

COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS
Committee on Regulatory and Legislative Affairs
Issues Summary – December 2003

1. Department of Transportation (DOT)

1.1 HM-230 RSPA Harmonization Rule (M. Doruff)

On April 30, 2002, NRC and DOT both published proposed rules to adopt the 1996 version of IAEA TS-R-1. For the most part, the rules are equivalent and there were no significant changes from the ANPR published in 1999. Relief from placarding WI and YII packages was retained, as was the A2 value for Mo-99. Most of the requirements in the rule have been followed by industry since HM-215D was put into effect with the adoption of ST-1 by IATA/CAO in July 2001. M. Doruff attended a NRC public meeting in August and provided verbal comments. Comments were also submitted to DOT on July 26, 2002, that opposed the requirement to mark excepted packages with the UN number, the new requirements for labeling overpacks and the proposed definition of quality assurance. The proposed rule was revised and submitted to the RSPA Secretary by October 14, 2003, awaiting the NRC version that is expected by December.

On June 10, 2003, RSPA published a notice of public meeting to accept comments on 63 proposed changes to TS-R-1, scheduled for revision in 2005. On August 5, 2003, M. Wojtas submitted comments on behalf of CORAR concerning the means of measuring 20% difference in radiation levels following performance testing and the deletion of the name of the consignor from transport documents. On October 14, 2003, RSPA published another notice of public meeting after receiving comments and published a consolidated draft of the changes RSPA would endorse at an IAEA review meeting in November in Germany. In the draft posted on their web site, DOT stated their position on each of the proposed changes. They were in agreement with CORAR that sought rejection of IAEA's proposal to delete the name of the consignor from shipping papers. DOT rejected the IAEA proposal, to which CORAR agreed, that the 20% limit on variation of package dose rate following performance testing should be based on TI and not surface dose rate. DOT stated that this would "weaken package requirements and transport safety."

Recommended Action: Continue to monitor progress and take advantage of opportunities to provide comments on DOT and IAEA positions.

Amendment of CSNC Packaging and Transport Regulations

The Canadian Nuclear Safety Commission (CNSC) published a proposed rule in January 2003 that would adopt 1996 IAEA-TS-R-1 requirements into their transport regulations. Comments were submitted by several companies including Amersham and MDS Nordion that included the need to allow a higher Type A Mo-99 limit for US/Canadian shipments and to only require placarding for Yellow-III packages. On July 26, 2003, CNSC published the revised proposed rule that was consistent with comments on these issues. The consultation period is now closed and the final rule is expected sometime soon.

Recommended Action: Review the final rule to ensure that there are no unexpected changes from the revised proposed rule. Assess any impact on industry.

1.2 Oak Ridge Study of A1 and A2 Values (K. Yoder)

An update report will be provided at the CORAR meeting on December 10, 2003.

1.3 **HM-215E (M. Wojtas)**

While the rulemaking process continues for HM-230 (see 1.1 above), DOT published a Proposed Rule (HM-215E) on December 3, 2002, seeking comment on the amendment of 49 CFR to be consistent with amended international requirements (UN Recommendations, IMDG Code, and ICAO) effective on January 1, 2003. On January 21, 2003, CORAR filed comments with DOT concerning specific changes as a result of this amendment. Of particular concern was elimination of the option to use radioactivity units to express the quantity of material on shipping papers. On July 31, 2003, RSPA published a final rule with an effective date of October 1, 2003, but with mandatory compliance date of October 1, 2004 for most of the changes. RSPA retracted the revision that would have disallowed the use of radioactivity units to express the quantity of hazardous material. However, excepted packages will need to be marked with the UN number and proper shipping name and with an air eligibility marking effective October 1, 2004.

In the meantime, the ICAO Dangerous Goods Panel met in Montreal in November to discuss their 2005/6 regulations for air transport. Working papers included those to propose 1) elimination of the air eligibility marking, 2) specification of a sequence of information on shipping papers, and 3) special treatment for medical radionuclides with restrictions for small RAM packages in aircraft cabins. Comments were submitted by RSCC to the head of the DOT delegation and by an Amersham Health representative at the ICAO meeting. The panel agreed to eliminate the air eligibility marking and it will remain as a voluntary requirement with a mandatory declaration on the shipping paper. The panel also agreed not to adopt prohibition of excepted packages of RAM in passenger compartments.

