



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

(FSME-08-017, February, Program, Vulnerabilities)

February 11, 2008

ALL AGREEMENT STATES, PENNSYLVANIA, NEW JERSEY, AND VIRGINIA

**AVAILABILITY OF THE INDEPENDENT EXTERNAL REVIEW PANEL'S DRAFT REPORT  
AND OPPORTUNITY TO COMMENT (FSME-08-017)**

**Purpose:** To provide notification that the Independent External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's (NRC) Materials Licensing Program has issued its draft report and is seeking comment on its draft report.

**Contents:** - Draft Report of the Independent External Review Panel

**Background:** As part of the NRC's response to the U.S. Government Accountability Office's "sting" operation in 2007, the NRC chartered a new short-term advisory committee to identify vulnerabilities in the NRC's radioactive materials licensing program on October 2, 2007. The advisory committee, named the Independent External Review Panel (the Panel), was tasked with performing a comprehensive evaluation of the NRC's materials licensing program. The Panel's membership includes a former Agreement State program director, the current chair of the NRC's Advisory Committee on Nuclear Waste and Materials, and a representative from the Defense Threat Reduction Agency.

Over the past 4 months, the Panel has received briefings on a number of subject areas, including: specific licensing, general licensing, import/export licensing, the pre-licensing guidance, Web-based Licensing, the National Source Tracking System, the Increased Controls, and the "good faith" presumption. The Panel has been briefed by individuals from the NRC's Office of Federal and State Materials and Environmental Management Programs, the NRC's Office of Nuclear Security and Incident Response, several NRC Regional Offices, the State of Florida, and the American College of Radiology.

**Discussion:** On February 8, the Panel issued its draft report, detailing its interim observations and findings, to the NRC's Executive Director for Operations. A copy of the Panel's draft report is enclosed for your review. The Panel welcomes comments on its draft report. The Panel will accept written or oral comments. **Written comments should be directed to the point of contact listed below by March 5, 2008. Oral comments will be welcomed at the Panel's remaining public meetings, scheduled for February 19-21 and March 5-7 at the NRC's Headquarters in Rockville, MD.** Individuals wishing to participate remotely should call or e-mail the point of contact listed below to make arrangements.

**NRC Point of Contact:** If you have any questions on this correspondence, please contact me at 301-415-8722 or the individual named below.

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Terrence Reis, Deputy Director  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosure:  
As stated

## MEMORANDUM

**To:** Luis A. Reyes  
Executive Director for Operations

**From:** Independent External Review Panel  
Thomas E. Hill, Chairman /**Original Signed by Thomas E. Hill**/

**Date:** February 8, 2008

**Subject:** Draft Report of the Independent External Review Panel

In accordance with the Commission-approved staff's Action Plan, please find attached the Draft Report of the Independent External Review Panel. We believe the report addresses the Panel's objectives, scope of activities, and duties delineated in Item 2 of our Charter.

We will be happy to discuss the findings and recommendations in this report with you at your convenience if you have any questions or feedback on the report.

**cc:** Martin J. Virgilio,  
Deputy Executive Director for Materials, Waste,  
Research, State, Tribal, and Compliance Programs  
Office of the Executive Director for Operations

Charles Miller, Director  
Office of Federal and State Materials  
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Aaron McCraw, Review Panel's Staff Liaison  
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DRAFT

March XX, 2008

The Honorable Dale E. Klein  
Chairman  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001  
SUBJECT: Report of the Independent External Review Panel

Dear Chairman Klein:

As part of the U.S. Nuclear Regulatory Commission's (NRC) Government Accountability Office (GAO) response plan (SECY-07-0147), the Independent External Review Panel was chartered by the Commission on October 2, 2007. The Panel is pleased to provide its findings and recommendations in this report. The Panel conducted six meetings over the last six 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, time was allotted 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 bibliography of references and information sources that the Panel reviewed is provided in Appendix B.

