

maceuticals have ultra-short half-lives, PET centers and hospitals make radiopharmaceuticals in small quantities to fill individual orders—unlike the rest of the pharmaceutical industry which produces drugs in bulk amounts. Thus, it would be impractical and outrageously costly for a small facility to file an NDA every time it manufactures a new PET drug.

PET centers are required to come into compliance with this rule in 18 months, but Larson feels this is unrealistic. “The FDA has no mechanism in place to oversee these rules,” he said. Even the FDA admits in the proposed rule that it needs to amend certain principles of its current good manufacturing practice regulations for PET radiopharmaceuticals because the regulations may compromise safe handling or are inappropriate.

A few months before the rule was published, SNM had filed a citizen petition with the FDA outlining an alternative regulatory approach favored by the PET industry. “Application of the NDA regulatory process to PET radiopharmaceuti-

BACK IN TIME

120 years ago, William Crookes, PhD, developed the first radiometer to measure the proportional intensities of radiation in varying degrees of sunlight. Among Crookes' more notable accomplishments is his discovery of thallium.

60 years ago, some argue, was the actual birth of nuclear medicine. Karl Compton, PhD, then president of MIT gave a lecture at Harvard Medical School which explored the role of physics in biology and medicine. Robley Evans, a member of Compton's staff at MIT, dropped a bomb at the meeting by suggesting that iodine radioisotopes could be manufactured in the laboratory. In the ensuing months, Compton and James H. Means, MD, of Massachusetts General Hospital began studies to determine the viability of employing artificial radionuclides in medical procedures.

25 years ago, H. Saul Winchell, PhD, of the Donner Laboratory at Berkeley was awarded the first George Charles de Hevesy prize for his work on the visualization of radioactivity in canines following the administration of various ¹⁴C-carboxylates. The original value of the prize, which recognizes outstanding nuclear medicine pioneers, was \$2320.

cals would gain no significant safety benefits but would impose such severe economic burdens on the providers of PET as to effectively destroy all chances for clinical application of this highly promising

diagnostic procedure,” wrote SNM President James J. Conway, MD, in a letter to FDA Commissioner David Kessler, MD, that accompanied the petition. The FDA still has not responded to this petition. ■

OVERHEARD

“The Task Force makes a persuasive case that the national labs, working with the department, should sharpen their focus on areas of established excellence and not venture off in search of major new missions. The general message is that federal institutions must borrow a page from the private sector, where companies are achieving major performance improvements by consolidating around their essential strengths.”

—Hazel O’Leary, Secretary of Energy,
on the recent findings of a Federal advisory panel
which scrutinized the 10 national labs.

In a cross-sectional survey of physician faculty at U.S. medical schools, researchers found that 59% of women compared with 83% of men had achieved associate or full professor rank. Although women worked about 10% fewer hours per week and had authored fewer publications, they still remained less likely to be promoted than men after adjustments were made for productivity factors.

—Journal of the American Medical Association

A single network of brain regions apparently allows people to speak both their native language and a second language, concludes McGill University researchers who performed PET scans on English speak-

ing people who spoke French as a second language. If confirmed in further studies, the results could mean that a core brain system underwrites the capacity to speak any number of languages.

—Proceedings of
the National Academy of Sciences

Representative Robert Walker (R-PA), the new chair of the House Science Committee, intends to introduce new legislation this month which would combine most of the government’s nonmedical civilian research into a single Department of Science. The new department would merge four agencies: the Department of Energy, Environmental Protection Agency, National Aeronautics and Space Administration and National Science Foundation. The consolidation would eliminate 5000 jobs from a current work force of about 78,000.

—Science

Using supercomputers to model the inner core of the Earth, geophysicists have found evidence that this mass of solid iron has a crystalline structure that may explain mysteries of the Earth’s magnetic field, like the peculiar skewing of its field lines.

—The New York Times