Council on Radionuclides and Radiopharmaceuticals, Inc.

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Summary of CORAR Activities – February 2007

1.0 NRC Issues

1.1 NRC Jurisdiction over NARM

NRC was granted jurisdiction over NARM in the EPAct of 2005. They published their proposed rulemaking on July 28, 2006. Many of the early concerns with the rulemaking have been favorably resolved by the NRC and are contained in the proposed rule. The largest point of contention that remains is CORAR's desire to get a categorical exemption from the decommissioning funding and requirement to file a decommissioning plan for PET cyclotrons. CORAR would also like to see specific DACs listed for O-15 & N-13. Roy Brown presented CORAR's concerns on the decommissioning and DAC issues to the OAS at their annual meeting in Mobile. PET cyclotron activation data has been received from GE, but is also needed from Siemens, IBA and EBCO in order for all of the major PET cyclotron manufacturers to be covered. If all of this data from the various manufacturers shows that it is not possible for PET cyclotrons to achieve the activation levels in 10 CFR 30.35. NRC would be more inclined to issue this categorical exemption to PET cyclotrons if we could provide this data. CORAR has requested NRC to use specific DACs for O-15 & N-13, and is likely to do so.

1.2 Section 656 of EPAct: Secure Transfer of Materials

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. 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". There have been three meetings so far – 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 as 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).

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 three 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 it's concerns at the first committee meeting.

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.

1.7 NRC Implementation of the Import/Export Rule

The NRC sought to implement controls over the import and export of significant quantities of radioactive materials shipments in accord with the IAEA's Code of Conduct. NRC issued the final rulemaking on July 1, 2005. CORAR held one meeting on Nov 3, 2005, and several

teleconferences with NRC in an effort to coordinate a smooth implementation of the rule. CORAR also sent a formal letter to Chairman Diaz in an effort to delay implementation of the rule because CORAR did not feel NRC was prepared to implement the final rule. The NRC implemented the new import/export rule the end of 2005. They have been slow to qualify new countries into the approved list, but the rule is currently in effect.

1.8 Implementation of SAFE Ports Act (H.R. 4954)

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 drafted and sent a letter to the Committees of jurisdiction.

1.9 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. In response to the CORAR letter, 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 MQSC members on October 6, 2006, requesting information to be consolidated by HHK to prepare for the dialogue with the appointee. Since then, Alan Pasternak has expressed interest in having CalRad Forum partner with CORAR in this effort. Roy Brown 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.

1.10 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 have been drafted that revisit comments previously submitted in February 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. CORAR submitted comments prior to the December 6, 2006 deadline.

1.11 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.

1.12 NY 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.

1.13 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.

1.14 NRC Proposed Rule on Safeguards Information

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. The deadline for comments was January 2, 2007.

1.15 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 has prepared draft comments to the EPA.

1.16 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. Comments provided by industry (ISSPA) in the first draft were not reflected in the latest version and this was brought to the attention of IAEA.

1.17 IAEA Safety Guide: 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 in support of this Safety Guide.

1.18 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.

1.19 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.

1.20 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.

1.21 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.

1.22 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.

1.23 OSHA Request for information on ionizing on 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.

1.24 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 meting 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.

1.25 Michigan Application for Agreement State

CORAR members submitted comments to Michigan DEQ to assist them to develop regulations that are uniform with the NRC. CORAR submitted comments regarding 105CMR120 Regulations on September 29, 2005 to the MDPH. CORAR members also submitted comments. CORAR members participated in a stakeholder's meeting with the MDEQ on December 14, 2005. The revised regulations should be published soon.

1.26 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.

1.27 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.

1.28 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.

1.29 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 Persons Contaminated with Radionuclides" 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. NCRP published Report No 152 "Performance Assessment of Near-Surface Facilities for Disposal of LLRW", dated December 2005, addressing CORAR comments.

1.30 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 is expected to consolidate comments into final draft recommendations in the next two months.

1.31 Health Physics Society Liaison

At the 5/10/06 MQSC meeting there were two actions to liaise with the Health Physics Society on CORAR's concerns that HPS position papers promote decommissioning plans for cyclotrons and the tracking of Category 3 sources. On 5/20/06 CORAR obtained clarification that the HPS intent was only that the NRC review these areas and make a determination. The HPS expects that categories of facilities and sources will be exempted which is compatible with CORAR's position. The HPS is now sensitive of CORAR's concerns and intends to consult with us on future developments.

2.0 Transportation Issues

2.1 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. 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.

2.2 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. Status Update: 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, Transuranic 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. CORAR will work with the NEI Task Group and GIPA.

2.3 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.

2.4 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 A1 and 3000 A2. 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.

2.5 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.

2.6 Aviation Security/Air Cargo Security Legislation

Representatives Markey and Shays introduced legislation on May 3, 2005, (HR 2044) which would require all cargo transported on passenger and cargo planes to be physically inspected prior to being loaded onto the aircraft. Specifically, the bill would mandate that the Secretary of Homeland Security establish systems to inspect cargo, establish a system of regular inspections of shipping facilities and create a training and evaluation program for cargo handlers to improve the security and ensure that cargo is safeguarded from security breaches. In 2006, Congress decided to focus legislation on cargo inspections at ports instead of cargo transported in aircraft. The House Committee on Homeland Security during committee deliberations defeated an amendment offered by Representative Markey which would require all cargo in route to the Unites States from foreign port be inspected, (18-16). One of the Democrats first priorities is the enactment of the 9/11 Commission recommendations in the 110th Congress. The 9/11 Commission stated in its recommendations that the United States intensify efforts to identify, track, and screen air cargo. Representative Markey's bill goes further requiring 100 percent inspections. It is likely that some action is taken next year. The Senate Committee on Commerce approved a bill (S. 1052) contains a title devoted to hazardous material security and requires written plans for hazardous material routing and motor carrier tracking for "high hazardous materials" which is defined as quantities of poison inhalation hazardous materials, Class 2.3 gases, Class 6.1 materials, and anhydrous ammonia. The provisions on hazardous material security were included in the Senate version of the SAFE Ports bill via amendment by Senator Lautenberg during Senate floor consideration. Due to the limited timeframe to develop a conference report, the provisions were removed prior to floor consideration. The provisions enjoy bipartisan support and we expect similar language to be introduced or included in security-related bills developed next year. In 2007 CORAR will engage committees of jurisdiction to ensure the transport of radiopharmaceuticals are not unduly delayed due to new, more robust security requirements.

