

**POLICY ISSUE**  
(Notation Vote)

April 24, 2006

SECY-06-0094

FOR: The Commissioners

FROM: Luis A. Reyes  
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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)."

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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).<sup>1</sup> 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<sup>2</sup> and the Government

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<sup>1</sup>Other publications describing the IAEA Source Categorization and its development in more detail are "Categorization of Radioactive Sources," IAEA-TECDOC-1344 (2003), which was superseded 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).

<sup>2</sup> OIG-06-A-10, "Audit of the Development of the National Source Tracking System," February 23, 2006.

Accountability Office (GAO)<sup>3</sup>. 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<sup>4</sup>, 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<sup>5</sup> 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<sup>6</sup> 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<sup>7</sup> 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 Agreement States did

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

<sup>4</sup> PRM-31-05, published in 70 FR 75423, December 20, 2005

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

<sup>6</sup> Most recently LTR-06-0148, dated March 20, 2006

<sup>7</sup> 10 CFR 20.2201(a)(l)

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 accessibility 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:

1. The Commission approve staff option 2 to identify Category 3 sources and the licensees that possess them, and analyze their risks.
2. 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

## **Impacts of and Alternatives for Expanding the National Source Tracking System to Include Category 3 Sources**

The National Source Tracking System (NSTS) proposed rule solicited public comments on the issue of tracking Category 3 sources in the NSTS (70 FR 43646). The proposed rule's preamble stated that "a licensee possessing a large number of Category 3 sources could present a security concern." The proposed rule invited comments on the inclusion of Category 3 sources and asked input on the following:

- The number of additional licensees that would be impacted.
- The number of Category 3 sources possessed by licensees.
- How often those sources change hands.

Of the comments received on the NSTS proposed rule, NRC received little useful information on these particular questions and none is provided here.

### *Number of Licensees Affected by a Lowered Source Tracking Threshold to Category 3*

Three groups of licensees could potentially contribute to new licensees subject to the tracking requirements caused by lowering the NSTS criteria to Category 3. Occurring in the U.S. Nuclear Regulatory Commission (NRC) and Agreement State jurisdictions, there are:

- Specific Licensees whose possession limit is less than Category 2 but greater than Category 3. These licensees likely have never been contacted by NRC regarding source tracking, and may not be aware of NRC's recent efforts, such as the interim inventory for NSTS (also known as the "interim database").
- Specific Licensees whose possession limit is greater than Category 2, who have reported that they possess no Category 1 or 2 sources. Due to their possession limits, these licensees have been contacted by the NRC via recent agency accountability and security actions. These licensees may have at least one Category 3 source.
- General Licensees who possess a device exceeding the Category 3 quantities. These licensees are subject to registration requirements and are tracked in the general license tracking system (GLTS). These licensees report at least one Category 3 device. The number and activity of sources contained in a generally licensed device is not readily identifiable, but would clearly be considered co-located sources.

The following table is based on data obtained from the interim inventory for the NSTS (FY2005), NRC's licensing tracking system, and GLTS. Because GLTS records information based on devices – not licensees – the number of devices was divided by three for the purposes of comparison, because the average number of devices per general licensee is three. Agreement State numbers are estimated from the NRC numbers, using a factor of four. Table 1-1 presents ranges as opposed to discrete values, to provide a measure for the considerable uncertainty of these estimates.

Table 1-1: Estimated Number of Licensees Possessing Category 3 Sources, Not Possessing Category 1 or 2 Sources

<b>Group</b>	<b>NRC</b>	<b>Agreement State</b>	<b>Total</b>
Specific Licensees whose possession limit is less than Cat 2, and greater than Cat 3.	170 - 300	680 - 1,200	850 - 1,500
Specific Licensees whose possession limit is greater than Cat 2, but reported no Cat 1 or 2 sources.	243	665	908
General licensees who possess a device greater than Cat 3	14 - 86	55 - 343	68 - 428
<b>Total</b>	427 - 629	1,400 - 2,208	1,826 - 2,836 <b>1,800 - 2,800</b>

*Potential Number of Sources Affected by a Lowered Source Tracking Threshold to Category 3*  
 There is no good data set for assessing the number of Category 3 sources at this time. The best available nationwide data to estimate the relative number of devices between the Category 2 and 3 thresholds could be the sealed source and device (SS&D) registry. The following table illustrates the relative abundance of Category 2 and 3 sources, based on device data from the SS&Ds.

