I will summarize the accomplishments of SNM since the Mid-winter BOD meeting that I could not attend due to an injury. First I want to thank George Segall for stepping in my place at the last minute as President-Elect, chair the BOD meeting, and represent me at the HOD meeting. I also want to thank him for staying in close communication with me by phone during that period of time.

Advocacy at the Federal level for reimbursement and regulatory issues

Advocacy has implications in many of the other SNM goals. With the new lobbying firm Arent Fox and the new SNM director of Health Policy and Government Relations, Sue Bunning, SNM is now again appropriately staffed to lead to goals of the strategic plan related to advocacy and government affairs.

SNM continues to work with the medical community on long-term strategies for improving supply and strongly advocate for a domestic supply of Mo-99 in the United States. I want to thank Bob Atcher for attending the fourth meeting on high level group on the security of the supply of medical radioisotopes (HGL-MR) in Paris, France on January 27-28, 2011, with alternate funding, and submitting a comprehensive report to the SNM leadership and SNM HPRA department (See Appendix I).

The NRC had hearing in several cities in November 2010 about regulations for radiation exposure and release of patients treated with I-131. Several SNM representatives attended these meetings. Data are being gathered about radiation doses received by different types of radiation workers at academic institution and industry. SNM leadership is also revising the SNM brochure for patients treated with I-131 and will seek NRC approval as with the former version. The SNM Practice guideline for therapy of thyroid disease with I-131 is also revised.

The new FDA regulations regarding current Good Manufacturing Practice (cGMP) of PET radiopharmaceuticals is of great concern. Tremendous efforts were done to help the membership for new drugs and devices applications in collaboration with the FDA. The FDA has become hesitant to collaborate with a single organization and poorly responsive. SNM has formed a coalition to negotiate with the FDA an easier process for new drugs and devices applications. A progress report from Sue Bunning is in Appendix II.

Significant accomplishments of the Clinical Trials Network (CTN) include qualification of over 40 imaging centers over the world and development of a curriculum to educate these centers about the practice of clinical trials. The CTN business model has been reorganized and will be presented by Michael Graham, co-chair of CTN. These CTN programs will be marketed on an individual basis in the future. The National Comprehensive Cancer Network (NCCN) Specialized Research Consortium (SRC) is considering using the services of the SNM CTN for qualifications and education of the imaging sites performing PET imaging in their upcoming multicenter trials.

Comparative Effectiveness Research (CER) and Guidelines
This past year, major accomplishments occurred with CER and guidelines.

A strategic plan for CER has been drafted after the CER workshop from July 2010 and a session on CER was organized at the High Country meeting held on March 11-16, 2011 in Steamboat Spring, CO. Following the session, there was a CER strategic planning meeting where the next steps moving forwards were identified. Whereas modeling and registries will be further explored in the future, SNM will take a leader role in: 1) Education about CER, 2) Identification of evidence gaps, 3) Communication and building partnership with stakeholder organizations, and 4) Starting the development of evidence-based guidelines for nuclear medicine and molecular imaging which will include quality measurements. CER is on the agenda for Sunday afternoon when the next steps will be discussed.

Appropriateness Use Criteria (AC) and guidelines are included more and more commonly in computerized order entry system in attempts to promote appropriate utilization of diagnostic imaging. The American College of Radiology (ACR) and the American College of Cardiology (ACC) are the two primary organizations that have developed AC for diagnostic imaging including nuclear medicine procedures and SNM has become an established collaborative organization. SNM is also collaborating with ACR, ACC, American Thyroid Association (ATA) and National Comprehensive Cancer Network (NCCN) on various Practice Guidelines that are of common interest.

SNM continue to support the development and revisions of its own guidelines. A discussion about the inclusion in the guidelines of specific requirements for maintenance of certification is on the agenda for Sunday morning.

The SNM has published a comparison of various residency program requirements for therapeutic procedures using radiopharmaceuticals and recommendations for training in a conjoint statement from the SNM/ACNM/ABNM on credentialing and delineation of privileges for therapeutic procedures using radiopharmaceuticals has also been published in the February issue of JNM. Members from ABR and ACR have participate (as individuals) to discussions and helped making edits to the document in an attempt to facilitate future collaboration with ABR and ACR on training issues.

