Council on Radionuclides and Radiopharmaceuticals, Inc.

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Summary of CORAR Activities – June 2007

1.0 Radiation Safety/Security/General Issues

1.1 NRC Jurisdiction over NARM

NRC was granted jurisdiction over NARM in the EPAct of 2005. The NRC staff has completed the rulemaking and have submitted it to the Commissioners in SECY 07-0062 for their final review. Many of the early concerns with the rulemaking have been favorably resolved by the NRC and are contained in the proposed rule. NRC to use specific DACs for O-15 & N-13, and is likely to do so. NRC has issued a draft NUREG 1556 Volume 21 on the use of accelerators. They also plan to revise Volume 19 on nuclear pharmacies. Initially a 30 day comment period was planned. CORAR plans to request an extension of the comment period.

1.2 Section 656 of EPAct: Secure Transfer of Materials

Section 656 directs the NRC to establish a system to ensure that byproduct materials, source materials, special nuclear materials, high-level radioactive waste, spent nuclear fuel, transuranic waste, and low-level radioactive waste materials, when transferred or received in the United States by any party pursuant to an import or export license, are accompanied by a manifest describing the type and amount of such materials. It also requires each individual receiving or accompanying the transfer of such materials to be subject to a security background check conducted by appropriate federal entities. CORAR is concerned that the background checks could apply to all receivers of nuclear material, including hospital employees. The NRC is required to promulgate regulations one year after enactment on EPACT (or by July 2006) identifying radioactive materials or classes that are appropriate exceptions to the requirements these provisions. The NRC has just begun to focus in earnest on this issue and in previous conversations have assured us that they do not plan to include radiopharmaceuticals in the rulemaking. The NRC staff has been directed by the Commissioners to start looking at Category 3 and 3.5 sources for possible inclusion in the Secure Transfer process. If this is done, it will not include finished radiopharmaceutical shipments, but may start to include larger bulk shipments of radioactive raw materials.

1.3 Section 957 of the EPAct: Alternatives to Industrial Radiation Sources

This provision has been in the legislation since 2003 and has been brought to the attention of CORAR members. The provision requires the Secretary of Energy to develop a research and development plan in conjunction with a survey to develop alternatives to industrial large radiation sources, including miniaturized particle accelerators for industrial applications and portable

accelerators for short-lived radioactive material at industrial sites. The National Academy of Sciences (NAS) has begun their study on "Radiation Source Use and Replacement". So far meeting have been on July 10th, Sept 11th in Washington D.C. and Oct 26-28th in Houston, TX. CORAR has attended and have provided both formal presentations and regular "public" comment as industry experts. The 4th meeting was in Washington, D.C. on Fri 8th December. The quality of the testimony has continued to improve since the initial reviews provided by peripheral NRC staff and other Government entities such as the EPA. The main focus resides on category 1 (and 2) sources – particularly Co-60 used in gamma package irradiation facilities and Cesium-137 Chloride sources that are used in blood and small animal irradiators. Industry experts from the manufacturers and operators of facilities using these sources have made significant contributions and testimony has also been provided by alternative technology representatives e.g. x-ray, LINAC etc. Presentations on the importance and immediate lack of alternative technology were presented for the use of sources in geological formation evaluation, gamma radiography, gamma irradiation and medical therapeutics (Teletherapy). CORAR continues to monitor the committees' activity.

1.4 Section 631 of the EPAct: Safe Disposal of Greater than Class C Radioactive Waste

This section directs the Secretary of Energy to: (1) designate an Office within DOE charged with responsibility for developing a new or using an existing facility for safely disposing of all low-level radioactive waste with concentrations of radionuclides that exceed NRC limits for Class C radioactive waste (GTCC waste); and (2) develop a comprehensive plan for permanent disposal of GTCC waste, including plans for a disposal facility. On 5/22/06 at a meeting to review federal disposal options for commercial waste CORAR, Cal Rad Forum and several licensees urged the DOE to consider designing a GTCC disposal facility to accept Class B and C rad waste on an emergency basis when access to the Barnwell, S.C. facility is closed to most generators. The NRC was urged to consider reviewing DOE facilities to ensure that they meet the requirements of 10 CFR 61.

1.5 NAS Study on the future of Nuclear Medicine

The NAS was asked by Congress to conduct a study on the State of Nuclear Medicine. The committee plans to look at current issues in nuclear medicine including technical developments, isotope availability, training of nuclear medicine professionals, and funding for research. The NAS committee performing this study has met six times and has reviewed a variety of topics including impediments to further radiopharmaceutical development, shortages of trained individuals in the field, and future technologies. CORAR presented its concerns at the first committee meeting. At the February 19, 2007 meeting CORAR presented comments on DOE's new National Isotope Program. The comments largely supported the program and encouraged the NAS committee to support the program.

1.6 NAS Study on LEU Production of Medical Radionuclides

The NAS committee had it's first meeting on February 15, 2007. CORAR, Nordion, Mallinckrodt and ANSTO made presentations representing industry. IAEA and several non-proliferation presentations were also made. The committee clearly wants to pursue further information on pricing and marketing of Mo-99 in subsequent meetings. The committee also met on April 10-11 to review FDA and other regulatory issues associated with the use of LEU to produce Mo-99. The next NAS committee meeting is scheduled for June 11-12. A majority of that meeting will be devoted to the FDA review and approval of new Drug Master Files for LEU Mo-99.

1.7 9/11 Implementation Bill

The 110th Congress is focusing on national security and attempting to fill any identified legislative and regulatory gaps. As a result, the House passed on January 9. 2007 the 9/11 bill (HR1) and on March 27, 2007 passed legislation to enhance rail, and motor carrier security (HR1401). The

Senate has joined the House by passing S 4 on March 13, 2007, which includes enhanced security requirements for rail, motor carrier, and aviation modes of transportation. At this time, the House and Senate conference committee has not been convened to resolve the differences between the House and Senate passed bills. We anticipate that a final bill will be sent to the President this Fall. CORAR has reviewed the legislation and has identified several provisions that require modification. CORAR's concerns are being presented to the House and Senate committee staff in an attempt to resolve the issues prior to enactment.