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

1. List (with explanations) of vulnerabilities concerning NRC's licensing and tracking programs for import, export, specific and general licenses (GL). (Observations and Recommendations 2, 3, and 7)
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 9)
4. Evaluate 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, 6, and 8)

The Panel, unless otherwise noted, has made its observations and recommendations in the framework of the International Atomic Energy Agency (IAEA) Code of Conduct categorization of radioactive sources (Category 1 through Category 5) that has been adopted by the NRC. The Panel also recognizes that NRC staff is currently evaluating

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whether further controls are needed for sources that contain 10 times less than the amounts of radioactive materials specified in Category 3. The Panel believes that its observations and recommendations should not be extended to sources less than Category 3 without integrating the staff's assessment of the risks to health, safety, environment, and security of less than Category 3 sources.

The Panel believes the 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 GAO, security must be upgraded as a fourth cornerstone to NRC operations. 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 development of a comprehensive protective scheme designed to prohibit an adversary from legally obtaining and using radioactive materials as part of malevolent actions must include both proactive and reactive countermeasures. A proactive countermeasure must accomplish the primary objective of being capable of blocking a threat without knowing specifically what or who the threat is. Instead of relying on physical or procedural measures designed to detect, deny, and counter an identified threat, they must be capable of affecting either the behavior or capability of an adversary. Reactive countermeasures, on the other hand, provide the detection and denial aspects of a security program.

Current security thinking advocates an effect-based approach to security that relies on countermeasures. Comprehensive countermeasure development relies on determining what will happen, or will not happen, because of actions taken to counter and impact adversary actions and goals. As applied to NRC licensing of radioactive material, the security goal is prevention of procurement of radioactive material for malevolent actions.

There are three types of countermeasures. The types of countermeasure are:

1. Type 1 - affect the behavior of the adversary
2. Type 2 - affect the operational capability of the adversary
3. Type 3 - limit the courses of action available to the adversary

Type 1- This type of effect is the most proactive and has the best chance of preventing the adversary from obtaining a radioactive materials license, and in turn, radioactive materials. The primary reason the GAO was successful hinged on the fact that they were easily able to gather all necessary information to produce a credible license application. This was the first step in making it possible to obtain a license under false pretense. Once the application was submitted, the GAO team specifically knew all actions the NRC was going to perform when processing the application because it is discussed in the guidance, (NUREG-1556 – Consolidated Guidance on Radioactive Material Licenses). As a result,

they were in an advantageous position to respond to the license reviewer to validate their application.

The Panel recognizes that it is difficult to have a successful licensing process without the availability of certain information to applicants. There is a risk of exploitation by malevolent entities by having detailed information available. For this reason, the Panel believes that a site visit should be required for all new applicants as discussed below. The GAO was not successful with its attempt to obtain materials in Maryland because the licensing staff indicated they would perform a pre-licensing site visit. The GAO withdrew their expression of interest. An early site visit was outside the scope of preparation the GAO had performed, so they were unsuccessful.

Type 2 - This level of countermeasure relies on traditional physical and procedural measures designed to deter adversarial activity. The GAO identified in its report how they obtained a license, modified the license using commercial software to increase the possession limits, and submitted intents to purchase radioactive materials from multiple suppliers at higher than authorized quantities. If the license contained security features designed to prevent tampering or counterfeiting, or if license verification checks by vendors had been conducted, this may have prevented access to materials. If there was a system be it a required telephone confirmation or an access-controlled, real-time tracking system that allowed a supplier to confirm that a license was valid and the requested quantities were allowed under the license, the actions available to GAO would have been significantly limited, making it difficult to gather significant quantities for malevolent purposes.

Type 3 -The final type of countermeasure consists of the traditional physical security measures designed to defend against an attack. These countermeasures include guards, guns, locks, and barriers. These countermeasures physically prevent an adversary from attacking an asset. This aspect was not addressed in the GAO report; however, should the procurement processes become too difficult for a terrorist to exploit, the only recourse to obtain radioactive material would be to steal it. Physical security requirements must be designed to protect adequately radioactive material from theft by an adversary.

