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Summary of CORAR Activities – February 2008

1.0 Radiation Safety/Security/General 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 were contained in the proposed rule. The final rule was approved by the Commissioners on May 14, 2007 and was published on October 1, 2007. In the December 4, 2007 Federal Register the NRC published the termination notice for the state waivers. This allows the states to assume all licensing responsibility under the final rule. The NRC has published draft Volumes 13 and 9 of NUREG 1556 incorporating NARM changes. NRC has also finalized Volume 21 and in it acknowledged comments received from CORAR in this guide for accelerator licensing. Accordingly, NRC rescinded the component-specific requirements for license possession radionuclide and quantity limits. NRC did not accept comments on grandfathering user qualifications but did confirm that the authorized user did not have to be a Health Physicist. The NRC released NUREG 1556 Volumes 9 for medical use licensees in January, 2008.

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 the meetings 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. The committee is expected to release their report in early 2008.

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 radwaste 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. These recommendations were also made to the DHS on 5/09/07. On 9/17/07 the Health Physics Society provided public comment on the U.S. DOE 7/23/07 notice of intent to prepare an environmental impact statement on the disposal of GTCC. The HPS comments fully endorse CORAR's position on considering class B and C waste in a GTCC disposal facility.

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 looked 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 met several times and 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. The NAS published their final report in 2007 with several recommendations.

1.6 NAS Study on LEU Production of Medical Radionuclides

The two year study by the NAS is looking at the technology and cost of using LEU for the production of medical radionuclides. The committee has now met four times and CORAR has made presentations at each of the meetings. The focus through most of 2007 has been on the FDA

involvement in the use of a new LEU process. The next phase of the committees' efforts will be on site visits. Site visits began in late 2007. Sites visits have already been made to Covidien (St. Louis), MURR and Nordion. Scheduled visits include ANSTO in Australia and Covidien in the Netherlands.

1.7 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 NOVs. CORAR continues to monitor this issue.

1.8 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 and presented key talking points. 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. A draft Proposed Rule was published on October 3, 2007 with additional requirements to reduce possibility of subsurface contamination. The parent company guarantee provision was retained and without collateral although a standing trust fund would be required. On October 3, 2007 NRC released their SECY 2007-0177 on the decommissioning rulemaking effort. The SECY included revised thinking on decommissioning including additional requirements on licensees to reduce the likelihood of subsurface contamination and to include relevant costs in estimate and financial surety; and revised financial assurance option with the option for parent-company guarantee being retained without collateral. There are, however, other conditions including a standing trust fund, minimum A bond rating and minimum tangible net worth increase from 10M to 19M. The Final Rule expected to be published after October 2008, effective 60 days thereafter.

1.9 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 the proposed rule was 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.

1.10 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. There is no new information to report on this issue. CORAR will continue to monitor this topic with OSHA.

1.11 CA Reorganization of the Rad Health Dept.

The 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 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.

1.12 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. 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 on May 9, and Aug 30, 2007. NSCC-R is currently trying to get traction with the GCC on key issue actions. CORAR members presented NSCC-R and CORAR activities to the Health Physics Society Homeland Security Committee on July 10, 2007. Follow-up on comments submitted concerning effects of pandemic flu on security. CORAR will continue to promote full federal government participation in GCC.

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. CORAR continues to monitor this issue closely.

1.14 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.

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

The NRC's Advisory Committee on Nuclear Wastes (ACNW) issued this white paper as NUREG-1853 dated January 2007. CORAR's main concern with this white paper is the lack of discussion of stakeholder's perspectives or the benefits to society of our products that justify the generation of radwaste. CORAR prepared a brief review of this white paper on February 23, 2007 to be used in future discussions with NRC and ACNW. CORAR will continue to monitor NRC and ACNW LLW activities and seek opportunities to participate in developments.

1.16 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.

1.17 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. There has been no change in status since the last report.

1.18 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. NRC is close to a decision on this petition and a rulemaking from the Commissioners is expected early in 2008.

1.19 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.

1.20 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. CORAR will continue to monitor this issue.

