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Attached are the Council on Radionuclides and Radiopharmaceuticals comments on RSPS-TF. A signed copy has been sent by overnight courier.

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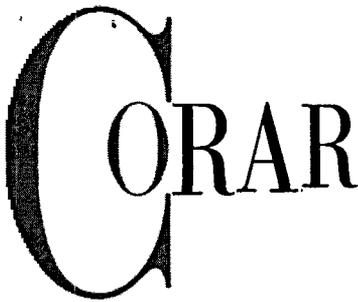
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February 8, 2006

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**RE: (RSPS-TF) Radiation Source Protection and Security Task Force; Request for Public Comment.  
FEDERAL REGISTER Vol 71, No 17, January 11, 2006.**

These comments concerning Radiation Source Protection and Security Task Force are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications.

CORAR member companies have been subject to the numerous security regulations recently promulgated as well as the orders for safeguarding sensitive information and enhancement of security measures. CORAR understands the need to ensure that radioactive sources are adequately secured from potential criminal or terrorist threats. Its member companies have taken necessary precautions, whether mandated by regulation or in a voluntary capacity as a result of internal risk assessment, to enhance the protections afforded to this material. At the same time we have come to appreciate that the resources required to implement and maintain security enhancement measures are also in demand to manufacture and distribute our products and to ensure that other radiation protection obligations are fulfilled. The network in which our short-lived and time sensitive products are manufactured and delivered for medical diagnosis and treatment is vulnerable to any measures that may cause interruptions or delays in the supply chain. In the efforts to satisfy the obligations established in the Energy Policy Act of 2005, the task force must take into account the potential impact any recommended actions may have on the medical radioisotope supply chain by making the necessary risk-benefit assessments and including industry representatives in the necessary discussions.

A common theme that runs throughout the various topics in the NRC request for public comment is that many of the activities mandated by the Energy Policy Act of 2005 have already been addressed, some in duplicative or conflicting measures, by agency orders, regulations and recommendations of standards-setting

organizations. There is, therefore a profound need for the task force to address current and avoid additional duplication and conflict.

The wide range of government agencies comprising the task force includes many of the constituents of the Government Coordinating Council, responsible for collaborating with DHS and the private sector on actions required by the protection plan for the nuclear sector. CORAR members have been active in this effort and strongly urge the task force to take into account the work already done in this collaboration to 1) ensure that the agencies are on the same page in terms of promulgating any new regulations and 2) leverage the experience and technical knowledge of industry in matters pertaining to radiation sources and their security by providing the opportunity for their participation in task force proceedings.

With these concerns and as a significant stakeholder in the issue of radiation source security, CORAR appreciates the opportunity to provide the following comments and information concerning the topics for discussion in the NRC Request for Public Comments.

***Topic No. 1 – The list of radiation sources requiring security based on potential attractiveness of the source to terrorists and the extent of the threat to public health and safety.***