Each level of countermeasure plays an important role in solving the problem of security of radioactive materials. In order to provide the best possible protection, the three types of countermeasures are essential. Integrating these three types of countermeasures increases the difficulty for an adversary to design an attack and the risk of being compromised. It also limits the courses of action available to an adversary.

## **Observations and Recommendations**

### **Observation 1**

The Panel believes there are many qualified and conscientious license reviewers at NRC and in the Agreement States who diligently issue licenses and make licensing decisions in a timely fashion. Based on the vulnerabilities identified in the GAO report, security is

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being enhanced in the licensing process. This will complement and strengthen protection of health, safety and the environment. The practice of relying on the “good faith presumption” that applicants will be honest in providing information on an application has been demonstrated as a vulnerability. Rather, a shift to verify and establish trust may be necessary. The Panel learned that some Agreement States may have this same vulnerability, while other Agreement States that require site visits for “new applicants” make such exploitation less likely.

The Panel believes the validation process used by license reviewers may not adequately assure that the entity applying for the license is legitimate. Current procedures used by license reviewers to validate the legitimacy of a company do not prevent an adversary from obtaining a license. The staff has an ongoing effort for a number of initiatives aimed at assessing and reducing this vulnerability in the licensing process. Immediately following the issuance of the GAO Report, the staff:

1. made a retrospective assessment of licenses issued in the previous 18 months using interim guidance for pre-licensing visits to assess any vulnerabilities,
2. issued interim guidance requiring pre-licensing site visits for all unknown applicants, and
3. issued a Regulatory Information Summary (RIS) 2007-13, advising licensees to heighten their awareness regarding transfer of radioactive materials.

Following these initial steps the staff:

1. issued revised pre-licensing guidance that requires a pre-licensing site visit for applicants that meet certain criteria;
2. formed the Materials Program Working Group that developed recommendations regarding license verification and anti-counterfeiting;
3. issued Order EA-07-305 requiring fingerprinting and criminal history checks for individuals with unescorted access to radioactive materials at facilities subject to Increased Controls, and
4. developed a plan to assess the types, numbers, and quantities of sources between Category 3 and Category 4 of the IAEA Code of Conduct.

### **Recommendation 1a**

The Panel recommends, 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., Category 1 versus Category 2 or 3), that:

1. the good faith presumption be temporarily suspended;

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2. a review of health, safety, environmental and security plans be performed (Data contained in these plans must conform to the requirements included in the licensing guidance 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 is one indicator of an inexperienced applicant.)
3. an on-site visit be 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 be conducted of the company and its key personnel, including responsible members of management, the Radiation Safety Officer, and personnel with unescorted access; and
5. a review of business plans be conducted to further assess whether the requested radioactive materials comport with planned activities.

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, and;
- customer reference checks.

### **Recommendation 1b**

The Panel recommends that a process and criteria be developed that will allow new licensees to be recognized as having a record of credible performance leading to the establishment of trust. The Panel believes that this process is *not* necessary for licensees with a well-known and current history of performance under other NRC or Agreement States licenses that are supported by regulatory inspections.

### **Observation 2**

The Panel believes that the NRC's openness policy regarding public access to licensing information provides excellent information for license applicants to apply for, obtain, and maintain a license. At the same time, however, it also provides very useful information to



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an adversary attempting to obtain a license or circumvent regulations designed to prevent unauthorized access to radioactive material.

Exploiting open sources (publically available information), in this case the information provided by the NRC itself, provided a vast amount of data on security and the licensing process, ranging from government policies and specific procedures to training methods and systems used. The ability to gather all the necessary information to produce a legitimate license application and supporting documentation was the primary reason the GAO was successful. Once submitted, the GAO knew and understood all actions the NRC was to take in processing the application. This understanding allowed the GAO to anticipate, prepare for, and counter any actions taken by the NRC.

The Panel recognizes that increasing control of regulatory information is contrary to current NRC practice, and the Panel is not advocating the abandonment of this practice. Providing the necessary information for an applicant to submit a complete application is essential to the ease and efficiency of the licensing process.

