Cronin Named ERF President

Val Cronin, CNMT, FSNMTS, manager of imaging services at Women and Children's Hospital, Buffalo, NY, assumed office as the 2010–2012 president of the Education and Research Foundation (ERF) for SNM during the society's 57th Annual Meeting in Salt Lake City, UT, in June. "Over the next year, I look forward to working with foundation donors, SNM leadership, and other stakeholders to ensure the foundation is able to continue to provide grants, awards, and scholarships in nuclear medicine and molecular imaging," said Cronin on assuming the presidency. "In today's economy, providing educational support to the best and brightest physicians, scientists, and technologists in the field is more critical than ever."

The ERF for SNM is a separately incorporated, 501c3 charitable foundation dedicated to advancing excellence in health care through the support of education and research. During her 2-y term, Cronin will focus on ERF's sole mission: raising funds and managing foundation assets to maximize funding for grants, awards, scholarships, and educational programs in nuclear medicine and molecular imaging. "Our goal is to provide over $1 million in funding for research and educational programs," she said. "The coming year is giving each of us an unprecedented opportunity to really make a difference and to have an immediate impact on the recruitment of new talent into our specialty."

Val Cronin, CNMT, FSNMTS

Cronin has served in numerous leadership capacities with the SNM Technologist Section (SNMTS) and SNM, including as president of SNMTS, member of the SNM Board of Directors, member of the Molecular Imaging Outreach Task Force, chair of the Patient Advocacy Task Force, and vice president of the ERF. Cronin is an active member of the American Society of Radiologic Technologists, the Medical Group Management Association, and the Healthcare Executive Forum. She is currently pursuing a master's degree in health science administration from D'Youville College (Buffalo, NY).

Other ERF officers elected for 2010–2012 are Peter Conti, MD, PhD, as vice president, and Roy Brown as treasurer.

Education and Research Foundation for SNM

MOLECULAR IMAGING UPDATE

CGMP for PET Drugs: Important Steps to Take Now

The U.S. Food and Drug Administration (FDA), taking into consideration the unique nature of PET drugs and PET drug production, published the final rule 21 CFR Part 212, "Current Good Manufacturing Practice (CGMP) for Positron Emission Tomography Drug Products," on December 10, 2009 (*Fed Reg.* 2009;74:65409). This regulation contains *binding* requirements for CGMP for PET drugs and is enforceable in court. The guidance "PET Drugs. . .CGMP," published at the same time as Part 212, describes FDA's current thinking on specific approaches to comply with Part 212 requirements (*Fed Reg.* 2009;74:65538).

Part 212 requires that producers of PET drugs for clinical use be compliant with the rule by December 12, 2011—only 1 y away. Any facility that produces PET drugs for clinical use is required to submit either a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) for each of its clinical PET drugs, whether or not the drugs are produced for commercial distribution. The following requirements apply to all PET drug producers.

Step 1: Establish an electronic portal with the FDA. All PET drug producers are required to electronically register their establishments as manufacturing facilities. Electronic Drug Registration and Listing Instructions are available at www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm177328.htm, where the list of requirements can be downloaded. In addition, FDA Guidance, "Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration & Drug Listing," is available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf. Producers are required to e-mail the FDA, then submit a letter of nonrepudiation. Response from the FDA allowing the set-up of a test account will take approximately 1 mo, followed by the set-up of a Web trader account. This account will be used for submission of all communications with the FDA, including NDA or ANDA submission. Completing the electronic connection with the FDA could require up to 6 mo, so starting early is advised.

Step 2: Submit an NDA or ANDA for each clinical PET drug. SNM is working toward facilitating the process for submission of the NDA or ANDA for all manufacturers, as all sites manufacturing diagnostic FDG will need to submit these as a requirement of the FDA. Because NDAs have been approved by the FDA for ^{18}F-FDG injection and ^{13}N-ammonia, ANDAs may be submitted.

SNM has established an FDA Part 212 Working Group to support the community and facilitate submission of ANDAs. Over the coming months, the society will be providing information via the SNM Web site at http://interactive.snm.org/index.cfm?PageID=9740 and through other outreach tools.

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