1.8 Implementation of the SAFE Ports Act

The SAFE Port Act (HR 4954) is designed to provide a more robust port security regime including deploying radiation detection systems to cover 98 percent of cargo coming into United State's ports. In addition, it modifies the C-TPAT program and Container Security Initiative. The House and Senate passed the SAFE Ports Act (HR 4954) prior to adjourning for the midterm election. The law may commit many Federal agencies to activities and responsibilities that either duplicate or conflict with actions planned or already taken to improve security and does not require agencies to consult with the NIPP. CORAR has drafted and sent a letter to the Committees of jurisdiction and plans to have a series of meetings with appropriate Congressional and Regulatory Staff

1.9 NRC Proposed Revision of Enforcement Policy

NRC published a Proposed Plan for Major Revision of its Enforcement Policy on January 25, 2007, soliciting input on what should be added or removed to the existing policy that underwent its last revision in June 1995. Comments were submitted to NRC by CORAR on March 23, 2007. Comments include those on the enforcement conference process, disclosure of self-audit findings during inspections, relief for self-reporting, advanced notice of issuance of NOV's.

1.10 NRC Public Meeting on Decommissioning Shortfalls

NRC held a public meeting on January 10, 2007, as part of its rulemaking process to address decommissioning funding shortfalls, particularly at legacy sites. CORAR attended the public meeting to present key talking points and to monitor discussions. At the meeting, NRC indicated 1) they are not proposing to do away with the option of self-guarantee, 2) guarantee may need to be backed up with collateral and 3) a proposed rule is expected in the summer of 2007.

1.11 NRC Proposed Rule on Safeguards

On October 31, 2006, NRC published a Proposed Rule to amend its regulations for the protection of Safeguards Information (SGI) to protect SGI from inadvertent release and unauthorized disclosure that might compromise the security of nuclear facilities and materials. The amendments would affect certain licensees, information, and materials not currently subject to SGI regulations, but which are within the scope of Commission authority under the Atomic Energy Act of 1954, as amended (AEA). Due to the Orders the NRC has issued many facilities which previously were not subject to Safeguards requirements are required to meet them today. This includes Safeguards-Modified. Comment period for proposed rule ended January 2, 2007. CORAR submitted comments to the proposed rule on December 28. The majority of licensees affected by the proposed rule making were issued Orders that require compliance with safeguard measurements that are very similar to those in the proposed rule. The final rule is at NRC's OGC, awaiting sign-off/approval.

1.12 OSHA Request for Information on Ionizing Radiation

On May 3, 2005, OSHA published in the Federal Register a request for information on ionizing radiation. OSHA seeks information on radiation sources and uses, occupational exposure, health effects and control practices. CORAR provided substantial comments to OSHA on July 29, 2005 indicating that NRC regulations are comprehensive and sufficient. OSHA intends to review

comments and determine whether any further action is needed. Several stakeholder meetings have been conducted by OSHA to collect information in addition to that already provided in writing in response to the Request for Information. CORAR attended a meeting on March 16, 2007 and reiterated key points already addressed in writing in July 2005.

1.13 CA Reorganization of the Rad Health

California legislature passed SB-162 that mandates the transfer of the California Radiological Health Branch to the new State Department of Public Health. CORAR members have experienced an unsatisfactory service level with the state agency with regard to timeliness of licensing transactions, decommissioning approvals, inspection and enforcement interpretations, etc. CORAR sent a letter to the Governor just prior to the enactment of SB-162 that recommended a number of issues be addressed with the forthcoming organizational change. The letter was sent to the Governor's office. The Governor's staff has asked the agency to brief them on our concerns. The proposed plan is to work with the staff to arrange for a meeting with the to-be-appointed State Public Health Officer to address the issues of CORAR members with operations in CA. A questionnaire was sent to MQS members on October 6, 2006, requesting information to be consolidated by HHK to prepare for the dialogue with the appointee. Since then, CalRad Forum has expressed an interest in partnering with CORAR in this effort. CORAR spoke with representatives of the DHS on October 30, 2006. They stated that with the passage of SB-162 the Bureau of Rad Health now has a new focus and stability that will lead to improved performance. However, additional interaction with the state is needed to increase the likelihood of their level of performance improving.

1.14 NSCC Activities

The Nuclear Sector Coordinating Council (NSCC) was established in collaboration with the DHS and relevant agencies to provide private sector input supporting the development of a plan for protection of the nuclear infrastructure. The Radioisotope Subcommittee was established to represent the interests of industry beyond the scope of nuclear power and fuel cycle. Co-chairs and key members of the RSCC-R includes CORAR members and significant work has been done to establish a charter, objectives, a list of key issues, and to provide input on the development of the Sector Specific Infrastructure Protection Plan. Most of the issues arising from the NSCC-R concern the risks and security issues related to IAEA Category 1, 2 and 3 Sources. A priority objective of the NSCC-R is to monitor the regulatory agenda and work with the various agencies to avoid duplicative or conflicting regulations. Meetings are held monthly to provide an update on issues, to assign responsibilities and actions and to review the status. NSCC-R has collaborated with CORAR on response to NRC rulemaking concerning security. Most recently, the NSCC-R has met with the Government Coordinating Council (GCC) to discuss key issues and to coordinate on actions to address these in working Groups. There was a NSCC-R/GCC working group meeting on May 9, 2007 in Washington.

1.15 NRC SRM on Category 3 & 3.5 Sources

The NRC staff has been directed by the Commissioners to start looking at Category 3 and 3.5 sources for possible inclusion in the Secure Transfer process. If this is done, it will not include finished radiopharmaceutical shipments, but may start to include larger bulk shipments of radioactive raw materials. The NRC staff is currently looking at category 3 and 3.5 sources. They do not appear to want to include any nuclear medicine shipments in this coverage, but it is still under study.