### **Recommendation 2**

The Panel recommends that information specific to the review and decision-making procedures used by 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.

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:

1. identifying essential elements of information needed by an adversary to exploit the licensing process;
2. conducting a thorough review of all licensing guidance to identify publication containing essential elements;
3. conducting a risk analysis in order to identify the benefit of releasing the information versus the potential advantage gained by an adversary, then making a risk-informed decision regarding the release of the information;
4. establishing and implementing measures to safeguard and control the release of this information.

### **Observation 3**

The Panel learned about the current process for validating the authenticity of licenses and methods to verify current inventory of radioactive material prior to transfer. These

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procedures do not provide the sufficient controls to prohibit an adversary from modifying or counterfeiting a license or prevent a licensee from exceeding authorized quantities.

The Panel learned the NRC has several programs, including the Web-based Licensing (WBL) system and the National Source Tracking System (NSTS), under development with features to enhance the security and accountability of radioactive material, in addition to ensuring health, safety and environmental protection.

The Panel believes that development of a WBL system offers several advantages regarding the security of radioactive material, as well as providing both convenience and consistency to the license review process. The potential security advantages of this system include the verification of the license and its conditions by each party involved in the transfer of radioactive material.

A tracking system, NSTS, is currently being developed for radioactive materials that comport with IAEA Categories 1 and 2. The Panel also learned that the staff is currently evaluating Category 3 and 10-times-less-than Category 3 to assess what if any additional sources should be tracked in the same manner as Category 1 and 2 with particular regard to the risk of aggregation of many sources. The NSTS, if up to date, can ensure no licensee has more material than is authorized on the license.

The Panel believes that Agreement State participation in the development and implementation of the combined WBL/NSTS is crucial because the Agreement States have the vast majority of the current and future licenses.

The Panel believes that comprehensive and real-time tracking of radioactive materials transfer would confirm the licensee's compliance with established limits, ensure accountability of radioactive materials during acquisition and provide an additional means of validating the licensee's legitimacy. Had this system been in place, up to date, and used by the vendors contacted by GAO, the altered license would likely have been detected. In turn, appropriate actions could have been taken to thwart the GAO's efforts.

The Panel's Charter requires the Panel to document other options that were considered and the reasons for not adopting them. In this regard, the Panel considered information on the integrity of license documents. The Panel learned that the staff is considering near-term steps to make license documents less susceptible to counterfeiting. The Panel further believes verification of license quantities can be verified by vendors with the appropriate regulatory agency instead of relying solely on a facsimile copy of the license from the licensee. The Panel learned that the Materials Program Working Group recommended that vendors "...prior to transferring radioactive material, the licensee contact the recipient's regulatory authority to verify the authenticity of the transferee's license..." This recommendation is applied only to certain cases. The Panel believes that the process recommend by staff with provide adequate controls for most high-risk transfers. However, this leaves a gap that could easily be exploited by a malevolent entity seeking high risk sources or seeking to aggregate sources.

### **Recommendation 3a**

The Panel recommends that the NSTS and WBL be integrated to allow for real-time sharing of information between the systems. This combined 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 data base as discussed in recommendations 1 and 2 directly above.

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

1. the system must be integrated to present licensees, vendors, and regulators controlled access (as appropriate) to license information to verify licenses and properly accomplish transfer of radioactive materials between authorized users in full compliance with the licenses of the parties involved in each transfer, and
2. the system should 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 that there are cases where there may be 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 to:

1. develop and test the system,
2. get Agreement State and licensee input and participation in the development and trials using the system, and
3. roll out and implement the system.

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

#### **Observation 4**

The Panel learned that current guidance establishes guidelines for the security of radioactive material. However, these guidelines are subject to a range of interpretation, resulting in inconsistent security across source categories. Staff has identified security measures needed for these materials and NRC has issued Increased Controls (IC) Orders to licensees possessing these materials. The Panel learned that staff is also developing additional guidance for security of materials. The Panel learned that radioactive materials used by the medical licensees that are of security concern are those larger sealed sources used in blood irradiators, radiostereotactic therapy units, and to a lesser extent, the high dose rate afterloaders. This is a significant part of the inventory of licensed Category 1 and Category 2 sources.

