



Council on Radionuclides and Radiopharmaceuticals, Inc.

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COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS COMMITTEE ON MANUFACTURING, HEALTH AND SAFETY ISSUE SUMMARIES

ACTION ITEMS

1. Medical Isotope Bill S99/Radwaste Management (R. Brown)

Background: HR 3276 (Markey Bill) passed the House last year, but stalled in the Senate. When Congress adjourned last year the bill died. The Senate has drafted a new version of the legislation, S. 99. The bill places a ban in the export of HEU for medical isotope production six years after enactment of the legislation. Some extension of that deadline is possible. It is very similar to last year's HR 3276, except with more favorable language for the industry in the waste and uranium waste take-back provisions. In the bill DOE is directed to take back any radioactive waste for which there is no commercial disposal pathway. The bill also uses a definition for that waste considering its characteristics rather than its origin.

DOE has published a draft EIS in the FR which deals with GTCC waste. DOE has asked CORAR to encourage any new Mo-99 producer to consider submitting comments to the draft EIS docket, so that GTCC forms can be considered in the final EIS. Any GTCC waste forms that are included in the final EIS will be evaluated under the requirements of the National Environmental Policy Act (NEPA) in this programmatic EIS. This could address the requirements for NEPA review later when the facility or technology is deployed.

Status: S.99 was introduced in the Senate on January 25th by Senators Bingaman and Murkowski. The Senate Energy Committee held a hearing on the legislation on February 1st. CORAR testified before the Committee. On April 12th the Senate Energy Committee approved the bill. After a lengthy negotiation with Senate Members opposed to new Federal government spending, the Senate approved S.99 on November 17th. The focus now shifts to the House and their consideration of S.99.

2. NRC Final Rule – Decommissioning (R. Brown/L. Smith)

Background: NRC held a public meeting on January 10, 2007, as part of its rulemaking process to address decommissioning funding shortfalls, particularly at legacy sites. Proposed Rule published 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 submitted on May 7, 2008. NRC issued SECY 09-0042 dated March 13, 2009 and Draft NUREG 1757 Vol 3 Rev 1, and issued a Final Rule on June 17, 2011, effective December 17, 2012, amending regulations to improve decommissioning planning to reduce the probability of any licensee creating legacy sites.

Status: Draft Reg Guide DG-4014 “Radiological Surveys and Monitoring During Operations”, describing survey methods for residual contamination, was released in the Federal Register on December 13, 2011 for public comment, and CORAR submitted comprehensive comments on 02/03/12 to the NRC and NEI. A final version of DG-4014 is expected to be published by 12/17/12.

Action: Monitor further developments of DG-4014 and implementation of the rule and be prepared to provide clarifications and additional comments.

3. NRC Proposed Rule – 10 CFR 37 Physical Protection of Byproduct Material (K. Roughan)

Background: On June 15, 2010, NRC published a Proposed Rule to amend its regulations to establish security requirements for the use and transport of IAEA Category 1 and category 2 quantities of radioactive material and to codify requirements previously included in orders to licensees. The objective of the PR is to provide reasonable assurance of preventing the theft or diversion of Category 1 and 2 quantities of radioactive material. The proposed rule would affect any licensee that is authorized to possess category 1 or category 2 quantities of radioactive material and any licensee that transports these materials using ground transportation. Due date for comments was October 13, 2010.

NOTE: This was discussed in detail during the December 7, 2010 meeting of the CORAR Transportation Committee. Requirements in PR are not consistent with NRC Orders, particularly with regard to administrative requirements.

On October 8, 2010, NRC published an extension of the comment period to January 18, 2011. On April 19, 2011, the Commission was briefed by industry representatives and NRC staff on the proposed rulemaking for Part 37. K Roughan made a presentation on behalf of ISSPA.

Status: The staff has completed its resolution of comments and has submitted a draft final rule to the Commission for their review. The draft does remove some of the more commented on issues, i.e. credit checks; however, it still maintains the large administrative burden on licensees without real justification for the significant monetary impact on industry estimated at \$300-488 million. However, the Commission amended its 10 CFR 73.57 fingerprinting requirements for non-power reactors as published on August 4, 2011 (SECY-11-0107). The draft final rule was approved by the NRC Commission and is expected to be published in the Federal Register at the end of 2012 along with the implementation guidance. The rule will have a one year implementation deadline for NRC licensees and a three year implementation deadline for Agreement State licensees. On 10/25/12 the NRC published notices in the Federal Register of revised orders to specific licensees concerning safeguards of SGI-M materials.

Action: Collaborate as needed with ISSPA and Transportation Committee. Assess the impact on CORAR members authorized to possess Category 1 or 2 quantities of radioactive materials needs to be assessed to determine CORAR's response to the PR.

