POLICY ISSUE
(Notation Vote)

April 24, 2006 SECY-06-0094

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: TRACKING OR PROVIDING ENHANCED CONTROLS FOR CATEGORY 3 SOURCES

PURPOSE:

To inform the Commission of the staff's analysis of tracking or providing enhanced controls for Category 3 sources; and to seek Commission approval of the staff's recommendations to proceed with (1) a one-time data collection of Category 3 sources, and (2) a rulemaking to change certain regulations governing the possession, use, and distribution of generally licensed radioactive material.

SUMMARY:

This paper presents four options regarding enhancing the level of controls for Category 3 sources. This analysis extends to a wide variety of radioactive materials (byproduct material, source material, and special nuclear material) and licensees (general and specific). Particular emphasis is devoted to sources possessed by general licensees. The staff recommends selection of two of the four options at this time: (1) perform a one-time data collection of Category 3 sources which would be used to determine appropriate regulatory actions, which could include expanding the National Source Tracking System, and (2) change certain regulations governing the possession, use, and distribution of generally licensed radioactive material, involving stakeholders in the rulemaking process. The focus of this paper is on Category 3 sources because sources less than Category 3 (i.e., Category 4 and Category 5 sources) have minimal potential for deterministic radiological consequences. The total resource estimate for the two recommended options is 2.6 - 3.5 FTE and $330,000 - $500,000 in contracted support through FY2008.

BACKGROUND:

In the staff requirements memorandum (SRM) to "Proposed Rule: National Source Tracking of Sealed Sources" (SECY-05-0092), dated June 30, 2005, the Commission directed staff to "provide a paper to the Commission regarding tracking or providing enhanced controls for sources below the Category 2 thresholds." An example of enhanced controls that the staff should consider is "a short provision in Part 32 which would specifically license all sources containing radionuclides of concern greater than Category 2.5 (or 2.75 or 3)."

CONTACT: Andy Imboden, NMSS/IMNS
(301) 415-6128

The International Atomic Energy Agency (IAEA) has categorized radioactive sealed sources according to the potential for radiological consequences that the sources pose (IAEA Safety Guide no. RS-G-1.9, "Categorization of Radioactive Sources," 2005).[1] The IAEA categorization system is based primarily on the potential for radioactive sources to cause deterministic health effects, without any regulatory controls in place. Along with the categorization, the IAEA has published a set of recommendations, in the "Code of Conduct on the Safety and Security of Radioactive Sources" (IAEA/CODEOC/2004), referred to as the "Code of Conduct." The IAEA guidance gives countries the option of including Category 3 sources in a national register, stating: "In view of the fact that Category 3 sources have the potential to cause severe deterministic effects, the regulatory body may also consider including them in a national register together with the Category 1 and 2 sources" (IAEA Safety Guide no. RS-G-1.9, "Categorization of Radioactive Sources," paragraph 3.8). However, it should be noted that the IAEA's conclusion that Category 3 sources have the potential to cause deterministic effects is based on conservative scenarios where no regulatory controls are in place, and would require relatively long exposure times (for some hours).

The U.S. Nuclear Regulatory Commission (NRC) has taken steps to increase the oversight for Category 1 and 2 sources, by imposing controls through Orders, proposing a National Source Tracking System (NSTS) (70 FR 43646), and finalizing export and import controls (70 FR 37985). These agency actions have focused on establishing a comprehensive radioactive source oversight program for radioactive materials of greatest concern, primarily for licensees possessing Category 1 and Category 2 sources. A final rulemaking package for the NSTS was provided to the Commission on April 6, 2006, and the Commission Assistants were briefed on NSTS and controls for less than Category 2 sources on April 12, 2006.