Reduction of radiation exposure, when appropriate is a high priority for SNM. The Pediatric Council of the SNM is actively participating in the Image Gently initiative to reduce radiation exposure in children. At the RSNA, the Image Wisely program has been launched. The SNM committee on council has drafted a plan and timeline to launch the SNM Image Wisely website in the fall 2011. This topic will be addressed by Fred Fahey, vice-President-Elect who has been instrumental with that initiative, as well as Chris Palestro.

**Education**

Another area of high importance in which SNM have made significant strides is education.

The SNM Annual Meeting remains one of the main educational venues for nuclear and molecular imaging professionals. The 2010 meeting in Salt Lake City, UT was attended by approximately 3,000 professionals, 25-30% of which were international. The 2011 meeting will
be June 4-6, 2011 in San Antonio, TX and will celebrate the completion of the Molecular Imaging (MI) campaign. Molecular imaging has now been integrated in the disease tracks. The conjoint SNM/ACNM meeting will take place January 26-29, 2012 in Orlando, FL. As in previous years, SNM has also organized successful sessions at RSNA, ASTRO in the fall 2010 and ASCO in June 2011.

The Center for Molecular Imaging and Translation (CMIIT), the former Molecular Imaging Center of Excellence, has organized several Molecular Imaging Symposia including the Breast Imaging Symposium in Bethesda April 21-22, 2011. The MI curriculum for scientists developed by CMIIT has been published in the April issue of JNM.

SNM web-based education has focused on maintenance of certification with the Lifelong Learning and Self-Assessment Program for Part II (LLSAP) and the Practice Performance Assessment Program for Part IV, in addition to modules of interactive CT and PET/CT cases and CT case review workshops. Under the leadership of George Segall, SNM has also created a new radioimmunotherapy (RIT) program this year: the RIT–Resources, Information, and Tools as an education and awareness program to recognize the importance of radioimmunotherapy. The RIT program will be launched on the SNM website before the Annual Meeting.

The other educational flagship of the SNM is the JNM. Under the leadership of Heinz Schelbert as Editor-in-Chief, the JNM is currently ranked number one imaging journal with an ISI impact factor of 6.424 at an all-time high, with more than 50% of the accepted manuscripts submitted from foreign countries. The term of Heinz Schelbert is coming to completion in December 2011 and I will succeed to Heinz. Heinz will be honored and congratulated at the plenary session on Monday. I did offer the current associate editors to continue to serve for the term of one year and did replace the ones who declined. The slate is being reviewed by the publication committee.

The SNM leadership has work with the two co-chairs of the ACR/SNM Joint training Task force to finalize the draft of a position article summarizing training options for nuclear medicine and radiology residency programs and making recommendations for future training options. The report of the task force will be published in the June issue of both the JNM and JACR. A session on Integrating nuclear medicine and diagnostic radiology training was organized by SNM/APDR/APCR/AMSER/SCARD at the AUR meeting in Boston, MA, on April 12-15, 2011. There were presentation from the ABR, ABNM, and ACGME and I had the opportunity to present the SNM Perspective. The recommendations of the ACR/SNM task force were discussed and this was followed by a productive panel discussion. After the session, I met with John Patti, Chair of the ACR Board of Chancellors, and we decided to appoint ACR/SNM Training task force II with the goals of creating a meaningful and practical residency training program(s) that will address the current needs for nuclear imaging and therapy as well as look to the future of molecular imaging. For example 1) Defining a combined residency training program Rad/Nucs in 4 years with 16 months nuclear medicine with eligibility for both ABR and ABNM; and 2) Defining a combined residency training program Rad/Nucs in 5 years with 24 months nuclear medicine with eligibility for both ABR and ABNM. ACGME accreditation of combined program will be considered for funding issues, and listing in the match program for visibility. In addition to leader representatives and co-chairs from ACR and SNM, other stakeholder organizations (ABR, ABNM, both RRC and both PD) will be asked to appoint two representatives. The task Force members will represent their organization.
International Education
Collaboration with international organizations is becoming more and more critical to success and this year many SNM leadership and members and volunteers have accepted to participate to international educational meetings on behalf of SNM, for example including the participation of Young Professionals at the Sino-American Conference organized by the Chinese Society of Nuclear Medicine (CSNM) and SNM on February 24-27, 2011. At these international meetings, SNM leadership has met with the leadership of these organizations to plan future collaborations.

Outreach
Outreach and education to referring physicians, patients and administrators/regulators has become a priority in the current economic environment. A strategic plan and timeline are in place.