4. NRC Final Rule-Import/Export Materials and Equipment (K. Roughan)

Background: NRC published a Proposed Rule on June 23, 2009 to update and clarify regulations concerning export and import of nuclear equipment and material. NRC proposed 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 revised 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. CORAR did not respond, however NEI and QSA Global submitted comments in support of the PR with the exception of the seven day advanced notification requirement.

On July 28, 2010, the NRC published a Final Rule (75 FR 44072) that updates, clarifies, and corrects several provisions in Part 110 to improve NRC's regulatory framework for the export and import of nuclear equipment, material, and radioactive waste. The final rule also clarifies and corrects the regulations addressing the general license for the export of byproduct material (10 CFR §110.23). In addition, the final rule amended the regulations governing the export and import of Category 1 and 2 quantities of materials listed in Appendix P to Part 110 and the definition of "radioactive waste" in Part 110.

With the revised definition of "radioactive waste," the three prior exclusions are retained, with some modifications, and exclusions are added including sealed sources or devices containing sealed sources of U.S. origin returned to any manufacturer, distributor or other entity which is authorized to receive and possess them. This change allows the return of U.S. origin sources or devices to distributors and other appropriately authorized entities. A specific import license is required for the importation of sources/devices originating outside of the US for disposal in the US.

Section 110.50 (c) is revised to require notifications of imports to be submitted seven days in advance of shipment. Previous rule was seven day in advance, to the extent practical, but in no case less than 24 hours in advance of each shipment. Additionally, the advance notification requirements for imports of Category 1 and 2 quantities of material in §110.5 (c) now requires the exporting facility name, location, address, contact name and telephone number as part of the pre-shipment notification.

Status: NEI and ISSPA sent letters to NRC in December 2010 to raise concerns including the limitations on material of non-U.S. origin on source returns to manufacturers. On 9/26/11, CORAR commented to NRC in support of GE Hitachi's request for a license to import Co-60 sources from China, citing issues also related to the non-U.S. origin limitation. According to NEI, NRC staff have drafted a guidance document (Branch Technical Position or BTP) and expected to receive final concurrence/approval from each of the NRC offices on 11/14/11. Their next step would be to publish a draft BTP in the Federal Register for comment "sometime in the near future."

Meanwhile, in comments to NRC submitted on 10/6/11 regarding Enforcement Policy, NEI requested a public meeting to discuss challenges (and perhaps best practices/lessons learned) from an industry perspective and hearing from NRC on their experience with implementation of the 7 day advanced notification requirement. In advance of any such meeting, NEI has prepared a draft agenda and requested comments. The BTP was published by 01/13/12 and NRC held a meeting to get industry comments. CORAR members participated in a public meeting with the NRC on 01/24/12. The BTP was modified with comments received from that meeting and reissued for public comment. The BTP clarified some issues but still significantly restricts the industry's historical and effective practice of one for one exchange, allowing for sealed sources to be handled/disposed in a safe manner. On 10/22/12 the BTP was published in the Federal Register for public comment with regulatory interpretations that accommodate most of industry's concerns. The waste compact states may have difficulty with the NRC's view of "presumed US origin" as they cannot take foreign origin waste. This should be addressed in the final BTP.

Action: Need to collaborate with NEI and ISSPA on any opportunity with NRC to address import issues including material of non-US origin and 7 day advance notification.

5. NRC and Agreement State Multiple Licenses for PET Distribution (A. Chance)

Background: In October, 2009 the NRC and Agreement States finalized extending regulatory control to include accelerator produced radioactive materials. This development was welcomed by our industry as an opportunity to promote uniform regulations and simplify the licensing of reactor and accelerator produced radionuclides.

Status: Instead of requiring one materials license NRC Headquarters is taking the position that PET facilities need manufacturing and medical distribution licenses and do not need a nuclear pharmacy license. The NRC Region 3 Office has required NARM production/distribution and nuclear pharmacy licenses. Also the Nevada Bureau of Health Protection Services-Radiological Health Section is requiring 2 licenses: one for NARM production and one for distribution (nuclear pharmacy). There is no clear guidance to licensees in the matter although, as Nevada has demonstrated, the NRC is beginning to push Agreement States to require multiple licenses.

Action: Establish subcommittee to review this new active issue and make recommendations.

6. NSCC Activities (S. Surovi)

Status:

Even though the NSCC-R focus groups have been sun-setted, there is still concern that industry issues have not been fully addressed. The current method is for NRC Source and Security Task Force to request input from DHS, which then solicits information from NSCC-R for industry input. This creates a filter where industry does not have a direct interaction with NRC and their activities. On 09/18/12 CORAR reviewed a GAO report on radiological security in hospitals.

Action: MHSC members should consider potential CORAR actions in response to the GAO report and be alerted to support any significant new developments.