Recommended Action: Continue to monitor the development of new ICAO regulations and take advantage of opportunities to provide input.

1.4 **RSPA Security Awareness Guidance (M. Doruff)**

A subcommittee of CORAR developed a matrix of security measures with user guidelines applicable to various activities in the shipper, carrier and recipient segments of radioactive material transportation. The matrix provides guidance on security measures to be taken for specific types of RAM shipments, ranging from limited quantities to highway route-controlled shipments. The latter would obviously be subject to the most rigorous measures, many of which are already in practice as required by regulation or interim advisories. This document was prepared with the knowledge that DOT and NRC were conducting rulemaking on the security of RAM transport, and that it would be good for the industry to be prepared with a list of measures it would be prepared to take to enhance security, either in response to or facilitate compliance with prescriptive regulations. Before subcommittee consensus was agreed on the content of the guidance, input was sought by the carrier community via the Radiopharmaceutical Shippers and Carriers Conference (RSCC). Feedback on the draft guidance was repeatedly solicited but to date not received. While the guidance has not been finalized, it has been reported that it has been used by CORAR members as an outline for the preparation of transportation security plans and training mandated by HM-232 (see 1.7 below).

Recommended Action: No further action but maintain the current version and its availability to interested members and RSCC.

1.5 DOT HM-229 Hazardous Material Incident Reporting (M. Doruff)

DOT published a NPRM on July 3, 2001, that proposed changes in the requirements for reporting transportation incidents involving hazardous materials including expansion of reporting responsibility to anyone having custody of undeclared hazmat. A status NRP was issued on November 1, 2002, indicating that RSPA is developing a revised version of DOR Form F 5800.1 that will be used for reporting under the new rule. RSPA also indicated that the form would be available electronically to streamline the reporting process. As proposed, the reporting obligations to which carriers are currently subjected would now apply to anyone in physical possession of a shipment at the time of a reportable incident. This would add a DOT reporting requirement to shippers currently obligated to NRC or state agency reporting. The final rule is expected sometime in 2003 after focus groups selected by RSPA have reviewed and commented on the form.

Recommended Action: Review the final rule once published and determine the impact on industry.

1.6 DOT HM-223 Regulatory Jurisdiction (M. Doruff)

In continuation of rulemaking initiated in 1998, RSPA published a NPR on June 14, 2001, that would establish nationally uniform standards for activities related to transport and to make the distinction between functions under the jurisdiction of the DOT and those that were not. CORAR responded with comments on January 30, 2002, that DOT should maintain its jurisdiction over transportation including preparation, loading, storage, movement and unloading. On October 30, 2003, RSPA published a Final Rule for the most part unchanged, effective October 1, 2004, that intends to clarify the applicability of DOT regulations to specific functions and activities related to transportation by:

- establishing and defining the terms pre-transportation function, transportation, movement, storage incidental to transport, loading incidental to movement, and unloading incidental to movement.
- amending 171.1 to list functions that are subject to DOT regulation.
- amending 171.1 to indicate that storage of material before taken by a carrier and after carrier delivery, unloading by non-carrier personnel, and movement of material within the boundaries of a facility are not subject to DOT regulation.
- amending 171.1 to indicate that *facilities* where transportation functions are carried out are still subject to other Federal (e.g. OSHA and EPA), state and local regulation except to the extent that local laws may be pre-empted by DOT.

The rule states that DOT regulation where applicable to transportation functions can preempt state or local hazardous material regulation. However, fixed facilities and working conditions are subject to other Federal regulation. A table summarizing applicability of the rule and notes of explanation has been prepared and distributed. The final rule provides needed clarification with regard to transportation functions and regulatory jurisdiction. DOT has indicated that there will be a follow up rule publication regarding applicability to transloading and bulk shipments.

Recommended Action: Consider support of the Air France petition for preemption over local regulation in Houston, TX.