2.7 TSA Reauthorization Legislation

Legislation to require DHS to regulate the transport of extremely hazardous material was introduced March 17, 2005 (HR 1414) by Representative Markey. The bill is designed to re-route hazardous material away from "areas of concern." The bill would require DHS to define both the "areas of concern" and grants the Secretary the authority to add additional items to the definition of "extremely hazardous material." Nuclear materials are not currently included in the definition of extremely hazardous materials. On November 10, 2004, RSPA published a proposed rule to revise the requirements for stowage of hazardous materials on aircraft. Comments were filed by CORAR with DOT on February 21, 2005 that were in favor of the proposals to adopt the >50 TI exemptions and conditions into the HMR and the fact that DOT did not proposed across-the-board revisions to the limited quantity authorizations. CORAR did however offer comments on other

proposals including clarification of the applicability of part 175, including deficiency reporting, to individuals such as air freight forwarders and other indirect air carriers, revision of the definition of "research" in the passenger aircraft provision, clarification on the requirement to report deficiencies "as soon as practicable" and the scope of applicability, and responsibility for reporting shipment discrepancies. Representative Markey offered his bill as an amendment to the TSA Reauthorization during consideration of the bill at the Subcommittee level in the House Committee on Homeland Security and the Subcommittee accepted it. The TSA reauthorization bill is currently pending in full Committee. The Full and Subcommittee Chairs and staff opposed the inclusion of Representative Markey's legislation in the TSA Reauthorization and the bill is not expected to be acted on by the full Committee. To date there is no Senate companion measure. The Democratic takeover of the House and Senate will increase the likelihood of the passage of language regulating "extremely hazardous material." CORAR has developed a white paper in an effort to educate staff and ensure that radiopharmaceuticals are not adversely impacted by this proposal and similar legislation. CORAR will schedule meetings with Members and staff on the House Committee on Homeland Security and the Senate Committee on Commerce, Science, and Transportation.

2.8 IAEA Transport Security Guidance

In 2003, the IAEA published a draft TECDOC on Security in the Transport of Radioactive Material – Interim Guidance for Comment. Specific comments were provided concerning difficulties with terms and security plan expectations in the TECDOC. In January 2004, IAEA published its Code of Conduct on the Safety and Security of Radioactive Sources. It uses the same Category 1-3 framework as TECDOC-1344 and provides roles and responsibilities for states, regulatory agencies and IAEA. The initial Transport Security Document was never be finalized. On April 18, 2005, IAEA announced that an ambitious initiative will be undertaken to take a more comprehensive approach to security of radioactive material by developing a new TECDOC on security guidance of non-nuclear radioactive material to address the potential for sabotage and other malicious acts taking into account the attractiveness of these materials. The objective is to harmonize the new guidance with that which already exists. The methodology, critical parameters and terms of reference (which include denial of shipments) were to be reviewed at an IAEA consultant meeting in May and July, 2005. Some CORAR member companies provided comments prior to the May meeting. The first consultant meeting established the radiological basis for setting the threshold to define "high consequence" radioactive material and developed a simple dispersion model and calculated the radioactivity of each radionuclide required to cause "relocation" (per ICRP 82). The second consultant meeting established the security provisions that should be applied to shipments. Those recommendations were to stay with the previously recommended 3 categories and a "per package" approach rather than a consignment/conveyance approach. A third consultant meeting on October 17-21, 2005, was held to draft the security document based on the previous two consultant meetings. A technical meeting to review the draft document was held January 23-27, 2006. 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 that was presented at plenary and will be forwarded to the UN Committee of Experts for inclusion in the UN Orange book is as follows. The level where 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. Excepted packages, LSA-I and SCO-I are exempt for all security requirements. The security measures to be applied during transport were not finalized during the meeting. These will be completed by the IAEA secretary

and the working group chairman. 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. The enhanced security measures (Co-60, Ir-192) go beyond the enhanced security measures described in the UN Orange Book. An advance copy of the IAEA guidance document was circulated to January meeting attendees for comments. ISSPA circulated the guidance document to CORAR and prepared comments that were provided to the IAEA in October 2006. Once the final document is completed it will be sent to the IAEA Member States for a 120-day comment period.

2.9 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. 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.

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

The IAEA continues to review and revise its TS-R-1 regulations every two years. On April 27, 2005, the NRC and DOT solicited comments on changes proposed by IAEA to the 2007 revision of TS-R-1. Comments on the 2007 TS-R-1 revision were submitted by CORAR on June 21, 2005, regarding designation of responsibility for requirements on overpacks, and emphasis on compliance with RPP requirements. A general comment was also made to challenge the need for the two-year revision cycle. The 2007 revision of the TS-R-1 regulations is complete and the document is with the IAEA for final approval and publishing. 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. The 2009 revision cycle was not initiated at the IAEA. The next revision cycle 2011 is expected to being in the Spring 2007 with a request for change proposal.

2.11 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.

2.12 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.

2.13 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. IAEA was not able to present our NGO status application at the Board meeting last Spring. We are on their agenda for the meeting in June 2007. Currently, they have all of the information they need to act on our NGO request. They will notify CORAR after the June meeting.

2.14 Excepted Package Papers and Press Article

There was a press article published in the UK and two papers titled "The Excepted Package - Consignor's Friend or Pandora's Box" which appeared in the a publication of the Packaging, Transport, Storage & Security of Radioactive Material magazine and a paper titled, "Safe and Secure Transport of Radioactive Materials - A Consignor's View," which was presented at the Radioactive Transportation Conference in London on October 5 and 6. The paper titled "Safe and Secure Transport of Radioactive Materials - A Consignor's View," is fairly innocuous and raises problems with regulatory discrepancy between ADR requirements and UK regulations for excepted packages, lack of guidance documents for excepted packages, problems with measuring dose rate for excepted packages, security requirements for excepted packages, confusion over the training requirements etc. However, the paper titled "The Excepted Package - Consignor's Friend

or Pandora's Box" and the news article make more sensational claims such as the use of second hand cardboard boxes for the transport of radioactive material (excepted packages); the probability of an event involving an excepted package is greater than other packages; questions the radiological safety of an excepted package; and that radioactive material are "made to fit" in an excepted package. It was suggested that a response should be written to the Pandora's box paper and news article. CORAR decided not to write an article as no further article or dialogue was heard surrounding the press article and papers.