7. LLRW Disposal (L. Smith)

Background: CORAR supports the development of long-term, reliable, safe and cost-effective access to LLRW disposal. The NRC NARM regulations preserves better access for cost-effective disposal provided for NARM waste at the Richland Washington LLRW disposal site. The need to maintain access to disposal sites is perceived to be necessary to improve the security of LLRW. Licensees need guidance on the extended storage of LLRW when viable disposal is not available.

Status: CORAR is a member of the NRC Working Group on the Extended Storage of LLRW which issued SECY-10-0164 on 12/23/10 and RIS 2011-09 on 08/16/11, updating guidance on this topic. With the Texas LLRW Site opening access to generators in out-of-compact states, NRC decided to not publish a more comprehensive NUREG on this topic and discontinued the Working Group on Extended LLRW Storage on 04/18/12. On 07/06/12 CORAR responded to a request from the NRC to review and provide information on the radiological protection requirements for material licensees with LLRW in storage.

Action: 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. Monitor developments at the Clive, Utah Site to support their continual acceptance of certain Class A LLRW. Monitor NRC development of 10CFR61. Provide NRC staff with case specific LLRW storage issues when requested and inform NRC of any new issues that they may not be aware of.

8. NRC 10CFR61 LLRW Management Issues (L. Smith)

Background: During the past 2 years the NRC has been engaging stakeholders in public discussions on consideration of changes to 10CFR61 to accommodate current LLRW disposal capabilities, practices and needs.

Status: On 03/04/11 CORAR participated in a DOE/NRC public workshop in Phoenix, AZ on LLRW disposal and commented on needed changes to LLRW disposal regulations in 10CFR61 and submitted written comments to the NRC on 04/12/11 recommending the need for radwaste classification based on arid disposal sites. On 03/02/12 CORAR participated in a public workshop on 10CFR61 where the NRC presented the many issues that were being considered in updating the rule. On 07/16/12 CORAR submitted substantive comments to the NRC on potential changes to 10CFR61.

Action: Monitor and participate in ongoing developments.

9. Texas LLRW Disposal Site (L. Smith)

Background: On 01/14/09 Waste Control Specialists (WCS) received a license from the Texas Commission on Environmental Quality (TCEQ) to dispose commercial LLRW at the Andrews County, Texas LLRW Disposal Site. In January, 2011 WCS was authorized to accept LLRW from commercial generators in Texas and Vermont. On 12/10/09 CORAR presented "Biomedical Research Products Deleted Due to Radioactive Waste Issues" to the Texas LLRW Disposal Compact Commission and recommended opening access to the Andrews County, Texas LLRW Disposal Site for the importation of LLRW from generators in Out-of-Compact States. This was reported in Radwaste Monitor on 12/14/09 and issued for the NRC website on 12/17/09. On 02/12/10 the TLLRWDC published a proposed rule in the Texas Register to import LLRW. On 04/12/10 CORAR submitted comments in support of the proposed rule and the need to ensure the economic viability of the disposal site and the flexibility to establish a disposal fee schedule that the medical and research community can afford. CORAR positions were reported in Radwaste Monitor on 03/08/10 and CORAR met with stakeholders at the Waste Management Symposia in Phoenix on 03/10/10 and 03/11/10 to promote these recommendations. Revised versions of the proposed rule were reviewed by the TLLRWDC at public meetings on 04/29/10 and 11/13/10 and a final rule published on 01/05/11.

Status: In March 2012 WCS started accepting LLRW for interim storage from generators in out-of-compact states and is currently working with the TCEQ and all LLRW generators to establish disposal fees. The backlog of LLRW in Extended Interim Storage at generators' sites exceeds the LLRW Site's annual Ci limits and may take 2-3 years to be disposed. CORAR was invited to tour the Andrews, Texas LLRW Disposal Site which was done on 02/09/12 after participating in the HPS Mid-year Meeting on Radioactive Waste in Dallas, Texas. The facility design appears suitable for IAEA classified Intermediate Level Radwaste which requires more engineered containment than LLRW. CORAR attended the annual Waste Management Symposia in Phoenix on 02/27/12 and 02/28/12 and learned that the TLLRWDC was processing critical disposal permits but did not yet have the funds for sufficient staff to process all applications. On 06/29/12 the TLLRWDC approved the disposal of LLRW from several out-of-Compact generators. The identification of radionuclides in LLRW from manufacturing was confirmed on 07/26/12 by WCS and the TCEQ and disposed in August. The TLLRWDC is meeting on 11/08/12 to discuss definitions of "waste" and "generators" as recent import permit requests have had some negative comments regarding waste brokers and processors.

Action: CORAR should continue to closely monitor these developments and be prepared to promote cost-effective disposal access for the biomedical community.

