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## SNM is Addressing the Need for Production of Medical Isotopes in the US

In November 2007, the Atomic Energy of Canada Limited (AECL) shut down the National Research Universal (NRU) reactor at the Chalk River Laboratories for over a month to install safety-related equipment and comply with the Canadian Nuclear Safety Commission (CNSC) license requirements. However, AECL was unsuccessful in complying in the time allotted, and decided to keep the NRU reactor in an extended shutdown until the work could be completed. The NRU produces roughly half of the world's supply of radioisotopes. This extended shutdown caused a shortage of molybdenum-99 (Mo-99) – an isotope frequently used in cardiac imaging – throughout much of North America until the Parliament of Canada, in response to the patient care crisis caused by the shortage, used a rare emergency legislative process to bypass the CNSC's regulatory authority over the NRU reactor license for a period of 120 days. During the 120 days, the AECL is permitted to safely operate the NRU reactor while continuing to move toward full compliance with their CNSC license requirements. Full production of Mo-99 resumed late in December, 2007.

In May of this year, the AECL announced that it would discontinue the development of two MAPLE reactors at the Chalk River Laboratories, effective immediately. AECL stated the decision was based on "a series of reviews that considered, among other things, the costs of further development, as well as the time frame and risks involved with continuing the project." The discontinued medical isotope reactors are not expected to impact the current supply of medical isotopes produced by the NRU reactor at the Chalk River facility. "We recognize the important role that NRU plays in the supply and delivery of medical isotopes to patients in North America and around the world," stated AECL's President and Chief Executive Officer Hugh MacDiarmid. "AECL is committed to supplying medical isotopes from NRU in a safe and reliable manner."

With the shutdown late last year of the aging NRU reactor, the SNM began researching alternative means for isotope production within the US because there are currently no facilities in the US that are totally dedicated to manufacturing medical isotopes. The cancellation of the Maple Reactors has added an urgency to these deliberations.

"For all intents and purposes, there is nothing, which is a sad state of affairs," SNM president-elect Dr. Robert Atcher professed. "Most of the places that have an operating reactor do not have the processing capability in the form of hot cells and a staff that would work 24/7 toward that activity. There are some facilities that have the hot cell capability, but don't have the manpower or the reactor nearby."

An SNM working group is currently putting together a report of possible radioisotope suppliers for the US market, and expects to release it at SNM's 2008 Annual Meeting. The report likely will not contain suggested final solutions, but will provide an update on talks with potential sources with the physical and intellectual resources to develop production capabilities, where those facilities are located, and estimates on development/production costs.

To read the AECL Press Release, please click [here](#). To access SNM's Molybdenum-99 Supply Resource Center, please click [here](#). To read "SNM explores feasibility of US medical isotope source" from Aunt-Minnie.com, May 22, 2008 click [here](#) (registration required).
NRC Issues New Guidance on Release of Thyroid Patients Administered Radioactive Iodine

The Nuclear Regulatory Commission (NRC) has issued new guidance to medical licensees to strengthen existing precautions against the possibility that infants and young children who come in contact with thyroid cancer patients may receive unnecessary doses of radiation. The guidance recommends that patients given therapeutic doses of radioactive iodine-131 should avoid direct or indirect contact (for example, through shared living space) with infants and young children for a specific period of time following the therapy. The guidance also recommends that physicians should consider hospitalizing patients whose living conditions may result in the contamination of infants and young children.

The new guidance is explained in a Regulatory Issue Summary (RIS) (RIS 2008-11) for NRC medical licensees and for medical licensees in the 35 Agreement States that regulate the use of radioactive materials.

NRC Denies Crane Petition

The Nuclear Regulatory Commission (NRC) has denied a petition for rulemaking (PRM–35–18) submitted by Peter G. Crane (petitioner), requesting that the NRC amend the regulations that govern medical use of byproduct material concerning release of individuals who have been treated with radiopharmaceuticals. The petitioner believes that this regulation is defective on legal and policy grounds.

The petitioner requested that the patient release rule be partially revoked insofar as it allows patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of radioactive iodine I–131 (I–131) in their bodies. The NRC has determined that the issues raised in the petition do not justify a rule change. To read the Federal Register Notice, please click here.

NRDC Petitions the NRC for Rulemaking Regarding Licensing the Use or Export of Highly Enriched Uranium

The Nuclear Regulatory Commission (NRC) is requesting public comment on a petition for rulemaking filed by the Natural Resources Defense Council (NRDC). The NRDC is requesting that the NRC amend the regulations that govern domestic licensing of production and utilization facilities, and special nuclear material to establish a date when the NRC will no longer license the use or export of highly enriched uranium (HEU) except for restricted use by a few specialized facilities. The NRDC believes that the amendment is needed to protect the public from potential exposure to an improvised nuclear explosive device made with HEU and used by terrorists. Comments are due by August 11, 2008. To read the Federal Register Notice, please click here.