Table 1-2: Abundance of Active Sealed Source and Device Certificates, by the International Atomic Energy Agency (IAEA) Categorization

<b>Category</b>	<b>Active SS&amp;D Certificates</b>	<b>Number of SS&amp;D Certificates, Relative to Category 2</b>
Category 1	85	0.6
Category 2	135	1.0
Category 3	266	2.0

This comparison shows the relative abundance of devices and sources approved for use, but it does not have any measure for the numbers of devices and sources actually distributed. Therefore, this comparison is best used as an indication of the general abundance of Category 2 to Category 3 sources, and is notable because it is comprised of devices approved by NRC and Agreement States. Another source-based data set comes from the sources recovered by the U.S. Department of Energy (DOE). The DOE has made public the results of their Offsite Source Recovery Project (OSRP), which are unwanted sources recovered from the private sector<sup>1</sup> and may be a better indication of the numbers of devices and sources actually

<sup>1</sup>GAO-05-967 Security of Unwanted Radiological Sources

distributed. The OSRP, as part of the DOE's sealed radioactive source accountability and control regulations, has also reported its current inventory of sources awaiting disposal, through a so-called "data call," for FY2005.<sup>2</sup>

Table 1-3: Sources Recovered from the Private Sector by DOE's Offsite Source Recovery Program, Current, Total, and Relative Abundance

<b>Category</b>	<b>All Sources Recovered (as of 7/7/2005)</b>	<b>Number of Sources, Relative to Category 2</b>	<b>Sources in Inventory FY2005</b>	<b>Number of Sources, Relative to Category 2</b>
Category 1	37	0.3	0	0.0
Category 2	129	1.0	134	1.0
Category 3	4,941	38.3	2,875	21.5

Again, there are many reasons why these data may provide inaccurate measures for the purposes of estimating the number of Category 3 sources currently possessed by licensees nationwide. However, these data could be indicative of the potential for a prohibitively large number of Category 3 sources relative to the Category 1 and 2 sources currently tabulated in the interim inventory. If the number of Category 3 sources is too large, there is the possibility that expanding the NSTS to include Category 3 sources could divert resources from oversight of Category 1 and 2 sources.

#### *Conclusion and Recommendation*

The data are insufficient to support comprehensive and accurate cost estimates for including Category 3 sources in the NSTS. The staff recommends a one-time data collection of Category 3 sources to collect data on the number of licensees and sources at the Category 3 level. This approach will better identify the impact of tracking Category 3 sources on NRC, Agreement States, and licensees. This one-time data collection effort would likely require an Office of Management and Budget (OMB) clearance in order to comply with Paperwork Reduction Act requirements.

#### *Estimate of the Effort Required to Identify Category 3 Licensees*

Some staff effort will be required to identify licensees who possess at least one Category 3 sealed source. The staff recommends that this task be undertaken prior to any expansion of the NSTS. A manual search of NRC licenses by staff at Headquarters and in the Regions will be necessary. A similar effort performed by the Energy Policy Task Force to determine which specific licensees may possess at least one Category 2 sealed source took approximately one week of a very intensive effort by headquarters and regional staff to sort through approximately 4,500 licenses. Agreement States also searched their specific licenses. Because the number of specific licenses that need to be examined is lower (approximately 1,350 licenses do not need to be examined because they have been confirmed by the Interim Inventory for the

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<sup>2</sup>Personal communication, DOE-G, February, 2005

NSTS), based on the Energy Policy Task Force data, approximately 0.2 Full Time Equivalent (FTE) would be needed to determine an accurate count for specific licensees that may possess at least one Category 3 sealed source, with at least half of the work performed by the Regions. The efforts required to identify Category 3 sources possessed by general licensees would be obtained from preexisting data in GLTS (and equivalent systems in Agreement States, if existing), and would not add significant costs to the efforts required to identify specific licensees.

The staff estimates that the total national effort to identify Agreement State licensees is approximately 0.8 FTE, based on applying a factor of four to account for the more numerous Agreement State licensees.