- CORAR strongly urges the NRC and the task force to be consistent in its approach to categorization for applicability of source protection and security measures with the IAEA Code of Conduct thresholds for specific radionuclides and activities.
- The task force should collaborate with the Government Coordinating Council as part of the effort to establish the Nuclear Sector Infrastructure Protection Plan to ensure that their approaches to enhance security do not conflict and to have access to the same input from the radionuclide sub-sector of the Nuclear Sector Coordinating Council regarding the assessment of risk from radiation sources in their numerous applications. It must be noted that industry representatives have provided significant input to NRC and DHS regarding the radionuclides, activities and relative risk of radioactive materials and sources in the variety of non-nuclear power and fuel cycle applications. This input was provided with the understanding that it was needed to characterize the applications in terms of relative risk so that certain applications using higher risk materials would be given priority consideration in allocation of resources determined to be necessary for protective purposes within the radionuclide sub-sector of the nuclear infrastructure. The approach taken to characterize these materials was determined to be consistent with that taken by the NRC and the IAEA Code of Conduct in terms of radionuclides and activities warranting priority status.
- A radiation source is defined in Section 170H in the Energy Policy Act of 2005 as a Category 1 Source or a Category 2 Source, as defined in the Code of Conduct; and any other material that poses a threat such that the material is subject to this section, as determined by the Commission, by regulation, other than spent nuclear fuel and special nuclear materials. This definition leaves open the potential for Category 3 and other materials to be considered by the task force. The approach taken by the Task Force to determine the scope of applicability of enhanced security measures needs to stay on course with existing domestic and international regulations and standards by limiting this to IAEA Code of Conduct Category 1 and 2 sources. The security of other materials such as non-source material and including those in Category 3 could be regulated, if warranted, by site-specific license conditions and by existing regulations such as those for sites (10 CFR 20, Subpart I), and in transport (49 CFR 172).
- With regard to consideration of Category 3 sources, CORAR has the concern that some radiopharmaceuticals may fall into the scope of this, particularly Mo-99 generators with activities greater than 0.3 TBq, the threshold of Category 3 in IAEA TECDOC-1344. Mo-99 should not be subject to the enhanced security measures required for Categories 1 and 2. It decays too rapidly to be practicable for malevolent use and it is used in dispersed locations making it difficult to aggregate. Other medical radioisotope products such as radioiodine therapy products and low activity brachytherapy devices may also be needlessly subjected to

enhanced security measures if included as Category 3 materials. Radioiodines also tend to have short half-lives and if I-131, for example, were to be deployed in an RDD, it would be rapidly dispersed and diluted in atmosphere, having potential significant effect on those located very close to the point of release. In light of this, CORAR contends that I-131 and Mo-99 in Category 3 should not be included as radionuclides of concern. In addition, CORAR strongly emphasizes the need to adhere to the provision, also in Section 170H, for the Commission to consider the impact on the availability of radiopharmaceuticals to physicians and patients.

- In addition to the preceding comments concerning the definition of a radiation source in Section 170H, CORAR believes that there has already been a significant amount of technical assessment as the basis of IAEA standards and regulations, including those of the NRC, that concludes the scope of applicability for enhanced security measures should be Category 1 and 2 sources. The task force needs to take the same approach to ensure that the appropriate effort and resources are allocated on a priority basis to these higher risk materials and to be consistent with the established standards and regulations.

- Regarding security of radiation sources in transport, the task force needs to take into consideration the "Security of Radioactive Material during Transport: Specific Guidelines" being developed by IAEA to ensure consistency with this document.

***Topic No. 2 – The national system for recovery of lost or stolen radiation sources.***

- CORAR members have been diligent in the accountability of radioactive sources and acknowledge the importance of timely reporting of missing, lost or stolen materials to the appropriate agency or authorities. However, we are concerned that a very conservative approach (in terms of quantity of activity) that some agencies have taken regarding reporting expectations on licensees, has resulted in the needless expenditure of valuable resources to report and investigate on an escalated basis the temporary misplacement of exempt or very small quantities of extremely low risk materials (e.g. packages containing microcurie quantities of short-lived gamma emitters that are not delivered as expected, traced over a 24 hour period and then accounted for by the carrier a day or two later). There need to be more reasonable and practical requirements for the reporting of missing material. These need to be consistent across all jurisdictions and with a level of escalated activity that is commensurate with the level of potential risk the material presents. The most rigorous reporting and tracking requirements should be limited to Category 1 and 2 sources and any move to expand this scope should consider the impact on industry. CORAR is available to provide the task force with the metrics on this and should be called upon to participate.

- CORAR commends the efforts taken by the NRC, DOE and Conference of Radiation Control Program Directors to establish and implement the national Off-Site Source Recovery Project (OSRP). CORAR members have benefited from the support and technical expertise this program provides, and our only concern is that this program needs to be reinforced with additional funding and technical resources to ensure that ongoing needs to recover and provide responsible custody of problematic sources are addressed. Alternatively, funding should be provided along with collaboration with private industry to bridge the gap between OSRP and source owner resources.