2.15 BF_3

There has been discussion on the removal on an air transport exemption for BF_3, including neutron detectors utilizing BF_3. It would appear that this material can not been transported by air and has never been authorized for air transport. BF_3 is specifically listed in the Hazardous Materials Table 49 CFR §172.101 with UN 1008 Hazard Division 2.3. Column 9(A) Passenger Aircraft/Rail and 9(B) Cargo Aircraft are completed as “Forbidden”. There is a quantity exception in some cases of “Forbidden” cargo. However, Section 2.7.2 Dangerous Goods Not Permitted in Excepted Quantities of the IATA Dangerous Goods Regulations states that hazardous materials in division 2.3 must not be transported under the excepted quantities provision. Section 2.6.1 of the IATA Regulations does provide an exemption for dangerous goods to be transported by air. However the section begins as “In cases of extreme urgency, or when other forms of transport are in appropriate, or when full compliance with the prescribed requirements is contrary to the public interest…” So if there ever was an exemption for BF_3 (in neutron radiation detectors) then it was probably on shaky ground. CORAR Members did not believe this to be a problem.

3.0 Reimbursement/Coverage Issues

3.1 Hospital Outpatient Prospective Payment System (HOPPS) Update

The Centers for Medicare and Medicaid Services (CMS) agreed to continue Medicare hospital outpatient prospective payment system (HOPPS) payment for radiopharmaceuticals based on the cost to charge ratio for another year through 2007. CMS asked for further recommendations on how to set fixed payment levels for radiopharmaceuticals. CMS noted that hospitals should 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. The threshold for separate payment for drugs and radiopharmaceuticals was raised from $50 to $55, starting in January 2007. Medicare payment for most nuclear medicine procedure APCs changed only modestly with slight increases in payment for 2007 in several APCs.

3.2 HOPPS – Medicare Hospital outpatient payment-Development of Recommendations and Methods for Payment for Radiopharmaceuticals

CMS published a proposed HOPPS rule on August 23, 2006 and a final HOPPS website rule on November 1, 2006 (Federal Register on November 24, 2006). CORAR met with CMS (September 21, 2006), submitted comments on the proposed HOPPS rule (September 26, 2006), worked with the Nuclear Medicine APC Task Force, and participated in the August 24, 2006 CMS APC Advisory Panel meeting. In the proposed rule, CMS recommended fixed payment amounts for radiopharmaceuticals (see attached chart). CORAR pointed out that hospitals had not updated their charges as CMS had instructed in 2005 and data did not yet reflect coding changes that went into effect in 2006. CMS’ final HOPPS rule agreed to continue payment in 2007 based on hospital charged reduced to costs, recognizing that there were no average sales prices for radiopharmaceuticals. This was consistent with the statutory exemption from ASP reporting for

radiopharmaceuticals under Medicare Part B. CMS restated its request for recommendations on how to pay for radiopharmaceuticals under a fixed payment method.
CORAR has prepared and submitted recommendations to the Nuclear Medicine APC Task Force. (see attached) The Society of Nuclear has recommended to CMS that nuclear pharmacies report ASPs for radiopharmaceuticals. CORAR updated its recommendations and participated with the Nuclear Medicine APC Task Force at the December 6, 2006 meeting and explored and sought a consensus on methods to pay for radiopharmaceuticals. CORAR will consider efforts to support hospitals adjusting their charges in 2006 and 2007 for radiopharmaceuticals to reflect more accurately all overhead and handling charges. This may improve the data base upon which CMS makes payment determinations in 2008 and 2009. This could be approached through CMS or through the specialty societies and hospital associations, in the form of a nuclear medicine "coding college". CORAR will continue to work with the Moran Company to analyze CMS data on radiopharmaceuticals. CORAR will plan to meet with CMS in the first quarter of 2007 with its recommendations and alternate models. Because some options may require legislation, CORAR will fully assess the need for and likelihood of any legislative opportunities on Medicare reform in 2007. CORAR is prepared to draft comments and participate in APC Advisory Panel meeting. CORAR will monitor CMS, MedPAC and GAO for any studies or recommendations on corrections to charge compression or drug payment that could impact radiopharmaceuticals.

3.3 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. Medicare resource based relative value scale (RBRVS) payment for many nuclear medicine procedures will be reduced by approximately 5% in 2007, along with all physician and diagnostic imaging procedures in compliance with the sustainable growth rate (SGR) payment limits. Some nuclear medicine procedures will see payment cut more significantly and reduced to the level of the HOPPS APC payment, as required under the Deficit Reduction Act of 2005. Nuclear medicine imaging continues to be exempt from the 25% reduction for the second and subsequent imaging procedures on continuous body parts. CMS continues local payment for radiopharmaceuticals and is implementing three changes, two that will reduce payment for nuclear medicine procedures when performed in the physician office or a non-hospital affiliated imaging center.

Radiopharmaceuticals are exempt from payment based on ASP and thus payment continues to be based on invoice or other local carrier methods. CORAR will monitor carrier payment methods for any significant local changes. CORAR will also be alert that some changes in payment methods for hospital administered radiopharmaceuticals, could "roll-over" to physician office payment. CMS has tried to structure drug payment in the hospital to be comparable to physician office.

A second potential payment reduction in RBRVS based payment will arise if the RBRVS technical component of a nuclear medicine imaging procedure is higher than the Medicare HOPPS APC payment for that procedure. If so, the RBRVS technical component will be reduced to the level of the HOPPS APC payment. CMS has exempted nuclear medicine procedures from this reduction if the procedure is a non-imaging diagnostic or therapeutic service. CORAR will maintain contacts with SNM, ASNC, ACNP and other physician groups to support, if needed, limited application of these reductions to nuclear medicine procedure, parallel with exemption of nuclear medicine procedures from multiple procedure reduction for imaging on contiguous body parts.

3.4 Medicare Coverage

MCAC Meeting on non-invasive diagnostic imaging compared CTA, MRI and electron beam tomography to angiography. CMS hints it may issue a regulation to further explain the criteria for

coverage under the broad "reasonable and necessary" authority. MCAC meeting on December 13, 2006 to examine Medicare coverage of clinical trials and research.

CMS convened a Medicare Coverage Advisory Committee (MCAC) meeting to assess the clinical effectiveness of CTA, MRI and electron beam tomography compared to coronary artery catheterization. The attached chart reports the voting on issues raised at the May 18, 2006 MCAC meeting. The questions addressed by the panel consider the diagnostic accuracy, use of imaging in place of coronary artery catheterization, whether there was any incremental net health benefit, and whether the evidence is generalizable to the Medicare population.