#### *Estimate of the Effort Required to Identify Category 3 Sources*

Staff effort to identify Category 3 sources will be comparable to that of preparing the annual interim inventory of Category 1 and 2 sources. For the 2005 interim inventory, staff contacted 2,271 specific licensees at a cost of 1.0 FTE and \$280,000 in contracts. This calculation assumes the Category 3 licensees would be as amenable to complying with this voluntary interim inventory as are the Category 1 and 2 licensees. Licensees using solely Category 3 sources – as compared to licensees using Category 1 and 2 sources – are expected to be less sophisticated and consist of smaller businesses. Therefore, more follow-up may be required than for the interim inventory of Category 1 and Category 2 sources. Using the above estimates for the number of licensees, and scaling appropriately, it is estimated resources to add Category 3 sources to the interim inventory will be approximately 0.4 to 0.8 additional FTE and from \$110,000 to \$240,000 in additional contracts. Assuming the additional effort to include Category 3 could be conducted concurrently with the ongoing interim inventory activities, data on Category 3 sources could be expected within one year. Preexisting data in GLTS (and equivalent systems in Agreement States, if existing) can be sorted to determine the exact number of generally licensed devices currently accounted for, and would not add significant costs relative to the efforts required to identify sources possessed by specific licensees. All labor estimates and contracted technical assistance costs will be within one year.

The staff estimates that the total national effort to identify Agreement State sources is approximately 2.4 FTE, based on applying a factor of four to account for the more numerous Agreement State licensees.

## **An Analysis of Potential Regulatory Changes to the General Licenses**

The Commission has authority to issue both general and specific licenses. A general license appears in regulations<sup>1</sup> and grants authority to a person or individual for certain named activities involving the licensed material. The fundamental difference between a general license and a specific license is that a general license is provided by regulation and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person, and a specific license is issued to a named person who has filed an application for the license.

The U.S. Nuclear Regulatory Commission (NRC) and Agreement States ensure the public health and safety differently for general licensees than for specific licensees. For general licensees, safety concerns are addressed generically by extensive regulatory review of the design of the device and the practices of the devices' manufacturer so that, even in accident scenarios<sup>2</sup>, there is no unacceptable risk to public health and safety. This generic assessment focused on the device obviates the need to assess the user's proficiency with radiation safety practices. As a result, the requirements (and fees) for a person or individual operating under general license may be substantially less than for those persons or individuals operating under a specific license.

The NRC and Agreement States ensure protection of the environment similarly for general and specific licenses. In either case, the devices must be transferred to a properly-authorized specific licensee at the end of the device's useful life. Because of events resulting in radiation exposure to the public and damage to the environment and property involving generally licensed devices, those devices that pose a higher risk, if disposed of improperly, are subject to a registration system. Registration is required "for those devices considered to present a higher risk (compared to other generally licensed devices) of potential exposure of the public or property damage in the case of loss of control" (65 FR 79162), and has been in effect nationwide since 2004. The registration system has not been implemented in a uniform fashion amongst the States and the NRC. The issue of the general licensee registration compatibility is currently the subject of a request for compatibility category change filed by the Florida Department of Health and associated with a petition for rulemaking filed by the Organization of Agreement States (PRM-31-05).

Many factors may impact the security of radioactive material used by general licenses. Among the several types of general licenses, there is considerable variation in the requirements prior to the general licensee receiving the material, the reporting requirements placed on the distributor and the user, and other requirements that would impact the security of sources possessed under general license.

In most cases, there is no review of the facilities or personnel for a person or individual seeking to use generally licensed material, because no application is required. However, some general

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<sup>1</sup>General licenses for byproduct material are found in 10 CFR Part 31, general licenses for source material are found in 10 CFR 40.20 through 40.28, and general licenses for special nuclear material are found in 10 CFR Part 70, Subpart C.

<sup>2</sup>10 CFR 32.51(a)(2)(iii)

licenses carry the condition that the general licensee must also possess a specific license. For other general licenses, the vendor cannot provide the product without first verifying that its customer has preregistered the device with a regulatory body. Other requirements may apply to the manufacturer – a specific licensee – for example, that certain devices must be installed by a vendor in the gauge's place of use.

The major assurances of safety of generally licensed material rely on requirements of each general license, such as radionuclide and quantity limits, and for others, the design and manufacture of the device. Generally licensed devices containing byproduct material are evaluated by the NRC and some Agreement States against safety criteria. The device must be designed so that a person or individual untrained in radiological protection can operate it safely. The shielding and containment of the licensed material must be designed so that the user will not be exposed to more than a fraction of the occupational dose limits. Accident scenarios are also evaluated. The generally licensed devices containing relatively large quantities of byproduct material therefore are heavily shielded and tamper resistant, for safety reasons.