Governance
SNM underwent a restructuring to focus on the new strategic plan. As part of the restructuring, SNM has focused on the budget. More conservative assumptions for the budgeted income, significant cuts for budgeted expenses and a 3% surplus were implemented. So far, SNM is on track to meet its FY 2011 budgeted surplus. I want to thank Richard Noto and Vince Pistelli, and the finance committee for their guidance.

In an effort to improve communication, quarterly conference calls are now organized with the HOD and the past-Presidents, in addition to the monthly conferences calls with the BOD, and bi-monthly calls with the Executive Committee. Minutes of governance meetings are also posted on the SNM website.

The SNM leadership is committed to look at the future of Molecular Imaging and Nuclear Medicine as a specialty. A Nuclear Medicine 2020 Task Force is currently working to bring together a broad cross section of health care professionals to discuss the future of the profession and the SNM, and make recommendations that will serve as guiding principles to meet the challenges that lie ahead. This topic is on the agenda and will be discussed further by George Segall, President-Elect.

Finally this year is the celebration of the end of the MI campaign at the Annual Meeting. This event brought another discussion about a name change for the society. The new name under consideration, Society of Nuclear Medicine and Molecular Imaging (SNMI) would both retain the identity of “Nuclear Medicine” and embrace the future of “Molecular Imaging”. The rationale for changing the name has been addressed in a newline article in the May issue of JNM. This topic is also on the agenda for later Sunday morning and will be discussed by Carolyn Anderson.

I wanted to thank all of you on the Board of Directors and Chairs of Commission and Committees for their contribution to the accomplishments of SNM the past quarter and in general. It was a difficult year economically but I think that we have made the right decisions and it would not have been possible without your time, engagement and expertise. I also want to thank the SNM department directors who are in the audience and ask them to extend my appreciation to the entire SNM staff.
Dominique Delbeke, MD, PhD
SNM President
Appendix I

FOURTH MEETING OF HIGH-LEVEL GROUP ON THE SECURITY OF SUPPLY OF MEDICAL RADIOISOTOPES (HLG-MR)

DRAFT SUMMARY RECORD

27-28 January 2011
OECD Conference Centre, Paris, France

27 January 2011: Open Session

Agenda item 1 (Welcome)

1. The Meeting Chair, Harrie Seeverens (Netherlands), and Luis Echávarri, Director-General, NEA, welcomed the participants. Mr. Seeverens noted that Serge Dupont (Canada), the Chair of the HLG-MR, was unable to attend the meeting but that Serge had confirmed Canada’s commitment to global cooperation on security of supply of medical radioisotopes. Mr. Echávarri highlighted the success of the HLG-MR as a forum for all supply chain players to get together, share information, communicate and co-operate in achieving results that help with security of supply. He indicated the great interest of the NEA Steering Committee in this topic and also stressed the importance of the HLG-MR developing recommendations on the fundamental changes that need to occur in the supply chain to realise long-term security of supply. The agenda was adopted without discussion. [The Agenda is given in Attachment 1 and the final list of participants is given in Attachment 2.]

Agenda item 2 (Introduction)

2. The Meeting Chair noted that the principle goal of the meeting was to discuss a policy approach that the HLG-MR could endorse at the fifth HLG-MR meeting. This policy approach would be expected to set the supply chain on the path to long-term economic sustainability and security of supply of molybdenum-99 (99Mo) and technetium-99m (99mTc). He also pointed to a number of documents that were provided to meeting participants that provided updates on key issues, including on the progress of the third instalment of the rolling action plan.

3. The Meeting Chair then called on supply chain participants to provide an update of the current market situation. The representative from the Atomic Energy of Canada Limited (AECL) and the delegate from the Netherlands provided updates on their reactors that had returned to service since the last HLG-MR meeting (the NRU and HFR respectively). Both noted that the reactors were operating as expected and supplying 99Mo to the market at pre-outage levels. The representative from AECL noted that the NRU operating licence expires in October 2011 and they have been working since 2008 to ensure the renewal of the licence out to 2016. He noted that the process for relicensing was progressing well. The delegate from Canada noted that the Government of Canada was doing everything to ensure renewal of the NRU out to 2016. The
delegate also noted that they were investing in alternative technologies to produce $^{99m}$Tc to ensure Canadian supply post-2016.