#### **Recommendation 4**

The Panel recommends development of prescriptive physical security requirements using a risk-informed, graded approach. These standards would likely be more prescriptive 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.

#### **Observation 5**

The Panel believes that NRC and Agreement State personnel tasked with licensing responsibilities are very conscientious and include security as a concern in their work. At present, security matters that rely on a “verify to establish trust” approach are not part of the culture of NRC licensing. The Panel believes that it will take some time and concerted effort to integrate security with health, safety, and environmental protection in the licensing process.

In March 1999, the Commission issued SECY-98-144 - White Paper On Risk-Informed And Performance-Based Regulation. This paper defines risk in terms applicable to the entire range of activities involving NRC-licensed use of radioactive materials. The risk definition takes the view that when one asks, "What is the risk?" one is really asking three questions: "What can go wrong?" "How likely is it?" and "What are the consequences?" These three questions constitute the "risk triplet." (Kaplan and Garrick, 1981) This approach has worked very well for assessment of risk for health, safety, and environmental protection. It can also be used as a framework for security risk management.

The Panel believes that security threat information, including an adversary’s capability, intent, and objectives, should be part of the licensing process especially for “new applicants.” At present, the NRC does not have a formal threat awareness program available to NRC or Agreement State staff to support risk-informed decisionmaking regarding security in the licensing process.

### **Recommendation 5**

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:

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 decision making in core training curriculum and qualification programs;
3. a process to report and investigate all suspicious applications, including reporting procedures to involve local or federal law enforcement agencies as necessary; and
4. information management data bases, 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 and rollout and ongoing support for design and use of the program.

### **Observation 6**

The Panel learned that NRC has a program to train staff in accordance with Inspection Manual Chapter (IMC) 1246. Likewise, the Agreement States have training programs equivalent to IMC 1246.

The NRC Licensing Process and Procedures Course is the primary course for both NRC and Agreement State license reviewers.

Licensing for both NRC and Agreement State staff is primarily learned on the job, with supervisory review of case work while progressing from simple license and amendment reviews to more complex reviews. Training courses are completed in the core areas, (e.g. health physics, medical, and industrial uses and transportation of radioactive materials. License reviewers as well as inspectors also are trained in specialized areas such as internal dosimetry, environmental monitoring, and air sampling. Mastery of licensing skills typically is completed in approximately two years with delegation of authority to sign certain licenses granted by license type for NRC license reviewers. Agreement States have similar schemes for license reviewer training and qualification. It is common for Agreement State license reviewers to be cross-trained to perform compliance inspections.

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The Panel recognizes that NRC and Agreement State inspectors have started to receive security training for verifying licensee compliance with IC Orders. Security is not, however, ingrained in the licensing culture of NRC or the Agreement State licensing staff at this time.

The Panel recognizes that staff has begun to outline challenges to incorporate security into NRC and Agreement States licensing culture, practices and procedures.

### **Recommendation 6**

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 fashion. This heightened state of awareness can best be accomplished by assuring that training programs include more comprehensive training on security issues, aimed at recognizing a malevolent applicant.

### **Observation 7**

The Panel learned that licenses of NRC's Office of International Programs (OIP) are issued to both NRC and Agreement States licensees. A licensee must possess a specific license authorizing possession of radioactive materials before applying to OIP for a license to import or export radioactive material or devices containing radioactive material. As such, a new license applicant of OIP will have a history with either the NRC or an Agreement State that can be evaluated when determining the validity of the import/export applicant.

