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Summary of CORAR Activities – January 2010

1.0 Radiation Safety/Security/General Issues

1.1 NRC Adoption of ICRP 103

On June 30, 2008, NRC staff published SECY 08-0092, to inform NRC Commissioners of the review of ICRP Publication 103 – Standards for Protection Against Ionizing Radiation, and plans to provide options for possible revision of the NRC regulatory framework. NRC published Solicitation of Public Comments on July 7, 2009. CORAR has approached NRC (Donald Cool) and expressed interest in NRC's review and intent to possibly revise NRC regulations, and to express CORAR's interest in discussions on this with NRC and any opportunity for involvement in the process. Dr. Cool, NRC presented on this program at the December 2008 CORAR meeting. CORAR will provide comments to NRC by the March 31, 2010 deadline.

1.2 Congressman Markey Letter to NRC on Patient Release Criteria

On October 14, 2009, Congressman Edward J. Markey (D-Mass.), chairman of the Energy and Environment Subcommittee of the Energy and Commerce Committee, sent a letter to NRC Chairman Greg Jaczko asking why its rules governing the treatment of patients with radioisotopes allow for much higher levels of public exposure to radioactive materials than those adopted by other countries, and whether these rules are being properly enforced, citing specifically I-131 patient release criteria and the brachytherapy incidents at the Philadelphia VAMC. Markey asked for answers by October 30, 2009. NRC Commissioner Jaczko responded on November 17, 2009, with answers to each question in the Markey letter. NRC has not changed their thinking on the denial of the Petition. CORAR is prepared to respond in line with previous comments on Crane Petition. NRC denied the petition from Peter Crane on May 21, 2008. On March 27, 2008, NRC published RIS 2008-07, to inform licensees of NRC's intent to pursue rulemaking to clarify the 5 mSv (0.5 rem) limit in 10 CFR 35.75 as an annual limit, rather than a per-release limit. On May 12, 2008, NRC published RIS 2008-11 regarding supplemental guidance on protection of children from exposure to I-131 therapy patients.

1.3 Congressman Markey Letter to EPA

On October 22, 2009, Representative Edward J. Markey (D-Mass.), chairman of the Energy and Environment Subcommittee of the Energy and Commerce Committee, sent a letter to EPA Administrator Lisa Jackson raising concerns over the potential for weakening federal policies designed to protect the public from the effects of radiation and concern over the EPA's draft Protective Action Guidance for radiological incidents. Markey requested answers to his questions no later than Tuesday November 16, 2009. CORAR has not seen the response yet.

1.4 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. Draft revised Policy published by NRC on September 15, 2008, with request for comments. Comments on the draft revised Enforcement Policy were submitted to NRC by CORAR on November 8, 2008 and included CORAR comments from March 23, 2007, in response to NRC proposed policy revision plan. Comments included those on the enforcement conference process, disclosure of self-audit findings during inspections, relief for self-reporting, advanced notice of issuance of NOV's, and the need for Enforcement Manual to be updated to be consistent with revised Enforcement Policy. One of the comments expressed the concern that NRC had reportedly revised its examples of violations and severity levels in the enforcement manual but did not make this available to interested parties for review. NRC acknowledged this and published another request for comments on June 8, 2009. Comments included those on the enforcement conference process, disclosure of self-audit findings during inspections, relief for self-reporting, advanced notice of issuance of NOV's, and the need for Enforcement Manual to be updated to be consistent with revised Enforcement Policy. CORAR submitted input to NEI on their comments to NRC regarding the examples of violations in the supplementary information provided by NRC.

1.5 NRC Proposed Rule on Import/Export

NRC published a Proposed Rule on June 23, 2009 to update and clarify regulations concerning export and import of nuclear equipment and material. NRC proposes changes to 10 CFR 110 to allow import of Category 1 and 2 sources under a general license (with seven day advanced notification and once the NSTS is fully implemented) and revises the definition of "radioactive waste" to exclude radioactive material that is contained in a sealed source, or device containing a sealed source, that is being returned to a manufacturer, distributor or other entity which is authorized to receive and possess the sealed source or the device containing a sealed source. Comment period ended on September 8, 2009. Several CORAR member companies submitted comments in support of the PR with the exception of the seven day advanced notification requirement.

