March 11, 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:

In accordance with the Commission-approved staff's Action Plan, attached is the Final Report of the Independent External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Materials Licensing Program. The Panel is pleased to provide its observations and recommendations in this report. The Panel believes that this report addresses the concerns and vulnerabilities identified by the U.S. Government Accountability Office. The Panel looks forward to discussing its findings and recommendations with the Commission on March 18, 2008.

Regards,

/Original signed by Thomas E. Hill/

Thomas E. Hill, Chairman
Independent External Review Panel

Enclosure:
Final Report of the Independent
External Review Panel

cc w/enclosure:
The Honorable Gregory B. Jaczko

The Honorable Peter B. Lyons

Luis A. Reyes, Executive Director for Operations

Aaron T. McCraw, Staff Liaison to the Panel

Final Report of the 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). 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.

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 Panel, unless otherwise noted, has made its observations and recommendations consistent with the International Atomic Energy Agency (IAEA) Code of Conduct Categorization of Radioactive Sources (Safety Guide RS-G-1.9). The IAEA classifies radioactive sources into five categories—Category 1 being the most potentially dangerous to health if not safely managed and Category 5 being the most unlikely to be dangerous. The Panel recognizes that NRC staff is currently evaluating 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 apply to the risk-significant categories of sources as determined by the Commission. This is likely to include Category 1, 2, and 3 sources and perhaps other sources less than Category 3 that the Commission may determine are risk significant.

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 prevent an adversary from 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 blocking a threat without knowing the specifics of the threat. Instead of relying on physical or procedural measures designed to detect, deny, and counter an identified threat, proactive countermeasures must be capable of affecting either the behavior or the 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 or will not happen because of actions taken to counter and impact adversary actions and goals. As applied to the NRC's radioactive materials licensing program, the security goal is to prevent the procurement of radioactive material for malevolent purposes.

There are three types of countermeasures.

1. Type 1 affects the behavior of the adversary.

2. Type 2 affects the operational capability of the adversary.

3. Type 3 limits the courses of action available to the adversary.

Type 1—This is the most proactive type and has the best chance of preventing the adversary from obtaining a radioactive materials license, and in turn, radioactive materials. The GAO easily obtained an NRC license under false pretense because of their ability to gather all necessary information to produce a credible license application. Once the application was submitted, the GAO team knew all actions the NRC was going to perform when processing the application, because the agency outlined the process in publicly-available guidance (NUREG-1556, "Consolidated Guidance on Radioactive Material Licenses"). As a result, the GAO team was 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 providing applicants certain information; however, that same information provides malevolent entities

information that can be used to exploit the licensing process. 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 in obtaining a radioactive materials license from Maryland, because the licensing staff there indicated they would perform a pre-licensing site visit. The GAO subsequently withdrew their application, because an early site visit was outside the scope of the GAO team's preparations.

Type 2—This level of countermeasure relies on traditional physical and procedural measures to deter adversarial activity. In its report (GAO-07-1038T, "Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources Are Not Effecitve"), the GAO team describes how they obtained a license, modified the license to increase the possession limits using commercial software, 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 the vendors conducted license verification checks, this would 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 licensing processes become too difficult for a terrorist to exploit, their only recourse to obtaining radioactive material would be theft. Physical security requirements must be designed to protect radioactive material from theft by an adversary.

Each level of countermeasure plays an important role in ensuring the security of radioactive materials, and utilizing all three types of countermeasures simultaneously provides the best protection. Integrating these three types of countermeasures increases the difficulty for an adversary to design an attack and 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 manner. In response to the vulnerabilities identified in the GAO report, the NRC and the Agreement States are enhancing security in the licensing process. This will complement and strengthen protection of health, safety, and the environment. The GAO demonstrated the

practice of relying on the "good faith presumption," that applicants will be honest in providing information on an application, is 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 agrees with the GAO report in that the validation process used by license reviewers may not adequately ensure that the entity applying for the license is legitimate. NRC staff has introduced a number of ongoing initiatives aimed at assessing and reducing vulnerabilities in the licensing process. Immediately following the issuance of the GAO Report, NRC staff initiated the following actions:

1. Issued interim guidance requiring pre-licensing site visits for all unknown applicants.

2. Made a retrospective assessment of licenses issued in the previous 18 months using interim guidance for pre-licensing visits to assess the legitimacy of applicants.

3. Issued Regulatory Information Summary (RIS) 2007-13, "Verification of the Authenticity of Materials Possession Licenses," advising licensees to heighten their awareness regarding transfer of radioactive materials.

Following these initial steps, NRC staff took the following actions:

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, "Order Imposing Fingerprinting Requirements and Criminal History Checks for Unescorted Access to Certain Radioactive Material."

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 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.

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, it also provides very useful information to an adversary attempting to obtain a license or circumvent regulations, designed to prevent unauthorized access to radioactive material.

The Panel recognizes that increasing control of regulatory information is contrary to current NRC practice. 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.

Licensing guidance provides license reviewers with information regarding decisionmaking and further lines of inquiry used during application reviews. This information may have the unintended consequence of providing a malevolent applicant with information on how to exploit the licensing system.

The GAO was able to gather all the necessary information to produce a legitimate license application and supporting documentation using publicly-available information. Additionally, 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. This was the primary reason that GAO was successful.

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.

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 procedures do not prevent an adversary from modifying or counterfeiting a license or prevent a licensee from exceeding authorized quantities.