3.5 MCAC on Clinical Trial Policy

CMS is convened a MCAC meeting on December 13, 2006 for Medicare clinical trial policy to revisit the existing policy on coverage for certain aspects of clinical trials and research, and raise the following issues:

Clarify payment criteria for clinical costs in research studies other than clinical trials;

Devise a strategy to ensure that Medicare covered clinical studies are enrolled in the National Institute of Health (NIH) clinical trials registry website;

Develop criteria to assure that any Medicare covered clinical research study includes a representative sample of Medicare beneficiaries, by demographic and clinical characteristics;

Clarify the definitions of routine clinical care costs and investigational costs in clinical research studies including clinical trials;

Remove the self-certification process that was never implemented;

Clarify the scientific and technical roles of Federal agencies in overseeing IND Exempt trials;

Determine if coverage of routine clinical care costs is warranted for studies beyond those covered by the current policy.

Clarify how items/services that do not meet the requirements of 1862(a)(1)(A) but are of potential benefit can be covered in clinical research studies as an outcome of the National Coverage Determination process;

Clarify whether and under what conditions an item/service non-covered nationally may be covered in the context of clinical research to elucidate the impact of the item or service on health outcomes in Medicare beneficiaries; and

Discuss Medicare policy for payment of humanitarian use device (HUD) costs.

CORAR intends to monitor this meeting and keep CORAR members apprised of any developments important for radiopharmaceuticals or nuclear medicine imaging.

3.6 HCPCS Coding

CMS issued a slightly revised HCPCS application and denied many applications based on absence of evidence of improved benefit. CMS has finalized it HCPCS codes for 2007. There do not appear to be any new codes for radiopharmaceuticals, although final publication of the new codes is expected in late November. Most important, the HCPCS process increasingly seeks evidence of a national program operating need, and significant clinical benefits, documented in scientific literature to approve a new code. CORAR members may want to consider filing applications by December 31, 2006 for products newly approved by FDA in 2006 that do not yet have HCPCS codes. If codes do not have correct descriptors, these applications can also request clarification or modification in units or descriptors, which can be important for payment. Applications for new codes should address the newly framed questions from CMS, including documentation of improved benefits, as a basis to issue a new and distinct code.

3.7 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.

3.8 5% cut – SGR

All physician and diagnostic services are subject in 2007 to a 5% reduction based on the SGR mandated reductions. Some nuclear medicine procedures had increases in practice expense relative value units (RVUs), so that the technical component for some nuclear medicine procedures is higher in 2007 than 2006 and thus there are some modest increases in certain procedures. See attached chart. There has been considerable attention by the physician community to this cut and it is expected there will be substantial legislative efforts to repeal this 5% cut through Congressional action late in 2006 or early in 2007.

3.9 Compounding and Medicare

Over the years, CORAR has urged the FDA to take action against large-scale, inappropriate compounding of copies of approved radiopharmaceuticals by independent nuclear pharmacies. The FDA has recently issued warning letters to several pharmacies, but certain nuclear pharmacies have continued this practice with respect to radiopharmaceuticals. In addressing a related matter, the FDA recently shared with CMS its concerns related to inappropriate compounding of inhalation drugs and how CMS's reimbursement policies may inadvertently create an incentive for the inappropriate compounding* of these drugs. Subsequently, CMS has established new HCPCS codes for some inhalation drugs and intends to implement new payment and coding policies for providers to follow when billing for compounded drugs. In light of these recent developments, CORAR Members scheduled a call to discuss adopting a multi-prong FDA/CMS approach to address compounding of RPs. CORAR will engage CMS at the national level for a educational / informative meeting explaining the safety and effectiveness concerns related to inappropriate, large-scale compounding using non-FDA approved products, explore options for new HCPCS codes specifying "pharmacy-compounded from chemical grade products" (long-term approach), meet with one or two local Medicare carriers to discuss safety and effectiveness issues related to inappropriate large-scale compounding. The primary purpose would be to have the Medicare CMD publish guidelines applicable to compounded RPs and requiring providers to use unspecified RP HCPCS billing codes rather than the product specific codes established for FDA approved products. CORAR will also work with SNM as well as CMS and encourage them to alert physicians by sending out "Dear Healthcare provider letters" discussing the safety issues related to RPs that have been inappropriately compounded on a large scale basis, request that the FDA inform CMS that inappropriate compounding is also a problem for certain RPs.

Note: The FDA and CMS believe that traditional compounding, defined as "the compounding, mixing, or altering of ingredients in response to a prescription from a licensed practitioner to create a medication tailored to the needs of an individual patient" can play a legitimate role in patient care.

LIST OF ATTACHMENTS

Proposed 2007 HOPPS payment levels for Radiopharmaceuticals, with CCR as final method for 2007
Comparison of radiopharmaceutical HCPCS descriptor from 2005 to 2007 and crosswalk to proposed 2007 payment rates
Comparison of 2006/2007 Hospital APC payment rates for nuclear medicine
Comparison of 2006/2007 Physician RBRVS technical component (TC) and payment
May 18, 2006 MCAC Voting on CTA, EBT, and MRI and comparison with cardiac catheterization
CORAR October 27, 2006 Options on Medicare Payment Methods for Radiopharmaceuticals under HOPPS, submitted to NM APC TF

HOPPS Radiopharmaceutical Payment Developments -- 2007

The table below lists radiopharmaceuticals with the proposed 2007 amounts that CMS proposed to pay in 2007. Payment for radiopharmaceuticals with median costs below $55 will continue to be bundled into the APC payment for the associated procedure.