As noted in NRC's rule implementing the general license registration requirement (65 FR 79161, December 18, 2000), individuals who possess devices under general license are not always aware of applicable requirements. Historically, the NRC has not contacted the majority of these licensees or inspected these licensees on a regular basis because of the relatively small radiation risk posed by these devices. If so warranted, the general licensees are subject to inspections, orders, and enforcement actions. 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 is substantially less than for those persons or individuals operating under a specific license.

Reporting requirements vary amongst the several general licenses, and there is variation in the reporting requirements of the various Agreement State and NRC general licenses. As a result, the NRC has up-to-date data for some general licenses, and none for others.

In summary, considerable variation among the NRC's general licenses, which this Enclosure attempts to clarify. This enclosure presents the staff's analysis as follows. First, all general licenses are examined with respect to the International Atomic Energy Agency (IAEA) Categorization. Second, the general licenses with the potential to be a security concern are identified. Third, areas where increased regulatory oversight could be warranted are identified. Fourth, recommendations are made for rulemaking to amend the regulations governing the use and distribution of generally licensed sources.

### **General Licenses Provided by the NRC for Possession and Use of Radioactive Material**

General licenses for byproduct material are found in 10 CFR Part 31, general licenses for source material are found in 10 CFR 40.20 through 40.28, and general licenses for special nuclear material are found in 10 CFR Part 70, Subpart C. Most general licenses are provided for particular radionuclides and subject to explicit activity limits. It should be noted that devices, not sources, are authorized for use under general license, but because the sources are contained within one housing, the devices are treated as if they were equivalent to the sum of their aggregated sources. Where applicable, quantity limits of the various general licenses are compared, in the following table, to the IAEA Categorization (Table 2-1).

Table 2-1 – General Licenses Providing Authorization to Use and Possess Radioactive Material under the Atomic Energy Act of 1954, as amended, and Their Correlation to the IAEA Categorization.

Radionuclide	Regulation Providing the General License	Activity Limit		A/D Value (From IAEA. 1 = Cat 3 and 0.01 = Cat 4)
		μCi	TBq	
Thorium-228	§ 40.22	5.6E+12	2.1E+05	up to Cat 1
Uranium-232	§ 40.22	1.5E+11	5.6E+03	up to Cat 1
Thorium-229	§ 40.22	1.5E+09	5.4E+01	up to Cat 1
Various (byproduct material)	§ 31.5	Unlimited	Unlimited	up to Cat 2, for practical purposes
Polonium-210	§ 31.3	500	1.85E-05	0.000308
Promethium-147	§ 31.7	300,000	1.11E-02	0.000278
Hydrogen-3 (tritium)	§ 31.7	1.0E+07	3.70E-01	0.000185
Selenium-75	§ 31.11*	200	7.40E-06	0.000037
Iodine-125	§ 31.11*	200	7.40E-06	0.000037
Iodine-131	§ 31.11*	200	7.40E-06	0.000037
Americium-241	§ 31.8*	5	1.85E-07	0.000003
Plutonium-236	§ 70.19*	5	1.85E-07	0.000003
Plutonium-238	§ 70.19*	5	1.85E-07	0.000003
Plutonium-239	§ 70.19*	5	1.85E-07	0.000003
Plutonium-240	§ 70.19*	5	1.85E-07	0.000003
Plutonium-241	§ 70.19*	5	1.85E-07	0.000003
Strontium-90 (Y-90)	§ 31.10	50	1.85E-06	0.000002
Hydrogen-3 (tritium)	§ 31.3	50,000	1.85E-03	0.000001
Hydrogen-3 (tritium)	§ 31.11*	Unlimited	Unlimited	very small**
Carbon-14	§ 31.11*	Unlimited	Unlimited	very small**

Note: General licenses not listed above include § 31.11 for iron-59, for which the IAEA has not yet published a 'D-Value', and § 40.25 for depleted uranium, for which the IAEA does not consider a dangerous radionuclide in any quantity. Any general license for radium-226 would be under § 31.5. \*The general licenses in §§ 31.8 and 70.19 are only available to specific licensees. The general license in § 31.11 requires a specific license or pre-registration. \*\*The term "very small" is used to contrast the "unlimited" quantities allowable under § 31.5, which could be a concern, to the "unlimited" quantities allowable under § 31.11, which are not a concern. Under § 31.11, several tens of millions of units will need to be aggregated to create a quantity which approaches the 'D-Value' for these radionuclides.