1.16 NRC Draft MARSAME

On January 16, 2007 a draft "Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual" was published in the federal register for public comment. MARSAME was developed by staff from the NRC, EPA, DOE and DOD as a comparison guide to MARSAME and MARLAP for decommissioning and clearance purposes. On April 3, 2007 CORAR submitted comments to the NRC on draft MARSAME recommending that licenses need more concise, specific and practical guidance.

1.17 GAO Report on Status of LLW Disposal

GAO issued a final report titled "Low-level radioactive Waste Management: Approaches Used by Foreign Countries May Provide Useful Lessons for Managing U.S. Radioactive Waste" dated March 2007 incorporating CORAR's comments. On 3/18/06, CORAR issued comments to GAO on "Questions for LLRW Management Experts" providing reasons and suggestions for better cost-effective and reliable access for LLRW disposal, which were included in the final GAO report.

1.18 ACNW White Paper on History of LLRW Management in U.S.

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1.19 South Carolina Legislation-Barnwell Site

A South Carolina House Committee vote, posted on March 28, 2007, overwhelmingly opposed a proposed bill H3545 to keep the Barnwell S.C. LLRW Disposal Site open beyond 2008 for out of state generators. The discussion was based entirely on economic considerations the legislative deciding that is was in the interest of the State to remove economic development from being based. CORAR and Cal Rad Forum will continue to monitor these developments and seek an opportunity for constructive participation.

1.20 NRC Clearance of Materials

The NRC is working on rulemaking to establish criteria for disposal of low level radioactive material as unregulated material. NRC was expected to publish a rulemaking for comment very soon but has held back on this project. A limit that requires a public dose of less than 1 mrem per year may make disposal of low-level waste decayed to background, very difficult.

1.21 NRC National Source Tracking Initiative

The NRC Final Rule on National Source Tracking of Sealed Sources was published in the Federal Register on November 8, 2006, with an effective date of February 6, 2007. NRC will be implementing the rule as "public health and safety" and not "common defense and security". As a result, the Agreement States will be responsible for implementing and enforcing use of the National Source Tracking database. It will be a compatibility "B" regulation, meaning the Agreement states must retain the essential elements of the rule. NRC retains responsibility for maintaining the database. Reporting requirements for Category 1 sources are effective on November 15, 2007 and for Category 2 sources on November 30, 2007. The final rule addressed the comments and feedback from CORAR.

1.22 NRC Patient Release Criteria

On December 21, 2005 the NRC published in the Federal register a petition for Rulemaking from P.G. Crane proposing a longer isolation time before releasing nuclear medicine patients and prohibiting the release of patients with > 30 mCi of I-131. On March 6, 2006 CORAR provided comments to the NRC. There has been no change on this issue.

1.23 NRC Radiation Source Protection and Security Task Force

On January 11, 2006 NRC published in the Federal Register a request for public comment on issues to be considered by the Interagency Task Force as mandated by the Energy Policy Act of 2005. Comments were submitted by CORAR on February 8, 2006 that focused on the need for a consistent approach by all agencies, consistency with IAEA Code of Conduct and enhanced security to be limited to Category 1 and 2 sources. There has been no change on this issue.

1.24 NRC Regulation of Exempt Quantities

On January 4, 2006 the NRC published in the Federal Register a proposed rule on Exemptions from Licensing, Federal Licenses and Distribution of Byproduct Material: Licensing and Reporting Requirements. CORAR issued comments to the NRC on March 8, 2006 requesting the clarification of NRC and Agreement State jurisdiction and simplifying the classification of exempt quantity products chemical and physical form. CORAR may need to consider new regulatory interpretations of imported radioactive material distributions that may affect how exempt quantity and other products are shipped to the customer.

1.25 NRC Proposed Rule on Radiation Dose Reporting

On September 22, 2006, NRC published a proposed rule that would revise the requirements for the reporting of annual dose monitoring results to workers. The requirement to report annually the results of occupational dose monitoring would be limited to those who receive an annual whole body dose in excess of 100 mrem. CORAR comments were issued to the NRC on November 17, 2006 that revisit comments previously submitted in April 2004 on draft rule language on this subject and to urge NRC to adopt a reporting threshold but increase it from 100 to 500 mrem.

1.26 EPA White Paper on Radiation Risk Models

EPA published a draft report dated August 1, 2006, entitled "Modifying EPA Radiation Risk Models Based on BEIR VII." In this report, EPA proposes to adopt many of the recommendations of BEIR VII for the purpose of estimating radiogenic cancer risks. EPA has also indicated that BEIR VII does not address risks from some specific types of cancers (e.g. bone, skin and fatal thyroid) and will address these and other perceived deficiencies with proposed EPA methodologies for estimating risk. CORAR submitted comments to the EPA on December 14, 2006 providing technical corrections.

1.27 NY State Legislation

NY state passed Bill A 3255 by the Assembly (4/18/06) and Senate (6/13/06). The Bill defined and prohibited the sale or distribution of "radioactive secondary material." That material was loosely defined as any material that originated from processes, operations, deactivation or decontamination activities from radioactive materials licensees of the state, NRC or DOE. It was feared that nuclear pharmacies and/or nuclear medicine departments might fit into that definition, and consequently prohibit their sale or transfer. Governor Pataki vetoed the bill on .July 14, 2006. CORAR wrote a letter to Governor Pataki over our concerns with A 3255 on July 17, 2006. We also helped generate letters from SNM and several other state physicians and organizations to the Governor encouraging him to veto the bill. Although the 2006 version has been vetoed, there is concern that the state assembly will try to re-introduce the bill in the 2007 session. CORAR has initiated a conversation with the sponsor of the bill (DiNapoli) in order to develop language

that is not so potentially harmful to the nuclear medicine community. At this point it does not appear as though any similar legislation will have traction in the state legislature this year.

