

Senate Health, Education, Labor and Pensions (HELP) Committee passes S. 1042 CARE legislation out of committee

On Thursday, March 13, 2008, the Senate HELP committee voted to move forward the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy bill, or CARE bill (S. 1042) out of committee. I would like to thank all of the AAPM and ACMP members that have responded to the various "Calls for Action" and contacted their Congressional representatives. If you have not done so, it is not too late go to: <http://capwiz.com/aapm/home/> and follow the instructions for calling or emailing your members. If you have contacted your members, please follow up and ask what action have they taken based on your request. The next major effort will be focused on the Senate Finance committee and having S.1042 voted on by the full Senate. This will be followed by a push in the House. If you have questions, please contact, Lynne Fairbent, AAPM's manager of Legislative and Regulatory Affairs at lynne@aapm.org.

National Academies of Science/National Research Council (NAS/NRC) issues report on "Radiation Source Use and Replacement"

The NAS/NRC completed a study requested by the Congress to address concerns that devices containing cesium-137 and other high-risk radionuclides could be stolen for use in a terrorist attack, i.e., as a potential ingredient for a dirty bomb. The committee that wrote the report was asked to examine the uses of high-risk radiation sources and to identify lower-risk alternatives.

The overall conclusion reached by the Panel was that "the U.S. government should take steps to promote the replacement of radioactive cesium chloride radiation sources, a potential "dirty bomb" ingredient used in some medical and research equipment, with lower-risk alternatives." Copies of Radiation Source Use and Replacement are available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at http://www.nap.edu/catalog.php?record_id=11976. This study was sponsored by U.S. Nuclear Regulatory Commission.

The following summarizes the Findings and Recommendations of the Committee.

Finding 1: The radiation sources examined in this study are used in applications that are important to the nation's health, safety, and economic strength.

Recommendation 1: Replacement of some radionuclide radiation sources with alternatives should be implemented with caution, ensuring that the essential functions that the radionuclide radiation sources perform are preserved.

Finding 2a: The U.S. NRC ranks the hazards of radiation sources primarily based on the potential for deterministic health effects (especially death and severe bodily harm) from direct exposure to the radiation emitted by the bare (unshielded) sources. The U.S. NRC's analyses that support the commission's security requirements for nuclear materials licensees are based only on these potential consequences.

Finding 2b: Factors other than the potential to cause deterministic health effects are important when evaluating hazards from radiation sources, especially the potential to cause contamination of large areas resulting in economic and social disruption (area denial).

Recommendation 2: For prioritizing efforts to reduce risks from malicious use of radiation sources, the U.S. NRC should consider radiation sources' potential to cause contamination of large areas resulting in economic and social disruption (area denial) to determine what, if any, additional security measures are needed.

Finding 3a: Because of its dispersibility, solubility, penetrating radiation, source activity, and presence across the United States in facilities such as hospitals, blood banks, and universities, many of which are located in

large population centers, radioactive cesium chloride is a greater concern than other Category 1 and 2 sources for some attack scenarios. This concern is exacerbated by the lack of an avenue for permanent disposal of high-activity cesium radiation sources, which can result in disused cesium sources sitting in licensees' storage facilities. As such these sources pose unique risks.

Finding 3b: In view of the overall liabilities of radioactive cesium chloride, the committee judges that these sources should be replaced in the United States and, to the extent possible, elsewhere.

Finding 3c: In most (and perhaps all) applications, radioactive cesium chloride can be replaced by (1) less hazardous forms of radioactive cesium, (2) radioactive cobalt, or (3) non-radionuclide alternatives. However, not all of these alternatives are commercially available now, and all are currently more expensive than radioactive cesium chloride for the users.

Finding 3d: Government action is required to implement replacement of radioactive cesium chloride sources because the alternatives cost more and the liabilities or social costs of the sources currently are not borne by the end users.

Recommendation 3: In view of the overall liabilities of radioactive cesium chloride, the U.S. Government should implement options for eliminating Category 1 and 2 cesium chloride sources from use in the United States and, to the extent possible, elsewhere.

The committee suggests these options as the steps for implementation.