## **Occurrence of General Licenses Authorizing Greater than Category 3 Quantities**

Viewed from the perspective of the IAEA Categorization – even considering general licenses authorizing the possession and use of unsealed material – only two out of all the types of general licenses authorize possession of material greater than a fraction of Category 4: §§ 31.5 and 40.22. It is possible for a person or individual to use and possess an individual Category 2 source within the authorization of these general licenses, to the extent that the regulations do not prohibit such quantities. Additionally, these general licenses do not limit the number of smaller devices that a person or individual may use or possess in one location, so that if aggregated, the devices collectively could exceed a Category 2 quantity. These concerns are greater for the general license in § 40.22, due to the very large activities allowable. The title of § 40.22, “Small quantities of source material,” refers to the small amount of mass (or weight) allowable under its general license. In terms of activity however, the title may be misleading (see Table 2-1) because millions of curies of certain thorium isotopes could conceivably be authorized for possession and use under this general license.

A preliminary search of the general license tracking system (GLTS) which is only applicable to NRC’s Part 31 general licenses has shown that either Category 2 or Category 3 quantities have been obtained by general licensees. Although there is no equivalent mechanism for searching for a large source possessed under § 40.22, a search of the sealed source and device (SS&D) registry shows that the largest known high-activity, isotopically-separated sources that have been reported to be possessed under § 40.22 are Category 4. Besides §§ 31.5 and 40.22, no other general license has the potential to reach the Category 3 threshold.

## **Proposed Changes to the General License in § 40.22**

Theoretically, very large activities of thorium-228 and thorium-229 could be possessed under the general license in § 40.22, which allows up to 15 pounds of source material to be used at one time and up to 150 pounds of source material to be used in one calendar year. Under the current regulatory structure, it is possible for a source material general licensee to possess a Category 1 source. For example, a person may possess 10,000 Category 1 thorium-228 devices under the general license in Part 40. This is because the general license in Part 40 is bounded on a mass basis, not activity. Similarly, 80 Category 1 uranium-232 devices could be possessed under the general license in Part 40. This is because these radionuclides have very high specific activities. However, NRC records indicate that only small quantities of isotopically separated thorium-228 or thorium-229 have been available commercially. Therefore, as a preliminary thought prior to rulemaking and subject to change as a result of Commission direction and stakeholder input, the staff recommends that significant quantities of isotopically separated source material would be no longer be authorized under this general license.

The general license in § 40.22 differs significantly from that in § 31.5. The risks are controlled only by the quantity limits in terms of weight. It is not limited to material contained in devices, nor are there limits on the chemical or physical form. There are no reporting requirements on distributors, so that the identities of the general licensees are not provided to the regulatory bodies. Additionally, there is no tracking of these general licensees or the materials distributed to them. As a result, there is no mechanism to verify if any isotopically separated thorium-228, thorium-229, or uranium-232 has been distributed for use under this general license, and if so, which persons or individuals may currently possess this material.

In “Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License,” (SECY-01-0072), dated April 25, 2001, the staff recommended rulemaking to better control and track persons operating under the general license in § 40.22, as well as additional controls to ensure public health and safety during the use of source material under this provision. This rulemaking is assigned and tracked as RM#564.

In the staff requirements memorandum to SECY-01-0072, the Commission requested that the staff collect additional information to support such a rulemaking. One difficulty in collecting the information has been that, without a past reporting requirement for either distributors or licensees, the staff has had to resort to novel and voluntary means of gathering the needed information. The staff is scheduled to provide the additional information and recommendations to the Commission in November, 2006.

Staff has considered major revisions to source material licensing to increase the accountability of licensees using source material (See generally SECY-01-0072). Given that very large quantities of radionuclides of concern are theoretically permissible under the general license in § 40.22, and the regulatory framework is not as well-developed as for byproduct material, initial steps are recommended to effectively enhance the security and accountability of sources under § 40.22. Regulatory provisions could be included to ensure that significant quantities of isotopically separated thorium-228, thorium-229, and uranium-232 would not be authorized under a general license. If pursued in isolation, due to the current framework for source material general licensees, regulations specific to enhancing security are unlikely to be effective. One main reason is that there are no reporting requirements on distributors, so that the identities of the § 40.22 general licensees are not provided to the NRC; the NRC has no ability to identify the licensees.