1.6 NRC RIS 2009-09 on External Dosimetry

On July 23, 2009, NRC published a Regulatory Issue Summary informing licensees of that it is acceptable to use the ANSI/HPS 13.41-1997 protocol for determination of effective dose equivalent using multiple dosimeters and compartment factors. Multiple dosimeters may be used with compartmental weighting factors as part of an occupational monitoring program. This approach may be appropriate in situations where external exposure may not be uniform. There is no need for site/license specific regulatory approval. CORAR did not see the need to respond to the RIS.

1.7 Nuclear Sector Coordinating Council 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. Three focus groups were established in December of 2008. The three groups focused on: 1) Removal & Disposition of Disused Radioactive Sealed Sources (leads DOE/DHS) – formal whitepaper developed with join input by GCC and industry. Well organized document addressing various storage and disposition issues. Anticipate final approval of whitepaper in early 2010; 2) Transportation Security (leads DOT/DHS) – much work has been focused on determining ownership of the issues/concerns (DOT, NRC & TSA). MOU among the groups still a pending issue. The term "transshipment" further defined; waiting for Focus Group membership approval. DOT indicates further progress later this year/early 2010; and 3) Source Tracking (leads DHS/EPA) – draft whitepaper presented to Focus Group membership. Anticipate comments to be submitted in late November (2009) and subsequent draft document for early 2010. Other NSCC activities include Real ID – primary impact to power reactors; potential impact to other entities as well as general public; National Level Exercise – emergency response drills planned for 2010 and 2011; formally known as "Top-Off" exercises; Mo-99 supply-chain inter-agency overview and assessments; Transportation Security (TSA); and proposed changes to 10 CFR 37.

1.8 NRC National Source Tracking System/License Verification/Category 3 Sources

The GAO reported in October 2007 that the NRC licensing process was vulnerable to those seeking materials licenses under fraudulent pretexts. In response, an NRC Independent Review Panel recommended changes to the NRC licensing process that have been incorporated into a draft order to materials licensees. NRC is now taking this up as part of the National Source Tracking System. NSCC-R obtained a copy of the draft order and submitted comments in January 2008. Most of the comments related to the difficulties associated with authentication of each license, particularly with state agencies. NRC will now integrate license verification into NSTS once implementation issues have been resolved. NRC Commission voted 2 –2 on expanding scope of NSTS beyond Category 1 and 2 sources, thereby limiting expansion for now. However, we expect this issue to resurface with the Commissioners.

1.9 NRC FRN Part 31 – Generally Licensed Devices

On August 3, 2009, NRC published a Proposed Rule to limit generally-licensed devices to sources at $1/10^{th}$ of IAEA Category 3 materials. The proposed approach would result in approximately 1400 licensees nationwide being subject to the requirements for a "specific license" rather than a general license. This proposed rule also responds (favorably in part) to petitions from the OAS and State of Florida filed in 2005. Comments were due on October 19, 2009. CORAR did not respond since none of the members expressed any interest in this PR.

1.10 Low-level Radioactive Waste Security

NRC invited CORAR to participate in a LLRW Generator Panel at a public meeting on April 17, 2009 on LLRW Security since the Barnwell S.C. LLRW Disposal Site restricted access on July 1, 2008. CORAR provided to the NRC an updated discussion paper "Summary of Main Issues Concerning LLRW" and position papers on LLRW and Mixed Waste. These were posted on the NRC website concerning the April 17, 2009 meeting on LLRW Security. Roy Brown represented CORAR on the LLRW Generator panel and presented the main issues from CORAR's position papers on LLRW. Commissioner Lyons questioned whether important medical research had been stopped due to the deletion of CORAR products due to Radwaste difficulties. Subsequently, the Commissioners requested NRC staff to work with CORAR, the Campus Radiation Safety Officers (CRSO) and other stakeholders to identify specific examples of restricted research. On 10/07/09 CORAR, CRSO and numerous other stakeholders presented examples of restricted research to the NRC in a second public meeting published on the NRC website and reported by Radwaste Monitor. A participant from Waste Control Specialists requested CORAR to present this issue to

the Texas LLRW Compact Commission in December and the radwaste community in March 2010. This issue is expected to open access for LLRW disposal in the Andrews County, Texas radwaste site to licensees in out-of-compact states.