10. NRC Solicitation for Comment-ICRP 103 (L. Smith)

Background: 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 has also provided options for possible revision of the NRC regulatory framework. NRC published Solicitation of Public Comments on July 7, 2009 and on September 27, 2010 notice of three public workshops in October and November to obtain early public comments on these options and alternatives and extend the comment period until January 31, 2011. CORAR provided comments to NRC on March 29, 2010 and served on a panel at the NRC public workshop in Los Angeles on November 3 and 4, 2010. CORAR members also participated in NRC workshops in Washington DC (K Roughan) and Houston (J Miller) in October and November, 2010. Additional comments were sent to the NRC on 01/28/11 emphasizing that licensees (rather than licensing agencies) should determine constraints appropriate to their operations. Many comments received by NRC by other responders indicate that current regulations are adequately protective and no changes to dose limits are needed.

Status: On 08/19/11 CORAR provided surveys of occupational TEDE and prenatal dose distributions from CORAR member's operations and further comments on the potential impact of reduced dose limits. NRC staff issued SECY-12-0064, dated April 25, 2012 recommending a comprehensive review and revision of radiation protection regulations and guidance with comprehensive stakeholder input during the next 8 years. An analysis of this Policy Paper was distributed to CORAR on 06/25/12.

Action: Monitor and be prepared to participate in further considerations of changes in dose limits and constraints.

11. NRC DG-4018-Airborne Release Constraints (L. Smith)

Background: On 06/25/10 the NRC published in the Federal Register a notice of issuance of draft Regulatory Guide DG-4018, "Constraints on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors"

Status: CORAR submitted comments to the NRC on 08/18/10. Comments were provided to address issues associated with calculations of effluents from non-stack release points particularly in hospital facilities, application of the NRC constraint, clarification of guidance on NRC's graded approach to monitoring, the treatment of intermittent releases and the conversion factor applied by NRC to age groups other than adults. On 04/25/12 the NRC issued a final version as Regulatory Guide 4.20 including most of CORAR's comments but adding a section, without public review, on non-stochastic exposures which are irrelevant at the environmental constraint level.

Action: Consider informing NEI and the NRC of the need to clarify the treatment of non-stochastic public exposure.

12. ANSI/HPS Draft N 13.30,"Performance Criteria for Radiobioassay" (L. Smith)

Background: On 07/16/10 CORAR issued comments requesting that the title, scope and definitions be changed to clarify that the Standard only applies to Service Laboratories.

Status: CORAR comments were initially not accepted and, after numerous communications, only minor changes were made that did not fully address our concern. CORAR returned a negative ballot but the Standard was approved by N13 representatives from national labs, regulatory agencies, nuclear power and unions. Representatives from professional societies and individual technical experts mostly abstained. The final Standard was approved on 12/16/11. On 03/20/12 CORAR was provided with a draft guide on the interpretation of N 13.30 which was approved for use by CORAR members on 05/22/12 and filed with CORAR Position Papers.

Action: Delete from agenda.

13. ANSI/HPS Draft N13.12 – Surface and Volume Radioactivity Clearance (L. Smith)

Background: A 1999 version of this Standard was not adopted by regulatory agencies due to their perception of its weak technical basis. The current version attempts to have a more rigorous technical basis and reflect recent IAEA recommendations.

Status: CORAR submitted comments on this draft Standard on 05/02/11, which were mostly accepted, and provided additional comments on 10/19/12.

Action: Monitor.

14. NCRP Draft Report SC 2-5-Incident Investigation (L. Smith)

Background: The NCRP issued draft Report SC 2-5, "Investigation of Radiological Incidents"

Status: CORAR submitted comments to the NCRP on 02/01/12. The final Report, NCRP 173, was published in October 2012.

Action: Monitor.

15. ICRP Draft Radiological Protection in Security Screening (L. Smith)

Background: On 08/28/12 ICRP released this draft report for consultation.

Status: Like recent similar NCRP reports, this draft only addresses the occupational and public radiation protection and not the potential effect of screening on the cargo.

Action: Develop CORAR comments.

16. ICRP Draft Occupational Intakes Part 2 (L. Smith)

Background: On 9/20/12 ICRP released this draft report for consultation.

Status: The report does not reference biokinetic cases from industry

Action: Develop CORAR comments.

17. ICRP Draft Occupational Intakes Part 3 (L. Smith)

Background: On 9/20/12 ICRP released this draft report for consultation.

Status: The report does not recognize the medical use of I-124

Action: Develop CORAR comments.

PENDING ISSUES

18. Markey Letter to NRC on Patient Release (R. Brown)

Background: 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. NRC denied the petition on May 21, 2008. On March 6, 2006, CORAR provided comments to the NRC. NRC denied the petition 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. On July 29, 2009, NRC published IN 2003-22, Supplement 1, "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations." This advised licensees on measures for adequate instruction of diagnostic or therapy patients prior to release.