HPRA Staff is looking for your input on this petition for rulemaking. Please send your comments to Cindy Tomlinson, Associate Director, Health Policy and Regulatory Affairs at ctomlinson@snm.org no later than close of business on Monday, July 7, 2008.

NRC to Consider Petition from the AAPM in Rulemaking Process

The Nuclear Regulatory Commission (NRC) will consider the issues raised in the petition for rulemaking (PRM-35-20) submitted by E. Russell Ritenour, PhD, on behalf of the American Association of Physicists in Medicine (AAPM), in the rulemaking process. The petitioner requested that the NRC amend its regulations that address training requirements for experienced Radiation Safety Officers (RSOs) and Authorized Medical Physicists (AMPs). In its review and resolution of the petition, the NRC concluded that revisions made to the regulations in 2005 may have inadvertently affected a group of board certified professionals. Click here to read the Federal Register Notice. Click here to read the AAPM petition.

SNM/ACR Issue Joint Comments to HCPCS Workgroup

On May 7, 2008 the SNM and the American College of Radiology (ACR) attended the 2008 HCPCS meeting at CMS headquarters in Baltimore, MD and jointly issued comments regarding the following preliminary HCPCS workgroup decisions:

08.91 Existing code G3001 "ADMINISTRATION AND SUPPLY OF TOSITUMOMAB, 450 MG" adequately describes the product that is the subject of your request.

08.92 Existing codes A9544 "IODINE I-131 TOSITUMOMAB, DIAGNOSTIC, PER STUDY DOSE" adequately describe the product that is the subject of your request.

08.124 Establish Axxxx "SODIUM FLUORIDE F-18, DIAGNOSTIC, PER STUDY DOSE, UP TO 30 MILLCURIES"
08.61 (Revise existing code A9502 which currently reads: "TECHNETIUM TC-99M TETROFOSMIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 40 MILLICURIES" to instead read: "TECHNETIUM TC-99M TETROFOSMIN, DIAGNOSTIC, PER STUDY DOSE").

To read the full SNM/ACR comment letter, please click here.

HHS and CMS Announce New Efforts to Help Improve Medical Products for Patient Safety and Quality of Medical Care

The Department of Health and Human Services (HHS) together with the Centers for Medicare and Medicaid Services (CMS) announced efforts underway at the U.S. Food and Drug Administration (FDA) and CMS that will complement each other to improve patient safety and the quality of medical care.

In a white paper released by the FDA, the agency describes plans for the Sentinel Initiative, which will include the development of a new electronic system that will enable FDA to query a broad array of information to identify possible post-market adverse events. The Sentinel System will be created through public-private partnerships and will capitalize on existing large electronic claims and medical records data sources maintained by private and government entities that agree to participate in this nationwide effort.

A CMS final regulation will make it possible for federal agencies, states, and academic researchers to use claims data from the Medicare prescription drug program (Part D) – subject to protections for beneficiary privacy and commercially sensitive data – for public health and safety research, quality initiatives, care coordination and other research and analysis.

Quick Notes

USP General Chapter <797> Educational Resources
The revision of US Pharmacopeia (USP) General Chapter <797>, Pharmaceutical Compounding - Sterile Preparations, will go into effect on June 1, 2008. The USP is now offering educational programming—both in-person and online—to help healthcare practitioners properly interpret and incorporate upcoming changes into their work. Click here for USP Educational Resources. Click here for USP Status Update of Chapter <797>.

FDA Draft Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan Available for Comment
The Food and Drug Administration's (FDA) draft Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan is now available for public comment. The plan is intended to communicate FDA's strategy for meeting the commitments for enhancing and modernizing the drug safety system within the context of the PDUFA IV program. Comments are due by June 19, 2008. Click here to read the Federal Register Notice.

Nuclear Regulatory Commission Publishes Semiannual Regulatory Agenda
The Nuclear Regulatory Commission (NRC) has published its semiannual regulatory agenda in accordance with Public Law 96-354 “The Regulatory Flexibility Act” and Executive Order 12866 "Regulatory Planning and Review." The agenda is a compilation of all rules on which the NRC has recently completed action or has proposed or is considering action. This issuance updates any action occurring on rules since publication of the last semiannual agenda on December 10, 2007 (72 FR 70204). Click here to read the Federal Register Notice.