The Panel learned that the NRC has several programs, including the Web-based Licensing (WBL) system and the National Source Tracking System (NSTS), under development. These programs will 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 increases the security of radioactive material and provides 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 Categories 1 and 2 radioactive materials. The Panel also learned that the staff is currently evaluating Category 3 and 10-times-less-than-Category 3 sources to assess if any additional sources should be tracked in the same manner as Category 1 and 2 sources, with particular regard to the risk of aggregation of many sources.

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

The Panel believes that a combined WBL/NSTS can work in a similar manner to banking or credit card transactions with the following attributes:

- A licensee would have an account with a balance of authorized possession limits.

- The licensee would notify a vendor of an intended purchase and would authorize the vendor to log into their license and validate that the transaction comports with licensed radionuclides and limits.

- The vendor would receive an authorization code that would be added to the shipping paperwork.

- The amounts of each radionuclide would be reserved from the licensee's available limits.

- The licensee would log into the system and acknowledge receipt when the material arrives and the radioactive materials in the shipment would be added to the inventory for that licensee.

- The approach provides the basis for an integrated real-time inventory in a single system that incorporates licensing and source tracking.

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 required the Panel to document other options that the Panel 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 learned that the Materials Program Working Group (the Working Group) recommended that the NRC not modify the license documents to reduce counterfeiting. Instead, the Working Group recommended that the NRC and the Agreement States require licensees to verify the validity of license documents by directly contacting the appropriate regulatory authority. The Panel supports the Working Group's recommendation and believes that licensees could verify possession limits with the appropriate regulatory agency instead of relying solely on a facsimile copy of the license from the licensee.

The Panel learned that the Working Group recommended that licensees authorized to possess Category 3 or larger quantities of radioactive material should be required, prior to transfer, to contact the recipient's regulatory authority to verify the authenticity of the transferee's license when certain conditions exist. The Panel believes that the process recommended by the Working Group will provide adequate controls for all transfers of risk significant quantities since all transfers from licensees authorized to possess Category 1, 2, and 3 sources will require prior notification.

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.

Observation 4

The Panel learned that current performance-based guidance establishes expectations for the security of radioactive material; however, these expectations could be subject to a range of interpretation. Increased Controls (IC) Orders (consistent with IAEA Code of Conduct) have been issued to licensees possessing Category 1 and 2 sources. The Panel learned that staff is also developing additional guidance for security of materials.

The Panel believes that fully integrating security with health, safety, and environmental protection when regulating radioactive material will require a culture change at the NRC and in the Agreement States. The following discussion briefly outlines aspects for security to be included as a complement to health, safety, and environmental protection.

Security starts with identifying an appropriate level of protection based on the type, form, and quantity of radioactive material. The processes currently used to make risk-informed decisions for health, safety, and environmental protection are identical to those used to determine risk as it applies to security. The strategies for responding to security threats are different from the strategies for responding the health, safety, and environmental concerns in that they must consider malevolent action.

Once threats have been characterized, controls to protect radioactive material can be developed in a risk-informed manner. Rather than focusing solely on specific physical and procedural countermeasures, security plans could be developed by answering the following questions:

- What type of protection should the countermeasure(s) provide (e.g., deter, delay, detect, destroy, defend, or defeat)?
- What type of undesirable events do they guard against (e.g., surreptitious entry, forced entry, technical implant, or theft of sensitive material)?
- When are they effective — during which hours of the day/night and under what conditions?
- Where are they effective? What areas do they cover?
- What is the history of reported malfunctions (e.g., type, time, cause, and pattern)?
- What is the correlation of countermeasure effectiveness to security incident reports that may indicate that the countermeasure was defeated?
- What is the history of countermeasure maintenance/upgrades?

These considerations are not normally part of the risk analysis performed for health, safety, and environmental protection but are essential for appropriate risk-informed security. Any analysis is specific to the asset being protected, therefore, the guidance should focus on the goals necessary for protection, methods for the analysis, and countermeasures that are appropriate based on the identified risks.

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.

Observation 5

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 2 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.

At present, security matters that rely on a “verify to establish trust” approach are not part of the culture of NRC licensing. 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, fully ingrained in the licensing culture of NRC or the Agreement State licensing staff at this time.

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.

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

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.

Providing current threat information will provide license reviewers with information that addresses the realistic capabilities of an adversary. This information will aid licensee reviewers in making effective risk-informed licensing decisions consistent with historical and contemporary threat information and consistent with health, safety, and environmental protection.

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.

Observation 6

The Panel learned that licenses of the 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 the following:

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 licenses (GL) authorized in Title 10 Code of Federal Regulations (10 CFR) Part 110, "Export and Import of Nuclear Equipment and Material."

5. A recent rule change reduced the number of sources eligible for import and export under GL authorization.

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.

Observation 7

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 Orders, 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 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.

Observation 8

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 Panel believes that there are several examples in this document where the "good faith presumption" is still relied upon. For example, 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…"

As another example, 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 03.03b, 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 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.

Appendix A—Glossary of Terms

"New" Applicant—A new applicant is an entity that has never held an NRC or Agreement State license. A former licensee that has not held an NRC or Agreement State license in the last 5 years should also be considered a "new" applicant.

Risk-Informed Decisions—Risk-informed decisions and decisionmaking are used in the same way they are defined in SECY-98-144, "White Paper On Risk-Informed And Performance-Based Regulation," issued by the Commission in March 1999.

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