Code	Description	Proposed 2007 Payment	Final 2007 Payment
A4642	In-111 satumomab pendetide	$192.12	CCR
A9500	Tc-99m sestamibi	$82.58	CCR
A9502	Tc-99m tetrofosmin	$73.81	CCR
A9503	Tc-99m medronate	--	--
A9504	Tc-99m apcitide	--	--
A9505	Tl-201 mCi	$27.18	CCR
A9507	In-111 capromab pendetide	$928.19	CCR
A9508	Iobenguane sulfate I-131	$429.55	CCR
A9510	Tc-99m disofenin	--	--
A9512	Tc-99m pertechnetate	--	--
A9516	I-123 sodium iodide capsule	$27.44	CCR
A9517	I-131 sodium capsule	$14.54	CCR
A9521	Tc-99m exametazime	$317.07	CCR
A9524	Iodinated I-131 albumin	$36.78	CCR
A9526	Ammonia N-13, per dose	$230.77	CCR
A9528	Dx I-131 iodide cap mCi	$24.86	CCR
A9529	Dx I-131 iodide sol mCi	--	--
A9530	Th I-131 iodide sol mCi	$12.60	CCR
A9531	Dx I-131 so iodide uCi	--	--
A9532	I-125 serum albumin micro	--	--
A9536	Tc-99m depreotide	$67.91	CCR
A9539	Tc-99m pentetate	$56.77	CCR
A9540	Tc-MAA	--	--
A9541	Tc-99m sulfur colloid	--	--
A9542	In-111 ibritumomab, dx	$1344.34	CCR
A9543	Y-90 ibritumomab, rx	$12130.20	CCR
A9544	I-131 tositumomab, dx	$1368.17	CCR
A9545	I-131 tositumomab, rx	$11,868.78	CCR
A9546	Co-57/58	$149.44	CCR
A9547	In-111 oxyquinoline	$306.51	CCR
A9548	In-111 pentetate	$262.81	CCR
A9549	Tc-99m arcitumomab	$255.95	*
A9550	Tc-99m gluceptate	$236.53	CCR
A9551	Tc-99m succimer	$84.79	CCR
A9552	F-18 FDG	$235.56	CCR
A9553	Cr-51 chromate	$167.62	CCR
A9554	I-125 iothalamate, dx	--	--
A9555	Rb-82 rubidium	$239.83	CCR

Code	Description	Proposed 2007 Payment	Final 2007 Payment
A9556	Ga-67 gallium	$22.73	CCR
A9557	Tc-99m bicisate	$254.46	CCR
A9558	Xe-133 xenon 10 mCi	--	--
A9559	Co-57 Cyano	$63.74	CCR
A9560	Tc-99m labeled RBC	$132.95	CCR
A9561	Tc-99m oxidronate	--	--
A9562	Tc-99m mertiatide	$180.08	CCR
A9563	P-32 Na phosphate	$117.11	CCR
A9564	P-32 chromic phosphate	$222.35	CCR
A9565	In-111 pentetreotide	$185.60	CCR
A9566	Tc-99m fanolesomab	$527.31	CCR
A9567	Tc-99m aerosol	--	CCR
A9600	Sr-89 chloride	$533.58	CCR
A9605	Sm-153 lexidronm	$1316.41	CCR

Table 26.-- Proposed Payment Rates and Payment Crosswalk for CY 2007 Separately Payable Radiopharmaceuticals

2005 HCPCS	Description	2007 HCPCS	Description	2005 Days	2005 Units	CY 2007 Proposed Payment Rate	CY 2007 Proposed Payment Crosswalk
A4642	Supply of satumomab pendetide, radiopharmaceutical diagnostic imaging agent, per dose	A4642	Indium in-111 satumomab pendetide, diagnostic, per study dose, up to 6 millicuries	557	613	$192.12	Unit cost
A9500	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc 99m sestamibi, per dose	A9500	Technetium tc-99m sestamibi, diagnostic, per study dose, up to 40 millicuries	380,256	608,483	$82.58	Unit cost
A9502	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc 99m tetrofosmin, per unit dose	A9502	Technetium tc-99m tetrofosmin, diagnostic, per study dose, up to 40 millicuries	222,588	353,488	$73.81	Unit cost
A9505	Supply of radiopharmaceutical diagnostic imaging agent, thallous chloride tl 201, per mci	A9505	Thallium tl-201 thallous chloride, diagnostic, per millicurie	132,448	407,956	$27.18	Unit cost
A9507	Supply of radiopharmaceutical diagnostic imaging agent, indium in 111 capromab pendetide, per dose	A9507	Indium in-111 capromab pendetide, diagnostic, per study dose, up to 10 millicuries	2,109	2,109	$928.19	Unit cost
A9508	Supply of radiopharmaceutical diagnostic imaging agent, iobenguane sulfate i-131, per 0.5 mci	A9508	Iodine i-131 iobenguane sulfate, diagnostic, per 0.5 millicurie	423	593	$429.55	Unit cost
A9516	Supply of radiopharmaceutical diagnostic imaging agent, i-123 sodium iodide capsule, per 100 uci	A9516	Iodine i-123 sodium iodide capsule(s), diagnostic, per 100 microcuries	32,098	73,760	$27.44	Unit cost
A9517	Supply of radiopharmaceutical therapeutic imaging agent, i-131 sodium iodide capsule, per mci	A9517	Iodine i-131 sodium iodide capsule(s), therapeutic, per millicurie	9,836	231,507	$14.54	Unit cost

2005 HCPCS	Description	2007 HCPCS	Description	2005 Days	2005 Units	CY 2007 Proposed Payment Rate	CY 2007 Proposed Payment Crosswalk
A9521	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc-99m exametazine, per dose	A9521	Technetium tc-99m exametazime, diagnostic, per study dose, up to 25 millicuries	4,258	4,355	$317.07	Unit cost
A9524	Supply of radiopharmaceutical diagnostic imaging agent, iodinated i-131 serum albumin, 5 microcuries	A9524	Iodine i-131 iodinated serum albumin, diagnostic, per 5 microcuries	356	1,543	$36.78	Unit cost
A9526	Supply of radiopharmaceutical diagnostic imaging agent, ammonia n-13, per dose	A9526	Nitrogen n-13 ammonia, diagnostic, per study dose, up to 40 millicuries	63	80	$230.77	Unit cost
A9528	Supply of radiopharmaceutical diagnostic agent, i-131 sodium iodide capsule, per millicurie	A9528	Iodine i-131 sodium iodide capsule(s), diagnostic, per millicurie	4,246	20,556	$24.86	Unit cost
A9530	Supply of radiopharmaceutical therapeutic agent, i-131 sodium iodide solution, per millicurie	A9530	Iodine i-131 sodium iodide solution, therapeutic, per millicurie	1,931	66,609	$12.60	Unit cost
A9511	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc 99m, depreotide, per mci	A9536	Technetium tc-99m depreotide, diagnostic, per study dose, up to 35 millicuries	582	777	$67.91	Per Day Cost
A9515	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc-99m pentetate, per mci	A9539	Technetium tc-99m pentetate, diagnostic, per study dose, up to 25 millicuries	18,523	211,597	$56.77	Per Day Cost
C1082	Supply of radiopharmaceutical diagnostic imaging agent, indium-111 ibritumomab tiuxetan, per dose	A9542	Indium in-111 ibritumomab tiuxetan, diagnostic, per study dose, up to 5 millicuries	384	384	$1,344.34	Unit cost