NRC to Consider Petition from the Organization of Agreement States in Rulemaking Process
The Nuclear Regulatory Commission (NRC) will consider the issues raised in a petition for rulemaking (PRM–34–06) submitted by Barbara Hamrick, Chair, Organization of Agreement States, Inc. (OAS) in the NRC's rulemaking process. The petitioner requested that the NRC amend its regulations to require that an individual receive at least 40 hours of radiation safety training before using sources of radiation for industrial radiography, to revise the requirements for at least two qualified individuals to be present at a temporary job site, and to clarify how many individuals are required to meet surveillance requirements. The petitioner also requested that NUREG–1556, Volume 2, be revised to reflect the proposed amendments. The NRC has determined that this petition will be considered through NRC's rulemaking process. Click here to read the Federal Register Notice. Click here to read the OAS petition.

Contact hpra@snm.org to be notified by email of new newsletters.
HPRA Newsletter: A Year in Review

Here are some of the headlines from the past year's HPRA Newsletter. (Please click on each date to see the full issue of the newsletter.)

January 2007. Introducing the HPRA Newsletter In an effort to more clearly define for our members, industry partners, and other colleagues the services we provide, the Public Affairs Department has changed its name to the Department of Health Policy & Regulatory Affairs (HPRA). ~ Focus On: Medical Imaging Cuts, AMIC Throughout 2006, SNM, and approximately 40 other imaging societies, manufacturers, and patient advocacy groups worked together as the Access to Medical Imaging Coalition (AMIC) to find a solution to the Medicare reimbursement reductions for independent imaging facilities and physician offices brought on by the Deficit Reduction Act (DRA) of 2005. ~ CARE Bill Introduced in the House The federal legislation now known as the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) bill (H.R.583) was introduced into the U.S. House of Representatives on Friday, Jan. 19, by Representative Mike Doyle (D-PA 14th) and referred to the House Committee on Energy and Commerce. ~ NRC 313A Forms and Guidance The U.S. Nuclear Regulatory Commission (NRC) released RIS-06-027 announcing the availability of the new Form 313A series ("Training and Experience and Preceptor Attestation Forms") for those seeking recognition as Radiation Safety Officers, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Authorized Users) and accompanying guidance documentation for their completion. ~ McGaffigan to Leave NRC NRC Release - ROCKVILLE, MD ~ Nuclear Regulatory Commission member Edward McGaffigan, Jr., a 31-year veteran of public service and member of the Commission since 1996, announced today (January 5, 2007) he will leave the regulatory body upon the confirmation of a successor. ~ SNM Comments on Medication Management Standard 4.10 The SNM, together with the SNM Technologist Section, submitted comments to the Joint Commission (formerly Joint Commission on Accreditation of Healthcare Organizations) regarding the "Proposed Revisions to the Medication Management Standards MM.4.10 and MM.8.10: Prospective and Retrospective Review of Medication Orders and Prescriptions by a Pharmacist." ~ UnitedHealthcare to Require Accreditation for Reimbursement UnitedHealthcare (UHC) has released a policy requiring that all participating, freestanding imaging facilities and physician offices performing Nuclear Medicine / Cardiology, PET, CT, CTA, MRI, MRA and Echocardiography obtain accreditation by March 1, 2008 as a condition for reimbursement. ~ SNM Coding Corner Now Available to the Public The SNM is pleased to announce that access to the Coding Corner will now be available free of charge.