1.28 LLRW Disposal

CORAR seeks urgent action in developing new long-term reliable, safe, cost-effective access to LLRW disposal by 2008 when the Barnwell, S.C. disposal site is scheduled to close for licensees in most States. CORAR had hoped that the Clive Utah disposal site would have its license amended to accept class B or C LLRW. However, its application for amendment was recently withdrawn. The NRC is required to implement NARM regulations but preserve the better access for cost-effective disposal provided for NARM waste. The need to maintain access to disposal sites is perceived to improve the security of LLRW. On 3/18/06, CORAR issued comments to GAO on "Questions for LLRW Management Experts" providing reasons and suggestions for better cost-effective and reliable access for LLRW disposal. CORAR participated in a Compact Commission meeting on 5/22/06 to discuss potential use of federal facilities for LLRW disposal. On 8/23/06 CORAR submitted extensive comments to the NRC on the NRC's LLRW program recommending use of federal facilities and better use of commercial disposal facilities. CORAR will monitor NRC and LLRW disposal site developments and any action by the Senate Committee on Energy and National Resources and GAO and should seek any opportunity for using government resources to improve the security of LLRW by reducing barriers to cost-effective disposal.

1.29 IAEA Draft Guide on Source Security

In September, IAEA published for comment a Draft Guide on the Security of Radioactive Sources. This supersedes IAEA TECDOC-1355 and provides more detail in terms of security enhancements commensurate with IAEA source Categories 1 - 3. CORAR members who are also participants NSCC-R believe that this document may be viewed as a key reference in the effort to establish security measures for non-nuclear power nuclear industries. It utilizes the IAEA security framework that has been widely accepted by agencies in the US, particularly the NRC, and it is likely that this document will continue, as was TECDOC-1355, to be incorporated into the nuclear security rulemaking process in the US. NSCC-R believes this document could be useful in the effort to establish a system of hazard level and relevant security measures for the radioisotope sub-sector. CORAR representatives on the NSCC-R via ISSPA provided comments in November 2006 that generally supported the guide but pointed out some deficiencies including the fact that it did not directly address non-sealed materials nor did it provide for protective measures to responders in the event of an interaction with an adversary. There has been no change on this issue.

1.30 IAEA Safety Guide on Classification of Radioactive Waste

The IAEA issued a draft revision of Safety Guide No DS 390 "Classification of Radioactive Waste" for comment. This topic is of interest to CORAR since it provides a basis for effective disposal of radioactive waste, and could serve as a useful reference to support rational waste disposal developments. CORAR submitted comments to the IAEA on November 17, 2006 in support of this Safety Guide.

1.31 HPS/ANSI N.13 Standard Committee

CORAR provided comments to the HPS on numerous draft ANSI standards including N13.54: "Fetal Radiation Dose Calculations in Nuclear Medicine" on 10/20/05; N13.59: "Characterization of Land Areas and Structures in Support of Decommissioning" on 8/24/05; and N13.58: "Guide for Control and Release of TENORM". In each case CORAR has made substantive comments that could significantly change these standards. N13.54 on Fetal Dose and N13.58 on TENORM should be finalized soon including CORAR recommendations. The N.13 subcommittee to review

NRC Reg. Guides and ANSI standards expects to start working with the NRC in June, 2007. N13.12 on volumetrically contaminated material clearance is being developed to be more compatible with international standards.

1.32 ANSI N. 14.36 Committee

This standard on surveillance of radioactive material packages offered for transport is being revised and expanded to include all packages and their conveyance. CORAR is concerned that practices for monitoring fuel casks might be applied inappropriately to type A and excepted packages. CORAR joined this committee and assisted in the development of a scope statement completed on 10/10/06. CORAR will continue participating in these developments and consider serving on the standard's writing committee in the future. There has been no change on this issue.

1.33 ANSI N43.1 Committee

CORAR has concerns that draft ANSI N 43.1 "Radiation Safety for the Design and Operation of Particle Accelerators promotes practices appropriate for complex research facilities and provides insufficient focus on radionuclide production cyclotrons. CORAR issued substantive comments on N 43.1 on 8/19/06 recommending consideration of the need for a separate standard for radionuclide production accelerators. CORAR will consider writing a separate standard and be prepared to continue participation in these developments. There has been no change on this issue.

1.34 NCRP Collaboration Committee

CORAR is established as a collaborating organization with the NCRP and as such have the opportunity to review and comment on draft NCRP reports. NCRP reports in progress include "Operational Safety in Medical Radiation Therapy", "Radiation Protection Recommendations for First Responders in Radiological Terrorism Events," "Design of Effective Effluent and Environmental Monitoring Programs", "Management of contaminated persons and " Management of Patients Who Have Received Therapeutic Doses of Radionuclides".
CORAR submitted comments to the NCRP on "Development of a Biokinetic Model for Radionuclide-Contaminated Wounds and Procedures for their Assessment, Dosimetry and Treatment" on 7/11/06 and on "Radiation Protection in Educational Institutions" on 8/25/06.
CORAR submitted a 2007 survey on TI from radiopharmaceutical shipments to the NCRP on April 5, 2007 to assist in updating the NCRP Report on public exposure in the U.S. to all sources of ionizing radiation.

1.35 ICRP Recommendations

ICRP is making a great effort to enable stakeholders worldwide to participate in developing the ICRP 2006 recommendations. This is another opportunity for CORAR to contribute to the basis for regulation and their global harmonization. CORAR presented comments on ICRP's draft recommendations at an OECD meeting on 8/30/06 and sent written comments to the ICRP on 9/18/06. CORAR's primary focus was on the need for a new skin dose limit more compatible with other dose limits. The ICRP consolidated comments into final recommendations in March 2007. CORAR is preparing additional comments and is seeking a method to convey these to NCRP working groups. CORAR is preparing comments on draft ICRP guidance document on the "Interpretation of Bioassay Data".

1.36 States Seeking Agreement Status

CORAR and CORAR members have been assisting Michigan Department of Environmental Quality to attain NRC Agreement status. RI has requested NRC to take back direct jurisdiction and rescind its Agreement status.

