to ensure accuracy, patient safety, and precision of results. All reagents must be labeled to indicate identity, date of preparation, and assay. Instrument calibration procedures sufficient to affirm proper performance shall be conducted each day the instrument is used and the results recorded. All safety survey instruments in the facility should be calibrated at least annually. The recommendations of the National Council on Radiation Protection and Measurement should be known and applied.

5. Quality control procedures shall be developed to guide personnel in the standardized performance of diagnostic studies and therapeutic procedures and to ensure that the identity, strength, and integrity of all radiopharmaceutical agents are maintained.

6. Records to be maintained on radionuclides and radiopharmaceuticals, should include at least: a) the dates, amounts, and methods of receipt and disposal, b) the supplier and lot number, and c) the use, date, amount administered, and the identity of any recipient.

KEEPING UP WITH THE JOURNAL OF NUCLEAR MEDICINE Two articles of interest to nuclear pharmacists appear in the November 1976 issue of the Journal of Nuclear Medicine. Adrian Le Blanc and Phillip Johnson published procedures for receiving and opening packages containing radioactivity, which they suggest reduce Part 20.205 of Title 10, Chapter 1 of the Code of Federal Regulations to an operationally functional form (pp. 1013-1014). In another article (pp. 1015-1016), John Straw, Anthony Bendetto, and Martin L. Nusynowitz described a record-keeping system for radiopharmaceutical accountability.

RADIOPHARMACEUTICALS SHOWING UP FREQUENTLY ON NDA LIST Nuclear pharmacy is getting to be big business for pharmaceutical manufacturers, or so it would seem from the increasing number of radiopharmaceuticals which are appearing in the Food and Drug Administration's periodic list of new drug approvals. For example, all 10 'original NDA's' on the agency's November 24, 1976, list were radiopharmaceutical products, and all seven of those on the December 1, 1976, list were also radiopharmaceuticals. There can be little doubt that the armamentarium of products available to the nuclear physician and pharmacist is growing rapidly.