Interested Parties Rulemaking Petition: 49 CFR 106.120

On November 12, 2003, the Interested Parties, of which CORAR and RSCC are undersigned parties, filed a petition to DOT to request an extension of the 30 day time period to appeal the rulemaking decision on HM-233. This appeal was made on behalf of certain IP groups with

companies with bulk transfer and transloading operations who are significantly impacted by the rule.

1.7 DOT HM-232 Security Requirements for Hazardous Materials Transportation (M. Doruff)

DOT published a Final Rule on March 25, 2003. While the rule did not adopt the proposed additional requirements for shipper certifications and shipping papers, it does add provisions for security plans and additional training, particularly for shippers and carriers of placarded (Yellow-III) consignments. New employees must be trained and tested in security awareness within 90 days of March 25, 2003, the effective date of the rule. The Dangerous Goods Advisory Council filed a petition for reconsideration with DOT on March 27, 2003 on the grounds that the rule does not provide enough time between publication and date of effectiveness. A security awareness component of DOT training was required by March 2003 and within 90 days for employees hired thereafter. Security plans were to be in place where applicable by September 2003 and the details of these are to be included in in-depth training provided by December 22, 2003.

Recommended Action: CORAR should solicit any input from members concerning difficulties with implementation and compliance and prepare communication to DOT as warranted.

1.8 DOT HM-232A Security Requirements for Hazardous Materials Transportation by Motor Carriers (M. Doruff)

RSPA and the Federal Motor Carrier Safety Administration (FMCSA) jointly published a supplemental ANPR on July 16, 2002, that proposed additional security requirements for motor carriers including pre-notification, escorts, vehicle tracking, anti-theft devices and safe havens. The ANPR sought information on feasibility of these measures and the cost impact. The comment period was extended until November 13, 2002. Comments were submitted on November 13, 2002 urging a risk-based approach to motor carrier security and that DOT coordinate rulemaking on security with NRC and with the various departments within its own agency. On March 19, 2003, DOT published a notice that RSPA had assumed the "lead role" in this rulemaking as the Homeland Security Act of 2002 gives RSPA enhanced authority to regulate hazardous materials transportation security.

HM-232C Enhancing Hazardous Materials Transportation Security

Following the March 19, 2003 notice (see 1.8), the Transportation Security Administration (TSA) under the authority of the Department of Homeland Security published an interim final rule on May 5, 2003, establishing standards for security threat assessments for individuals applying for a hazardous materials endorsement (HME) on a commercial drivers license, including fingerprint-based criminal background checks. TSA would not authorize a state to issue HME unless the state had a background check program established by November 3, 2003. On November 4, 2003, TSA published an amended interim final rule that extended the deadline for state collection of fingerprint-based criminal background information to April 1, 2004. If a state is unable to collect this information by then, it must request an extension from TSA by April 1, 2004.

Recommended Action: Continue to monitor the development of new regulations and take advantage of opportunities to provide input.

1.9 HMTA Reauthorization (Alpine)

The Administration released its SAFETEA proposal on May 12, 2003, that contained HMTA provisions which stipulated that the Department of Transportation (DOT) has the authority to inspect and open packages they believe may contain hazardous materials. The provision reflects would ensure that packages are not stopped inappropriately by requiring any parcels that were examined be repackaged and placed back into transit if the inspection yields nothing threatening. The Administration continues to craft separate stand-alone HMTA Reauthorization legislation but has yet to circulate to staff on the Committees of jurisdiction.

Congress is drafting a comprehensive transportation measure which will include HMTA Reauthorization. The Senate Committee on Commerce, Science, and Transportation reported out the portion of the legislation they have jurisdiction over (which includes HMTA) on June 26, 2003. Section 439(c)(D) specifies that they may contact the offeror, carrier, packaging manufacturer, or responsible person to obtain more information about the contents of a package. If the package is determined not to pose a threat, the DOT is required to assist in the resumption of transportation of the package. A new section was created that requires the Secretary of Transportation to issue a rulemaking regarding the new package inspection and emergency orders, which is different from the Administration's proposal.

The House Committee on Transportation and the Infrastructure has introduced its version of comprehensive transportation legislation that does not include any provisions on HMTA Reauthorization. Per the Committee staff, they plan to address HMTA but are waiting for the Administration to distribute their proposal.