On March 18, 2010, Rep. Markey released a staff report entitled "Radioactive Roulette: How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety." The Markey staff report was prepared after reviewing NRC's latest response to an inquiry by Chairman Markey into the NRC's regulations surrounding the treatment of cancer patients with radionuclides as well as other materials.

On October 20, 2010, Rep. Markey has sent another letter to NRC Commissioner Jaczko regarding release of patients treated with radioiodine. He reported results of investigation by Subcommittee on Energy that conclude the public is being "unwittingly exposed to radiation from patients who are discharged after being treated with radioisotopes" due to inadequate NRC regulations and oversight. He is requesting NRC rulemaking to address this concern and to add incident reporting requirements. He requested NRC to respond by November 5, 2010. At the October 21, 2010 Commission briefing, the ACMUI reaffirmed their belief that the current release criteria was a balance of safety, access to treatment and cost.

Status:

On June 23, 2011, the Commission directed agency staff to evaluate the potential need for and feasibility of a study to determine radiation doses to members of the public due to the release of patients treated with medical radioisotopes. NRC would need further funds and staff time to produce a report to Congress.

Action: CORAR will monitor any ongoing correspondence and any report from NRC on their study and prepare a response when needed to any resulting regulatory or legislative activity.

19. Markey Letters to NRC – Medical Radiation and to the EPA (R. Brown)

Background: On October 14, 2009, Representative 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. On 10/22/09 Markey 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 and requiring a response by 11/16/12.

Status: Markey asked for answers from the NRC by October 30, 2009. R Brown spoke with Cindy Flannery at NRC on October 22, 2009 and NRC was preparing a response including details on the process they used to deny the Crane Petition. 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.

On October 20, 2010, Markey wrote a letter to Chairman Jaczko on behalf of the House Subcommittee on Energy and Environment regarding their investigation and findings related to release of iodine therapy patients. He requested that NRC:

- Commence rulemaking to revise patient release regulations with mandatory hospitalization for patients with doses above limits
- Revise regulations to prohibit patients from recovering in hotels and from public transportation, and take enforcement action against licensees who fail to provide patient guidance
- Enhance oversight of medical licensees and Agreement States
- Implement a reporting requirement for incidents involving intended public exposure

NRC Chairman Jaczko responded to Markey on January 21, 2011, maintaining the position that current regulations are adequate to provide public safety. The letter included a copy of the ACMUI report of December 13, 2010 where ACMUI recommends that NRC update their instruction to licensees regarding patient information to minimize public dose. NRC subsequently published RIS 2011-01, NRC Policy On Release Of Iodine-131 Therapy Patients Under 10 CFR 35.75 To Locations Other Than Private Residences, dated January 25, 2011 (ML103620153).

Action: Alpine Group will follow-up to determine status.

20. NRC Consideration of Rulemaking on Prompt Remediation of Residual Radioactivity During Operations (L. Smith)

Background: On 06/17/11 the NRC issued a Final Rule on decommissioning including provisions for prompt remediation of residual contamination. On 07/18/11 the NRC issued a notice of public webinar and request for comments on consideration of rulemaking to further address prompt remediation.

Status: On 07/25/11 CORAR participated in the webinar and on 09/01/11 CORAR submitted comments to the NRC recommending exemption of manufacturer and distributor licensees from unnecessary new rules and the need for guidance rather than new regulations. NRC decision on rulemaking is expected in April 2012.

Action: Monitor rulemaking developments.

21. NRC NSTS/License Verification – Category 3 (K. Roughan)

Background: 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.

Status: 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, with current verification regulations applicable for Category 3+ sources. There are significant difficulties with NSTS software for verification of Category 1 and 2 sources. NRC will be downgrading the security classification for access to the NSTS, so full credentialing will not be required.

NRC is still working to correct NSTS discrepancies and other issues. NRC is also working with stakeholders on license verification system (LVS) software to streamline integration of the system with licensee operations. Reciprocal Recognition has been acknowledged by the LVS development team, but initially LVS will not support any functionality with it. Plans are to include some form of functionality in a future revision. One thing they haven't determined yet – if a licensee can use this system instead of their own license check system, it is possible that licensees will have to keep their system and use the NRC system as the final check, resulting in two systems instead of just the one. The LVS and Web-Based Licensing project is behind schedule.

Action: Monitor and maintain needed stakeholder involvement.

22. NRC Safety Culture (L. Smith)

Background: 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.