2.0 Transportation Issues

2.1 State Transportation Fees

Several States have implemented transportation fees related to the carriage of hazardous materials. This issue is becoming prevalent as more States are enacting legislation to impose fees for the transport of radioactive material. As per the Hazardous Materials Transportation Act, a State can impose fee relating to the transportation of hazardous material. Illinois and Iowa currently have legislation-imposing fees. Missouri and Ohio are currently considering legislation to impose fees. Illinois and Iowa currently have legislation-imposing fees. Missouri and Ohio are currently considering legislation to impose fees. Traditionally, States have imposed fees on the transport of High-level waste, Spent Nuclear fuel, Transuranix waste but are now considering Highway Route Controlled Quantities and lower quantities such as Radioactive Material Quantities of Concern (RAMQC). The Gamma Industry Processing Alliance (GIPA) has been pursuing possible legislative action or Federal DOT pre-emption. NEI has been following this issue for a couple of years and has set up a task force to address this issue.

2.2 DHS Implementation of the SAFE Ports Act, H.R. 4954

The Congress passed the SAFE Ports Act (HR 4954) prior to adjourning for the midterm election. The law may commit many Federal agencies to activities and responsibilities that either duplicate or conflict with actions planned or taken to improve security. The law does not require agencies to consult with the NIPP. The SAFE Port Act (HR 4954) is designed to provide a more robust port security regime including deploying radiation detection systems to cover 98 percent of cargo coming into United State's ports. In addition, it modifies the C-TPAT program and Container Security Initiative. CORAR has sent a letter to the Committees of jurisdiction and has begun to have a series of meetings with appropriate Congressional and Regulatory staff.

2.3 9/11 Implementation Bill

The 110th Congress is focusing on national security and attempting to fill any identified legislative and regulatory gaps. As a result, the House passed on January 9. 2007 the 9/11 bill (HR1) and on March 27, 2007 passed legislation to enhance rail, and motor carrier security (HR1401). The Senate has joined the House by passing S 4 on March 13, 2007, which includes enhanced security requirements for rail, motor carrier, and aviation modes of transportation. At this time, the House and Senate conference committee has not been convened to resolve the differences between the House and Senate passed bills. We anticipate that a final bill will be sent to the President this Fall. CORAR has reviewed the legislation and has identified several provisions that require modification. CORAR's concerns are being presented to the House and Senate committee staff in an attempt to resolve the issues prior to enactment.

2.4 TSA Final Rule on Air Cargo Security

On November 10, 2004, TSA published a proposed rule that would establish additional requirements for the security of transportation of all cargo by air. This rule makes proposal that include requirements for enhancements to the known shipper program, mandatory security programs for operators of aircraft over 45,000 kg, screening of all cargo aboard passenger aircraft as soon as practicable, vetting of indirect air carriers (e.g. freight forwarders), strengthen foreign air carrier security requirements, and "comparable" security programs for shippers of air cargo. Note that this rule applies to all air cargo, not just hazardous materials. A review of this rule has identified the need for additional detail, particularly for the scope of "indirect air carriers" and "comparable security programs." CORAR did not submit comments in advance of the January 10, 2005 deadline. However, a significant number of carriers (e.g. FedEx) and industry groups (e.g.

IATA, ATA) did comment with many contesting the estimated cost of implementation and requesting an extension of the comment period. All requests were denied. TSA competed a regulatory and economic analysis with the conclusion published on May 12, 2006 that there would be significant costs incurred by carriers and aircraft operators. TSA published the Final Rule on May 26, 2006 with the effective date of October 23, 2006. There has been no change in the status of this issue.

2.5 IAEA Transport Security Guidance

A technical meeting to review the International Atomic Energy Agency, Nuclear Security Series, Security of Radioactive Material during Transport was held in Vienna from January 23-27, 2006. The final recommendation presented at plenary divided the security levels into Basic and Enhanced. The enhanced security measures will be needed is at 3000 A2 in a single package except for the radionuclide found in the Code of Conduct for Category 1 and 2 sources. In practice, the limit is high enough not to include any other isotopes except for those in the Code of Conduct. Enhanced security measure will not be needed for Moly, Iodine or other nuclear medicine isotopes. Enhanced security measures will apply for activities that exceed 0.3 TBq for Cobalt 60, 1 TBq for Cs-137 and 0.8 TBq for Ir-192. The basic security measures that would applied to most shipment of radioactive material including Nuclear Medicine products will be inline with the security measures found in the UN Orange Book. These measures have already been implemented by the modal organizations in January 2006 and are similar to the security measures found in 49 CFR. Excepted packages, LSA-I and SCO-I are exempt for all security requirements. The enhanced security measures (Co-60, Ir-192) go beyond the enhanced security measures described in the UN Orange Book. The final version of the Transport Security document was published for comments in November 2006. CORAR prepared and provided comments to the USDOT on February 23, 2007. The final US comments prepared by the USDOT were sent to CORAR members along with the ISSPA comments on April 17.

2.6 DC Surface Transportation Board/CSX Petition

On February 15, 2005, the Mayor of D.C. signed into law the District of Columbia City Council Act passed on February 1 banning the transportation of certain classes of hazardous materials within a 2.2 mile radius of the US Capital without a permit issued by the D.C. Department of Transportation. On February 7, 2005, CSX filed a petition with the US DOT Surface Transportation Board (STB) seeking a Board order declaring the D.C. Act preempted by federal law. On February 15, 2005, CORAR submitted a letter to STB supporting the CSX petition on the grounds that the D.C. Act should be preempted by federal law otherwise a dangerous precedent would be set. On April 18, 2005, a federal judge refused to block the ban that would go into effect on April 20, 2005, but on April 19, 2005, the US Court of Appeals for D.C. issued a stay in response to an emergency motion filed on April 19 by CSX. On April 27, 2005, the Sierra Club filed a petition with TSB seeking reconsideration of its earlier decision to preempt enforcement of the D.C. Act. On May 3, 2005, the STB was scheduled to conduct a hearing on the matter and the U.S. Court of Appeals for D.C. reversed the district court ruling and issued a preliminary injunction on enforcement of the D.C. Act on the grounds that it would be preempted by federal law. In addition, Representatives LaTourette and C. Brown introduced legislation intended to keep the D.C. ordinance from taking effect. The bill was referred to the House Committee on Government Reform. No action was taken. Counsel for the Council on Safe Transport of Hazardous Materials (COSTHA) indicate that the DC Surface Transportation Board/CSX Petition is still in the court of appeals. Apparently, the judge overseeing this appeal is trying to find a way to side with the District of Columbia. However, the appeal is based on a DOT pre-emption based on road movement; not sure if there is applicability to rail. It is anticipated some type of ruling will be issued in the near future.