February 2007. SNM Joins Effort in Renewing Battle to Halt Imaging Payment Cuts On Wednesday, February 28, 2007, several Members of Congress announced that new legislation is being introduced to delay further implementation of the deep payment cuts in medical imaging services for Medicare patients, which went into effect January 1, 2007. ~ FDA CDER DMIHP Update Dr. George Mills's current replacement at FDA CDER is Dr. Rafel (Dwaine) Rieves, a hematologist and published poet. ~ CARE Legislation, February Alliance Meeting On February 26, the Alliance for Quality Medical Imaging and Radiation Therapy—a group of 20 radiologic science organizations representing more than 350,000 imaging technologists, radiation therapists and medical physicists—held their Winter/Spring meeting to discuss the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy bill (CARE bill) and work on potential draft regulations to propose to the U.S. Department of Health & Human Services should the CARE bill be enacted. ~ IAEA and ISO Introduce International Supplemental Radiation Symbol On February 15, 2007, the International Atomic Energy Agency (IAEA) and the International Organization for Standardization (ISO) launched a new ionizing radiation warning symbol to supplement the traditional international symbol for radiation, the three cornered trefoil, which has no intuitive meaning and little recognition beyond those educated in its significance. ~ CMS Releases Updated RVUs for 2007 DRA Affected Codes The Centers for Medicare and Medicaid Services (CMS) has released an update to the 2007 Medicare Physician Fee Schedule Relative Value Units (RVUs). Codes subject to the Deficit Reduction Act (DRA) imaging provisions were revised in order to closely match their payment amounts with the Hospital Outpatient Prospective Payment System (HOPPS) amounts to which they are capped. ~ FDA/FDG Industry Survey In January 2007, SNM and the Nuclear Medicine Industry Leaders Working Group (NMIWG) compiled a survey to determine the range of specifications for [18F]FDG across the industry for submission to the Food & Drug Administration (FDA). ~ NAS Studies on State of the Science and Isotope Production Without HEU The National Academy of Sciences (NAS) "State of the Science in Nuclear Medicine" committee held their sixth and final meeting on February 19-20, 2007, in Washington, DC. ~ NRC IN Regarding Sodium Iodide I-131 Capsules Remaining in Vials After Administration The U.S. Nuclear Regulatory Commission (NRC) issued an information notice (IN) (.Pdf file) to alert addressees about events in which patients were administered dosages of sodium iodide iodine-131 (I-131) that were less than the prescribed dosages, because of sodium iodide I-131 capsules that remained in vials, containing multiple capsules, after administration. ~ NRC Announces Appointment of New Member to the ACMUI The Nuclear Regulatory Commission announced the appointment of Darrell R. Fisher, Ph.D., as the patient's rights advocate on the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

March 2007. CMS Sends Letter to MedPAC on 2008 Sustainable Growth Rate; SNM Weighs in on Issue On February 28, 2007, the Centers for Medicare and Medicaid Services (CMS) sent a letter to the Medicare Payment Advisory Commission (MedPAC) providing the estimate of the 2008 physician fee schedule (PFS) update, conversion factor, and sustainable growth rate (SGR), along with
the data used in making the estimates. ~ Mallinckrodt Tc-99m Generators Return to Market Following Voluntary Recall In early March 2007, Mallinckrodt initiated a voluntary recall of all lots of its Ultra-TechneKow® DTE Generator (Technetium Tc-99m Generator) manufactured on or after February 23. ~ RT in DC Hill Event Held to Support CARE Legislation The American Society of Radiologic Technologists (ASRT) held their annual "R.T. in D.C." event on March 18-20, 2007, in Washington, D.C., to support the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy bill (CARE bill). ~ SNM Reimbursement Roadshows Continue to Satisfy 2007 marked another successful year for the SNM Reimbursement Roadshows. ~ Notice Regarding Revised CMS-1500 Form It has recently come to the attention of Centers for Medicare & Medicaid Services (CMS) that there are incorrectly formatted versions of the revised CMS-1500 (08-05) form being sold by print vendors, specifically the Government Printing Office (GPO). ~ Why do the 2007 HOPPS cap rates appear to be lower than expected? Denise Merlino, SNM coding and reimbursement consultant, and Pamela Kassing, American College of Radiology staff, authored an article exploring why the Hospital Outpatient Prospective Payment System (HOPPS) cap rates seem to have been reduced since January 2007. ~ March 16 OSHA Stakeholder Meeting On March 16, 2007, the Occupational Safety and Health Administration (OSHA) hosted the first of four stakeholder meetings on "Occupational Exposure to Ionizing Radiation." ~ NRC Call for Nominations for the Nuclear Pharmacists Position of ACMUI The U.S. Nuclear Regulatory Commission (NRC) is advertising for nominations for the position of nuclear pharmacist on the Advisory Committee on the Medical Uses of Isotopes (ACMUI). ~ June 2007 NRC ACMUI Meeting to Consider Part 35 T&E Requirements At this writing, the NRC staff is currently in the process of compiling a preliminary agenda for the June 2007 public meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

April 2007. NRC Draft Final Rule on Accelerator Products The U.S. Nuclear Regulatory Commission’s (NRC) proposed rulemaking on naturally occurring and accelerator produced radioactive material (NARM) to implement Section 651(e) of the Energy Policy Act of 2005 was published in the Federal Register on July 28, 2006 (71 FR 42952) for a 45-day public comment period. ~ AMA and SNM to Conduct Physician Practice Information Survey The American Medical Association (AMA), with the support of the SNM and more than 60 other medical specialty societies, will conduct a multi-specialty survey of America’s physician practices in 2007. ~ CMS Announces NPI Deadline Extension The Centers for Medicare & Medicaid Services (CMS) is initiating a contingency plan that extends the compliance date for the National Provider Identifier (NPI) from May 23, 2007 to May 23, 2008. ~ Action Alert: CARE Medical imaging and radiation therapy professionals everywhere are asking their Representatives and Senators to cosponsor and support the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) bills. ~ FDA Releases Draft Guidance for Industry Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products