The House and Senate passed an extension of TEA 21 which continues federal funding for the highway programs through February 29, 2004. While staff desires to complete work and reconcile the House and Senate versions of the comprehensive transportation legislation by February, it is very unlikely that this will occur. Instead, staff are projecting they will complete the bill in Summer 2004.

Recommended Action: Representative Burgess, a Member of the House Committee on Transportation and Infrastructure, has agreed to offer amendments on our behalf to address any concerns we have with the HMTA Reauthorization. Please see Attachment 1.

1.10 Volpe Study (M. Doruff)

CORAR worked with NEI by contributing to the completion of a report drafted by the Volpe Center. The NRC is looking to obtain a comprehensive, updated report on the transportation of radioactive material. The NRC wanted this for consideration in future rulemaking but it appeared that RSPA might also be interested in this, as much of the information is relevant to current rulemaking on security of radioactive material in transport. CORAR last provided specific industry data and other information to NRC in October 2002, but to date we are unaware of any developments.

1.11 DOT FY '03/'04 Funding (M. Doruff/Alpine)

The Transportation, Treasury, and Independent Agencies Appropriations Act was included within the omnibus spending measure and provides more than \$88.9 billion in total budgetary resources; an increase of nearly \$500 million over the President's request and \$4.9 billion above the FY03 level. RSPA was allocated \$46,441,000. The House passed the measure on

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December 8, 2003, but objections were raised when it was brought to the Senate floor and, therefore, the Senate will not act on the Omnibus bill until they return in January.

Please see Attachment 2.

1.12 IAEA Transport Security Guidance (M. Doruff)

Prior to its Technical Meeting in Vienna in October 2003, the IAEA published a draft TECDOC on Security in the Transport of Radioactive Material – Interim Guidance for Comment. This document provides guidance security measures for consignments of radioactive material that fall within two security levels. Level 1 applies to special form shipments greater than 100 A₁ or 3000 A₂ and greater than 3000 A₂ for normal form. Level 2 applies to special form shipments greater than 10 or 100 A₂ or between 100 and 3000 A₂ for normal form. Some radiopharmaceutical shipments could fall into Level 2. CORAR provided comments to RSPA on September 30, 2003 on the TECDOC which expressed the need for consistency between IAEA and DOT requirements. Specific comments were also provided concerning difficulties with terms and security plan expectations in the TECDOC.

Recommended Action: Continue to monitor the development of IAEA guidance and take advantage of opportunities to provide input.

2. Nuclear Regulatory Commission (NRC)

2.1 NRC Security for Materials Licensees (M. Doruff)

NRC has issued several security alerts and advisories to byproduct material facilities since the terrorist attacks of 9/11/01. Orders have since been imposed on nuclear power licensees and fuel cycle transporters that require them to take additional security and safeguard measures. NRC has indicated that a similar order is forthcoming for materials licensees and that applicability would be based on criteria for Category 1 or 2 in IAEA-TECDOC-1344. NRC would require measures for licensees who fall into these categories, based on radionuclide specific activities such as those for I-125 and I-131 (50 Ci), Mo-99 (80 Ci) and Tc-99m (200 Ci). There has been some indication from NRC and Agreement State representatives that medical radionuclides will be excluded from the applicability tables with a focus on higher risk materials such as Cs-137, Co-60 and Am-241. Licensees who license authorizations exceed the limits will receive the orders but will likely have the option of reducing license possession limits in lieu of taking mandated security and safeguard measures.

Recommended Action: CORAR should solicit any input from members concerning difficulties with implementation and compliance and prepare communication to NRC as warranted.