Status: 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 11/06/09 the NRC published in the Federal Register a "Draft Safety Culture Policy Statement" and "Request for Public Comments". CORAR submitted comments on this Statement to the NRC on 02/12/10. On 09/17/10 the NRC published in the Federal Register a "Revised Draft Safety Culture Policy Statement" and "Request for Public Comments." CORAR submitted comments on this statement to the NRC on 10/15/10, requesting the inclusion of more specific traits for different licensees in future guidance documents. On 06/11/11 the NRC published a final Safety Culture Policy that is appropriate for material licensees. On 02/03/12 CORAR talking points were provided to J. Schlueter (NEI) for participation on a NRC panel at a public meeting on 02/09/12 with NRC Commissioners and senior staff. However, there was no substantive discussion on this topic of interest to CORAR.

Action: Monitor the NRC development of guidance documents and implementation of the policy and be prepared to comment and assist. Members should alert CORAR of any issues.

23. NRC Risk Management Concepts in Regulatory Programs (L. Smith)

Background: On 11/22/11 the NRC published in the Federal Register a request for public comments on the "Incorporation of Risk Management Concepts in Regulatory Programs." The NRC requests stakeholder input as they update the "risk-informed and performance-based approaches" in its material licensee regulatory programs documented in the late 1990s in the NUREG-1556 series, Volumes 1-21. The update is intended to include risk management considerations and address security and other issues. The NRC task force intends to complete these developments by May 2012.

Status: CORAR comments were issued to the NRC on 01/04/12 recommending the need for discussion of specific risk management examples at stakeholder workshops.

Action: Monitor and be prepared to participate in stakeholder workshops.

24. NNSA Security Upgrades (L. Smith)

Background: CORAR representatives have worked with DHS and NNSA (DOE National Nuclear Security Administration) GTRI (Global Threat Reduction Initiative) staff who are funded to recover potentially unsecured sealed radioactive sources and assist facilities improve security provisions for radioactive materials. The primary focus of government assistance has been on sealed sources mostly at medical and research facilities.

Status: NNSA has now started to assist facilities to improve security of unsealed sources. On 12/06/11 Kristina Hatcher (NNSA) presented their security cooperation program mentioning invited meetings with members of our industry to review the security of operations with sealed and unsealed radioactive materials. They found security provisions to be much better than they normally encounter but, nonetheless, were prepared to fund upgrades to modernize physical security and communications systems provided they continue to be funded for this. CORAR members reported timely progress in establishing contracts with NNSA to fund practical security upgrades.

Action: CORAR participants were requested to share their experiences with this program (if allowed) to assist other CORAR members who may want to consider participating in this program.

25. NRC LLRW Blending (L. Smith)

Background: Since 07/01/08, when the Barnwell S.C. LLRW Disposal Site closed access to radwaste generators in Out-of-Compact States, generators have been exploring the blending of Class A and Class B LLRW to produce radwaste forms that are acceptable for disposal at

accessible disposal sites. The NRC is collecting information on needs and practices with the purpose of developing guidelines and/or rules on acceptable treatment practices.

Status: On 01/14/10 CORAR participated in a NRC public workshop on blending Class B and Class A LLRW to enable disposal as Class A waste. CORAR issued comments to the NRC on 02/26/10 indicating that most LLRW generated by our industry and customers was unsuitable for blending and small scale LLRW treatments were done to improve the stability and shielding of the waste rather than to change the waste classification. On 10/13/10 the NRC Commissioners approved NRC staffs' SECY-10-043 Option 2 recommendation which closely corresponds to CORAR's position. CORAR was requested by the NRC to provide additional comments on blending from a materials licensee perspective. Comments were submitted to the NRC on 04/15/11 but inadvertently omitted in the NRC Draft Branch Technical Position (BTP) dated August 2011 to be addressed later. On 01/19/12 CORAR advised NRC on the need for higher concentration limits for the disposal of sealed source LLRW which will be accepted in the revised BTP.

Action: Monitor future NRC developments of specific guidance and potential regulatory clarifications.

26. States Seeking Agreement State Status (L. Smith)

Background: Connecticut is currently seeking Agreement State status with the NRC.

Action: Monitor

27. ICRP Draft Report on Threshold Doses for Tissue Reactions (L. Smith)

Background: ICRP103 Recommendations, 2007, mentioned the ongoing review of tissue reactions from radiation and the need to reevaluate new data for effects on the lens of the eye and circulatory systems. The ICRP is using the term "tissue reactions" to replace "Deterministic Effects".

Status: On 03/31/11 CORAR issued substantive comments to the ICRP on the draft report issued for consultation on Early and Late Effects of Radiation in Normal Tissues and Organs: Threshold Doses for Tissue Reactions and Other Non-cancer Effects of Radiation in a Radiation Protection Context. CORAR's primary concern is that the review of extremity and skin dose effects was insufficient to determine appropriate dose limits for radiation protection. Also ICRP's definition of a threshold to be 1% incidence seems unduly conservative.

