

NEWS BRIEFS

NRC Drops Record-Keeping Requirements

The U.S. Nuclear Regulatory Commission has deleted the record-keeping requirements for deviations from a manufacturer's instructions for the use of radiopharmaceuticals. Effective October 2, 1992, amendments to Parts 30 and 35 of the NRC's regulations

eliminate requirements for a written justification for each departure, a precise description of each departure, and the number of procedures performed that depart from registered indications. The Society of Nuclear Medicine and the American College of Nuclear Physicians had strongly objected to the record-keeping requirements, and praised the coordinated effort of the NRC and the U.S. Food and Drug administration in reaching the decision.

The NRC imposed the requirements in August 1990 as part of an interim final rule that allowed departures from manufacturer's instructions for preparing diagnostic radiopharmaceuticals using generators and reagent kits for which the FDA has approved a new drug application (NDA). The rule also included the record-keeping requirements.

The NRC drafted the interim final rule in response to a petition filed by SNM and ACNP in 1989 that requested rule changes to allow departures from manufacturer's instructions and to allow the use of radiopharmaceuticals for therapeutic indications and methods of administration not included in FDA-approved package inserts. But SNM and ACNP objected to the criteria included in the interim final rule, maintaining that they limited the physician's ability to exercise medical judgement, particularly in situations of emergency care.

Last June the NRC announced that after examining the records collected under the interim final rule and consulting with the FDA, regulators decided that the information collection requirements were no longer necessary. NRC officials said that they and FDA staff agreed that the major trends in departures that might be identified by the record-keeping requirements were already clear and that the collection of additional data was therefore unnecessary. The amended rules say that for diagnostic studies, a licensee may depart from a manufacturer's instructions for FDA-approved eluting generators and reagent kits by follow-

ing the directions of an "authorized user physician." For preparing therapeutic radiopharmaceuticals, the NRC still requires an authorized physician's written directive for any indication or method of administration not listed in package insert instructions. ■

SPECT Project Underway, Chairman Selected

Nuclear medicine physician Leon S. Malmud, MD will serve as the first chairman of the steering committee for the SPECT Project, an industry sponsored program to develop the use of single-photon emission computed tomography. The steering committee met on September 26 during the interim meeting of the American College of Nuclear Physicians.

Dr. Malmud, immediate past-president of The Society of Nuclear Medicine, is chief executive officer of Temple University Hospital and vice-president of the Health Sciences Center.

The SPECT project was established, according to its mission statement, to advocate "equitable" reimbursement for clinical SPECT, to encourage clinical and research utilization of SPECT, and to advance the training of physicians and technologists in clinical SPECT imaging. The project is supported by radiopharmaceutical companies and instrument manufacturers and managed by the Joint Government Relations Office of the ACNP and SNM.

The project steering committee consists of three representatives from ACNP, three from SNM, and five from industry. Nine corporate members have pledged an initial \$300,000 to fund the project for one year. Out of 18 study proposals, the steering committee selected five that are likely to be undertaken this year.

Among them is a proposed survey of insurers that would determine current coverage for SPECT and help in deciding appropriate studies in the future. For example, if the survey

1992 Scientific Exhibit Prizes

The Scientific Exhibits Subcommittee of the Scientific Program Committee awarded the following prizes during The Society of Nuclear Medicine's 39th Annual Meeting:

FIRST PRIZE: I-123-MIBG Imaging of Neural Crest Tumors. M.J. Gelfand, H.J. Paltiel, A.H. Elgazzar, L.C. Washburn, C.C. Williams, R.E. Harris, P.R. Masters, H.R. Maxon. University of Cincinnati, Children's Hospital Medical Center, Ohio.

SECOND PRIZE: An Interactive Computer-Based Atlas of Clinical Neurologic PET. S.U. Berlangieri, T. Schifter, J.M. Hoffman, T.C. Hawk, S.M. Hamblen, and R.E. Coleman. Duke University Medical Center, Durham, North Carolina.

THIRD PRIZE: Whole Body Imaging with Positron Emission Tomography. E.J. Hoffman, S.C. Cherry, P.D. Cutler, M. Dahlbom, T.M. Guerrero, D.K. Mahoney, R.A. Hawkins, C.K. Hoh, J. Maddahi, S.R. Meikle, M.E. Phelps and D.C. Yu. University of California School of Medicine, Los Angeles.

HONORABLE MENTION: Brain SPECT Imaging: A Multimedia Multimodality Interactive Computer Tutorial. H.D. Tran, B.J. Barron, L.M. Lamki, G.C. Carson, T.W. Twiford, E.H. Zuniga. University of Texas Health Science Center, Houston.