2005 HCPCS	Description	2007 HCPCS	Description	2005 Days	2005 Units	CY 2007 Proposed Payment Rate	CY 2007 Proposed Payment Crosswalk
C1083	Supply of radiopharmaceutical therapeutic imaging agent, yttrium 90 ibritumomab tiuxetan, per dose	A9543	Yttrium y-90 ibritumomab tiuxetan, therapeutic, per treatment dose, up to 40 millicuries	362	362	$12,130.20	Unit cost
C1080	Supply of radiopharmaceutical diagnostic imaging agent, i-131 tositumomab, per dose	A9544	Iodine i-131 tositumomab, diagnostic, per study dose	249	249	$1,368.17	Unit cost
C1081	Supply of radiopharmaceutical therapeutic imaging agent, i-131 tositumomab, per dose	A9545	Iodine i-131 tositumomab, therapeutic, per treatment dose	191	191	$11,868.78	Unit cost
C1079	Supply of radiopharmaceutical diagnostic imaging agent, cyanocobalamin co 57/58, per 0.5 microcurie	A9546	Cobalt co-57/58, cyanocobalamin, diagnostic, per study dose, up to 1 microcurie	125	2,401	$149.44	Per Day Cost
C1091	Supply of radiopharmaceutical diagnostic imaging agent, indium 111 oxyquinoline, per 0.5 millicurie	A9547	Indium in-111 oxyquinoline, diagnostic, per 0.5 millicurie	4,296	4,591	$306.51	Unit cost
C1092	Supply of radiopharmaceutical diagnostic imaging agent, indium 111 pentetate, per 0.5 millicurie	A9548	Indium in-111 pentetate, diagnostic, per 0.5 millicurie	5,065	6,381	$262.81	Unit cost
C1122	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc 99m arcitumomab, per vial	A9549	Technetium tc-99m arcitumomab, diagnostic, per study dose, up to 25 millicuries	145	145	$255.95	Unit cost
Q3006	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc 99m glucepatate, per 5 mci	A9550	Technetium tc-99m sodium gluceptate, diagnostic, per study dose, up to 25 millicurie	58	72	$236.53	Per Day Cost

2005 HCPCS	Description	2007 HCPCS	Description	2005 Days	2005 Units	CY 2007 Proposed Payment Rate	CY 2007 Proposed Payment Crosswalk
C1200	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc 99m sodium glucoheptonate, per vial	A9550	Technetium tc-99m sodium gluceptate, diagnostic, per study dose, up to 25 millicurie	48	48	N/A	N/A
C1201	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc 99m succimer, per vial	A9551	Technetium tc-99m succimer, diagnostic, per study dose, up to 10 millicuries	447	447	$84.79	Unit cost
C1775	Supply of radiopharmaceutical diagnostic imaging agent, fluorodeoxyglucose f18 (2-deoxy-2-[18f]fluoro-d-glucose), per dose (4-40 mci/ml)	A9552	Fluorodeoxyglucose f-18 fdg, diagnostic, per study dose, up to 45 millicuries	136,012	136,012	$235.56	Unit cost
C9000	Injection, sodium chromate cr51, per 0.25 mci	A9553	Chromium cr-51 sodium chromate, diagnostic, per study dose, up to 250 microcuries	438	488	$167.62	Per Day Cost
C9102	Supply of radiopharmaceutical diagnostic imaging agent, 51 sodium chromate, per 50 mci	A9553	Chromium cr-51 sodium chromate, diagnostic, per study dose, up to 250 microcuries	279	326	N/A	N/A
Q3000	Supply of radiopharmaceutical diagnostic imaging agent, rubidium rb-82, per dose	A9555	Rubidium rb-82, diagnostic, per study dose, up to 60 millicuries	2,059	3,837	$239.83	Unit cost
Q3002	Supply of radiopharmaceutical diagnostic imaging agent, gallium ga 67, per mci	A9556	Gallium ga-67 citrate, diagnostic, per millicurie	3,597	15,880	$22.73	Unit cost
Q3003	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc99m bicisate, per unit dose	A9557	Technetium tc-99m bicisate, diagnostic, per study dose, up to 25 millicuries	1,622	1,652	$254.46	Unit cost
C9013	Supply of co 57 cobaltous chloride, radiopharmaceutical diagnostic imaging agent	A9559	Cobalt co-57 cyanocobalamin, oral, diagnostic, per study dose, up to 1 microcurie	3	3	N/A	N/A

2005 HCPCS	Description	2007 HCPCS	Description	2005 Days	2005 Units	CY 2007 Proposed Payment Rate	CY 2007 Proposed Payment Crosswalk
Q3012	Supply of oral radiopharmaceutical diagnostic imaging agent, cyanocobalamin cobalt co57, per 0.5 mci	A9559	Cobalt co-57 cyanocobalamin, oral, diagnostic, per study dose, up to 1 microcurie	112	112	$63.74	Per Day Cost
Q3010	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc99m - labeled red blood cells, per mci	A9560	Technetium tc-99m labeled red blood cells, diagnostic, per study dose, up to 30 millicuries	20,662	274,695	$132.95	Per Day Cost
Q3005	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc-99m mertiatide, per mci	A9562	Technetium tc-99m mertiatide, diagnostic, per study dose, up to 15 millicuries	23,306	120,392	$180.08	Per Day Cost
Q3007	Supply of radiopharmaceutical diagnostic imaging agent, sodium phosphate p32, per mci	A9563	Sodium phosphate p-32, therapeutic, per millicurie	307	623	$117.11	Unit cost
Q3011	Supply of radiopharmaceutical diagnostic imaging agent, chromic phosphate p32 suspension, per mci	A9564	Chromic phosphate p-32 suspension, therapeutic, per millicurie	23	87	$222.35	Unit cost
Q3008	Supply of radiopharmaceutical diagnostic imaging agent, indium 111-in pentetreotide, per 3 mci	A9565	Indium in-111 pentetreotide, diagnostic, per millicurie	2,856	4,546	$185.60	Unit cost
C1093	Supply of radiopharmaceutical diagnostic imaging agent, technetium tc 99m fanolesomab, per dose (10 - 20 mci)	A9566	Technetium tc-99m fanolesomab, diagnostic, per study dose, up to 25 millicuries	1,123	1,123	$527.31	Unit cost
A9600	Supply of therapeutic radiopharmaceutical, strontium-89 chloride, per mci	A9600	Strontium sr-89 chloride, therapeutic, per millicurie	519	1,311	$533.58	Unit cost
A9605	Supply of therapeutic radiopharmaceutical, samarium sm 153 lexidronamm, 50 mci	A9605	Samarium sm-153 lexidronamm, therapeutic, per 50 millicuries	959	1,631	$1,316.41	Unit cost