2.7 IAEA Revisions TS-R-1 including Radiation Protection Programs

The IAEA continues to review and revise its TS-R-1 regulations every two years. The 2007 revision of the TS-R-1 regulations is complete but was not published. The changes were included as part of the 2009 edition rewrite to meet the UN Orange book format. Also, DOT solicited comments on the IAEA draft Radiation Protection Programme (RPP) (DS377) in advance of the IAEA meeting in October 2005. Comments were provided to DOT on DS377 on September 7, 2005, most of which were taken into account by DOT in their input to the IAEA. IAEA acknowledged or accepted comments including 1) the fact that demanding RPP requirements may exacerbate carrier denial of RAM shipments, 2) carriers should not be required to perform additional package monitoring, 3) established relationships between total TI and dose can be used as a dose assessment, and 4) the examples used in DS377 for RPPs are not useful. CORAR will continue to monitor progress on the development of this and will continue to be proactive with DOT in advance of any adoption of additional RPP requirements. TRANSSC 14/IAEA has released a new draft version of TS-R-1 (Transport Regulations) known as the 2009 edition. This draft document is available for comments by Member States. Changes to TS-R-1 are limited to the changes accepted in the 2005 review cycle and the changes coming from the Harmonization process with the United Nations' Orange book. Comments on this draft were due at the end of April. No comments were sent to the IAEA. In the coming months, the IAEA will initiate a review process for TS-R-1. This review process should lead to a 2011 edition of the document.

2.8 Agency/Organization Outreach Education Initiative

Several regulatory agencies are working on rulemaking affecting CORAR. Several of these including DHS and Customs and Border Patrol have limited knowledge of CORAR products. In addition, there is a need to reach out to pilots and other carriers to educate them to prevent additional delays or denials in the transport of industry materials. CORAR in collaboration with the International Air Transport Association have created a short video designed to educate the airline industry on nuclear medicine and the importance of these products. This video has been distributed at IAEA and ATA and has received favorable feedback.

2.9 IAEA – Denial of RAM Shipments

The industry has experienced increasing pressure on supply chains because of delays and refusals by carriers to carry our freight. This issue was also raised in discussions at IAEA and CORAR has responded to their solicitation for details on this and to similar requests from NRC and DOT. Fred Ferate of the DOT, Felix Killar, NEI and Paul Gray, MDS Nordion attended the IAEA denial of shipment meeting in Vienna May 8-12. Dr. Ferate requested information on the denial issue from CORAR and a letter was provided on April 26, 2006. During the May meeting the committee drafted the Steering Committee mandate, Terms of reference, Membership and Action Plan to be issued by IAEA in final form. Industry representation on this 11 member committee which will report directly to the Director General of the IAEA, will comprise 4 members (one each of sealed source, nuclear medicine, industrial ore and nuclear fuel cycle industries). Other participants will include one member each from IAEA, IMO, ICAO, and a TRANSCC (regulator) representative as well as three seats designated to transport trade organizations (e.g. IATA, VOHMA, IAPH, IFALPA, etc.). Mandate is "to identify, evaluate and implement appropriate courses of action necessary to alleviate actual or potential denials of shipments and provide regular reports to the Director General of the IAEA". The first Steering Committee meeting was held in Vienna in November 2006 during which the Steering Committee developed and accepted a detailed international action plan. The Steering Committee will be preparing a report for the IAEA Board of Governor's meeting in September 2007. CORAR is working with the World Nuclear Association to provide denial of shipment data from the U.S. This will be included in their report.

2.10 IAEA Non-Governmental Status

IAEA sets international guidelines on transportation of radioactive material that eventually are adopted into US and Canadian regulations. CORAR can have an impact by getting involved with IAEA during the development of guidelines before they are adopted into regulations. Some CORAR member companies have had representation in IAEA proceedings and CORAR has worked through US DOT and CNSC as competent authorities but there is a need for direct industry representation. CORAR has been invited to participate in their Board of Governors meeting in Vienna this September.

2.11 DOT Implementation of HMTA Reauthorization

HMTA Reauthorization was included in the comprehensive highway bill signed unto law on August 10, 2005. Included within HMTA title is a section, which grants DOT officials the authority to remove, inspect, and open packages in transit. In order to ensure that time sensitive medical material is not rendered useless, CORAR was able to include a provision, which requires DOT to develop expedited materials for perishable hazardous materials. November 2006: DOT/PHMSA indicates a NPRM will be issued in early 2007 based on comments/feedback gained during public meetings (March 2006). It is anticipated that key elements of the NPRM will address concern for inspector/public safety, product integrity, and timely resumption of transportation. Again, the focus will be on suspect single/combination packages with little impact to the transportation of declared Class 7 Radioactive Materials. There is still concern for other type of hazardous (i.e. excepted quantities, samples, consumer commodities) as well as non-hazardous (i.e., pharmaceuticals, temperature and time sensitive items) materials. DOT/PHMSA has been silent on this initiative; anticipate issuing a NPRM in November 2007.

2.12 DOT ANPRM Regarding Revision of Security Plans

The USDOT has issued an advance notice of proposed rulemaking seeking comments on the re-evaluation of the current security plan requirements. Currently, any shipment that requires placarding would require a security plan. It is suggested that the requirements be aligned with the United Nations Model Regulations and apply to shipments of class 7 radioactive material in quantities greater than 3000 A_1 and 3000 A_2. The notice has a series of questions they would like the commenter to address. There was a public meeting on November 30 to discuss this issue. The USDOT comment period ended December 20, 2006. CORAR sent comments on December 18, 2006. CORAR will monitor USDOT rulemaking progress.