4. The representatives from Covidien and Lantheus Medical Imaging noted that the supply situation has returned to normal. Covidien mentioned that their project with Babcock and Wilcox to develop a solution-based reactor for $^{99}$Mo production is advancing. Lantheus noted that they had their first commercial run using LEU-based $^{99}$Mo sourced from NTP (South Africa).

5. The delegate from South Africa raised a concern that during the shortage there was agreement among supply chain participants that important changes needed to occur to ensure security of supply, including changing the pricing structure to allow for the necessary investment in infrastructure. He noted, however, that as soon as the immediate shortage was over there was a return to unsustainable economic practices. He noted that if this approach continues there will be an on-going crisis because investments will not occur.

6. The delegate from Belgium confirmed this pricing situation and stressed that the crisis is not over; work needs to continue to ensure reliability. He noted that there are many things that are better than before the crisis, such as communication efforts, but that the industrial set-up is the same as before and therefore there is an on-going problem with pricing practices. This concern on how market conditions had evolved was reiterated by other meeting participants.

7. The representative from Lantheus noted that there has been a substantial drop in demand for $^{99m}$Tc compared to pre-shortage levels. He noted that there have been adjustments by the users, including moving to alternative modalities and isotopes.

**Agenda item 3 (Policy approach proposed by NEA Secretariat)**

8. The NEA Secretariat presented the proposed policy approach. The presentation described the work of the HLG-MR to date, its major findings and the connection to the proposed policy approach. The Secretariat presented the central pillars of reforms, the high-level policy approach and the proposed six principles of the proposed policy approach.

9. The discussion first focused on the central pillars of reform. There was a remark that a pillar was missing – the role of government in supporting health care. The NEA Secretariat noted that it was taken as given, for this group, that this role was important and noted that any external documents would include this notion within its introduction (but not as a central pillar).

10. Meeting participants engaged in a discussion on the role of government involvement in the industry, with some participants suggesting that governments were going from subsidising production to market engineering. Other participants noted that market mechanisms were important but that there is a government role to ensure that the market can operate effectively and with the proper incentives to take action to ensure long-term sustainability, such as sourcing reserve capacity.
11. It was generally agreed that the central pillars of reform covered the major issues and that they were all important to include.

12. The discussion on the principles started with a seeking of general views on the principles. Meeting participants confirmed that the principles were addressing the right things, but raised some questions on how the principles would be implemented. In addition, they noted that the wording of the principles should be drafted such that they would apply in future market situations, such as the introduction of alternative $^{99}$Mo/$^{99m}$Tc production technologies into the supply chain.

13. In regards to principle 1, meeting participants raised a number of elements that should be included in full-cost pricing, including safety and security requirements and the management and final disposal of waste. Meeting participants agreed that there should be a common methodology that would be applied in a harmonised fashion across countries and reactors.

14. The delegate from Canada pointed out that there are existing contracts in place and that it will take time to change these contracts. It was noted that forcing changes in contracts too fast could create tensions within the supply chain and could result in legal disputes that could make change occur slower.

15. The NEA Secretariat noted that there would be differences in costs even with a full-cost pricing methodology given differences at reactors. The Secretariat also noted that the principle should be applied to new innovative technologies once they are mature enough to enter the supply chain.

16. During further discussion on principle 1, the representative from the European Council suggested that processors should be included in the requirement for full-cost recovery. Some meeting participants noted that processors operate on a commercial basis now and therefore already undertake full-cost recovery. The notion of making the principle more inclusive of the entire supply chain was supported by a number of participants and the NEA Secretariat agreed to redraft the principle.

17. Given the uncertainty about what to include in a full-cost pricing methodology and how to implement such a methodology, the NEA Secretariat suggested that working group be developed under the HLG-MR to examine the issue further.

18. A number of delegates expressed concern around the original wording of principle 3 that stated that governments should “remove all $^{99}$Mo-related subsidies to reactors”. Some participants saw this wording as being too limiting as they provide domestic support to health care, which could feed back up to reactors and may be considered a subsidy. Participants agreed that the notion was right, but that wording could be limiting as to what they may be able to do within their own countries. In addition, many participants noted that governments support research reactors and while they expect to undertake full-cost recovery for $^{99}$Mo production, there was concern on how far the notion of “removing all $^{99}$Mo-related subsidies” could be applied. The NEA Secretariat agreed to redraft the principle to reflect these concerns.
19. Some delegates expressed a concern that the importance of the government role within the supply chain, especially related to safety and security and health care, seemed to be undervalued with the principles as presented, especially relating to principle 3. The NEA Secretariat noted that, for this discussion, the importance of the government in these roles had been taken as given but that it would include wording in the principle to highlight their important role. The Secretariat stressed that the role of government subsidisation for $^{99}$Mo production should be at the health care level to remove market distortions that would occur if one government did not require full-cost pricing for $^{99}$Mo production from the reactor.