May 2007. NRC Chairman to Speak at SNM Annual Meeting US Nuclear Regulatory Commission (NRC) Chairman Dr. Dale E. Klein is planning to speak at the SNM opening plenary session on the morning of June 3, 2007. ~ Senators Continue to Press for Relief from DRA’05 Imaging Payment Cuts US Senators Jay Rockefeller (D-WV) and Gordon Smith (R-OR) introduced the Access to Medicare Imaging Act of 2007 (S. 1338) on May 8, 2007. ~ NRC Approves Final NARM Rule The US Nuclear Regulatory Commission (NRC) approved the final rule on naturally occurring and accelerator produced radioactive material (NARM) by a vote of 5-0 on May 14, 2007. ~ SNM &AMA Conducting Physician Practice Information Survey For the first time in nearly a decade, SNM, the American Medical Association (AMA), and more than seventy other medical specialty societies, are working together to coordinate a comprehensive multi-specialty survey of America’s physician practices.

June 2007. Senate Appropriators Restore Funding for Basic Nuclear Medicine Research at DOE The full Senate Appropriations Committee approved the Senate Energy and Water (E&W) Development Subcommittee of Appropriations bill that restored funding for basic nuclear medicine research at the Department of Energy (DOE) Office of Science / Office of Biological and Environmental Research "Medical Applications and Measurement Science (MAMS) program for fiscal year (FY) 2008. ~ CMS to Consider Coverage of PET for Inflammation and Infection The Centers for Medicare and Medicaid Services (CMS) has posted a National Coverage Analysis (NCA) tracking sheet for FDG PET for infection and inflammation (CAG-00382N). ~ 2007 SNM Annual Meeting Government Relations Highlights The 2007 SNM Annual Meeting was a tremendous success from a government relations perspective—one that the molecular imaging and therapy community will continue to build upon for many years to come. ~ Physician Quality Reporting Initiative (PQRI) Starts Soon On July 1, 2007, the Centers for Medicare and Medicaid Services (CMS) will begin the voluntary Physician Quality Reporting Initiative (PQRI). ~ June 12-13 ACMUI Meeting Summary The key highlight of the US Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) meeting was an open discussion on the implementation of 10 CFR Part 35 Training and Experience (T&E) requirements. ~ NAS Report on Competitiveness of US Chemistry Research Statements address effect of Department of Energy funding cuts, need for domestic radioisotope production.

Complete the SNM Radiopharmaceutical Survey SNM is currently collecting data related to the cost of radiopharmaceuticals in the office and hospital settings. ~ SNM Meets with FDA Commissioner & CDER Staff SNM met with US Food and Drug Administration (FDA) Commissioner Andrew C. von Eschenbach, MD and FDA Center for Drug Evaluation and Research (CDER) staff to discuss the need for additional personnel with molecular imaging experience in the reviewing division, requested the reinstatement of the Medical Imaging Drug Advisory Committee, and introduced draft concepts and potential strategies for advancing emerging molecular imaging technologies. ~ House Passes PDUFA Reauthorization Legislation The US House of Representatives passed the Food and Drug Administration Amendments Act of 2007 (HR 2900) which amends the Federal Food, Drug and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, and enhances the postmarket authorities of the FDA with respect to the safety of drugs, and for other purposes.

August 2007. SNM Opposes Provisions in Section 309 of House CHAMP Bill SNM signed a letter opposing certain provisions of Section 309 of the Children’s Health and Medicare Protection (CHAMP) Act, which directs the Center for Medicare and Medicaid Services (CMS) to cut imaging reimbursement. ~ California Releases Clarification of June 18 Information Notice – Technologist Requirements for Operating PET/CT and SPECT/CT Specifically, a Certified Technologist, Nuclear Medicine (CTNM), who operates a CT/PET or CT/SPECT machine to perform PET or SPECT scan, respectively, is not required to be certified in Radiologic Technology if the machine, during the scan, uses X-rays only for attenuation correction and not for diagnostic CT imaging. ~ GE Healthcare Letter to Customers Regarding CERETEC® (Technetium Tc99m Exametazime) Supply GE Healthcare released a letter informing customers of an imminent shortage of CERETEC® (Technetium Tc99m Exametazime) due to their Gloucester, England manufacturing site temporarily closing because of flooding. ~ NRC Issues Supplement 1 to RIS 2006-27, Availability of NRC 313A Series of Forms and Guidance for Their Completion The NRC issued a supplement to Regulatory Information Summary (RIS) 2006-27, “Availability of NRC 313A Series of Forms and Guidance for Their Completion,” dated December 13, 2006, to inform addressees that revisions have been made to three of the NRC 313A Forms and to the guidance for completion of the forms. ~ 2007 Lung Perfusion Phantom Shipping The 2007 Lung Perfusion Phantom—the newest simulator from the SNM Quality Assurance Committee—will be shipping to participating US Department of Veterans Affairs (VA) hospitals on September 15, 2007.