- i. Discontinue licensing of new cesium chloride irradiator sources.
- ii. Put in place incentives for decommissioning existing sources.
- iii. Prohibit the export of cesium chloride sources to other countries, except for purposes of disposal in an appropriately licensed facility.

Finding 4a: Non-radionuclide replacements exist for nearly all applications of Category 1 and 2 radionuclide sources (not just radioactive cesium chloride). At this time, these replacements may not all be practical or economically attractive, but most of them are improving.

Finding 4b: Neither licensees nor manufacturers now bear the full cost of liabilities related to misuse of Category 1 and 2 radiation sources, nor do they bear the costs of disposal of cesium and americium sources.

Recommendation 4: In addition to actions related to radioactive cesium chloride, the U.S. government should adopt policies that provide incentives (market, regulatory, or certification) to facilitate the introduction of replacements and reduce the attractiveness and availability of high-risk radionuclide sources.

Finding 5: Accelerator neutron sources and californium-252 sources show promise as potential replacements for americium-beryllium sources in neutron well logging tools. However, there are technical obstacles for these replacement sources and they are at a sources.

Recommendation 5: The Society of Petrophysicists and Well Log Analysts (SPWLA) should task an industry working group, called a "Special Interest Group" (SIG) such as the Nuclear Logging SIG, to address the technical obstacles to implementing replacements for the americium-beryllium sources used in well logging and the challenges of data interpretation. The group should decide what obstacles are most important, but the issues might include development of new reference standards for these replacement tools, examination of the response of these tools relative to the americium-beryllium tools, and exploration of any differences in response when the replacement tools are used in combination with other nuclear and non-nuclear well logging tools.

The Nuclear Regulatory Commission (NRC) is already addressing many of the issues raised by the National Academies and its recommendations. The Radiation Source Protection and Security Task Force, mandated by

Congress in the Energy Policy Act of 2005, is analyzing potential impacts of so-called “dirty bombs” and radiation exposure devices, the potential for replacing cesium chloride sources, and alternative technologies for radioactive sources.

Report of the NRC’s Independent External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission’s Materials Licensing Program”

On October 2, 2007, the Commission chartered the Independent External Review Panel (the Panel) as part of the U.S. Nuclear Regulatory Commission’s (NRC) Government Accountability Office (GAO) Action Plan (SECY-07-0147 see link:

<http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2007/secy2007-0147/2007-0147scy.pdf>). This report provides the Panel’s observations and recommendations. The Panel’s membership includes Thomas E. Hill, Benjamin W. Nerud, and Michael T. Ryan. The Panel conducted seven meetings over the last 6 months in accordance with the requirements of the Federal Advisory Committees Act. The Panel gathered information from NRC and Agreement State staff, interested stakeholders, and members of the public. During each session, the Panel allotted time for input from members of the public and other interested stakeholders. Appendix A provides a list of definitions of terms used in this report. A copy of the Panel’s full report can be found at: <http://www.nrc.gov/reading-rm/doc-collections/commission/slides/2008/20080318/independent-external-review-panel-final-report.pdf>.

The overall conclusion of the Panel was that NRC has a clear record of success regarding health, safety, and environmental protection and has performed these functions in an excellent manner. Because of the changing environment resulting from the threat of malevolent actions, such as those demonstrated by U.S. Government Accountability Office (GAO), **security must be upgraded as a fourth cornerstone to NRC operations.** (See report GAO-07-1038T July 12, 2007 <http://www.gao.gov/docsearch/abstract.php?rptno=GAO-07-1038T>.) Appropriate security of radioactive materials requires seamless control and coordination among all stakeholders including the NRC (including import/export authorizations), the Agreement States, license applicants and licensees, and many commercial companies involved in managing radioactive materials. The ultimate goal of this coordinated effort is to achieve risk-informed and cost-effective protection.