Additionally the Panel learned:

1. licenses are issued by OIP for shorter time intervals compared to other licenses issued by NRC and the Agreement States. It is not unusual for OIP to work with the same applicant on many occasions.
2. frequently, one or more Executive Branch agencies in addition to the NRC must approve the proposed export of the radioactive material or device.
3. all specific license applications are made public with some requiring Federal Register notices.
4. various reporting requirements apply to persons operating under the different import and export general license (GL) authorized in 10 CFR Part 110.
5. a recent rule change reduced the number of sources eligible for import and export under GL authorization.

**Recommendation 7**

The Panel recommends that the requirements noted in Recommendation 1 for other licensees should be applied to import and export license applicants.

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

**Observation 8**

The Panel learned that approximately 10 percent of licensees have possession limits with no upper bound. The Panel also learned that financial assurance requirements, IC's, and observations during inspections have resulted in some licensees reducing their possession limits to only the quantities of radioactive materials they need. New licenses are being granted only with specific possession limits. At renewal, specific limits are being added to licenses that do not have them.

**Recommendation 8**

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. The Panel recognizes that this recommendation may not be appropriate to apply to medical use licensees under 10 CFR 35.100 and 35.200 that require unsealed, short-lived radioactive material. This recommendation provides awareness to licensees that disposition of unwanted or unused radioactive materials, as opposed to accumulation, is preferred.

**Observation 9**

The Panel reviewed the "Implementation Guidance for Completing the Checklist to Provide a Basis for Confidence that Radioactive Materials Will be Used as Specified on the License," dated January 11, 2008, developed by the Pre-licensing Guidance Working Group.

The guidance in paragraph 01.01 states "...all new applicants or licensees (new, renewal, or amendment) that are requesting risk significant quantities of certain radioactive materials (all forms, sealed and unsealed) indicated in the checklist (step 1, table of risk significant quantities) and that have not been subject to a Security Order or the additional requirements for increased controls will not be approved until the NRC or an Agreement State has determined with confidence that the applicants commitments will be implemented..."

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The Panel believes that there are several examples in this document that still rely on the “good faith presumption.”

A template paragraph 03.03a states in part, “when authorized to possess <radionuclide> you will be required to comply with the NRC Security Order before the date that you possess the material. SSSB will be contacting you regarding this matter.”

In the guidance in paragraph 03.03 b., the license reviewer is provided a template paragraph to include in any deficiency letter or email when an applicant requests risk-significant quantities of radioactive material.

The template paragraph currently states in part:

...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 and provide confirmation that you will not take possession of the additional radioactive materials in risk significant quantities until you are in full compliance with the Increased Controls...

### **Recommendation 9**

The Panel recommends that the pre-licensing 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 in paragraph 03.03a be modified to clearly inform the reviewer an on site inspection is needed to verify that the applicant has implemented the Increased Controls.
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 required increased controls and that the implementation has been verified by inspection.

...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...



## **Appendix A – Glossary of Terms**

**“New” Licensee** - A new licensee is an applicant that has never held an NRC or Agreement State license. Also, a former licensee that has not held an NRC or Agreement State license in the last 5 years should be considered as a “new” licensee.

**Risk-Informed Decisions** - Risk Informed decisions and decision making is used in the same way it is defined in SECY-98-144 - White Paper On Risk-Informed And Performance-Based Regulation issued by the Commission in March 1999. The risk triplet consists of three basic questions "What can go wrong?" "How likely is it?" and "What are the consequences?" (Kaplan and Garrick 1988).

**Vulnerability** - A vulnerability is a condition that exists that provides an adversary either (1) the ability to circumvent any portion of the controls in place designed to limit access to or acquire radioactive material; or (2) provides direct access to radioactive material of the radionuclide, quantity and composition potentially suitable for use by a persons or entities seeking to do harm with the material.

## **Appendix B – References and Information Sources**

SECY-98-144 – White Paper on Risk-Informed and Performance-Based Regulation

GAO-07-1038T – Actions taken by NRC to Strengthen Its Licensing process for Sealed Radioactive Are Not Effective

Kaplan, S., and B.J. Garrick. 1981. On the Quantitative Definition of Risk. Risk Analysis 1(1): 11-27.