September 2007. Action Alert: NAS Study Support Nuclear Medicine Research On September 20, the National Academy of Sciences released their "State of the Science in Nuclear Medicine" final report, entitled "Advancing Nuclear Medicine Through Innovation." ~ NRC Publishes Final Rule on Naturally Occurring and Accelerator Produced Radioactive Material The Nuclear Regulatory Commission (NRC) has published its final rule expanding the definition of radioactive materials subject to its regulatory authority, implementing provisions of the Energy Policy Act of 2005. The new regulations became effective November 30. ~ Joint Commission Medication Management Standards The Joint Commission is interested in revising the current MM.4.10 EP 1 for various settings. ~ SCHIP Reauthorization Update / Veto HPRA is pleased to report that the House Medicare provisions that would have severely cut reimbursement for imaging services in 2010 did not make it into the final bill. Additionally, the President vetoed the legislation on October 3, 2007. ~ PDUFA IV Signed by President Bush On September 27, 2007, President Bush signed the Prescription Drug User Fee Act (PDUFA) reauthorization legislation; the final compromise bill incorporated the House PET exemptions. ~ Armed Forces Institute of Pathology The Senate passed HR 1585 to authorize appropriations for fiscal year 2008 for the Department of Defense, which included an amendment from Senator Ted Kennedy (D-MA) addressing the Armed Forces Institute of Pathology.

October 2007. Health Care Professionals to Participate in "Virtual March" for Patient Safety Legislation Organizations representing more than 750,000 health care workers will participate in a "virtual march" on Capitol Hill in early November to rally support for the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy (CARE) bill. ~ SNM Ad Urges Congress to Fund Nuclear Medicine Research SNM took out a full-page, full-color ad in Roll Call urging Congress to fund basic nuclear medicine research. ~ 2008 CPT Codes: Important Changes for NM Professionals The AMA recently released the 2008 CPT codes that will be effective January 1, 2008. ~ Accreditation Standards for CT Laboratories Released The Intersocietal Commission for the Accreditation of Computed Tomography Laboratories (ICACTL) recently released standards for laboratories delivering CT imaging services. ~ Update on the Proposed Revisions of USP <797> According to information recently updated on the U.S. Pharmacopeia (USP) website, the Sterile Compounding Expert Committee (SCC) has completed their review of the public comments regarding the proposed revisions of USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations. ~ FDA Publishes Prescription Drug and Medical Device User Fee Rates for FY 2008 The U.S. Food and Drug Administration (FDA) published the prescription drug user fee and medical device user fee rates for fiscal year (FY) 2008 in the Federal Register. ~ NRC Denies Stein Petition In an October 24 Federal Register notice, the U.S. Nuclear Regulatory Commission (NRC) announced that they denied the petition for rulemaking (PRM-35-19) submitted by William Stein, III, MD.

performance Measurement Set The American Medical Association (AMA) Physician Consortium for Performance Improvement is soliciting public comments from November 15, 2007, through December 14, 2007, for its Nuclear Medicine: Radionuclide Bone Imaging Physician Performance Measurement Set, developed by SNM and the Consortium. ~ National Oncologic PET Registry (NOPR) Takes Another Step Forward The rationale and development of the National Oncologic PET Registry (NOPR) are described in the article entitled "The National Oncologic PET Registry (NOPR): Design and Analysis Plan" in the November 2007 Journal of Nuclear Medicine. ~ State Health Policy Liaison (SHPL) Program "Rebranding" SNMTS Advocacy Committee and SNM-ACNP Joint Government Relations Committee leaders are coordinating a "rebranding" and reinvigoration effort of the grassroots advocacy network (members of which were formerly called State Health Policy Liaisons, or SHPLs). ~ CDC-AHRQ Study Published in JNMM Newsline A report from the U.S. Centers of Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ) on the release of patients containing byproduct material in the context of radiation monitoring at security checkpoints was published in the December 2007 Journal of Nuclear Medicine.