Agenda item 4 (Supporting recommendations)

20. The NEA Secretariat presented the supporting recommendations of the proposed policy approach. The supporting recommendations provided additional actions or detail on the principles, addressing the specific actions required on the part of the market participants, the government and the international community.

21. A discussion followed, focussing first on the supporting recommendation regarding the need for contracts to recognise and facilitate implementation of the full-cost pricing methodology. Meeting participants pointed out that the medical community must be included in the application of this recommendation. It was noted that they are putting downward pressure on market prices so they must be made aware of the changes that need to take place and be willing to accept them; otherwise, processors and generator manufacturers will be caught between rising costs and falling revenues.

22. Some meeting participants noted that references to contracts in the supporting recommendations should not limit the ability for the supply chain to negotiate amongst themselves, especially regarding differences on such issues as quality of services. In addition, there was a concern raised about the recommendation to allow for open access in contracts, with the representative from Covidien noting that they make significant efforts to obtain exclusivity contracts and would not want to give them up.

23. The representative from AIPES pointed out that they are willing to continue coordination efforts regarding reactor maintenance schedules on a global level but that there are limits on what they are able to do. For example, he noted that AIPES could not manage outage reserve capacity nor be able to distribute production requirements among reactors.

24. There was substantial discussion around the supporting recommendation regarding the provision of outage reserve capacity and the setting of required levels based on an n-1 criterion. It was pointed out that requiring the supply chain to pay for outage reserve capacity would require a significant change in the mind-set of the market participants. Some participants pointed out that they were already sourcing reserve capacity and therefore providing greater reliability and they expected that customers would pay for that security. It was also pointed out that outage reserve capacity is very important and without a valuation and corresponding payment it will be seen as overcapacity and force prices down.
25. Some participants raised concern that there was not enough capacity now, let alone outage reserve capacity, which would result in prices rising substantially for any potential “capacity option”; others pointed out that there was currently excess capacity and prices were being driven down.

26. There were a number of comments on the difficulty of implementing the recommendation on outage reserve capacity, what the best system would be and what would be the final impact on the supply chain economics. The NEA Secretariat pointed out that from the work within the economic study, it would seem that paying for outage reserve capacity should not have a significant impact on end prices, but that they would be willing to undertake further study on various options. The delegate from the Netherlands pointed out that any system being suggested would have to be examined closely to ensure that any unintended consequences were brought forward.

27. It was suggested that a working group be formed to examine the issue of how to source, value and pay for outage reserve capacity. This idea was supported by a number of meeting participants.

28. The delegates from the United States and Canada raised some concern around the supporting recommendation wording “Ensure reimbursement rates (or isotope budgets) are sufficient”. Specifically, they noted that it runs counter to what is currently going on in the industry, with pressure to force down reimbursement rates. They suggested that it may be easier to achieve such a goal by tracking any price changes to get information, and then, if required, make the case for changes to the rate structure. It was also noted that there is normally a 2-3 year process to change reimbursement rates.

29. The representative from AIPES pointed out that they are working with the European Association of Nuclear Medicine (EANM) to develop a joint recommendation regarding the separate reimbursement for isotopes and radiopharmaceuticals from the imaging diagnostic procedure. As a result, they suggested an addition to the supporting recommendation to make that point clearer. The discussion following pointed out the differences between health reimbursement systems in different jurisdictions, but it was widely agreed that it would be useful (but difficult) to separate out the costs so that the payers could recognise the different components.

30. In regards to the supporting recommendation that governments could facilitate upfront investments by providing loan guarantees or low-interest loans, there was some discussion whether this was consistent with the central premise of full-cost recovery. The representative from Lantheus noted that financing is a key issue and if the risks were not addressed there may not be investment. Many participants agreed that such support would not be a subsidy given that the government would receive a return on their investment. The delegate from France suggested adding governments taking equity positions or developing public-private-partnerships to the list of possible financial arrangements. The NEA Secretariat indicated that it would redraft the supporting recommendation to include these comments.