1.21 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. On May 7, 2007 the NRC invited public comment on proposed collection of dose monitoring reports. 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. CORAR also made similar comments on July 5, 2007 on NRC's proposed collection activities. NRC published the Final Rule on December 4, 2007, effective January 3, 2008. Annual reports to individuals only required if annual dose > 1 mSv or individual requests a report. Licensees are no longer required to request lifetime exposure histories of employees unless a "planned special exposure" will occur. Still need to obtain dose record for current year for new hires.

1.22 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.

1.23 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.

1.24 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.

1.25 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.

1.26 ANSI N14.36 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.

1.27 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.

1.28 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.

1.29 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".

1.30 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 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 (HR 1) and on March 27, 2007, passed legislation to enhance rail, and motor carrier security (HR 1401). The Senate 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. The House and Senate convened and resolved the differences between the House and Senate bills and passed HR 1. The bill was signed by the President and became law on August 3, 2007. CORAR sought several clarifying revisions that were included in the legislation enacted into law. Specifically, air cargo screening has been revised to provide for exemptions and DHS has flexibility in determining the appropriate level of screening for specific types of cargo. CORAR also recommended Congress allow DOT and DHS many of the details of the new requirements that was included in the law. As a result, CORAR will need to be vigilant in representing our concerns with DOT and DHS during the development of the regulations required by this legislation. Rulemaking expected to start in the first quarter of 2008.

2.2 DOT Implementation of HMTA Reauthorization

HMTA Reauthorization was included in the comprehensive highway bill signed into 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 indicated 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. A NPRM has not been issued to date. However, lobbying efforts are underway, which address several concerns, including:

- Elimination of duplicative regulatory authority.
- Eliminate redundant background checks.
- Clarify HAZMAT Employer's training responsibilities.

- Inspection authority – issues concerning sensitive cargoes, training, and disposition of packages.
- Evaluate need for National Incident Response System.
- Facilitation of HAZMAT Employee Training.
- Update regulations for the transport of RAM.
- Matters concerning the Emergency Preparedness Grants Program.
- Reform of criminal penalty standards.

2.3 World Nuclear Association (WNA) Transport Survey

CORAR participated in a transport survey conducted by the World Nuclear Association (WNA). The focus of the survey was denial of shipments relative to the transport of radioactive materials. CORAR is not a member of WNA, though has been in communication regarding this survey and related matters/initiatives. The WNA Transport Study was finalized and released (September 2007), detailing various issues and data concerning delays and/or denials of Class 7 – Radioactive Materials. CORAR has been reviewing the results of this study and anticipates further interaction with this WNA initiative. CORAR participated in the WNA meeting (14 JAN 08, London).

2.4 IAEA General Conference and CORAR NGO Status

The IAEA has granted CORAR's Non-Government Organization (NGO) status. CORAR attended the 51st General Conference in the Fall of 2007, and presented an overview to key staff and delegates from member states. Overall, the presentation was favorable and several IAEA representatives have encouraged CORAR to continue with increased participation with IAEA initiatives.

2.5 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. The first Steering Committee meeting was held in Vienna in November 2006. Two face-to-face meetings have been held to date as have a number of Committee Conference calls. Working Process for denials was accepted at IMO Meetings in Spring '07 and subsequently adopted by IAEA SC (this includes Denial Reporting Form and mechanism). An action plan has been developed and is actively being worked on. All members of the CORAR Committee are being tasked with actions to ensure ongoing commitment and expediency of work. Routine conference calls are held with IAEA to maintain focus and gain necessary resources internally. The denials database is being populated and this helps form work definition and action plans. The committee is closely integrating with IMO. Significant attention is being applied to SC by IAEA routinely and at special meetings such as General Conference in Sept.'07. The last meeting was in Vienna Jan.'08. To reiterate, the objective of the SC is to develop and coordinate a comprehensive action plan of activities related to delays and denials of shipments of radioactive material at both national and international levels. Intent is that the action plan will involve concerned organizations (country regulators, carriers, Ports, other agencies and associations) and increase awareness about the uses of radioactive materials and the safety standards developed by international organizations, with an end goal of facilitated shipments.

2.6 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 at 3000 A2 in a single package except

for the radionuclides 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 be applied to most shipment of radioactive material including Nuclear Medicine products will be in line 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. Two hundred and twenty comments were received and addressed in the July Steering Committee. The document has been sent for publishing.