December 2007. Funding for Basic Nuclear Medicine Research at DOE Office of Science Restored for FY 2008 On December 26, 2007, President Bush signed an omnibus appropriations package for fiscal year 2008, containing $411,273,000 for biological research at the Department of Energy (DOE) Office of Science, including $31,500,000 for Medical Applications and Measurement Science. ~ Reimbursement Freeze for Radiopharmaceuticals Congress finalized legislation on December 20, 2007 to extend the 2007 reimbursement methodology for therapeutic radiopharmaceuticals into 2008. ~ Mo-99 Supply Update On December 12, the Parliament of Canada passed emergency legislation to bypass the Canadian Nuclear Safety Commission (CNSC) and allow the Atomic Energy of Canada Limited (AECL) to restart the National Research Universal (NRU) reactor. ~ CMS and President Delay Some Cuts for 2008 On Saturday December 29, 2007, the president signed S.2499 the Medicare, Medicaid and SCHIP Extension Act of 2007 into law. Additionally on Friday December 28, 2007, CMS issued a final rule delaying until January 1, 2009, the applicability of the anti-markup provisions in §414.50, as revised at 72 FR 66222. ~ CMS Posts Negative Decision for FDG PET for Infection and Inflammation CMS posted a proposed negative decision on infection and inflammation for PET. ~ CMS Posts National Coverage Determination for Cardiac CTA The Centers for Medicare and Medicaid Services (CMS) published a National Coverage Determination for Computed Tomographic Angiography. ~ NRC Announces Final NUREG-1556, Volume 13, Revision 1 The U.S. Nuclear Regulatory Commission (NRC) announced the availability of the final NUREG-1556, Volume 13, Revision 1, Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Commercial Radiopharmacies, in a December 10 Federal Register notice (Volume 72, Number 236). ~ FDA Semiannual Regulatory Agenda - PET Drugs CGMP The U.S. Food and Drug Administration (FDA) issued an inventory of the rulemaking actions being developed in a December 10 Federal Register "Semiannual Regulatory Agenda" notice (Volume 72, Number 236).

January 2008. SNM Sends Comments to CMS Responding to the 2008 Final HOPPS & MPFS Rules On January 28, 2008, the SNM sent comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (MPFS) final rules for calendar year (CY) 2008. ~ CMS Posts Instructions for NOPR QR Deletion CMS released Transmittal R1418CP, CR 5805 notifying PET facilities and Medicare Administrator Contractors that the discontinued QA, QR, and QV HCPCS modifiers are replaced by the new 2008 created modifiers Q0 (zero) and Q1 to identify investigational and routine clinical services provided in a clinical research study approved by Medicare. ~ Hospital Billing Alert: Claims without a Radiopharmaceutical Will Be Returned Effective January 1, 2008, CMS implemented an Outpatient Code Edit (OCE) that will result in the return of (for correction) any claim for a nuclear medicine procedure that does not contain a HCPCS Level II radiopharmaceutical code. ~ Canadian Nuclear Safety Commission President Stripped of Position Linda Keen, Canadian Nuclear Safety Commission (CNSC) President, was stripped of her position on January 16, 2008 due to concerns regarding CNSC's handling of the National Research Universal (NRU) reactor situation and subsequent MO-99 supply crisis. ~ FDA Draft PDUFA IV Information Technology Plan The U.S. Food and Drug Administration (FDA) announced the availability for public comment of the draft information technology (IT) plan entitled "Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan" in a December 28, 2007 Federal Register notice (Volume 72, Number 248). ~ UnitedHealthcare Extends Accreditation Requirement Until Third Quarter 2008 In response to physician feedback UnitedHealthcare has decided to extend the accreditation program implementation date until the third quarter 2008, effectively July – September 2008. ~ NRC To Hold Meetings on Security Requirements For Transporting Radioactive Materials The U.S. Nuclear Regulatory Commission (NRC) held three public meetings in January to obtain public comments on plans to revise security requirements for transporting Radioactive Material in Quantities of Concern (RAMQC), a term given to 16 radionuclides considered potentially of interest for a malicious act.