Category 3 sources are those containing a quantity equal to or greater than the Category 3 threshold (1/10th of the Category 2 threshold) but less than the Category 2 threshold. These sources have a wide variety of uses in industry, medicine, and research. Typical uses of Category 3 sources are in fixed industrial gauges, such as conveyor belt gauges, level gauges, dredger gauges, blast furnace gauges, and spinning pipe gauges. In medical fields, high-dose-rate (HDR) brachytherapy sources and plutonium-based pacemakers fall into this category. Category 3 neutron-generating applications are research reactor start-up sources and some well-logging sources utilizing americium/beryllium. Category 3 sources are being used increasingly by governmental agencies in security screening at ports and cargo terminals. Many of these sources, particularly the fixed gauges and cargo screening devices, are large, bulky, and heavy. Other sources, such as the HDR brachytherapy sources, consist of radionuclides that decay rapidly.

DISCUSSION:

This paper includes discussion of options to provide enhanced controls for Category 3 sources. The focus of this paper is on Category 3 sources because sources less than Category 3 (i.e. Category 4 and Category 5) have minimal potential for deterministic radiological consequences.
In order to seek stakeholder input on controls for Category 3 sources, the NRC invited public comment in the NSTS proposed rule and in public meetings. Specifically, the NRC invited public comment on whether Category 3 sources subsequently should be included in the NSTS. The public comments on the proposed rule indicated a mixed response. The comments have identified concerns with the potential for radiological consequences as well as concerns with the increased regulatory burden. Other organizations have expressed concern on this issue, including the NRC's Inspector General[2] and the

[1]Other publications describing the IAEA Source Categorization and its development in more detail are "Categorization of Radioactive Sources," IAEA-TECDOC-1344 (2003), which was superceded and replaced by RS-G-1.9; and "Method for Developing Arrangements for Response to a Nuclear and Radiological Emergency: Updating IAEA-TECDOC-953," EPR-Method 2003 (2003).

[2] OIG-06-A-10, "Audit of the Development of the National Source Tracking System," February 23, 2006.

Government Accountability Office (GAO)[3]. Many commenting stakeholders expressed concern with the costs involved with including Category 3 sources in the NSTS.

Stakeholders have also expressed interest in other aspects (besides tracking) of NRC's regulatory framework for Category 3 sources. As noted in a petition for rulemaking[4], a survey of Agreement States showed that 97% (30 of 31) of the responding States support taking action in the area of registered generally licensed devices, which would include all Category 3 generally licensed devices. The GAO has recommended[5] that the NRC and Agreement States determine the costs and benefits of requiring owners of devices that are now generally licensed to apply for specific licenses, which could include all Category 3 generally licensed devices. Additionally, Congressional stakeholders have inquired[6] regarding the NRC's plans to expand the current enhanced security requirements to Category 3 sources. Staff has considered these stakeholder comments in making the recommendations in this paper.

Another consideration related to controlling Category 3 sources includes providing a mechanism to verify licensee legitimacy. Radiation detectors installed in portal monitors can detect very small quantities of licensed material in shipments. The U.S. Department of Homeland Security's Domestic Nuclear Detection Office (DNDO) is facilitating the purchase of detectors by State and local authorities. These detectors will be deployed domestically, such as along major transportation routes. Therefore, there is an increasing ability of law enforcement officials to be able to detect licensed material in shipments. There also is considerable capability of detectors in the field, supported by offsite technical assistance, to identify specific radionuclides. However, because sources may be shielded in various configurations, it is difficult to use existing detectors to determine activity. Because of the potential for increased inquiries to NRC and Agreement States resulting from heightened radiological surveillance by State and local personnel, there may be a benefit in requiring increased accountability for certain radionuclides, even for small activity sources.

There are some groupings of Category 3 sources for which, were they included in NSTS, there may not be an appreciable benefit in control. Fixed gauge sources are an example because fixed industrial gauges rarely change hands in a transaction. Other Category 3 sources, such as those used in HDR brachytherapy, decay to Category 4 in a short time (6 months) and may not undergo a transaction in that period. Even while a decayed source is being replaced with a new one, the aggregated activity is still less than the Category 2 threshold.