2.13 Transportation Worker Identification Credential (TWIC) Program

46 U.S.C. § 70105, commonly known as MTSA 2002, requires the Secretary of DHS to promulgate regulations to prevent an individual from gaining access to a secure area of a vessel or facility which has a security plan unless they are authorized to be in the area and hold a "transportation security card" or they are "accompanied by another individual who holds a transportation security card." The law further states who the law applies to, that the individual must be determined not to pose a terrorism security risk, and general requirements for how the determination of terrorism security risk must be carried out. It is estimated that the TWIC Program will affect 14 million maritime, port and freight-handling transportation personnel when fully implemented. TWIC Program implemented on January 25, 2007 by the TSA and US Coast Guard. A select number of US ports (10) will be impacted during the initial phase; implementation at these ports to be completed by July 2007. TWIC includes biometric technology consisting of background check and issuance of an identification card. ID card to consist of name, digital photograph, expiration date, serial number, and fingerprints. Cost of background check and TWIC card estimated to be $130.00.

3.0 Reimbursement/Coverage Issues

3.1 Hospital Outpatient Prospective Payment System (HOPPS) Update

The Centers for Medicare and Medicaid Services (CMS) agreed with CORAR's recommendations to continue Medicare hospital outpatient prospective payment system (HOPPS) payment for radiopharmaceuticals based on the cost to charge ratio for another year through 2007, paying separately only for radiopharmaceuticals/drugs that had a per patient dose higher than $55. CMS expects that hospitals have adopted all coding changes and adjusted charges for radiopharmaceuticals to reflect handling and overhead costs in 2006 so that the data will be stable and appropriate for determining fixed payments in 2008. CORAR developed and presented to the APC Advisory Panel and to CMS a two-tiered proposal that would use CMS data from hospitals, adjusted for overhead to set fixed payments for certain first tier radiopharmaceuticals. For second tier radiopharmaceuticals, CMS should continue the cost to charge ratio method or use invoice or acquisition price data from hospitals to determine average acquisition costs. CORAR has commissioned data analyses to model whether edits or trimming of CMS' 2005 data will correct payment and generate appropriate payment levels, and to prepare for the release of 2006 data. CMS's proposed hospital inpatient DRG rule describes a recent study of cost compression that may offer some new options on payment for tier 2 RPs. CORAR provided a position statement and gave a presentation to the CMS APC Advisory Panel meeting on March 7, 2007. The APC Advisory Panel recommended that CMS evaluate data for different classes of radiopharmaceuticals and ensure that a nuclear medicine procedure claim always included at least one radiopharmaceutical. The Panel also recommended that CMS consider the use of external data and determined correct code descriptors for radiopharmaceuticals. CORAR obtained copies from CMS of initial data and analyses of RP payment for 2007 which were provided to the APC Advisory Panel. On March 29, 2007, CORAR met with Carol Bazell, M.D., Kim Neuman, Chris Ritter, and Rebecca Kane to present additional details on CORAR's recommendations for HOPPS RP payment (see April 6, 2007 follow up letter) and to query CMS on whether it had applied any edits to the hospital data on RPs.

3.2 Resource Based Relative Value Scale (RBRVS)

Radiopharmaceuticals administered in physician office or free standing (non-hospital affiliated) imaging centers continue to be paid by local carriers based on invoices or local fee schedules. New Medicare Administrative Contractors (MACs) may enable CMS to move toward more uniform Part B payment. Some nuclear medicine procedures had payment reduced to the level of the HOPPS APC payment, as required under the Deficit Reduction Act of 2005. There has been repeated efforts by CMS to cuts physician and diagnostic imaging payment based on the sustainable growth rates (SGR) requirements to limit Medicare physician payment. The physician community has successfully avoided these SGR cuts but we expect there will renewed activity in the proposed RBRVS rule in the summer of 2007 and possible further legislative efforts to protect physician payment levels.

3.3 Coding

A number of changes in HCPCS code descriptors are pending with CMS and were discussed at CMS HCPCS open meeting on May 15. While some changes in HCPCS descriptors will improve the uniformity of descriptors, for example "per dose", other changes raise questions about clarity in hospital reporting and could impact the calculation of HOPPS payment levels. CORAR will continue to coordinate with SNM on presentations at the open meeting.

3.4 Medicare Coverage

CMS has issued a draft national coverage decision that would expand coverage for certain clinical trials, especially if under the auspices of a federal agency, such as the National Institutes of Health.

3.5 Nuclear Medicine APC Task Force/SNM

CORAR continues to work closely with the Nuclear Medicine APC Task Force on HOPPS issues, along with the Society of Nuclear Medicine which has proposed alternate methods to CMS on RP payment, code descriptors, and may be considering a survey of hospitals for pricing information on RPs.

3.6 CPT Coding

There appear to be modest revisions in nuclear medicine CPT codes for kidney imaging morphology. CORAR will monitor CPT Editorial Panel for new or changed nuclear medicine CPT codes and coordinate, as needed with SNM, ACNM, ACR, and ASNC.

3.7 Compliance and Fraud & Abuse

New York State enacted legislation that would authorize private citizens to bring "qui tam" actions, parallel to federal actions, based on false claims involving Medicaid. This is indicative of growing state enforcement of fraud and abuse laws, with potential application to drug and device manufacturers. CORAR will keep its members informed of enforcement that involve issues important for radiopharmaceuticals.