2.2 NRC Review of Sewer Disposal Practices (L. Smith)

The NRC, EPA, and other agencies participating with the Sewerage/Sludge Subcommittee of the Interagency Steering Committee on Radiation Standards (ISCORS) are developing guidelines on sewer disposal practices. NRC expects to issue a Federal Registry Notice by the end of November 2003 announcing the availability of three reports which are: 1) a final report on Survey and Sampling at Publicly Owned Treatment Works, 2) a draft report on dose modeling and calculations for public comment and 3) a draft guidance document for sewerage plan operators also for public comment. The reports will be posted on the ISCORS web page at www.isors.org/library.htm. The public comment period will probably be sixty or ninety days. **Recommended Action: CORAR should be prepared to participate in the public comment process.**

2.3 NRC Clearance of Materials Study (M. Doruff)

The enhanced participatory rulemaking process began with a workshop in Washington on May 21-22, 2003 attended by K. Yoder and A. Chance at which verbal comments were submitted. Written comments were submitted on NRC June 24, 2003, and stressed the need for a dose-based standard for disposition of materials with a 1 mrem/year screening level and a limit for release of materials of 100 mrem/year to the public. Their key concern is the potential for very low-level materials (e.g. short-lived waste decayed to background) could be subject to requirements for disposal in a permitted or licensed landfill. NRC has indicated that their technical analysis of concentrations of radionuclides in materials corresponding to individual dose will take into consideration exposure to multiple sources be completed by March 2004. A proposed rule will be published in September 2004.

Recommended Action: CORAR should continue to maintain active participation in rulemaking process and prepare and submit comments on the proposed rule

2.4 NRC Extremity Dose Monitoring (L. Smith/J. Coffey)

On August 22, 2003, the NRC issued Information Notice 2003-12 "Problems involved in monitoring dose to the hands resulting from the handling of radiopharmaceuticals" providing recommendations accommodating some of CORAR's concerns. CORAR has issued a draft white paper on this topic to the NRC met with NRC staff on November 20, 2003. The meeting with NRC resulting in CORAR edited and condensing its original white paper recommending generally acceptable practices in monitoring extremity dosimetry. NRC will collaborate with us in developing this paper. The intent is to finalize an industry white paper in 6 months to a year which the NRC will endorse. The NRC might then issue their own information notice or perhaps encourage us to establish an ANSI-standard on this topic

Recommended Action: CORAR will revise and finalize its white paper on extremity dose monitoring and continue to collaborate with the NRC. Please see Attachment 3.

2.5 Low Level Radioactive Waste Disposal (L. Smith)

There has been little change in the national capacity for LLRW disposal. The Barnwell, S.C. facility continues its program of phasing out generator access from non-compact states in 2008 and the Clive, Utah facility can still only accept low level Class A waste. The Clive site operator, Environcare is expected to delay applying to be licensed to accept Class B and C waste until year 2008 approaches to avoid competing for revenue with the Barnwell site and will probably choose a time when the local political climate is more conducive.

The DOE has disposal capacity for LLRW, but does not want to initiate access for commercial disposal while they are handling political concerns over the Nevada waste isolation site.

On November 18, 2003, the EPA published an advanced notice of proposed rule making to allow disposal of "low activity" radioactive waste in facilities other than those sites specifically licensed for LLRW disposal. Low-level activity waste would be characterized as Class A waste with short-lived radionuclides in a concentration no greater than 0.1 Ci per cubic foot.

In June 2003 a new Texas law approved the siting and operation of the Texas, Maine, Vermont Compact LLRW disposal site for commercial and federal waste. The site's economic viability depends on DOE participation. However, it is not yet clear whether DOE

accepts the take title provisions in the Texas law. Meanwhile the Texas Commission on Environmental Quality is finalizing regulations (expected January, 2004) to accept operator license applications by June 31, 2004.

Action: CORAR should continue to track these developments and be prepared to participate in the public commentary and support a license increase for the Clive facility

2.6 Financial Assurance for Materials Licensees (M. Doruff)

NRC published a Proposed Rule on October 7, 2002, concerning Financial Assurance Amendments for Material Licensees. The PR proposed to add requirements for 1) irradiator facilities to provide site-specific decommissioning estimates, 2) brokers to provide financial assurance, 3) certification amounts for licensees to be raised by 50%, and 4) decommissioning estimates to be updated at least once every three years. Comments were submitted by CORAR on December 20, 2002, which contested the definition of waste broker, the increase in certification amounts and the requirement for updating decommissioning cost estimates. A final rule was published by NRC on October 3, 2003, and the Analysis of Public Comments in the preamble addressed the CORAR comments. NRC rejected the CORAR comment that credit should be given to salvageable assets in estimates of decommissioning liability. NRC agreed with CORAR's comment concerning the proposed definition of "waste broker" and withdrew the definition in the final rule. However, contrary to CORAR comment the NRC declined to provide a clear definition of the term "waste." Finally, NRC rejected the CORAR comment that decommissioning estimates should only be revised when licensees are renewed or when changes occur in facilities and operations that warrant license amendments. The rule is effective December 3, 2003, and requires decommissioning funding plans to be updated every three years.