February 2008. Budget Recommendations for DOE FY 2009 Released The Department of Energy (DOE) released its budget recommendations for Fiscal Year (FY) 2009 in early February. ~ SNM Thanks Congress for Restoring Nuclear Medicine Funding SNM has placed an ad in the March 5th issue of Roll Call, a nonpartisan newspaper that provides updates of legislative and political
interest on Capitol Hill, thanking Congress for restoring basic nuclear medicine research to the Department of Energy (DOE) Office of Science. ~ **AHRQ Proposes Patient Safety Regulations** The Agency for Healthcare Research and Quality (AHRQ) released proposed regulations in the February 12th Federal Register (Volume 73, Number 29) to implement certain aspects of the Patient Safety and Quality Improvement Act of 2005. ~ **NAS Report Encourages the Government to Spur Replacement of Radioactive Cesium Chloride in Medical and Research Equipment** The National Academies released a report on February 20, 2008 that encourages the Government to promote the replacement of radioactive cesium chloride radiation sources with lower-risk alternatives. ~ **2008 Thyroid Phantom Shipped** The 2008 Thyroid Phantom—the newest simulator from the SNM Quality Assurance Committee—was shipped to participating U.S. Department of Veterans Affairs (VA) hospitals on March 3, 2008. ~ **The Physician Quality Consortium Nine months after SNM President Dr. Sandy McEwan created a working group to develop measures for the AMA Physician's Consortium on Quality, the members voted unanimously in late February to pass two bone scan measures. ~ **SNM Comments to NRC Regarding "Medical Use of Byproduct Material—Amendments/Medical Event Definitions"** SNM submitted comments on March 3, 2008 to the Nuclear Regulatory Commission (NRC) on an Advanced Notice of Proposed Rulemaking Regarding "Medical Use of Byproduct Material—Amendments/Medical Event Definitions". ~ **MedPAC Releases March 2008 Report to the Congress: Medicare Payment Policy** The Medicare Payment Advisory Commission (MedPAC), the independent Congressional agency established to advise the U.S. Congress on issues affecting the Medicare program, has recently released their March 2008 *Report to the Congress: Medicare Payment Policy.*

**March 2008. NOPR Study Released: Confirms FDG-PET Has Major Impact on Management of Cancer Patient Care** According to a study of data from the National Oncologic PET Registry (NOPR) published in the online version of the Journal of Clinical Oncology (JCO), clinicians changed the intended care of more than one in three cancer patients as the results of FDG-PET scan findings. ~ **CMS Finalizes Negative Decision for Positron Emission Tomography (FDG) for Infection and Inflammation** "We are continuing our national noncoverage of FDG-PET for these indications. CMS has also determined that the request for coverage is not appropriate for the Coverage with Evidence Development (CED) paradigm." ~ **Independent External Review Panel Recommends Changes to NRC’s Materials Licensing Process** The Nuclear Regulatory Commission’s Independent External Review Panel has recommended several changes to the NRC’s process for granting licenses to possess radioactive materials aimed at eliminating vulnerabilities that could be exploited by terrorists or other adversaries. ~ **SNMTS Sends Letter to NYC Mayor Bloomberg** The SNMTS sent a letter earlier this month to New York City Mayor Bloomberg expressing opposition to proposed legislation (Proposed Int. No. 650-A) that would "amend the administrative code of the city of New York in relation to permits for biological, chemical and radiological detectors." ~ **R.T. in D.C. Hill Event Held to Support CARE Legislation** The American Society of Radiologic Technologists (ASRT) held their annual "R.T. in D.C." event on March 10-11, 2008, in Washington, D.C. to support the "Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act of 2007" (S. 1042/H.R. 583). ~ **CARE Bill Passed in Senate HELP Committee** The Senate Health, Education, Labor, and Pensions (HELP) Committee passed by voice vote the "Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act of 2007" (S.1042), in an unannounced markup on March 14th.

**April 2008. CMS Reconsiders Coverage for NOPR—Comment Deadline: May 10th** The reconsideration of the PET National Coverage Decision (NCD) (CAG-00181R) by the Centers for Medicare and Medicaid Services (CMS) is now open for public comment. ~ **NRC Proposes Expansion of National Source Tracking System** The Nuclear Regulatory Commission (NRC) is proposing to expand its National Source Tracking System (NSTS) to include an additional 3,500 NRC and state licensees and nearly 17,000 additional radioactive sources, to improve accountability and control of radioactive materials. ~ **CMS Updates Hospital Nuclear Medicine Procedure & Radiopharmaceutical OCE Edits for April 2008** CMS has posted revised OCE edits for diagnostic radiopharmaceuticals and nuclear medicine procedures. ~ **Noridian Posts Announcements Regarding PET Scan Services Denying Inappropriately** Noridian Administrative Services has recently released new information for Part B PET scan providers regarding the inappropriate denial of some PET services. ~ **Reminder: Hazmat Personnel Need to be Properly Trained and Documented** Hospitals and medical facilities that ship radioactive sources (including radiopharmaceuticals) may be subject to inspections by the Department of Transportation (DOT), including the Federal Aviation Administration (FAA).