Existing requirements of the NRC and Agreement State regulatory system provide some level of control regarding sources. For example, NRC (and equivalent Agreement State) regulations[7] require that a licensee who loses control of a source must immediately report the event, if the activity is greater than or equal to 1,000 times the quantity specified in appendix C to Part 20. All Category 3 sources – general and specific – meet this criterion. In addition, the NRC has undertaken a comprehensive review of nuclear material security requirements. Examples of the types of security measures that the NRC and Agreement States have issued through Orders are: access control; background investigations; transportation (shipments and transfers domestically); and monitoring, detecting, assessing, and responding to intrusions. In all cases, where appropriate, recent Orders issued by NRC and the

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[3] GAO-05-967, "NUCLEAR SECURITY: DOE Needs Better Information to Guide Its Expanded Recovery of Sealed Radiological Sources," September 2005

[4] PRM-31-05, published in 70 FR 75423, December 20, 2005

[5] GAO-03-804, "NUCLEAR SECURITY: Federal and State Action Needed to Improve Security of Sealed Radioactive Sources," August 2003.

[6] Most recently LTR-06-0148, dated March 20, 2006

[7] 10 CFR 20.2201(a)(I)

Agreement States did address aggregation of any sources (including Category 3) where the Category 2 threshold could be reached in a given physical location.

At this time, the staff has identified four options related to increased controls for Category 3 sources: (1) no action; (2) perform a one-time data collection of Category 3 sources; (3) change certain regulations governing the distribution, possession, and use of radioactive material under general licenses; and (4) initiate an inventory reporting rulemaking.

Option 1 – No Action
Under the "no action" option, the staff would continue its current activities. Where appropriate, recent Orders issued by NRC and the Agreement States addressed aggregation of any sources (including Category 3) where the Category 2 threshold could be reached in a given physical location. Many Category 3 sources are in fixed gauges, or are sources with radionuclides that decay rapidly. Other Category 3 sources, such as some well logging sources, are only possessed and used by specific licensees. In addition, given that few Category 3 sources have been lost or stolen, the "no action" option could be an appropriate decision at this time. The staff would continue to focus on licensees possessing Category 1 and Category 2 sources, and situations where licensed material exceeds the Category 2 threshold in a physical location.

Option 2 – One-Time Data Collection and Analysis of Category 3 Sources
Because of the potential significant increase in burden on licensees, potential implementation problems as a result of the expansion, and the resource impacts on the regulatory bodies, the staff believes that NRC lacks the data necessary to support tracking sources below the Category 2 threshold at this time. Prior NRC projects, such as the interim inventory for the NSTS (also referred to as the "interim database"), did not systematically collect data on Category 3 sources.

This option involves a one-time data collection of Category 3 sources, to be completed within one year. Details are provided in Enclosure 1. The primary objective would be to quantify the number of licensees, the number of sources, and the number of transactions. This data collection is necessary, not only to support decisionmaking, but to identify licensees so that the program can be effectively implemented if the Commission determines to expand the NSTS to sources of lower thresholds (somewhere between Category 2 and Category 3) or identifies other needed regulatory improvements. An Office of Management and Budget (OMB) clearance would be needed to comply with Paperwork Reduction Act requirements. A total

one-time NRC effort for determining the number of Category 3 licensees and sources would cost from 0.6 to 1.0 Full Time Equivalent (FTE) and approximately $110,000 to $240,000 in contract support. Specific licensees would be identified by license conditions. General licensees would be identified by reports received from vendors and also general license registrations. There may be considerable variation in the data available on general licensees in the registration tracking systems maintained by the individual Agreement States and the NRC, because general license registration is a recent requirement. NRC estimates that Agreement States would collectively expend approximately 3.2 FTE collecting this information, because the Agreement States have a total of approximately four times the number of licensees as NRC.