Action: Be prepared to provide additional technical information to support optimization of radiation protection for the exposure conditions in our industry and customer operations.

28. NRC Solicitation for Comment-ICRP Recommendations on Lens of Eye Dose Limits (L. Smith)

Background: On 04/21/11 the ICRP issued Statement on Tissue Reactions recommending an annual dose limit for the lens of the eye of 20 mSv (2 rem) averaged over defined periods of 5 years with no single year exceeding 50 mSv (5 rem). This is based on consideration that 0.5 Gy (50 rad) is the absorbed dose threshold for unacceptable tissue reactions. On 08/30/11 the NRC issued a request for public comments on these recommendations.

Status: CORAR participated in the ICRP Symposium on the International System of Radiological Protection during 10/24/11- 10/26/11 and was invited to collaborate with the ICRP on this topic by the Secretary and the Working Group Chairman. On 10/13/11 the HPS submitted comments to the NRC on the technical basis for these ICRP Recommendations. On 10/31/11 CORAR submitted comments to the NRC endorsing the HPS comments and informing of the potential impact of reduced lens of eye dose limits. On 12/06/11 CORAR considered completing a lens of eye dose distribution summary for our industry to submit to the NRC similar to the occupational TEDE and prenatal dose surveys submitted earlier this year, but decided that the data base would be too small to be useful.

Action: CORAR should closely track these developments and coordinate with the NRC and ICRP staff in developing regulations and guidance on lens of eye protection.

29. NRC Staff Study on Dose from Nuclear Medicine (TBD)

Background: NRC regulations finalized in 1997 allow patients treated with medical isotopes to be released from a clinic or hospital provided the expected radiation dose to any other individual from the treated patient is not likely to exceed 500 millirem. Doctors are required to give patients written guidance on how to limit exposures to others, especially infants and young children. In recent years, the NRC has expanded the guidance requirement to include advice that patients are strongly discouraged from checking into hotels immediately following treatment.

Status: On 7/23/11, the NRC directed the agency staff to evaluate the potential need for and feasibility of a study to determine radiation doses to members of the public due to the release of patients treated with medical radioisotopes. A Staff Requirements Memorandum said the staff “should evaluate whether there are gaps in the available data regarding doses being received by members of the public due to the release of patients treated with medical isotopes, as well as how the agency could go about collecting additional data, if needed.” The staff was directed to present recommendations to the Commission. The study should also “fully utilize” previous studies on patient release.

Action: CORAR should monitor any progress on this effort to identify opportunities where involvement is warranted.

30. IAEA BSS Final Publication (L. Smith)

Background: 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 11/11/09 and on Draft 3.0 on 2/10/11, 2010. Draft 4.0 was published by IAEA on 9/9/10 but the 2/10/10 CORAR comments on Draft 3.0 were not included and there was no mention of CORAR as a comment contributor. Some comments provided to ISSPA in collaboration with them have been included in the table and four of those comments appear in the IAEA resolution table. Draft 4.0 which took account of more than 1,500 comments from the Member States, was published on 11/11/10, with agreed recommendations and edits incorporated into Draft 5.0.

Status: On 9/12/11, the IAEA Board of Governors approved Draft 5.0 and the revised BSS are published as General Safety Requirements Part 3 (Interim) in the IAEA Safety Standards Series in an Interim Edition, pending final editing and typesetting.

Action: Monitor and continue to partner with individuals to ensure representation at IAEA and seek further recognition as NGO status.

31. NRC Draft Reg Guide DG-8050, “Applications of Bioassay for I-125 and I-131” (L. Smith)

Background: On 09/26/11 the NRC issued notice of this draft revision of Regulatory Guide 8.20 for public comment.

Status: Comments were submitted by CORAR on 11/21/11. NRC agreed to rename this RG to be “Applications of Bioassay for Radioiodine” and broaden the scope to include I-123 and I-124. On 01/18/12 CORAR submitted further information to the NRC on practices in handling these accelerator produced radioiodines.

Action: CORAR should monitor any developments and be prepared to assist further.

32. HPS/ANSI N.13 Standards Committee (L. Smith)

Background: CORAR is represented as a member of the Health Physics Society/American National Standards Institute (HPS/ANSI) N13 Accredited Standards Committee which has oversight of national radiation protection consensus standards. The N13 Committee votes to approve the need for each proposed radiation protection standard and the chairman and each member of each standard writing group and each finalized standard. 2011 has been N13's most productive year. The Committee continued to eliminate obsolete membership and standards and has made a concerted effort to update viable standards and has updated its operating procedures and information on the HPS website.

Status: CORAR commented on specified dates on the following standards still in process:
N 13.27, Dosimetry Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters. 09/25/07.