1.11 IAEA BSS 379 Draft 2.5

On July 2, 2008 IAEA published Draft DS379 revision of International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources. In collaboration with ISSPA members, CORAR developed comments and these were submitted to IAEA on September 29, 2008. The IAEA and cosponsoring organizations developed draft 2.0 in February to April 2009, taking into account the comments received on draft 1.0 and reflecting many of the CORAR comments in 2008. CORAR submitted comments on Draft 2.5 to IAEA on November 11, 2009.

1.12 OSHA Proposed Rule – Hazard Communication

On September 30, 2009, OSHA published and Proposed Rule and Request for Comments on its proposal to modify its existing Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The proposed modifications to the standard include revised criteria for classification of chemical hazards; revised labeling provisions that include requirements for use of standardized signal words, pictograms, hazard statements, and precautionary statements; a specified format for safety data sheets; and related revisions to definitions of terms used in the standard, requirements for employee training on labels and safety data sheets. OSHA is also proposing to modify provisions of a number of other standards, including standards for flammable and combustible liquids, process safety management, and most substance-specific health standards, to ensure consistency with the modified HCS requirements. It is likely that CORAR companies with global operations will benefit from the harmonization of OSHA requirements with global standards.

1.13 NRC Proposed Rule –Decommissioning

NRC held a public meeting on January 10, 2007, as part of its rulemaking process to address decommissioning funding shortfalls, particularly at legacy sites. The Proposed Rule was published on January 22, 2008 with additional requirements to reduce possibility of subsurface contamination. Parent company guarantee provision retained and without collateral, although a standing trust fund would be required. CORAR comments were submitted on May 7, 2008. SECY 08-0144 published by NRC on October 1, 2008, request by NRC staff to Commission to approve draft Final Rule (effective March 31, 2010). Radiopharmaceutical manufacturers will likely be able to justify waiver from additional environmental monitoring. Line of credit and escrow account options eliminated for financial surety and standby trust fund required for parent company guarantee. NRC issued SECY 09-0042 dated March 13, 2009 including a draft Final Rule and Draft NUREG 1757 Vol 3 Rev 1. Draft Reg Guide DG-4014 "Radiological Surveys and Monitoring During Operations" was released for public comment on May 29, 2009, workshop on June 30, 2009 and finalized at end of 2009. The Final Rule will be published in 2010 with an effective date 1 year later.

1.14 South Carolina Legislation- Barnwell Site

A South Carolina House Committee vote, posted on March 28, 2007, overwhelmingly opposed a proposed bill H 3545 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 on nuclear waste disposal. The local community and county had strongly supported the bill. CORAR and NEI met with NRC on April 2, 2008 at a public meeting on extending LLRW storage at generator's sites after the Barnwell disposal site restricts access in July 2008. Cal Rad Forum

and the Health Physics Society endorsed CORAR's position and concerns. CORAR participants are members of an NEI Task Force on LLRW, developing strategies for LLRW disposal. The NEI task force met with NRC on 9/18/08 to discuss issues related to onsite LLRW storage. Further meetings are planned with NRC. NEI task force had a strategy meeting on 11/19/08. Meanwhile, the Texas Commission on Environmental Quality granted a license for the Waste Control Specialists LLRW disposal facility on 1/14/09 and WCS expects to be accepting compact LLRW by July 2010.

1.15 NRC Safety Culture

On January 23, 2009 NRC published a notice in the FR requesting input on the development of a Safety Culture Policy Statement to include security considerations. NRC held a public meeting with stakeholders on February 3, 2009. NEI issued comprehensive comments to NRC on February 11, 2009 which supports the integration of Safety and Security culture which is compatible with CORAR's position. On November 6, 2009 the NRC published in the Federal Register a "Draft Safety Culture Policy Statement" and "Request for Public Comments" due by 02/04/10 which CORAR will respond to. NRC has also scheduled a three day workshop February 2-4, 2010 on their Safety Culture policy. There will be a plenary session followed with three breakout groups.

1.16 NRC Extremity Dose Study

NRC and CORAR members have been studying issues with using ring badges to monitor extremity dose during nuclear pharmacy operations. NRC committed to study models characterizing extremity exposure and how to use monitoring data to demonstrate compliance with operations dose limits. The intent is to develop guidelines for licensees. On February 4, 2009 NRC issued a draft report to CORAR on extremity dose modeling studied at ORAU requesting CORAR comments. CORAR provided comprehensive comments on April 23, 2009.