Recommended Action: CORAR should solicit any input from members concerning difficulties with implementation and compliance and prepare communication to NRC as warranted.

2.7 NRC Licensing Fees

An update report will be provided at the CORAR meeting on December 10, 2003.

3. Environmental Protection Agency (EPA)

3.1. Regulation and Mixed Waste (L. Smith)

In a final rule published in the Federal Register on August 7, 2003, the EPA delisted the use of catalytic chemical oxidation technology for the treatment of low-level-mixed waste containing tritium at the Lawrence Berkeley National Laboratory (LBNL) Tritium Labeling Facility.

Recommended Action: CORAR should continue to seek opportunities to broaden the scope of any similar delisting actions and should consider petitioning individual states to adopt the EPA's conditional exemption rule for treatment of mixed waste at NRC and Agreement State licensed facilities.

3.2 Reauthorization of Clean Water Act (Alpine)

Recommended Action: No action to report. Continue to monitor legislative proposals to ensure that CORAR is not impacted.

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4. Outstanding Projects

4.1 ANSI Standards Committee (F. Killar)

An update report will be provided at the CORAR meeting on December 10, 2003.

4.2 U.S. Customs Initiative (K. Yoder)

An update report will be provided at the CORAR meeting on December 10, 2003.

4.3 CORAR/RSCC Collaboration (M. Doruff)

The relationship between RSCC and CORAR was discussed with RSCC members at a meeting in October 2003. L. Bierlein, Counsel for RSCC, expressed the need for better coordination between he and Alpine with regard to Interested Parties activities to avoid duplication and ensure consistent representation on key issues.

Recommended Action: Coordinate the date of the spring meetings for the Reg/Leg Committee and RSCC. Establish a CORAR liaison to RSCC to help coordinate work and position on transportation legislative issues.

4.4 Security Detection of Patients (R. Carretta)

An update report will be provided at the CORAR meeting on December 10, 2003.

4.5 Emergency Contact Action Guidelines (H. Evans/H. Guilmette)

An update report will be provided at the CORAR meeting on December 10, 2003.

4.6 Prussian Blue (H. Kramer/Alpine)

We met with the Associate Commissioner for Legislation at the Food and Drug Administration (FDA) on Monday April 28, 2003. We raised CORAR's concerns with the statements that were posted on the FDA website regarding Thallium-201 and construction of a dirty bomb. We were informed that he had discussed this issue with the Administrator at FDA and all agreed that the material was factually inaccurate and it was removed from the website. In addition, we forwarded him the Department of Energy's letter that supported the claims made in our original letter.

The FDA has a publication available online entitled "Questions and Answers on Prussian Blue." Contained within this document is a description of Thallium-201 which is defined as "a natural element found in many minerals. Thallium is very toxic and different thallium compounds have a variety of uses-from rat and ant poison to the manufacture of optical glass and other industrial uses. **The radioactive form of thallium (thallium-201) is approved as a radio-imaging drug used in small doses for medical procedures. This use of thallium in low doses is very safe.** Exposure to a high dose of thallium generally results in severe stomach symptoms, followed by brain symptoms, and sometimes death. **However, the radioactive form of thallium (thallium-201) that is used for medical purposes is used in such small amounts that exposure to high doses is unlikely."**

Dirty bombs are also discussed in this publication but the reference to Thallium-201 has been removed. We believe this signifies that FDA has both received and responded to our concerns.

5. Pending Legislative Issues

5.1 Energy Bill (Alpine)

A. Dirty Bomb Legislation

In response to the terrorist attacks of September 11, 2001, legislation has been introduced in the Senate and the House aimed at preventing the use of a dirty bomb or nuclear device in an attack against the United States. As you recall, we have worked with Representative Markey and Senator Clinton's staff to ensure that radiopharmaceuticals were treated with the appropriate level of security.