2.7 Session Chair Invitation for ANS Embedded Topical Meeting

CORAR has been asked to chair the Distribution and Transportation session of the American Nuclear Society Annual Embedded Topical Meeting, Radioisotopes for Research, Medicine & Industry (June 2008). CORAR members will present several papers that illustrate some of the issues the medical community has with transportation and distribution of radioactive material. CORAR hopes to educate the general nuclear community to some of our special issues they may not face.

2.8 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 allowed in 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. Traditionally, States have imposed fees on the transport of High-level waste, Spent Nuclear fuel, and 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 signed-on with a recent communication to PHMSA by the Interested Parties for Hazardous Materials Transportation. The primary concern relates to the allocation and use of fees assessed to States and Indian Tribes.

2.9 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.

2.10 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. The USDOT comment period ended December 20, 2006. CORAR sent comments on December 18, 2006. The final rule was published on May 3, 2007 and became effective on October 1, 2007. CORAR comments were not incorporated into the final rule, as they were not considered to be related to the proposed changes

3.0 Reimbursement/Coverage Issues

3.1 Hospital Outpatient Prospective Payment System (HOPPS) Update

The Centers for Medicare and Medicaid Services (CMS) significantly changed its payment methodology for diagnostic and therapeutic radiopharmaceuticals under the Medicare hospital outpatient prospective payment system (HOPPS) for 2008. Payment for diagnostic radiopharmaceuticals is packaged into the payment for the nuclear medicine procedure. Fixed payment rates were set for therapeutic radiopharmaceuticals, based on hospital charge data. The threshold for separate payment for drugs and therapeutic radiopharmaceuticals was raised from $55 to $60 per dose starting in January 2008. Medicare payment for some nuclear medicine procedure APCs changed significantly based on the packaging of diagnostic radiopharmaceutical products, bundling of nuclear medicine add-on procedures, and restructuring of procedure APCs. For 2008, CMS will implement claims edits to assure that hospital are billing radiopharmaceutical HCPCS codes with nuclear medicine procedures. In response to these changes CORAR membership agreed to pursue 1) a legislative strategy to delay implementation of the packaging methodology for diagnostic RP's and continue separate payment for diagnostic and therapeutic RP's at hospital charges reduced to costs; and 2) Develop a proposal for manufacturer or nuclear pharmacy reporting of RP costs to CMS as an alternate data source for payment determinations.

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, a percentage of average wholesale prices, or local fee schedules. Medicare resource based relative value scale (RBRVS) payment for many nuclear medicine procedures will be reduced by approximately 10.1% in 2008, along with all physician and diagnostic imaging procedures in compliance with the sustainable growth rate (SGR) payment limits. Additional changes in payment are the result of transitioning to a bottom-up approach for the practice expense methodology (modest increases) and budget neutrality adjustments (modest decreases) to the work component of all CPT codes (including nuclear medicine procedures) to account for changes related to the Five-Year Work Review. Very

few nuclear medicine procedures are impacted by payment reductions required under the Deficit Reduction Act (DRA) of 2005. Nuclear medicine imaging continues to be exempt from the 25% reduction for the second and subsequent imaging procedures on continuous body parts.

3.3 Medicare Coverage

CMS abandoned proposed restrictions on Clinical Trial/Research Coverage; Current policy allows coverage for certain clinical trials and research. CMS continues to explore the role of comparative effectiveness as a basis for Medicare policy making. The initial focus appears to be therapeutic, not diagnostic procedures. Medicare coverage for certain PET imaging procedures requires data to be collected in registries.

3.4 Coding

CMS issued a several new diagnostic radiopharmaceutical HCPCS codes for 2008. AMA CPT issued revised CPT codes for nervous system and PET imaging for 2008.

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.