Comparison of 2006 / 2007 Nuclear Medicine APC Payment Rates
(Payment Increases from 2006 are Bolded)

APC	Title	2006 Payment	Final 2007 Payment
307	Myocardial Positron Emission Tomography (PET) Imaging	$2,484.88	$731.24
308	Non-Myocardial PET Imaging CPT codes 78608, 78811, 78812, and 78813	--	$855.43
376	Level II Cardiac Imaging	$299.43	$306.31
377	Level III Cardiac Imaging	$397.11	$399.62
378	Level II Pulmonary Imaging	$321.74	$313.33
389	Non-imaging Nuc Med.	$84.96	$84.54
390	Level I Endocrine Imaging	$146.77	$144.03
391	Level II Endocrine Imaging	$165.46	$166.86
393	Red Cell/Plasma Studies	$205.12	$230.89
394	Hepatobilliary Imaging	$256.53	$269.07
395	GI Tract Imaging	$224.33	$224.52
396	Bone Imaging	$237.57	$240.79
397	Vascular Imaging	$123.96	$148.78
398	Level I Cardiac Imaging	$250.17	$253.65
399	Nuclear Med Add-On Imaging	$89.50	$92.53
400	Hematopoietic Imaging	$233.05	$240.17
401	Level I Pulmonary Imaging	$197.37	$195.48
402	Brain Imaging	$307.73	$285.32
403	CSF Imaging	$208.38	$214.66
404	Renal & GU Studies Level I	$217.56	$210.28
405	Renal & GU Studies Level II	$246.93	$248.20
406	Tumor/Infection Imaging	$246.36	$245.47
407	Radionuclide Therapy	$230.65	$195.34
1507	New Technology – Level VII (Hematopoetic Nuc therapy)	$550.00	$550.00
1508	New Technology– Level VIII (Tumor imaging)	$650.00	$650.00
1511	New Technology– Level XI (PET/CT procedures) This APC will include CPT codes 78814, 78815, 78816.		$950.00
1513	New Technology – Level XIII (including non-myocardial PET procedures) See APC 308 for 2007.	$1,150.00	
1514	New Technology – Level IV (including PET/CT procedures) See APC 1511 for 2007.	$1,250.00	

Medicare Physician Fee Schedule – RBRVS Payment

HCPCS/ CPT code	Description	2006 TC RVUs/ TC Payment*	2007 TC RVUs/TC Payment*
Bone Imaging			
78300 TC	Bone imaging, limited area	2.63 / $100	2.94 / $106
78305 TC	Bone imaging, multiple areas	3.86 / $146	4.16 / $150
78306 TC	Bone imaging, whole body	4.50 / $171	4.78 / $172
78315 TC	Bone imaging, 3 phase	5.04 / $191	5.78 / $208
78320 TC	Bone imaging (3D)	6.24 / $236	5.92 / $213
Cardiac Imaging			
78428 TC	Cardiac shunt imaging	2.39 / $91	3.04 / $109
78460 TC	Heart muscle blood, single	2.50 / $95	2.94 / $106
78464 TC	Heart image (3d), single	7.46 / $283	6.99 / $252
78466 TC	Heart infarct image	2.77 / $105	3.13 / $113
78468 TC	Heart infarct image (ef)	3.86 / $146	4.33 / $156
78469 TC	Heart infarct image (3D)	5.52 / $209	5.64 / $203
78472 TC	Gated heart, planar, single	5.83 / $221	5.82 / $209
78481 TC	Heart first pass, single	5.52 / $209	5.34 / $192
78494 TC	Heart image, spect	7.39 / $280	7.02 / $253
78473 TC	Gated heart, multiple	8.70 / $330	8.35 / $300
78483 TC	Heart first pass, multiple	8.30 / $315	7.83 / $282
78461 TC	Heart muscle blood, multiple	4.98 / $189	4.64 / $167
78465 TC	Heart image (3D), multiple	12.44 / $471	12.13 / $436
Nuclear Medicine Add-on Imaging			
78020 TC	Thyroid met uptake	1.45 / $55	1.50 / $54
78478 TC	Heart wall motion add-on	1.66 / $63	1.41 / $51
78480 TC	Heart function add-on	1.66 / $63	1.41 / $51
78496 TC	Heart first pass-on	7.39 / $280	5.77 / $208
Level I Pulmonary Imaging			
78580 TC	Lung perfusion imaging	3.62 / $137	3.91 / $141
78586 TC	Aerosol lung image, single	2.74 / $104	3.03 / $109
78587 TC	Aerosol lung image, multiple	2.95 / $112	3.49 / $126
78591 TC	Vent image, 1 breath, 1 proj	3.00 / $114	3.22 / $116
78585 TC	Lung V/Q imaging Gas	5.96 / $226	6.48 / $233
78588 TC	Lung V/Q imaging Aerosol	3.39 / $128	4.53 / $163
78596 TC	Lung differential function	7.46 / $283	7.67 / $276
Tumor Infection			
78015 TC	Thyroid metastases imaging	2.72 / $103	3.30 / $119
78800 TC	Tumor imaging, limited area	3.59 / $136	3.70 / $133
78801 TC	Tumor imaging, mult areas	4.45 / $169	4.77 / $172
78805 TC	Abscess imaging, ltd area	3.59 /$136	3.67 / $132

* Payments calculated using total non-facility TC RVUs x conversion factor for each respective year ($37.8975 in 2006 and $35.9848 in 2007), when available. Otherwise global total non-facility RVUs used, as indicated. 2007 calculation based on year 2007 transitional non-facility total.

** Global total non-facility calculations are subject to a budget neutrality factor which slightly reduces payment amounts. The indicated calculations take the budget neutrality factor into account.

4.0 FDA Issues

4.1 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 intend, in the next Congress, to monitor the reauthorization of the Prescription Drug User Fee Act (PDUFA), with the objective of introducing a provision requiring FDA to reestablish the MIDAC. In the meantime, in the absence of a standing MIDAC, George Mills, MD, the Director of FDA's Division of Medical Imaging and Hematology Drug Products (DMIHDP), has implemented a system whereby medical imaging experts are retained as Special Government Employees (SGEs) and appointed as ad hoc voting members to existing standing advisory committees (e.g., ODAC) for purposes of reviewing a medical imaging product or issue. The first product-specific "test case" for FDA's ad hoc approach was a March 3, 2005 meeting of the Oncology Drugs Advisory Committee (ODAC), with the addition of ad hoc medical imaging experts, to review Combidex. Only three of the 19 panel members were radiologists, and the meeting exposed serious flaws with FDA's ad hoc expert approach. At an SNM meeting several months after the Combidex panel meeting, CORAR and MICAA publicly communicated to Dr. Mills their views on the problems of the SGE system and suggestions for improving it.