- The task force needs to take a look at factors that have contributed to the abandonment of sources in the first place. Most of these have to do with the lack of available options for the disposal of sources, particularly GTCC waste and problematic sources such as those that are leaking, have lost their special form status or do not meet the authorized configuration of a Type B container. More flexibility regarding containers authorized for greater than Type A shipments needs to be afforded to those transferring sources to responsible storage or disposal sites. Another contributing factor that has made it difficult for sources to be returned to overseas manufacturers has been the regulatory framework in which sources no longer used are defined as

“radioactive waste” and are then subject to the rigorous licensing and export/import authorization processes that essentially make this an unworkable option for responsible source management.

- Another significant factor contributing to the inability to ensure responsible source disposition is the lack of an available and cost effective disposable option. CORAR fully supports the view of the Health Physics Society as stated in their 2005 Position Paper entitled “Low-Level Radioactive Waste Management Needs a Complete and Coordinated Overhaul.” In addition, the obligations of the Federal Government to provide for the disposal of GTCC waste have yet to and need to be fulfilled.

***Topic No. 3 – Storage of radiation sources that are not used in a safe and secure manner.***

- CORAR believes that there are adequate regulatory requirements for the secure storage of radioactive material. The additional measures mandated in NRC Orders to enhance the security of “quantities of concern” sources in storage are warranted but should not be expanded to include Category 3 sources or other materials. This is particularly true for quantities of Mo-99 and I-131 in Category 3 of TECDOC-1344 because imposition of enhanced security and safeguards requirements would result in an excessive burden on the resources of the healthcare community.

- The industry that CORAR represents should be allowed to participate in task force proceedings to enable it to convey its experience and share best practices regarding responsible and competent handling and storage and to enlighten the task force as to regulatory and other obstacles than hinder progress toward securing safe storage and transfer. Some of these difficulties have been highlighted in our comments on Topic 2, above, but CORAR encourages NRC to take advantage of the opportunity to get our industry directly involved to enable additional details to be conveyed in an appropriate venue.

***Topic No. 4 – The national source tracking system for radiation sources.***

- We agree in principle with the NRC proposed rule for tracking Category 1 and 2 sources, but prospective users and the NRC must be given sufficient time to validate the system and to ensure an effective allocation of resources to launch and maintain it before it can be implemented in accordance with the timing prescribed in the regulatory mandate. CORAR also agrees with the need for enhanced accountability of radiation sources with the rigor of the system to be commensurate with the magnitude of risk posed by the sources to be tracked. The scope of the tracking system to the extent described in the PR needs to be limited to Category 1 and 2 sources to avoid the overextension of available but limited resources to materials that pose relatively low risk, particularly sources and other materials that are used for medical imaging and diagnosis. Any initiative to include all Category 3 sources, at least categorically, in the system must include a risk-benefit analysis and should take into account some of the work being done by the Nuclear Sector and Government Coordinating Councils. The industry that CORAR represents is in a position to provide metrics for this assessment and should be called upon to participate.

***Topic No. 5 – A national system to provide for the proper disposal of radiation sources.***

- Again, CORAR commends the efforts of the NRC, DOE and Conference of Radiation Control Program Directors to establish and implement the national Off-Site Source Recovery Project (OSRP) and we urge that this program be bolstered financially to enable it to meet outstanding needs for retrieval and disposal of problematic sources.
- CORAR understands that the NRC and Agreement States need to ensure financial surety is established for the radioactive materials possessed by their licensees so that provisions are available to address decommissioning of sites where the owners or operators no longer have the financial means to properly dispose of residual sources and materials. However, consistent with comments CORAR made in December

2002 concerning the proposed amendments to the financial assurance requirements in 10CFR30, there are problems with NRC's financial assurance requirements. First of all, it is the experience of our industry that estimates of decommissioning costs have been artificially inflated by the mandatory assumption that all material, including that in finished goods inventory, is a liability with an associated disposal cost. The regulations also fail to recognize that while decommissioning costs may have increased over the years, newer facilities may have incorporated designs and practices that, overall, would decrease the cost of decommissioning.