The Panel has addressed each of the specific areas listed in its charter, as follows:

1. List (with explanations) of vulnerabilities concerning the NRC’s licensing and tracking programs for import, export, specific, and general licenses (GL). (Observations and Recommendations 2, 3, and 6)
2. Validate the Agency’s ongoing byproduct material security efforts. (Observations and Recommendations 3 and 4)
3. Evaluate the apparent “good faith presumption” that pervades the NRC licensing process. (Observations and Recommendations 1 and 8)
4. Evaluate the Agency’s Pre-Licensing Guidance; Licensing Procedures and Licensing Process; License Possession Limits; and License Reviewer Training and Oversight. (Observations and Recommendations 1, 3, 5, and 7)

The following summarizes the recommendations:

Recommendation 1a

The Panel recommends the following for “new applicants,” as defined in Appendix A, and for licensees requesting changes to their authorized quantities of radioactive materials to a higher-risk Category (e.g., from Category 3 to Category 2):

1. The “good faith presumption” is temporarily suspended.

2. A review of health, safety, environmental, and security plans is performed. (Data contained in these plans should meet the essential objectives found in NUREG-1556. In addition, reviewers should ensure that all plans are tailored to the operation rather than just a reiteration of the requirements as worded in the licensing guidance. A lack of specificity in an application may be an indicator of an inexperienced applicant.)
3. An on-site visit is performed, including all locations identified on the license application where the material will be stored or used (excluding devices designed for mobile use such as moisture density gauges and well logging devices).
4. A background investigation is conducted of key personnel, including responsible members of management, the Radiation Safety Officer, and personnel with unescorted access.
5. A review of plans for activities using the requested radioactive materials is conducted to verify that the activities comport with the approved uses for the requested sources/devices.

Additional information that could be reviewed may include:

- verification of business licenses and registrations
- tax number verification from the Internal Revenue Service or a State agency
- financial records that validate legitimate business activities
- reference checks and credential verifications for key individuals on the license application
- customer reference checks

Recommendation 1b

The Panel recommends that a process and criteria be developed that will allow “new applicants” to obtain and use radioactive materials and over time and through inspection be recognized for having a record of credible performance leading to the establishment of trust.

The Panel believes that this process is *not* necessary for licensees who have a current history of performance under other NRC or Agreement States licenses that are supported by inspections.

Recommendation 2

The Panel recommends that information specific to the review and decisionmaking procedures used by license reviewers to evaluate and grant licenses be examined to determine if the release of this information provides an advantage to an adversary attempting to exploit the licensing process. This is not intended to restrict information that is designed to help an applicant prepare a complete license application.

The Panel recommends that the Commission consider expanding the current operational security program to include materials licensing guidance and the processes for review and issuance of licenses. Specific elements of this program that require development include the following:

1. Identifying the information needed by an adversary to exploit the licensing process.
2. Conducting a thorough review of all licensing guidance to identify publications containing exploitable information.
3. Conducting a risk-informed analysis in order to identify the benefit that may be associated with currently available licensing information for legitimate applicants, as opposed to the advantage provided to an adversary.
4. Establishing and implementing measures to safeguard and control the release of some licensing information.

Recommendation 3a

The Panel recommends that the NSTS and WBL be integrated to allow for real-time sharing of information between the systems. This integrated system should be developed so it is easy for the NRC, Agreement States, and licensees to use. The Panel believes that resources that would be needed to select and implement

more robust license documents are better used in creating a single web-based, real-time licensing and tracking database.

To realize the full potential of the system, it should include the following features:

1. The system must be integrated to provide licensees, vendors, and regulators controlled access (as appropriate) to license information to verify licenses and to properly accomplish transfers of radioactive materials between licensees in accordance with the terms and conditions of each party's license and the regulations.
2. The system must be designed so that the record of transactions is accomplished at the time the transaction is made to allow for real-time verification of transfer of sources.

Recommendation 3b

The Panel recommends that licenses be confirmed for *all* transfers of radioactive materials in risk-significant quantities (Category 1, 2, and 3 or as otherwise determined by the Commission) until the real-time WBL/NSTS is up and running. The Panel recognizes there are frequent transfers of radioactive materials in risk-significant quantities between parties where there is a record of credible performance leading to the establishment of trust (Recommendation 1b). This may require an exception to this recommendation.

Recommendation 3c

The Panel recognizes that the WBL/NSTS system will take time and resources to develop and recommends that a plan be developed for a phased approach by taking the following steps:

1. Develop and test the system.
2. Get Agreement State and licensee input and participation in the development and trials using the system.
3. Roll out and implement the system.