1.17 NYC Legislation 650-B, Registration of Nuclear Instrumentation

The City of New York has drafted and introduced legislation that will require that survey meters and instruments for the detection of hazardous material (chemical, biological, and radiological) be registered with the NYPD. It also requires that any "alarm" from the meter be reported to the NYPD. CORAR has been monitoring progress of this city legislation with the New York Hospital Association, the Mayor's Office and the Radiological and Medical Physics Society of New York. The current draft of the legislation exempts survey meters used in hospital, industrial or health care facilities. There has been no recent movement of this legislation.

1.18 HPS/ANSI N.13 Standard Committee

CORAR is represented as a member of the Health Physics Society/American National Standards Institute (HPS/ANSI) N13 Committee which has oversight of national radiation protection consensus standards. The N13 Committee approves the need for each proposed radiation protection standard and the chairman and each member of each standard writing group. N13 members comment on and approve or veto each finalized standard. Last year the N13 Committee made considerable progress in deleting non-participating memberships and recruiting new members. At its October 10, 2009 annual meeting the Committee terminated 13 obsolete standards to focus on 36 active standards. The N.13 subcommittee to review NRC Reg. Guides and ANSI standards expects to start working with the NRC soon. N13.12 on volumetrically contaminated material clearance is being developed to be more compatible with international standards. CORAR provided comments to the HPS on numerous draft ANSI standards including N13.59: "Characterization of Land Areas and Structures in Support of Decommissioning" on 8/24/05; N13.53: "Guide for Control and Release of TENORM" on 9/01/05; N13.56: "Sampling and Monitoring Releases of Airborne Radioactivity in the Workplace of Nuclear Facilities" on 10/10/08; N13XX: "Ionizing Radiation Health Dose" on 3/26/09 and N13.41: "Criteria for

Performing Multiple Dosimetry" on 4/10/09. In each case, CORAR has made substantive comments that could significantly change these standards. CORAR approved N13.35, "Specification for the Bottle Manikin Absorption Phantom" on 11/26/07 and 2/25/09, N13.53 "Guide for Control and Release of TENORM" on 8/25/08 and N13.27 "Dosimetry Performance Requirements for Pocket- sized Alarm Dosimeters and Alarm Ratemeters" on 9/25/07. The HPS recently published N13.59 "Characterization in Support of Decommissioning Using the Data Quality Objectives Process" and N.13.11, "Personnel Dosimetry Performance-Criteria for Testing". CORAR members who have concern on the potential impact of these standards on their company's radiation protection programs should apply to be members of standard writing groups.

1.17 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 members are serving on the standard's writing committee. Two new CORAR members were recommended to provide experience with radiopharmaceutical packages. The writing process is very slow due to the large quantity of information being processed. The writing group completed a new draft of the standard on October 10, 2009 which is less prescriptive and more accommodating of our package monitoring requirements.

1.18 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 in 2006 recommending consideration of the need for a separate standard for radionuclide production accelerators. In January of 2009 a new draft was provided and reviewed to determine the extent to which CORAR's comments were incorporated. Of the 66 comments submitted, 45 were accepted either in full or at least partially. Several of those not accepted represent issues associated with intentional production of radionuclides. Of particular concern is the insistence by the authors that this standard be incorporated as a "legal requirement" similar to the EPA adoption of N13.1.

1.19 NCRP Collaboration

CORAR is established as a collaborating organization with the NCRP and as such has the opportunity to review and comment on draft NCRP reports. NCRP published Report No 156 "Development of a Biokinetic Model for Radionuclide Contaminated Wounds and Procedures for their Assessment, Dosimetry and Treatment" and Report No 157, "Radiation Protection in Educational Institutions", incorporating CORAR's comments. 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", "Uncertainties in Internal Radiation Dosimetry," and "Ionizing Radiation Exposure of the Population of the United States." CORAR submitted comments on draft reports to the NCRP on "Uncertainties in the Measurement of Dosimetry of External Radiation", in 2007, "Radiation Protection and Measurement Issues Related to Cargo Scanning with Accelerator Produced High Energy X Rays" in 2007, and Management of Persons Contaminated with Radionuclides" in 2008. 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. CORAR will remain active with NCRP.

1.20 RADAR

Radiation Assessment Resource (RADAR) issued comments on CORAR's updated position on Skin Dose Limits. CORAR responded to RADAR explaining support for compatible regulations and recommendations. CORAR intends to maintain liaison with RADAR due to having similar technical interests. RADAR is developing guidance on patient skin does limits for infiltrated radiopharmaceutical administration.