Following the one-time data collection, staff would further analyze the data on Category 3 sources. The final product should provide a prioritized ranking of Category 3 sources, and possibly identify which, if any, subgroups of sources within Category 3 may benefit from inclusion in the NSTS or other enhanced controls. Where appropriate, recent Orders issued by NRC and the Agreement States did address aggregation of any sources (including Category 3) where the Category 2 threshold could be reached in a given physical location. Prior assessments have focused on larger quantities of radioactive material. Based on these prior studies, and given the information gathered by the one-time data collection, a systematic analysis of what regulatory controls are warranted, if any, for Category 3 sources is expected to be completed within six months and approximately $160,000. This analysis would, among other factors, give consideration to factors such as the accessability and portability of Category 3 sources as they are used in the current regulatory environment. Although there is a good understanding of the types of uses of these sources, the systematic study will allow the staff to better prioritize sources within Category 3.

Advantages:
- Data collection will support the decisionmaking process on the possible expansion of NSTS, and will allow the calculation of costs and benefits of any regulatory changes.
- Data collection will inform subsequent analysis and could be used to address stakeholder concerns.

Disadvantage:
- The majority of sources are expected to be in Agreement States; NRC or its contractor would have to collect data from the States and their licensees.

Option 3 – Amendments to the General Licenses
NRC's general licenses (and the regulations governing the approval and distribution of the associated devices) were analyzed in order to enhance regulatory control for these devices. Two general licenses (specifically, §§ 31.5 and 40.22) have the potential to authorize possession and use of at least Category 2 quantities.

This option involves instituting activity limits for general licenses. Limiting the amount of activity allowed in a generally licensed device would reserve authorization to possess higher-activity sources containing radionuclides of concern to specific licensees. One benefit of this would be that the NRC and Agreement States would have greater oversight of these licensees, which would also address some stakeholder concerns. The most fundamental difference between a specific licensee and a general licensee is that the specific licensee must file an application prior to receiving the licensed material. The specific licensing process gives the NRC or Agreement States an opportunity to review the purpose of use, applicant facilities and equipment, training and experience, and ability to meet other special requirements that may be applicable. In the absence of a license application, the regulatory body has no opportunity to perform any assessment of the applicant's legitimacy, or any other pre-licensing actions that the Commission may determine are necessary. Historically, NRC has not contacted the majority of its general licensees or inspected these licensees on a regular basis because of the relatively small radiation risk posed by these devices. As noted in NRC's rule implementing the general license registration requirement (69 FR 79161, December 18, 2000), individuals who possess devices under general license are not always aware of applicable requirements. As a result of the general license registration requirement rule, NRC has inspected general licensees more than in the past. However, the

frequency of these inspections and the overall regulatory oversight of general licensees is substantially less than that for those persons or individuals operating under a specific license.

This option includes the staff's recommendation that these general licenses should be limited to sources smaller than one-half the Category 2 threshold, also known as Category 2.5. The staff first considered a limit to the general licenses of Category 2. As a short-term measure, a general license limit corresponding to the Category 2 threshold would be justified on the basis that such a limit would ensure that all nationally tracked sources (as currently defined) would be possessed by specific licensees. Further investigation of the sealed source and device (SS&D) registry and the GLTS (see Enclosure 2) showed that few additional existing licensees would be affected if, instead of a limit of Category 2, the limit were to be lowered to Category 2.5. A source slightly below the Category 2 limit, authorized for use by general licensees, would be under considerably less regulatory oversight as compared with a source slightly above the Category 2 limit and authorized for use only by specific licensees. Therefore, a small difference in source activity could potentially result in a large difference in regulatory control and oversight, and a limit of Category 2.5 would avoid this situation.