N 13.XX, Ionizing Radiation Health Dose. 03/26/09.

N 13.41, Criteria for Performing Multiple Dosimetry. 04/10/09, 06/29/11

N 13.56, Sampling and Monitoring Releases of Airborne Radioactivity in the Workplace. 02/25/10

N 13.45, Incineration of LLRW. 10/26/10.

N 13.12, Surface and Volume Radioactivity Standards for Clearance. 05/02/11, 10/19/12.

N 13.14, Bioassay Program for Tritium. 02/13/12

Action: 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.

33. ANSI/HPS Draft N 13.14, "Bioassay Program for Tritium" (L. Smith)

Background: CORAR has participated in previous versions of this reissued Standard.

Status: On 02/13/12 CORAR submitted substantive comments on this draft Standard.

Action: Monitor.

34. ANSI/HPS Draft N 13.41, "Criteria for Multiple Dosimetry" (L. Smith)

Background: CORAR approved this Standard on 04/10/09 but also provided comments to improve it.

Status: CORAR comments were not addressed and were resubmitted on 06/29/11.

Action: Be prepared to address further questions on this Standard.

35. ANSI/HPS Draft N 13.45, "Incineration of LLRW" (L. Smith)

Status: This Standard was revised to include most of CORAR's comments and approved by CORAR on 11/03/11.

Action: Monitor as pending issue.

36. ANSI/HPS Draft N 13.56, "Sampling and Monitoring Releases of Airborne Radioactivity in the Workplace" (L. Smith)

Status: This Standard was revised to include most of CORAR's comments and was approved by CORAR on 10/31/11.

Action: Monitor as pending issue.

37. ANSI N 14.36 Committee (L. Smith)

Background: 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.

Status: M. A. Charette and L. Smith joined this committee and assisted in the development of a scope statement completed on 10/10/06. CORAR members are serving on the standard's writing committee. The draft Standard has adopted a graded approach to monitoring packages that accommodates our industry practices. This Standard was approved by the N14 Committee on 04/01/11, with minor comments that have been addressed, and is still in process.

Action: Continue supporting this Committee as needed.

38. NCRP Collaboration Committee (L. Smith)

Background: CORAR is established as a collaborating organization with the NCRP and as such has the opportunity to review and comment on draft NCRP reports.

Status: Draft NCRP reports in process of interest to CORAR include:

- Radiation Health Issues Associated With Use of Detection Technology Systems for Detection of Radioactive Threat Materials.
- Health Effects of Radiation on the Gamete, Embryo, Fetus and Nursing Infant.

Action: Continue supporting this Committee

39. NCRP Draft Commentary SC1-19 – Screening Cargo (L. Smith)

Background: The NCRP issued draft Commentary SC1-19, "Radiation Health Issues Associated With Use of Detection Technology Systems for Detection of Radioactive Threat Materials"

Status: CORAR submitted comments to the NCRP on 09/01/11.

Action: Monitor.

40. NCRP Draft Report SC 4-4- Pre- and Postnatal Radiation Health Effects (L. Smith)

Background: On 02/16/12 NCRP issued draft report SC 4-4-Health Effects of Radiation on the Gamete, Embryo, Fetus and Nursing Infant.

Status: CORAR issued comments to the NCRP on 03/22/12.

Action: Monitor.

41. ICRP Recommendations (L. Smith)

Background: CORAR submitted comments to the International Commission on Radiological Protection on ICRP 103, published in 2007, and to ICRP Committee 2 Task Group on draft guidance document on the "Interpretation of Bioassay Data". On 03/31/11 CORAR submitted comments on "Early and Late Effects of Radiation in Normal Tissues and Organs: Threshold Doses for Tissue Reactions and Other Non-cancer Effects of Radiation in a Radiation Protection Context."

Status: On 10/24/11 and 10/25/11, M Doruff attended the ICRP Symposium on the International System of Radiological Protection and offered CORAR's participation on any ICRP Committee efforts to develop recommendations or assess implementation of optimization in industry policies and practices. On 03/16/12 CORAR reviewed "Draft Report for Consultation- Occupational Intakes of Radionuclides Part 1" which introduces a new series of reports on limits on intakes to be published during the next 3 years. CORAR was invited to submit comments but this did not appear to be needed. ICRP 119, "Compendium of Dose Coefficients Based on ICRP60" was released as a free download on 9/20/12. On 11/23/12 the ICRP announced plans to expand formal relations with organizations.

Action: Consider applying to ICRP for "Special Liaison Organisation" status. CORAR is preparing comments, due in December 2012, on Draft Radiation Protection in Security Screening and Draft Occupational Intakes Part 2 and Part 3. Continue monitoring ICRP developments and be prepared to participate and provide technical information on radiation protection.