31. The representative from Covidien suggested, during the following discussion on the government role in planning capacity, that other national goals drive the construction of
research reactors and therefore we are seeing the same funding model that existed in the past. The delegate from France pointed out that the funding model is very different than in the past. As an example, he made reference to the Jules Horowitz project where industrial partners are paying for 40% of the infrastructure; it is not possible to expect them to support $^{99}$Mo production.

32. Meeting participants were supportive of the recommendations regarding conversion to LEU targets, pointing out that governments could play a significant role in encouraging joint R&D efforts, possibly by forcing industry to work together to solve the issues given the benefit for society and to support international agreements. The delegate from the IAEA highlighted that conversion is an issue impacting the long-term sustainability of the industry and planning needs to be done well in advance for when HEU may not be available. The delegate also provided an update on the International Working Group that is being formed under the IAEA to provide a multilateral, collaborative forum to identify and progress actions directly supporting the conversion efforts of $^{99}$Mo producers worldwide. It was noted during the discussion that if the industry can get the subsidy issue resolved it would minimise the issues around conversion, given there is currently a lack of ability to invest in conversion efforts.

33. Meeting participants noted that they felt that it was a good idea to continue a forum for sharing information and discussing policy issues related to the $^{99}$Mo/$^{99m}$Tc supply chain, such as the HLG-MR has served since June 2009.

34. The discussion on supporting principles was terminated by meeting participants expressing their views on the level of information necessary for transparency. It was recognised that the increased downstream communication related to available supplies was invaluable and needs to be continued. It was highlighted by a few participants that efforts towards transparency should be careful to not create a conflict with competition regulations. It was also pointed out that commercially confidentiality will need to be respected in any transparency efforts.

35. The NEA Secretariat pointed out that transparency efforts and the pricing methodology would not be to set prices but to ensure a common methodology for full-cost recovery and that transparency around whether producers were implementing full-cost recovery; it would not be necessary to enter into the books of individual firms as governments should be able and willing to say how their reactors are being funded. The Secretariat also pointed out that the information that would need to be provided to the proposed International Expert Panel would be provided on a voluntary basis.

36. There were no further comments provided on the other supporting recommendations when they were presented, presenting a tacit approval of the remaining proposed recommendations.

Off-Agenda item (IAEA work regarding denial of shipments)

37. The representative from the IAEA provided an update on their efforts to address the issue of denial of shipment of medical isotope products, setting a time frame of 2013 to have significantly dealt with the issues.
38. The representative noted that the IAEA is organising a series of meetings, including regional workshops, to analyse denial and delay reports, to update regional action plans and to develop communications strategies and tools, such as communication toolkits, brochures aimed at carriers, a simplified training course and e-learning packages on denial.

39. The representative also noted that the IAEA maintains a global network of Regional Coordinators and National Focal Points as liaison officers to work through issues of denial of shipment. He identified the process of dealing with denials of shipments to be that: 1) the industry tries to solve the issue; if that is not successful, 2) the issue is directed to the National Focal Point and they work with the parties to try to solve the denial issue; if that is not successful, 3) the issue is referred to the Regional Coordinators; if that is not successful, 4) referred to the international level, including working directly with the IAEA. He also pointed out that there were currently no National Focal Points in the United States or Canada.

40. The IAEA representative highlighted some key successes of this network. For example, Air Canada has revised their priority system. He noted that the IAEA is working with other air carriers to add medical radioisotopes to their priority list; if medical radioisotopes are given a high priority they will not be unloaded.

41. He also noted that the IAEA is working with regulators to harmonise the response to container approvals, exploring why there are different requirements for contained approval within different jurisdictions. The representative noted that if they were requested, they would be willing to approach nations and have them explain why extra regulations were needed. The HLG-MR members supported the IAEA doing this proposed action.

42. The representative noted the IAEA was also working with the International Air Transport Association (IATA) on transportation issues, including regarding airlines that have banned transport of medical radioactive materials. He also discussed the issue of developing a new UN shipping classification for medical radioisotopes, noting that the UN had indicated that they do not want to classify based on end use but prefer to find a property of the material to use for separate classification, such as being defined as molybdenum. He also noted that although the official reporting system for denial and delays was not being used extensively, informal reporting indicates a high level of denials.