1.21 DOE NSACI

DOE has formed the Nuclear Science advisory committee on Isotopes (NSACI) to advice the Office of Science on research isotopes and the strategic direction for the isotope program. CORAR (Roy Brown), SNM (Bob Atcher) and the NANP (Jeff Norenberg) have seats on the committee. The committee heard from researchers, government agencies and industry representatives who are stakeholders on the DOE's Isotope program. The NSACI also has the information presented to and discussed at DOE's Isotope workshop held in August. The report on Charge 1 of the committee, dealing mainly with radionuclide used in research, has been released. The following six recommendations were made by the committee:

1. Invest in new production approaches of alpha-emitters with highest priority for ^{225}Ac. Extraction of the thorium parent from ^{233}U is an interim solution that needs to be seriously considered for the short term until other production capacity can become available.
2. We recommend investment in coordination of production capabilities and supporting research to facilitate networking among existing accelerators.
3. We recommend the creation of a plan and investment in production to meet these research needs for heavy elements.
4. We recommend a focused study and R&D to address new or increased production of ^{3}He
5. Research and Development efforts should be conducted to prepare for the reestablishment of a domestic source of mass-separated stable and radioactive research isotopes.
6. We recommend that a robust investment be made into the education and training of personnel with expertise to develop new methods in the production, purification, and distribution of stable and radio-active isotopes.

Charge 2, dealing with the commercial radionuclides and the infrastructure was released in November of 2009. Those recommendations were as follow:

1. Maintain a continuous dialogue with all interested federal agencies and commercial isotope customers to forecast and match realistic isotope demand and achievable production capabilities.
2. Coordinate production capabilities and supporting research to facilitate networking among existing DOE, commercial, and academic facilities.
3. Support a sustained research program in the base budget to enhance the capabilities of the isotope program in the production and supply of isotopes generated from reactors, accelerators, and separators.
4. Devise processes for the isotope program to better communicate with users, researchers, customers, students, and the public and to seek advice from experts.
5. Encourage the use of isotopes for research through reliable availability at affordable prices.
6. Increase the robustness and agility of isotope transportation both nationally and internationally.
7. Invest in workforce development in a multipronged approach, reaching out to students, post-doctoral fellows, and faculty through professional training, curriculum development, and meeting/workshop participation.
8. Construct and operate an electromagnetic isotope separator facility for stable long-lived radioactive isotopes.
9. Construct and operate a variable-energy, high-current, multi-particle accelerator and supporting facilities that have the primary mission of isotope production.

The NSACI's current charge from DOE has been completed. It is not clear what the next assignment for the NSACI will be.

1.22 Mo-99 Production

The current Mo-99 supply issue continues to be a problem. The HFR reactor in Petten is due to be shut down for 22 weeks starting in February. The repairs of the corrosion in the NRU reactor tank are continuing. AECL recently announced they expected to be back on line in early April. There are significant shortages of Mo-99 anticipated in March. The return to service of the NRU will likely dictate any shortages after March. The BR-2, SAFARI and OSIRIS reactors have increased capacity at their facilities.

2.0 Transportation Issues

2.1 Drug Import Legislation

Congressman Dingell has proposed legislation to require foreign drug manufacturers to register their facilities and the registered facilities would be subject to fees ($10,000 per facility/year) and to periodic inspection. There is similar legislation in the Senate that has not been introduced yet. Congressional Health Committees are currently focusing on President Obama's health reform proposals and the reform of food inspections. The House and Senate will likely consider the bill later in 2010. Currently, CORAR is analyzing the impact of the bill.

2.2 Hazardous Materials Transportation Safety Act of 2009 H.R. 4016

The US House of Representatives Committee on Transportation & Infrastructure (Committee) conducted an investigation relative to the Special Permits and Approvals programs. The investigation turned up several safety and emergency response issues that Congress wanted to address. Many of the safety concerns raised are being addressed in H.R. 4016 – the "Hazardous Material Transportation Safety Act of 2009." The bill strengthens emergency response capabilities, strengthens hazmat safety, and addresses many special permit issues. H.R. 4016 passed out of the House Committee on November 19, 2009. It is expected to pass the House floor in early 2010.