A limit of Category 3, however, would affect many more licensees. Given the uncertainties involved in extrapolating the more numerous Agreement State licensees from the available NRC data, the staff is not recommending a general license limit of Category 3 at this time. An existing general licensee who, because of a new limit, would have to apply for a specific license would incur considerable additional fees and new compliance costs. This would create the potential for some of these devices to become unwanted and at risk of becoming orphan sources. Because of the greater number of Category 3 sources under general license, this "orphan source risk" is proportionally higher for a limit of Category 3 than for Category 2.5. The types of sources that would be affected by a limit of Category 2.5 relative to Category 3 have more activity, and in many cases may be more easily transportable and more easily dispersed, and thus pose more potential for deterministic radiological consequences. Other reasons to use a limit of Category 2.5, including regulatory efficiency and staff resources, are discussed in Enclosure 2. If the Commission directs the staff to proceed with option 2, the information collected in that effort would help confirm if Category 2.5, or another threshold, would be the optimal value.

Additionally, for the devices remaining under general license, staff has identified regulatory improvements that would ensure that similarly categorized sources are regulated more consistently. Details of how these goals would be accomplished for both byproduct and source material are provided in Enclosure 2. As a preliminary estimate – highly dependent on the rule's priority compared to other activities and assuming no rulemaking plan is needed – changes could be made to the NRC's byproduct material regulations within 24 months and approximately 2.0 FTE. This estimate is in agreement with budgeted FTE as shown in the Common Prioritization of Rulemakings for FY2007 and FY2008, and scheduled for a final rule to be provided to the Commission in October, 2008. Contractor support would be needed to support the rulemaking, and is estimated at this time to cost from $60,000 to $100,000 in total. Estimated resources for amending § 40.22 (and associated manufacturer and requirements in Part 40) were provided in SECY-01-0072.

The staff recommends initiating rulemaking to amend the general licenses in §§ 31.5 and 40.22 to limit the activity levels (to Category 2.5), and to make regulatory improvements in §§ 31.5 and 40.22 (and manufacturer and distributor requirements in Part 32 and Part 40) to ensure that similarly categorized sources are regulated more consistently.

Advantages:

- Would ensure that the sources with the greatest potential for radiological consequences would be possessed only by specific licensees, which would address most stakeholder concerns.
- Would address inconsistencies in NRC's regulations for similarly categorized sources related to reporting and registration requirements, and increase the oversight of these licensees.

Disadvantage:

- Changes in the regulatory status of existing devices, and associated costs and burdens, could result in orphaned or unwanted sources.

- A threshold such as Category 2.5 may lead to confusion and not address all stakeholder concerns.

Option 4 – Inventory Reporting Requirement
The NSTS was designed with the recognition that when licensees have to account for transactions of sealed sources, it fosters greater control of that radioactive material. However, because Category 3 sources are smaller and may be considerably more numerous than those already in the NSTS, a less burdensome regulatory mechanism may be needed to accomplish the goal of greater licensee accountability. An inventory reporting requirement – where each licensee only files one report per specified time period – would be less burdensome than a comparable requirement for source tracking, which generates one report per source per transaction. This approach would reduce the number of reports considerably, and would simplify program administration. An inventory reporting requirement for Category 3 sources could also be designed: (1) to address the aggregation of sources by including Category 3 sources, (2) to provide information useful to identify unwanted sources, and (3) to provide more information on certain licensees that may be useful to confirm that sources in shipment have legitimate recipients. These and other factors, such as stakeholder concerns, can be considered during the development of an inventory reporting requirement.

The NSTS database capacity and data structure is currently designed to accept annual reconciliation reports, therefore it could accept other inventory reports from licensees. Some user interface functionality would need to be enhanced slightly to address the needs arising from an inventory reporting requirement for other than Category 1 and 2 sources. The NSTS can be used with few minor maintenance changes to manage the inventory data. A new database would not have to be built.