- A more fundamental concern of CORAR is one that has implications for any regulation having to do with decommissioning financial assurance. The current regulatory approach regards sealed sources as a decommissioning liability regardless of their current value and despite the fact that there is no clear definition of radioactive "waste."

Historically, the term "waste" has been generally applied to sealed sources at the end of intended use regardless of whether they can be reused by someone else or their contents recovered as feedstock or reworked to extend the useful life of the sources. There are differing definitions in 10CFR63.2 and 10CFR110.2 with the latter specifically exempting sealed sources being returned to any qualified manufacturer from the import and export of waste regulations. In other contexts, there is no meaningful definition of radioactive "waste" as it applies to sealed sources or other radioactive materials. We take the position that the NRC cannot propose to define in a reasonable and practical sense the meaning of the term "waste broker" when the meaning of "waste" remains unclear.

Regardless of the lack of a clear definition of radioactive "waste," there is also a conflict in NRC policy and regulation as, on one hand some sealed sources are exempted from the definition of "waste" while, on the other hand, sources are included in the scope of licensed material subject to decommissioning financial assurance. The existing financial assurance requirements do not give credit to the licensee for the residual value of sources and, as a result, treat assets as liabilities, particularly in the tests used to determine whether or not a licensee can be self-insured.

- Regardless of the inadequacies CORAR believes exist in the financial assurance regulations, the cost basis of these provisions in any regulatory framework would be far less if the obstacles to efficient disposal of radiation sources, some of them highlighted in the discussion on Item 2, above, were removed. Again, there is a need to ensure economic access for disposal of radioactive waste. The elevated financial surety costs associated with this lack of a cost effective disposal option must be considered by the task force in the context of financial assurance as well. CORAR strongly supports the mandate in Section 631 of the Energy Policy Act of 2005 that requires designation of an office within DOE charged with responsibility for developing a new or using an existing facility for safely disposing of all low-level radioactive waste with concentrations of radionuclides that exceed NRC limits for Class C radioactive waste (GTCC waste); and development of a comprehensive plan for permanent disposal of GTCC waste, including plans for a disposal facility.
- CORAR finally recommends that the task force focus on the need to establish a national program to provide for the timely, cost effective and responsible disposal of radiation sources rather than impose burdensome financial assurance requirements on licensees and source owners. An alternative to a national program would be funding for responsible commercial entities in the U.S. to provide these services that would ultimately reduce the likelihood of lost, stolen or abandoned sources.

***Topic No. 6 – Import and export controls on radiation sources to ensure that recipients of radiation sources are able and willing to adequately control radiation sources.***

- Return of sources no longer used to foreign manufacturers of sources is subject to the regulatory framework in which these sources are defined as "radioactive waste" and are then subject to the rigorous

licensing and export/import authorization processes that makes this option for responsible source management unavailable. There is also a gap between NRC's Export and Import rule and the need for guidelines on the process and adequate time for affected licensees to make the necessary changes in procedures. Including Category 3 materials in the scope of these regulations should not be considered as it would result in an unwarranted burden on licensees. Any discussion to include these materials would need to be conducted with the participation of industry representatives.

- There are differences between NRC orders to licensees for safeguards and enhanced security measures and the amendments to 10CFR110 for Export and Import of Nuclear Equipment and Radioactive Materials. There are also issues regarding licensee obligations in the NRC orders, however these cannot be communicated here because of the sensitive nature of this information and the need for safeguards.

***Topic No. 7 – Procedures for improving the security and control for use and storage of radiation sources.***

- NRC Orders and implementing guidance contain expectations that are ambiguous and in some cases misleading. Many of these additional controls imposed on licensees are considered sensitive information and protected by safeguards. With this in mind, CORAR finds it difficult to discuss here any inconsistencies between these requirements and those in the regulations. This is additional justification in support of comments above to have the Task Force collaborate with the NSCC and GCC, and to engage representatives of our industry in task force proceedings.
- CORAR has previously commented on the inconsistent format and terminology of Agreement State licenses and how this complicates the process for verification of recipient licenses by manufacturers and distributors of radioactive materials. There is a potential for material to be received by unauthorized individuals. NRC and the task force should be encouraged to collaborate with the Organization of Agreement States and the Conference of Radiation Control Program Directors to ensure consistency.