2.3 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. Regional workshops were held in Europe during 2009. Denial Report Forms are being completed and submitted to UN organizations (IAEA, IMO, ICAO) for any and all denials. This is an ongoing action required of industry, and is the basis for determining issues and developing corrective actions. 240 instances of denial have been reported as of November 2009. AIPES (CORAR's European counterpart) has another 200 that have not been reported yet. Preliminary analysis of data indicates (3) main causes; (1) Education and Training, (2) Port/Airport Infrastructure, and (3) Communications. Key in the past year is the development and institution of NFPs (National Focal Points) and Regional Networks. An NFP is a person identified by the country to whom all issues regarding denials of shipments pass through. 70- NFPs identified as of January 2009. Five Regional Networks exist globally (Asia Pacific, Mediterranean, Latin America, English and French speaking African countries) where each Network represents a number of countries in a specific region. This allows a more focused action plan by geography, a smaller and ,more geographically cohesive opportunity for involved people to meet and resolve issues, and to be represented at all SC meetings where policy decisions are made. The next meeting is in late February 2010 with all NFPs and Regional Coordinators participating

2.4 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 2009 revision of the TS-R-1 regulations was published in July of 2009. At the October TRANSSC-19 meeting the safety standards committee voted to proceed with full revision to TS-R-1 and TS-G-

1.1. Certificates developed to the revised standard would be given a number -12 or -13 instead of -96. There was a consultancy meeting in December and there is a Technical meeting this month in Vienna. The 1st draft developed during these meetings will be released for 120 day comment. CORAR continues to follow activities at IAEA very closely because these standards are usually adopted by the U.S. DOT.

2.5 IAEA Transport Security Guidance

A technical meeting to review the International Atomic Energy Agency, Nuclear Security Series, Security of Radioactive Material during Transport was held in Vienna from January 23-27, 2006. The final recommendation presented at plenary divided the security levels into Basic and Enhanced. The enhanced security measures will be needed is at 3000 A2 in a single package except for the radionuclide found in the Code of Conduct for Category 1 and 2 sources. In practice, the limit is high enough not to include any other isotopes except for those in the Code of Conduct. Enhanced security measure will not be needed for Moly, Iodine or other nuclear medicine isotopes. Enhanced security measures will apply for activities that exceed 0.3 TBq for Cobalt 60, 1 TBq for Cs-137 and 0.8 TBq for Ir-192. The basic security measures that would applied to most shipment of radioactive material including Nuclear Medicine products will be inline with the security measures found in the UN Orange Book. These measures have already been implemented by the modal organizations in January 2006 and are similar to the security measures found in 49 CFR. Excepted packages, LSA-I and SCO-I are exempt for all security requirements. The enhanced security measures (Co-60, Ir-192) go beyond the enhanced security measures described in the UN Orange Book. IAEA Pub 1348, Security in the Transport of Radioactive Material, Nuclear Security Series No. 9 was published in October 2008, and is available on the IAEA web page. There have no further developments at IAEA on this topic.

2.6 State Transportation Fees

Several States have implemented transportation fees related to the carriage of hazardous materials. This issue is becoming prevalent as more States are enacting legislation to impose fees for the transport of radioactive material. As per the Hazardous Materials Transportation Act, a State can impose fee relating to the transportation of hazardous material. Illinois and Iowa currently have legislation-imposing fees. Ohio is 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. Illinois and Iowa currently have legislation-imposing fees. Missouri passed legislation in August of 2009 that imposes transportation fees for high level rad waste, transuranic Radwaste, spent fuel and highway route controlled quantities. The MO law requires annual fees and per mile charges. CORAR continues to work with NEI, GIPA and other industry groups in an effort to minimize the negative impact of this type of legislation, and try to prevent the legislation form affecting nuclear medicine shipments.

2.7 ANSI N14.7 Revision of the Type A Standard

The ANSI standard, N 14.7, "Guide to the Design and Use of Shipping Packages for Type A Quantities of Radioactive Materials," is being re-written. This standard has been under development for a number of years. CORAR has two members serving on the committee. Several committee members are reworking the “Design” section, which has a main part in defining aspects of responsibilities for shippers, users, fabricators, etc. 150 comments from 22 reviewers have been received. The Committee intends to have a comment resolution meeting in early 2010.

2.8 Risk-Based Adjustment of Transportation Security Plan Requirements (HM-232F)

Proposed Rule issued Sept. 9, 2008, comments were due on November 10, 2008. The proposed rule is an improvement regarding the Security Plans for Class 7. Prior to this rule change Security plans needed for HRCQ shipments and any Placarded shipment. Proposed rule requires security plan for Cat 1 and 2 and HRCQ only. DOT is currently working on comments. We expect a Final Rule soon.