Although not recommended by the staff at this time, an inventory reporting requirement could be considered to increase licensee accountability for Category 3 sources and to provide more information on licensed radioactive material. The specific requirements of inventory reporting would be addressed through a rulemaking. As a preliminary estimate – highly dependent on the rule's priority compared to other activities and assuming no rulemaking plan would be necessary – the technical basis would require up to 12 months and 0.5 FTE. If the Commission directs the staff to proceed with option 2, the information collected in that effort would add to the technical basis. Following the technical basis, a final rule could be published in approximately 24 months and require approximately 2.0 FTE. The total process could therefore be completed within 36 months and 2.5 FTE. The resources required for implementation of the system would then be determined as part of the rulemaking process. Contractor support would be needed for the NRC rulemaking, and is estimated at this time to cost from $50,000 to $100,000 in total.

Advantages:
- Inventory reporting – as compared to source transaction reporting – is likely to be less burdensome and more easily administered, and therefore more amenable to enhancing NRC knowledge of and licensee accountability for smaller sources.
- The information technology infrastructure developed for NSTS could be readily expanded to handle data received from inventory reports.

Disadvantage:
- Cannot provide the same information as NSTS or within the same time period as NSTS.

AGREEMENT STATE COMMENT ON THIS PAPER:

This paper has been provided first to the Commission to get feedback on preferred approaches prior to interactions with the Agreement States. If a decision is made that results in initiation of a rulemaking, staff will, in accordance with established procedures, seek Agreement State input and comments, involve the Agreement States in any working group and steering group, and coordinate closely with the Organization of Agreement States and Conference of Radiation Control Program Directors, Inc. Also, all options would be discussed with the Agreement States for possible future implementation.

RESOURCES:

The resource estimates will depend on the particular Commission direction. A detailed presentation of each recommendation's resources is provided in Enclosure 3. Resources associated with the rulemaking in option 3 are budgeted, but other options are not and would have to be identified or reprogrammed from lower-priority work. The total resource estimate for the two recommended options is 2.6 - 3.5 FTE and $330,000 - $500,000 in contracted support through FY2008.

The information on resources and schedule reflects the current environment. If a significant amount of time (greater than 30 days) passes, or if the Commission provides the staff direction that differs from or adds to the staff's recommended actions, this section of the paper would need to be revisited after issuance of the draft SRM.

COMMITMENTS:

Should the Commission approve any of the staff's options, the staff will provide a schedule for those commitments approved by the Commission. The national strategy being implemented by NRC is a risk-informed and integrated approach that also includes an evaluation of the adequacy of existing regulations and consideration of other measures to provide appropriate control of sources. Should the Commission direct the staff to proceed with its approved option(s), the staff will also evaluate the security implications (e.g., fingerprinting, background checks) that may be associated with the preferred option(s). Staff will address fingerprinting and criminal history record checks for licensees and applicants as part of a rulemaking to implement the requirements of section 652 of the Energy Policy Act of 2005.

RECOMMENDATIONS:

The staff recommends that:

9. The Commission approve staff option 2 to identify Category 3 sources and the licensees that possess them, and analyze their risks.
10. The Commission approve staff approach in option 3 to amend certain general licenses (§§ 31.5 and 40.22) and associated manufacturer requirements (Parts 32 and 40).

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection.

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. Impacts of and Alternatives for Expanding the National Source Tracking System to Include Category 3 Sources
2. An Analysis of Potential Regulatory Changes to the General Licenses
3. Resource and Commitment Matrix

adequacy of existing regulations and consideration of other measures to provide appropriate control of sources. Should the Commission direct the staff to proceed with its approved option(s), the staff will also evaluate the security implications (e.g., fingerprinting, background checks) that may be associated with the preferred option(s). Staff will address fingerprinting and criminal history record checks for licensees and applicants as part of a rulemaking to implement the requirements of section 652 of the Energy Policy Act of 2005.

RECOMMENDATIONS:

The staff recommends that:

11. The Commission approve staff option #2 to identify Category 3 sources and the licensees that possess them, and analyze their risks.
12. The Commission approve staff approach in option #3 to amend certain general licenses (§§ 31.5 and 40.22) and associated manufacturer requirements (Parts 32 and 40).

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection.

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