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 would 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. CORAR succeeded in using the reauthorization of the Prescription Drug User Fee Act (PDUFA) as a vehicle to address this issue. We persuaded the Senate HELP Committee and the House Energy and Commerce Committee to insert into their respective user fee bills a partial exception from establishment fees for PET drug sponsors, and we obtained agreement from the FDA for the provision. The provision was included in the user fee title of the Food and Drug Administration Amendments Act of 2007, which was enacted on September 27, 2007. It provides that the fee for each PET establishment identified in an application is one-sixth of the otherwise applicable fee. An academic medical center is exempt from all establishment fees provided it certifies to FDA that it is a not-for–profit medical center with only one PET establishment, and that at least 95 percent of the doses of each PET drug produced in the establishment during the fiscal year will be used within the medical center. There are several implementation details that are either ambiguous or not addressed in the legislation itself, such as whether several manufacturers that use the same contract PET establishment to prepare PET drugs will each pay the 1/6 fee or only their pro rata share of the 1/6 fee. As manufacturers submit NDAs for PET drugs, CORAR will monitor how FDA implements the PET establishment fee provision, and engage FDA where changes are warranted.

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 try to persuade Congress to put pressure on the FDA to reestablish the MIDAC. The legislation to reauthorize PDUFA, which began to be debated in Congress early in 2007, contained provisions relating to conflicts of interest on FDA advisory committees. Viewing this legislation as a potential vehicle for a mandate for FDA to reestablish the MIDAC, in April CORAR met with House Energy and Commerce Committee staff to gain support for such a mandate. Although the Committee declined to include a mandate in the bill, CORAR was successful in obtaining language in the Committee Report on H.R. 2900 in which the Committee "strongly encouraged" FDA to reconsider its decision to terminate the MIDAC, and directed FDA either to reestablish the MIDAC, or to report to the Committee within six months after enactment why the MIDAC is not being reestablished. The FDA Amendments Act of 2007 (FDAAA), as enacted, did not have a conference report, nor did the Senate HELP Committee issue a report on the Senate version of the bill, so that the House Energy and Commerce Report remains the only legislative history for the FDAAA. CORAR will monitor whether FDA complies with the Energy and Commerce Committee's direction to either reestablish the MIDAC or report on why it is not doing so. If FDA has not taken action by February, CORAR will consider sending a letter to FDA reminding the Agency of its obligation to do so. CORAR will also continue to monitor FDA's implementation of an advisory apparatus using medical imaging special government employees (SGEs), as well as any advisory committee meetings that may be held to address medical imaging products or issues.

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 has committed to conducting a workshop and developing a guidance on biomarker qualification, and also developing a guidance by FY 2011 on imaging standards for use as endpoints in clinical trials. The Subcommittee, along with the Regulatory Policy 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. CORAR and MICAA representatives, along with FDA, PhRMA, BIO, participated in a workgroup and subsequent conference sponsored by the Drug Information Association (DIA) on the harmonization of imaging review charters and the integration of imaging in therapeutic drug development. A workgroup meeting was held in June to plan the development of a draft Medical Imaging Standardization Technical Document, and participants developed this draft document in subsequent months. The Technical Document is intended to be an industry consensus statement, possibly with FDA's endorsement, on (1) the standardization of imaging review charters, (2) best practices for medical imaging review, (3) management of the site-core lab interface, and (4) data integrity and statistical analysis plans. The primary focus is on medical imaging used in clinical trials of therapeutic drugs, but the document also has application to trials of medical imaging drugs. The FDA has provided feedback on the document. On October 16 and 17, 2007, DIA held

a Medical Imaging Conference on these same topics at the University of Maryland, again with the co-sponsorship of CORAR, MICAA, FDA, PhRMA, and BIO. Among other things, the draft Technical Document was discussed. 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.

5.0 Nuclear Pharmacy Issues

5.1 CA Drug Pedigree Legislation

The state's Board of Pharmacy has an electronic pedigree requirement that is due to go into effect in 2008. The e-pedigree requirement was developed in an effort to discourage the distribution of counterfeit drugs. To-date the Board of Pharmacy has been reluctant to consider an extension of the implementation date. The pedigree would track every change of ownership of a drug from the manufacturer to the patient. Radiopharmaceuticals would create unique problems such as Tc-99m from generators being used with cold kits. CORAR is forming a subcommittee to work on this issue.

5.2 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.

5.3 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. This bill has not been introduced yet.

5.4 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 met in December, 2006. USP has recently released the Final version of General Chapter 797.

5.5 JCAHO - Med Verification of radiopharmaceuticals

CORAR has submitted a letter to JCAHO consistent with SNM's position requesting that radiopharmaceuticals be exempted from their med verification standard since established protocols are in place.

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