2.9 NRC National Tracking System System/Proposed Security Rules in Part 37

The National Source Tracking was rolled out January 31, 2009 with much fan-fare and has been in a state of disarray ever since. The NRC continues to go down the path of including Cat 3 and 1/10 Cat 3 sources in the National Source Tracking System. The Regulatory Analysis includes the NRC cost analysis of implementing the rule. This cost analysis is flawed as it was based on assumptions for implementing Cat 1 and Cat 2 tracking which have been proven wrong based on industry's attempts to comply with the requirements. A new Part 37 to Title 10 has been developed to implement the security measures that had previously been issued through Orders. Although the rule for Cat 3 and 1/10 Cat 3 was delayed, they are now beginning to write the rule and it is not clear if the other comments received concerning issues other than delay of the rule are being considered. The NRC Commissioners were briefed in 2009 on status and industry experience with implementation. There is still no batch upload capability. NRC needs to remove duplicative requirements once NSTS for Cat 1 and 2 is running smoothly. DHS focus group on physical source tracking is researching options and will need industry feedback on what is feasible. The NRC has released a draft preliminary rule for Cat 1 & 2 sources. This will be contained in a new 10 CFR 37. This contains physical security requirements for these types of sources. Comments to the Proposed Part 37 language were submitted. NRC is working on a revision to the system that is intended to make the bulk upload process easier. The NRC has contacted the licensees and asked for suggestions. Hopefully, some of our suggestions are incorporated. The NRC is allowing licensees to send source information on encrypted excel spreadsheets via email instead of by fax. CORAR did learn that even though a source has been destroyed it still remains in the database.

2.10 DOT Interpretation of 49 CFR 171.15

A letter of interpretation issued by the US DOT to several parties (Federal Express, RSCC, etc. - December 2008) states that immediate reporting is required following breakage "even if the inner packages remain intact." These parties are concerned that the conservative interpretation of "breakage" where any package that suffers even minor damage (i.e., torn outer package surface but otherwise intact) may be subject to this reporting. In as much, it is unclear as to whether or not DOT is capable field hundreds of immediate calls per week. Subsequent to the receipt of this letter of interpretation, several individuals representing CORAR and RSCC convened to further discuss DOT's latest position and possible action regarding this matter. CORAR may need SNM's help if this issue is not resolved with DOT.

3.0 Reimbursement/Coverage Issues

3.1 2010 CMS HOPPS Rule

In the 2010 CMS Hospital Outpatient Prospective Payment System (HOPPS) rule there was an overall increase of 1.9% in payments. The packaging threshold increased from $60 to $65 and CMS will continue its package policy for nonpass-thru radiopharmaceuticals (RP's) and contrast agents. For example, through comments, meetings and recommendations to the APC advisory panel, CORAR raised concerns regarding packaging of RP's and patient access. CMS, in the final rule, determined they will continue to study and analyze data. CORAR also recommended that therapeutic RP's be paid at ASP +4%, CMS agreed to this recommendation. CORAR commented that CMS was violating the 2x rule by packaging different RP's and procedures. CMS has stated that the 2x violations are specific to the total cost of the primary servicing including the packaged costs. CORAR is currently seeking a legislative fix for the 2x rule.

3.2 Medicare Reimbursement of Radiopharmaceuticals in Physician Office Setting

For the 2010 Medicare Physician Fee Schedule there was a 21.2% overall cut in Medicare payments to physicians as a result for the sustainable growth rate formula. Congress has proposed several options to fix this however and may be corrected legislatively before the end of the year or at the beginning of 2010. CORAR made several comments after the proposed rule was released. CORAR expressed concern over the CMS's proposal to use practice expense RVUs based on new data from the AMA Physician Practice Information Survey (PPIS). CMS has stated they will use the data but will phase it in over four years. CMS has also agreed to phase in new practice expense RVU's including imaging rate assumption changes and the use of new survey data over four years. CORAR had recommended phasing in all changes regarding the PE RVU's after CMS stated they will adopt a new policy that will reduce the RVUs for expensive diagnostic equipment. The new policy assumes 90% usage rather than 50%. Congressional action could preempt this however. There are four new codes in 2010 for myocardial perfusion imaging. The payment for these will be substantially lower than what providers are currently getting paid.