Resources to support this effort will need to involve planning for NRC and Agreement State participation from the first stages of development through rollout and ongoing support for continued use of the system.

Recommendation 4

The Panel recommends development of detailed physical security requirements using a risk-informed, graded approach. These standards would likely be more detailed than the requirements currently found in IC Orders. This would help assure that physical protection of licensed materials is in conformance with a risk-informed decisionmaking process regarding security and safeguards issues. In addition, licensees would be afforded the information necessary to understand the requirements and costs associated with risk-informed security controls. The Commission may wish to consider whether additional Orders or rulemakings are appropriate to impose more detailed, risk-informed security controls.

Recommendation 5a

The Panel recommends that security be incorporated into the licensing culture of NRC and Agreement State license reviewers. Security should be elevated to be equal with health, safety, and the environment in evaluating license applications in a risk-informed manner. This heightened state of awareness can best be accomplished by ensuring that training programs include more comprehensive training on security issues, aimed at recognizing a malevolent applicant.

Recommendation 5b

The Panel recommends that licensing personnel be provided the tools and training necessary to make risk-informed decisions that address security aspects as well as health, safety, and environmental protection. These tools could include the following:

1. A threat awareness program designed to inform personnel on the current tactics, techniques, and procedures of adversaries; current threat information; and distribution of lessons learned and best practices.

2. Increased emphasis on security aspects of risk-informed decisionmaking in core training curriculum and qualification programs.
3. A process to report and investigate all suspicious applications, including reporting procedures to involve appropriate law enforcement agencies, as necessary.
4. Information management databases, such as “ChoicePoint,” for use in NRC and Agreement States licensing programs.

Resources to support this effort will need to involve planning for NRC and Agreement State participation during development through rollout and ongoing support for continued use of these tools.

Recommendation 6a

The Panel recommends that staff verify that import/export licensees possess a valid and current license to which the materials will be imported. For first-time applicants for import/export licenses, the Panel recommends that more detailed assessments be made than for licensees with established records of satisfactory performance prior to authorization. If the first-time applicant has a new possession license, the Panel recommends that OIP verify that the possession license was issued in accordance with the objectives outlined in the Panel’s Recommendation 1a.

Recommendation 6b

The Panel recommends that importers and exporters operating under the GL granted by 10 CFR Part 110 be required to report electronically in real time into the WBL/NSTS when it becomes available.

Recommendation 7

The Panel recommends the NRC and Agreement States continue to encourage licensees to carry only as-needed possession limits as this helps determine appropriate financial assurance and applicability of IC Orders. This provides awareness to licensees that disposition of unwanted or unused radioactive material is preferred over accumulation. The Panel realizes that unsealed, short-lived radioactive materials are routinely used in nuclear medicine (10 CFR 35.100, “Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required,” 10 CFR 35.200, “Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is Not Required,” and 35.300, “Use of Unsealed Byproduct Material for Which a Written Directive is Required.”). **The Panel does not intend this recommendation to apply to those materials.**

Recommendation 8

The Panel recommends that the guidance be re-evaluated to eliminate reliance on the “good faith presumption” and replaced with on-site inspection and verification. Two examples are provided below:

1. The Panel recommends that the guidance be modified to clearly inform the reviewer that an on-site, pre-licensing visit is needed to verify that the applicant has implemented applicable Security Orders.
2. The Panel recommends the guidance in paragraph 03.03b be revised to clearly inform the reviewer not to issue the license until the applicant has implemented the applicable Security Orders and that the implementation has been verified by an on-site, pre-licensing visit.

...When authorized to possess <insert radionuclide> you will be required to comply with the additional requirements for Increased Controls before the date that you possess the material. Please submit your schedule for implementing the Increased Controls. You will not be allowed to take possession of the additional radioactive materials in risk-significant quantities until you are in full compliance with the Increased Controls and these controls have been confirmed by inspection...

There may be other examples in the guidance where positive verification of licensee commitments by inspection (pre-licensing visit) are not required rather certifications by the licensee are accepted in good faith.