HONORABLE MENTION: Clinical Validation of a Computer Program Optimized for Ordinary Gamma Camera First Pass Radionuclide Angiography (FPRNA). H.A. Bishop. West Virginia University Medical Center, Morgantown.

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showed that SPECT meets insurers' technology assessment criteria, efforts could be made to educate insurers. Gaps in research that might be identified could be filled in by targeted studies. If reimbursement for SPECT procedures appears low compared to planar studies, future research could be conducted to establish accurate cost information. A related project would revise Medicare relative value units (RVUs) to achieve higher reimbursement rates for SPECT procedures, which nuclear medicine physicians believe are undervalued. Revisions would be based on surveys of physicians and existing RVU data. ■

DOE, Biotech Firm Developing Labeled Antibodies

The Los Alamos National Laboratory and RhoMed Inc. announced in September their plans to study potential uses for copper radioisotopes under a recently signed Cooperative Research and Development Agree-

ment (CRADA). The U.S. Department of Energy is promoting CRADAs as a means for national labs and U.S. companies to bring new technologies to market quickly, while protecting patents and other intellectual property.

Scientists at Los Alamos labs in New Mexico, operated by the University of California for the U.S. Department of Energy, and at RhoMed have reported initial studies showing that copper-67 can be bound easily and efficiently to antibodies using methods developed for technetium-99m, many of them patented or in the process of being patented by Rhomed, a privately held biotechnology company based in Albuquerque, New Mexico.

By extending the labeling techniques to copper radioisotopes, researchers at the two institutions hope to develop antibodies and proteins for cancer therapy. The isotope ^{67}Cu can be used for imaging with standard gamma-ray cameras and isotopes such as ^{62}Cu and ^{64}Cu are compatible with positron emission tomography (PET).

Under the CRADA, RhoMed scien-

tists will conduct labeling studies and laboratory analyses of radioisotopes supplied by the Los Alamos Meson Physics Facility (LAMPF), a high-energy particle accelerator. The national lab will also supply expertise in the chemistry of labeling biomolecules with radioisotopes. Los Alamos and RhoMed considered the joint research venture for more than two years. The National Cancer Institute recently awarded a grant to RhoMed to support its research on ^{67}Cu compounds.

RhoMed has developed a series of $^{99\text{m}}\text{Tc}$ -labeled antibodies for detecting infectious diseases and cancer. The company's first product in the series, called LeukoScan, is undergoing preliminary human clinical trials and awaits approval for marketing from the Food and Drug Administration. ■

Election Results Revisited

Mickey T. Clarke, CNMT of St. Louis, Missouri, newly elected treasurer of The Society of Nuclear Medicine Technologist Section, was inadvertently omitted from the Tech Section election results printed in *Newsline* in September. ■

NBTF

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for the NBTF. Rep. John Myers, an Illinois Republican, sponsored the measure for the NBTF that was ultimately accepted in conference by the House and Senate. Rep. Myers is interested in the NBTF as a "needed commodity for the nation," according to aide Doug Wasitis. Rep. Myers, who is ranking minority member of the House Energy and Water Appropriations Subcommittee, sent a personal letter to DOE Secretary James Watkins in August urging him to fund the NBTF.

Rep. Myers and fellow Indianans Senators Lugar and Coats have a vested interest in the NBTF—Purdue University and Indiana University are

making plans for jointly developing the accelerator facility. Purdue held a workshop in April 1992 to work out a proposed mission for the NBTF with nuclear medicine researchers and representatives of the radiopharmaceutical industry. Purdue has estimated that the NBTF could be constructed for \$100 million dollars, according to a statement submitted to Rep. Synar's subcommittee by Kenneth Kliever, PhD, Purdue's assistant vice president for research.

Competing Proposals

The congressional patronage won't qualify as pork-barrel support if all goes as planned and proposals for the NBTF are peer-reviewed. A competitive field is shaping up, with con-

tenders from Los Alamos National Laboratory in New Mexico, Brookhaven National Laboratory in New York, the University of North Texas, and the University of California with Lawrence Livermore National Laboratory.

Given the growing momentum behind the NBTF, there is an outside chance that the Energy Department could find money in the current budget to go ahead with the competitive siting phase. Ms. Morris says one reason she urged lawmakers not to specify any particular appropriation was to give the DOE flexibility to act sooner. Says Ms. Morris, "The ball is in their court now."

J. Rojas-Burke