4.0 FDA Issues

4.1 PET User Fees

Under FDAMA § 121, FDA may not require the submission of NDAs or ANDAs for PET drugs until two years after FDA finalizes procedures for NDA and ANDA submission and cGMP requirements for PET drugs. FDA has not yet finalized these procedures and requirements. When PET drugs become subject to premarket approval requirements, they will also become subject to user fees, which include not only application fees but annual fees for each manufacturing establishment. The latter fees, which are $313,100 in FY 2007, will be a particular burden for commercial manufacturers of PET drugs, who must operate many facilities in order to supply the U.S. or even a region of the country. On August 31, 2005, CORAR submitted a Citizen Petition to FDA seeking a class waiver for PET manufacturers from having to pay multiple establishment fees. The FDA has not responded to date. We are currently focusing our efforts on using the reauthorization of the Prescription Drug User Fee Act (PDUFA), which is currently being considered by Congress, as a vehicle to address this issue. We succeeded in persuading the Senate HELP Committee to insert into the Senate bill a special exception from establishment fees for PET drug sponsors, under which the fee for each PET establishment identified in an application would be one-fifth of the otherwise applicable fee. Academic medical centers would be exempt from all establishment fees provided the PET drugs are used only in that medical center. We have also negotiated with the FDA and obtained their agreement to a reduction to one-sixth of the ordinary fee. We are currently meeting with House staff seeking support for a provision reducing PET establishment fees to one-sixth the ordinary fee, consistent with our informal agreement with the FDA.

4.2 Reestablishment of the MIDAC

On November 21, 2002, FDA announced its decision to terminate the Medical Imaging Drugs Advisory Committee (MIDAC), based on its finding that a separate advisory committee for these products was not necessary and that medical imaging issues could be adequately reviewed by existing standing advisory committees. In subsequent letters and discussions with the FDA, CORAR and MICAA have requested the reestablishment of the MIDAC, but the FDA has so far declined these requests. In light of the opposition of FDA management to the reestablishment of the MIDAC, CORAR and MICAA decided to seek a legislative solution. The PDUFA IV

reauthorization provides a potential legislative vehicle for reestablishing the MIDAC. In April 2007, the Alpine Group met with a House member's staff, who agreed to offer an amendment to the House PDUFA legislation directing FDA to reestablish the MIDAC. Alpine will continue to meet with Energy and Commerce Committee staff to obtain support for this issue. In addition, we have been in discussions with George Mills, former director of FDA's Division of Medical Imaging and Hematology Drug Products and currently a consultant with Parexel, Inc., about assisting us in this legislative effort.

4.3 Critical Path and Imaging Biomarkers

In March 2004, FDA initiated a Critical Path initiative to seek ways to reduce the barriers to the development of new drug therapies. As part of this initiative, FDA is encouraging the development, qualification, and use of biomarkers, including imaging biomarkers, for a variety of functions including screening promising drug candidates, enriching investigational study populations, evaluating the effectiveness of therapies during development, and serving as surrogate endpoints for approval purposes. In addition, as part of its PDUFA IV performance goals, FDA is proposing to conduct a workshop and develop a guidance on biomarker qualification. The Committee, along with the Regulatory Committee of MICAA, has determined that it is important for both groups to monitor FDA developments and actively participate in the public discourse on imaging biomarkers under the Critical Path initiative, and we have since had meetings with FDA and PhRMA on Critical Path issues. The American College or Radiology (ACR) is spearheading a multi-organization initiative to develop uniform protocols for imaging with various agents in clinical trials (UPICT). In October 2006, the UPICT steering committee issued a template for uniform imaging protocols. The template is intended to be subsequently used by UPICT working groups to develop uniform imaging protocols in specific disease areas. ACR invited CORAR's and MICAA's participation in the working groups, which are as yet unscheduled. CORAR and MICAA, along with FDA, PhRMA, BIO, are co-sponsoring a Drug Information Association (DIA) Medical Imaging Conference to be held on October 18 and 19, 2007.

5.0 Nuclear Pharmacy Issues

5.1 PET cGMPs

FDAMA § 121 requires FDA to issue special cGMP requirements for PET drugs. On September 20, 2005, FDA published in the Federal Register a proposed rule on PET cGMPs, and also released a draft guidance on the subject. CORAR submitted comments on the proposed rule and guidance on December 15, 2005. It has not been published yet.

5.2 PET User Fees

See item 4.1 above.

5.3 Inappropriate Compounding

CORAR has historically opposed the practice by some nuclear pharmacies of compounding large quantities of products that are copies of FDA approved radiopharmaceuticals. At various times, CORAR has complained to the FDA about specific pharmacies that engage in this practice. Senator Kennedy has drafted and intends to introduce a bill that will explicitly authorize pharmacy compounding under the FDC Act under certain conditions. The bill exempts radiopharmaceuticals and PET drugs. Members of the Committee recently debated whether to seek a deletion of this exemption, since the bill contains some restrictions on the compounding of copies of FDA-approved products, which would be helpful to our members. However, because the bill also

contains restrictions on legitimate compounding that would be too restrictive for radiopharmaceuticals, the members ultimately decided not to seek any amendment to the Kennedy bill.

5.4 Letter to Senate HELP Staff About Radiopharmaceutical Compounding

Senator Kennedy intends to introduce a bill that will explicitly authorize pharmacy compounding under the FDC Act under certain conditions. The bill is likely to be based on a compounding provision that was enacted as part of FDAMA in 1997 but was invalidated by the Supreme Court on First Amendment grounds in 2002. In April 2006, CORAR met with Senate HELP staffer Horatio Murillo to educate him about what types of radiopharmaceutical compounding are appropriate and what types are inappropriate. Mr. Murillo invited CORAR to submit an explanation of how radiopharmaceutical compounding should be regulated, which he would consider in drafting the legislation. We submitted the letter on May 24. Mr. Murillo subsequently left Senate HELP staff, but we have been in contact with the new responsible staff members to ensure that we are kept informed of any new legislation.

5.5 USP Chapter 797 Proposed Revisions

CORAR has been working with the USP 797 committee in their re-write of their pharmacy recommendation. Formal comments were submitted to USP by CORAR on August 14, 2006. The scientific committee was scheduled to meet in December, 2006. There is nothing further to report on this.

Roy W. Brown
Senior Director, Federal Affairs