***Topic No. 8 – Procedures for improving the security of transportation of radiation sources.***

- Another inconsistency is the difference between the radioactive transport security measures in 49CFR172 that, for example, apply to Yellow-III packages, and those required by NRC regulations. There needs to be consistency in thresholds of applicability regarding quantities of radionuclides and the specific measures to be performed when applicable. As recommended earlier in these comments, the task force needs to take into consideration the "Security of Radioactive Material during Transport: Specific Guidelines" being developed by IAEA to ensure consistency with this document.
- Shippers required to develop and implement a Transportation Security Plan in accordance with 49CFR172 are also required to complete a risk assessment to determine which materials were subject to these requirements and applicable security measures. On May 18, 2004, TSA published an Interim Final Rule that subjects those involved in transportation activities to measures for protecting sensitive security information (SSI), effective June 17, 2004. The rule was unclear as to the extent of applicability but could apply to shippers and carriers who have completed a vulnerability assessment. If this is the case, compliance is problematic as the TSA requirements pose conflicts with those of 49CFR172, particularly related to training and communication of information. TSA and DOT published a technical amendment on January 7, 2005 clarifying that the "need to know" limitations in the rule apply not only to air and maritime transport but to all modes. CORAR maintains that compliance expectations are conflicting and request that additional rulemaking that the January 2005 notice stated is forthcoming, address this concern. In the meantime, the Task Force needs to be aware of this conflict and the need for it to be resolved.
- The task force needs to take into account the difference in transport security requirement imposed by the various agencies with jurisdiction over a single consignment and consider that these inconsistencies have

put shippers and carriers in a position of unattainable compliance and this, along with the complexity of the regulatory landscape, has discouraged some carriers, particularly in the air mode, from accepting radioactive shipments. This is an issue that has been recognized by the industry as well as some agencies including IAEA as a threat to the radiopharmaceutical and medical radioisotope supply chain.

***Topic No. 9 – Background checks for individuals with access to radiation sources.***

- Safeguard requirements for sensitive information prevents the type of communication between commercial operations that could lead to gaps in security measures. The process to fulfill Section 149 of the Atomic Energy Act needs to be developed as a result of collaboration between agencies with relevant threat assessment requirements to avoid duplication or conflicting requirements. Since most of the personnel threat assessment requirements in existing regulations are limited to those who have access to Category 1 and 2 sources, any additional measures should be applicable to these materials. If there are any conflicts or gaps between existing and additional measures, these need to be resolved.

***Topic No. 10 – Alternative technologies.***

- While we appreciate the intent of the arrangement to have the National Academy of Sciences conduct an analysis of alternative technologies that would replace the use of radiation sources, it is our view that most of the low-hanging fruit may have already been harvested. The increasing economic, regulatory and practical burdens on applications using radioactive materials, some related to the cost of decommissioning and waste disposal as discussed above, have been driving the users of radiation sources to seek alternatives. Where alternatives have become available, it is very likely that these have already been employed. In some areas, particularly in the use of sources and radioactive material in the diagnosis and treatment of illnesses, alternatives may be available but the physical and economic impact as well as the detriment to quality of patient care may outweigh the perceived benefit of having eliminated the use of radiation sources. In the search for alternative technologies, it is important to ensure that this effort does not present additional burdens on the use of radiation sources in applications where alternatives have not been identified.

- In addition to the economic, regulatory and practical factors driving users away from the use of sources or toward any available alternatives, the development and implementation of positive incentive programs should be considered

CORAR appreciates the opportunity to comment and would be glad to assist the RSPS-TF by providing information or further clarification as needed.

Sincerely yours,

Leonard R. Smith CHP.  
Co-Chairman CORAR Manufacturing Quality and Safety Committee.