**Agenda item 5 (Closing of open session)**

43. The Meeting Chair closed the session, thanking all the participants for their continued support and efforts.
AGENDA

Fourth meeting of the
High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR)

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| 28 January 2011 - HLG-MR member-only session (09:00-18:00) |
Fourth Meeting of the High-Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR)

27-28 January 2011
OECD Conference Centre, Paris, France

Final List of Participants

**HLG-MR Members or Delegated Participants**

**Argentina**

Pablo CRISTINI  
Manager of Radioisotope Production  
National Commission of Atomic Energy  
Centro Atomico Ezeiza

**Australia**

Doug CUBBIN (delegated participant)  
Executive General Manager, Business Development & Commercialisation  
Australian Nuclear Science and Technology Organisation (ANSTO)

Ryan GILCHRIST (delegated participant)  
Counsellor (Nuclear)  
Australian Embassy and Permanent Mission to the UN

**Belgium**

Leo SANNEN  
Director of the Institute of Nuclear Materials Science  
SCK•CEN

Jean-Michel VANDERHOFSTADT  
CEO - General Manager I.R.E.  
Institut des Radio-Eléments (IRE)/The National Institute for Radioelements (IRE)

Bernard PONSARD (delegated participant)  
Head of Unit Radioisotopes and Silicon Production  
SCK•CEN/BR-2 Reactor

Dirk CEUTERICK (delegated participant)  
Head of Expert Group Business Support Unit  
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Canada

Cécile CLÉROUX (delegated participant)
Assistant Deputy Minister
AECL Restructuring
Natural Resources Canada

Sylvana GUINDON (delegated participant)
Director
Nuclear Energy Division
Natural Resources Canada

Alexander McEWAN (delegated participant)
Minister of Health's Special Advisor on Isotopes (Government of Canada)
Medical Director, Cross Cancer Institute
Professor and Chair, Dept. Oncology
University of Alberta

European Commission

Remigiusz BARANCZYK
European Commission
Directorate-General for Energy
Directorate D - Radiation protection

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Daniel IRACANE
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Alain ALBERMAN (delegated participant)
Commercial and Project Manager
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Tatsuo IDO
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Keiko SHIOTSUKI (delegated participant)
Manager, Radiopharmaceuticals and Radioisotopes
Japan Radioisotope Association

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Appendix II

April 21, 2011

Current Good Manufacturing Practice (CGMP) for PET Radiopharmaceuticals

The SNM formed a coalition of stakeholder societies to approach the FDA regarding concerns with the implementation of the 21 CFR Part 212, Current Good Manufacturing Practice (CGMP) for PET Radiopharmaceuticals. The Coalition for PET Drug Approval is comprised of ten organizations whose purpose is to help our community understand requirements related to the implementation of 21 CFR part 212 and the submission process for PET NDAs or ANDAs, and to make a positive impact on the overall implementation process through interaction with the FDA.

Issued on December 10, 2009, this regulation requires all manufacturers of PET used in clinical practice to submit an NDA or ANDA by December 12, 2011. The FDA held a public meeting on March 2, 2011 to discuss recently issued guidance for PET manufacturers. During this meeting, Coalition representatives asked numerous questions of the FDA resulting in additional clarification. The Coalition held an open meeting on March 3rd to discuss what was learned during the FDA public meeting and what questions still remain.

The Coalition is currently working on identifying the educational needs of the community and how best to address these. Information is continuously posted to the Coalition website (www.coalitionforpetdrugapproval) including a listing of the specific questions that were asked of the FDA during the public meeting. Answers are being developed and will be posted to this site as soon as possible.

SNM continues to be an active partner in the Coalition with two of our members serving in leadership roles. SNM staff provide the administrative support to the Coalition, coordinating conference calls, developing educational materials, and upkeep of the Coalition website. Additionally, SNM staff has initiated drafts of multiple articles on the subject - an article will appear in the upcoming May edition of NewsLine (in JNM) with information for manufacturers and those that purchase from vendors. SNM and the Coalition are working to provide as much information and assistance as possible to those who must comply with the regulation.

The Coalition is requesting a call with the FDA to discuss next steps and when we might expect answers to some of the questions raised at the workshop. Also, the Coalition will be requesting
FDA personnel attend the SNM Annual Meeting. There remains a concern that there may still be individuals who are unaware of the regulation. A lot of attention has been given to outreach.