During consideration of the energy legislation by the House Committee on Energy and Commerce, Representative Markey offered his bill in the form of an amendment.

Representative Markey withdrew the amendment after Chairman Tauzin promised rigorous oversight to ensure that the NRC would address his concerns.

As we had anticipated, Representative's Markey's dirty bomb language was not included in the final conference agreement.

B. Nuclear Security

The Senate Committee on Environment and Public Works approved S. 1043, "Nuclear Infrastructure Security Act of 2003." Nuclear security is an issue that has received much attention since 9/11 and a scaled down version of the bill was added to the energy bill. A provision on the secure transfer of material was included in the final conference agreement requiring background checks, which could be interpreted, to be applicable to all receivers of nuclear material including hospital and other industry employees. The NRC is mandated to issue regulations identifying radioactive material that should be exempted from this requirement. It is conference staff's intent that radiopharmaceuticals be exempt from this provision.

The provision regarding the regulation of NARM, which was present in earlier drafts, was not included in conference agreement.

C. Price-Anderson Reauthorization

The provision in the energy bill extends the Price-Anderson Act, the framework for nuclear liability protection, until 2023. Price-Anderson is not the vehicle of any amendments that could have negatively impacted the radiopharmaceutical industry.

D. Miscellaneous Included within the nuclear title is a scaled down version of Senators Bingaman and Akaka's bill the "Low Level Radioactive Waste Act of 2003," located in Section 635. As you are aware, the intent of the legislation was to address the efforts made by the Department of Energy (DOE) to recover and dispose of thousands of domestic Greater-than-Class-C (GTCC) radiological sources. CORAR has been supportive of efforts to dispose of these GTCC radiological sources.**Recommended Action: Action: Ongoing advocacy of radiopharmaceutical industry's concerns with nuclear security and dirty bomb proposals. Monitor the proposals and recommend modifications that address CORAR's concerns. Please see Attachment 4.**

5.2 **Homeland Security (Alpine)**

The Department of Homeland Security Appropriations bill contained funds directing TSA to develop an air cargo security program which incorporates a risk-weighted approach designed to identify cargo that requires closer scrutiny and utilizes the known shipper program. Newly confirmed Acting Deputy Secretary of Homeland Security, James Loy, testified that he believed it is not practical to screen every item that is transported via the commercial passenger aircraft.

It is necessary to continue to monitor the Department of Homeland Security and the Committees of jurisdiction as they continue to develop their legislative priorities to ensure that the radiopharmaceutical industry is not negatively impacted.

Recommended Action: Continue to monitor the evolution of the Department of Homeland Security.

5.3 **Aviation and Cargo Security Legislation (Alpine)**

Aviation security, specifically air cargo security, continues to receive attention on Capitol Hill. The Senate passed air cargo security legislation which mandates all cargo be screened which is transported in passenger aircraft operated by domestic and foreign air carriers in interstate and intrastate air transportation including regular inspections of shipping facilities for cargo security. The House Committee on Transportation reported out their version of aviation security legislation but excluded air cargo provisions. The bill did not see floor action this year.

Per conversations with staff on the House Committee on Transportation, it is unlikely that air cargo legislation will be reported out of Committee because Full Committee Chairman Young and Subcommittee Chairman Mica are opposed to it. We anticipate that this issue could arise in the House Select Committee on Homeland Security, as Representative Markey has a slot on the panel. Representative Markey has been extremely active and vocal regarding this issue and has spearheaded efforts to attach language to the Department of Homeland Security Appropriations bill that would require all air cargo being transported via commercial aircraft to be screened. The House has voted overwhelming in support of this amendment twice, which indicates that this is an issue that resonates with Members. We have met with staff on the Select Committee on Homeland Security to discuss CORAR's concerns and they indicated that while Member interest might exist, the Chairman was opposed to enacting cargo security legislation.

Conference report language included in the "Vision 100 – Century of Aviation Reauthorization Act" recommends that DHS and DOT conduct a study to review current procedures associated with the shipment of radiopharmaceuticals and suggest action to ensure their timely delivery.