During this period, CORAR has been monitoring FDA's implementation of the SGE system. Based on our contacts with Dr. Mills over the past several months, he has apparently made good faith efforts to improve the system. First, he has begun to qualify a number of experts as SGEs to form a Medical Imaging Advisory Group as a substitute for the MIDAC. Twelve individuals have so far been cleared for SGE status, and several more are in process. Second, he is seeking to convert this group into a standing Medical Imaging Drugs Subcommittee of the Oncology Drugs Advisory Committee (ODAC), which would have eight permanent members, and which could be convened to review medical imaging products or issues, whether or not related to cancer. Under this plan, the Medical Imaging Drug Subcommittee could be supplemented by SGE experts if additional expertise were needed. If a standing subcommittee is not feasible, Dr. Mills would seek to have medical imaging experts appointed as permanent members of the ODAC. See the Update sent to members on October 30, 2006. In the next session, members of Congress will begin to draft and introduce bills to reauthorize the Prescription Drug User Fee Act (PDUFA), which expires in 2007. CORAR will closely monitor these legislative developments with an eye toward introducing a provision requiring FDA to reestablish the MIDAC. CORAR will also continue to monitor FDA's implementation of an advisory apparatus using medical imaging SGEs, as well as any advisory committee meetings that may be held to address medical imaging products or issues.

4.2 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. Dr. Mills and others at FDA have been speaking at public programs and meeting with PhRMA and professional societies on this issue. CORAR, along with the Regulatory Committee of MICAA, 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.

4.3 Uniform Protocols for Imaging with various agents in Clinical Trials (UPICT)

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). The goal of UPICT is to develop imaging protocols primarily to assess efficacy in the development of therapeutic drugs. 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. CORAR and MICAA did not participate in the UPICT steering committee meetings, but ACR invited CORAR's and MICAA's participation in the working groups. In addition, ACR has invited CORAR and MICAA to comment on the uniform protocol template. CORAR will become involved in the UPICT working groups; and consider whether to comment on the UPICT template protocol.

4.4 DIA Medical Imaging Conference, October 2006

Along with FDA, PhRMA, BIO, and other organizations, CORAR and MICAA co-sponsored a Drug Information Association (DIA) Medical Imaging Conference on October 12 and 13, 2006. The conference focused on the role of medical imaging in the Critical Path. Bill Regan was involved in the planning of the meeting on behalf of CORAR and MICAA, and Bill also participated on one of the session panels. Also on behalf of CORAR and MICAA, Joel Lazewatsky of BMS Medical Imaging participated in a panel on performance standards for imaging displays.

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. Dr. Mills recently predicted that the PET cGMP documents will be finalized by the end of 2006.

5.2 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 seeking a class waiver for PET manufacturers from having to pay multiple establishment fees. However, we have been told by Jane Axelrad, Associate Director for Policy at CDER, that FDA does not intend to respond to our petition until after PDUFA has been reauthorized, since changes in the reauthorized statute might address our concerns.

On May 30, we sent a letter on behalf of CORAR to George Mills (copying Jane Axelrad) explaining that immediate relief from multiple establishment fees is needed so that companies will

not be discouraged from voluntarily submitting NDAs during the statutory moratorium on requiring NDAs and ANDAs for PET drugs (Attachment 3). Subsequently, George Mills communicated to us and later reported at the June SNM meeting that the medical imaging drug division and the Office of Generic Drugs had devised an approach for avoiding establishment fees for FDG. Under this approach, FDG products within certain tolerances could be approved under ANDAs that refer to the two existing FDG NDAs as reference listed drugs. ANDA drugs are not subject to establishment fees. However, this solution does not resolve the issue for non-FDG PET drugs. In August, representatives of the Committee met separately with staff of BIO and PhRMA to educate them about the establishment fee issue, and to get a sense of whether these organizations would support proposals for legislative or administrative relief advanced by CORAR. Both groups were sympathetic and agreed to communicate with their members on this issue. Neither thought that there would be any opposition to a CORAR proposal.

On August 25, representatives of CORAR met with Jane Axelrad, George Mills and Mike Jones of CDER on this issue. Ms. Axelrad and Mr. Jones agreed that some relief was necessary and that the best way to implement it would be through legislation, but there was no agreement at the meeting on what the relief should be. We agreed to provide them with any legislative proposals for their prior review. CORAR plans to develop draft legislation providing an exemption or partial exemption for PET manufacturers from establishment fees, and monitor the PDUFA reauthorization process in 2007 for opportunities to advance the legislation.

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. The legal status of pharmacy compounding is in flux. On one hand, FDA has recently become more active in enforcing against the practice of manufacturing commercially available products under the guise of pharmacy compounding. In August, the agency issued warning letters to two pharmacies based on such activities, and more recently has written to CMS about the risk of certain Medicare payment policies that could encourage such practices with respect to inhalation drugs. On the other hand, FDA's longstanding position that pharmacy compounds are new drugs was rejected by a federal district court in Medical Center Pharmacy et al v. Gonzales et al., which may undercut FDA's authority to enforce against compounding pharmacies. Although FDA has appealed the decision to the 5th Circuit, FDA may be less likely to actively pursue abusive compounding practices pending a decision on appeal. CORAR sent a letter to FDA asking for clarification of the agency's policy on pharmacies that compound copies of FDA-approved radiopharmaceuticals on a large scale

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 Possible Approach to CMS or Carriers Regarding Medicare Payment for Pharmacy Compounds

On November 9, CORAR held a teleconference to explore possible approaches to CMS or its contractors regarding coding and/or payment for radiopharmaceutical compounds. A number of options were proposed, including meeting with CMS at the national level, meeting with local carriers, and collaborating with nuclear medicine professional groups to draft a billing guideline. These options are described in more detail in section VI of the Report to the CPR Committee on Reimbursement Activities. Their objective would be to ensure that, when a nuclear pharmacy compounds a radiopharmaceutical that is a copy of an FDA-approved product, it is paid by Medicare at an amount reflecting the pharmacy's acquisition costs, rather than at the payment amount of the FDA-approved version. The group decided to discuss these options further at the December meetings and early in 2007.

5.6 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.

Roy W. Brown
Senior Director, Federal Affairs