3.3 Other Medicare Issues

CORAR submitted a comment letter on February 5, 2009 on proposed Medicare NCD on Positron Emission Tomography (PET) for Solid Tumors. The final NCD issued on April 3, 2009 stated that the new coverage framework replaces 4-part diagnosis with a 2-part framework. It also differentiates FDG PET imaging used to inform initial antitumor treatment strategy from other uses related to guiding subsequent antitumor treatment strategies after the completion of the initial treatment.

In the ARRA bill there is $1.1 billion to fund comparative effectiveness. The final version of ARRA does not permit the Council for Comparative Effectiveness to mandate coverage or reimbursement policies for any payer. That said, while the Council cannot mandate reimbursement policies, CMS and other payers could use the CE research to guide policies.

4.0 FDA Issues

4.1 Reestablishment of the MIDAC

CORAR/MICAA met with CDER officials in February regarding the re-establishment of MIDAC. The FDA agreed with CORAR/MICAA's concerns (e.g. difficulty of training new SGE's, inexperience of SGEs with the advisory committee process, too few imaging participants resulting in the imaging perspective not getting sufficient attention). At the meeting the FDA asked for an indication of the number of medical imaging applications that companies intend to submit to FDA over the next several years that might warrant advisory committee review. A survey was sent to CORAR and MICAA members asking for their confidential response to how many medical imaging drug approvals companies would be seeking in the next five years. CORAR followed up with the FDA in June with a letter providing the results of the survey. The letter also stated that by demonstrating compelling need it would be possible to get past the executive order FDA claimed was a barrier to reestablishing MIDAC. In August, CDER informed MICAA and CORAR that it was going to formally request the FDA Commissioner to reestablish a MIDAC. CORAR will continue to monitor this issue and see if anything needs to be done to speed this process along.

4.2 OCP Draft Guidance – New Imaging Indications for Devices & Approved Drugs

FDA issued a draft guidance on September 30, 2008. The guidance permits devices in certain circumstances to add a new indication for use with contrast through a PMA process, even where the contrast is used off-label. CORAR has commented that the guidance needs to be more clear. There was an FDA public stakeholder meeting in August which CORAR attended. The FDA is now considering issuing a new draft of the guidance. CORAR will continue to follow this issue closely.

5.0 Nuclear Pharmacy Issues

5.1 Update on Ammonia N-13 exclusivity

The FDA Orange Book currently had shown Feinstein had 5 years of exclusivity for Ammonia N-13. In the Summary Basis of Approval documents for Ammonia N-13, it appears that both exclusivity and application user fees were waived. FDA has recently removed that exclusivity from the FDA Orange Book listing for Ammonia N-13.

5.2 Alzheimer's Indication/Coverage

CORAR has been reviewing the possibility of going to the FDA to see if they are open to new indications for Alzheimer's based on a literature review instead of using the FDA review. CORAR looked for another organization to help. CORAR has been discussing joining forces with IMT and SNM's Brain Council on the matter. Initially, CORAR, IMT and SNM would need to get an idea of the extent of what the literature needs and then they would need to find someone to do the review. It may be possible for SNM's Brain Council to perform this literature review.

5.3 NIOSH Hazardous Drug List

NIOSH developed a standard for pharmacists preparing chemo drugs. The original 2004 standard included Bexxar and Zevalin in a list of drugs that required additional engineering controls and PPE. In a later revision NIOSH added Metastron and Quadramet. APhA petitioned NIOSH to remove the two later drugs because these and all radiopharmaceutical prepared in nuclear pharmacies already used PPE and engineering controls. As a result NIOSH removed Quadramet and Metastron. APhA is sending another letter to NIOSH requesting Bexxar and Zevalin be removed from the list for the same reason. It is hoped these two radiopharmaceuticals will also be removed from the NIOSH list requiring additional engineering controls and PPE.

5.4 PET cGMPs from FDA

On December 9, 2009 FDA released the final cGMPs on PET. They also held a conference call to review the guidance the following day. In the preamble of the guidance FDA states that two years after the date of publication, the moratorium on not needing NDAs for PET products is lifted. As a result anyone producing PET drugs will need to have an NDA or aNDA after that two year period. The cGMPs will apply to all facilities producing these drugs. FDA did state the cGMP requirements are based on the size of the operation, but as a matter of principle they are not disguising between for-profit and not-for-profit producers.

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