Recommended Action: Continue to educate staff, monitor proposals, and work to ensure the continued flow of radiopharmaceutical shipments. Please see Attachment 5.

5.4 **Chemical Security Legislation (Alpine)**

After the events of September 11, 2001, numerous chemical security measures have been introduced that could adversely impact the radiopharmaceutical industry. The Senate Committee on Environment and Public Works reported S. 994, the "Chemical Facilities Security Act of 2003," out of Committee without Democratic support. The legislation has not

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been considered on the Senate Floor. CORAR is concerned that the legislation contains duplicative NRC and EPA regulatory authority.

At the request of Representatives Tauzin and Dingell, Chairman and Ranking Member of the House Committee on Energy and Commerce, the GAO commissioned a report which recommended that the Department of Homeland Security and EPA develop a comprehensive national chemical security strategy. In response to this report, Representative Pallone announced he was developing chemical security legislation that would be reflective of the suggestions GAO had made. On October 10, 2003, Representative Pallone sent a letter to Chairman Tauzin requesting a hearing on chemical security legislation. In addition, Representative Fossella has introduced a chemical security bill described by staff as more stringent than S. 994.

Recommended Action: Canvass CORAR to identify potential impacts by duplicative regulations, develop a CORAR position, and craft a legislative solution. Please see Attachment 6.

5.5 Port Security Legislation (Alpine)

The aftermath of 9/11 has prompted Congress to focus more closely on the security of points of entry into the United States. Senator Domenici introduced the "Border Infrastructure and Technology Modernization Act" in March. While our analysis of the legislation is that it should not have a detrimental impact on the flow of legitimate commerce, it reflects a growing concern that security of our borders be more stringent. In addition, Representatives Tauzin and Dingell, Chairman and Ranking Member of the Committee on Energy and Commerce, sent a letter requesting funds for additional radiation detectors for our Nation's ports and borders in response to the Subcommittee on Oversight and Investigations 18-month investigation regarding the Federal government's ability to protect against the threat of nuclear terrorism. Both the House Committee on Energy and Commerce and the House Committee on Transportation and Infrastructure have considered hearings on port security.

Action: Monitor the status of the legislation and investigation and update CORAR members on developments.

5.6 DOE FY '04 Funding (Alpine)

The Energy and Water Appropriations conference report passed the House and Senate on November 18, 2003. Included within this bill is the funding for DOE. Nuclear energy programs are funded at \$393 million, an increase of \$23.9 million from the budget request and \$133 million above fiscal year 2003. The Chairman's mark funds Nuclear Energy Plant Optimization (NEPO) program at \$3 million, the Nuclear Energy Research Initiative (NERI) at \$11.6 million, and nuclear energy technologies at \$44.0 million.

Please see Attachment 7.

5.7 California Legislative Actions (M. Doruff)

CORAR had commented on and is tracking four bills in the California legislature: SB-13 proposes that waste with trace quantities of radioactive material must be disposed in a LLRW site; SB-201 transfers regulatory jurisdiction over radiation protection from DHS to DTS (i.e. NRC to EPA based regulatory frameworks); SB-208 proposes new restrictive decommissioning standard for a specific site; SB-415 requires deed restrictions on decommissioned sites. SB-13, SB-201 and SB-208 were placed on the Senate Appropriation Committee's "suspense file" due to their excessive estimated implementation costs. SB-415 has not had a hearing yet. Another bill AB-926 to repeal the prohibition on using the Ward

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Valley LLRW disposal site, supported by CORAR, failed passage on April 8, 2003 and has not been reactivated.

Action: CORAR should continue to support the CalRad Forum in opposing these suspended bills and supporting the Ward Valley site

5.8 **GAO Study of Low-Level Waste Disposal (L. Smith/M. Doruff)**

On September 12, 2003 CORAR sent a letter to Senator Domenici in support of his request to the General Accounting Office (GAO) to determine the status of LLRW disposal. On November 5, 2003, a CORAR representative participated in a meeting with GAO, the CalRad Forum and some Californian LLRW generators to review the status of LLRW.

Action: CORAR should send comments to GAO and consider participating in a survey of LLRW status to enable GAO to decide whether new legislation is needed.