The staff is not re-recommending the same option as in SECY-01-0072 (Option #4 was recommended at that time). At this time, the staff would like to build on another option in that rulemaking plan – Option #5 – which could be easily modified to enhance controls for the sources of highest concern held within the § 40.22 general license. Among other things, Option #5 in SECY-01-0072 included reporting requirements for distributors of source material and requirements for certain sources to be used only under specific license. Another difference between the prior recommendation and the present time is that the IAEA Categorization could be used as a basis to establish the limit for use under general license, rather than the staff expending resources to establish such a limit independently. Although considerable changes would have to be made to the regulations, the staff’s prior effort (having already produced a rulemaking plan in SECY-01-0072) could be used to expedite the rulemaking process, given that the rulemaking plan would only have to be modified slightly and not developed anew.

### **Potential Changes to the General License in § 31.5 and Manufacturer/Distributor Requirements in Part 32**

Changes could be made to the general license provided in § 31.5, “Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere,” by amending the reporting requirements, expanding the registration requirements, and instituting explicit activity limits. These changes would affect existing and future licensees. Changes to manufacturer and distributor requirements in Part 32 could be

made to limit what devices are distributed to general licensees in the future. The Commission has the authority to issue orders to general licensees. Normally, changes to the general licenses would be made through notice-and-comment rulemaking.

#### *General Licensee Reporting Requirements*

A § 31.5 general licensee possessing a Category 2 quantity of material would not have to report source transactions to the national source tracking system (NSTS). Because paragraph § 31.5(c)(10) exempts the general licensee from the requirements of 10 CFR Part 20, except for §§ 20.2201 and 20.2202, a general licensee possessing a Category 2 source would be exempted from reporting to the NSTS. This section of § 31.5 could be amended to extend the general licensee's reporting requirement to the NSTS, in the case that sources meeting the criteria for NSTS are possessed under general license.

As NSTS would operate on a source basis, and this general license is on a device basis, some clarification of terms may be helpful. No known sources approved for use in generally licensed devices exceeds the Category 2 threshold. However, there is at least one device, multiple sources, which has a maximum allowable total activity of the Category 2 threshold. There are two reasons to treat sources contained within generally licensed devices equivalent to the sum of its sources as opposed to the sources individually. First, because such sources are contained within a single device, the sources will meet any co-location or aggregation concerns equivalent to the sum of its sources. A second reason for treating a device as if it were equivalent to the sum of its sources is, for practical reasons, that a unique serial number is critical to the operations of the NSTS. Generally licensed devices have been assigned and labeled with a unique serial number. There is no guarantee that all sources contained within the generally licensed devices have been assigned their own unique serial numbers. Therefore, the sources could be difficult to track.

General licensees under § 31.5 are exempt from all of Part 20 requirements, with the exception of §§ 20.2201 and 20.2202 (reporting thefts and losses, and reporting incidents, respectively). In effect, this means that a Category 2 source possessed by a specific licensee would be subject to the requirements of NSTS, but a Category 2 source possessed by a § 31.5 general licensee would be exempt from the reporting requirements of NSTS. In order to ensure that any future expansion of NSTS would apply to any generally licensed device that meets the criteria for source tracking, the staff recommends that § 31.5(c)(10) be revised so that these § 31.5 general licensees would not be exempt from § 20.2207 (reporting of transactions involving nationally tracked sources). This change would lay the foundation for the future application of NSTS equally to sources whether possessed under general or specific license.

#### *General Licensee Registration Requirements*

The general license registration requirement applies to devices containing certain named radionuclides, however it does not compel registration for all radionuclides of concern. See Table 2-2. Section 31.5(c)(13)(i) could be amended to require registration of all radionuclides of concern. This provision is the subject of a request for compatibility category change filed by the Florida Department of Health and associated with a petition for rulemaking filed by the Organization of Agreement States (PRM-31-05).

Table 2-2 – Byproduct Material General License Device Registration Thresholds, IAEA Categorization, and Certificates Authorizing Distribution to General Licensees

Radionuclide of Concern (Byproduct Material)	General Licensee Registration Requirement (mCi)	Registration Requirement A/D Value (From IAEA. 1 = Cat 3 and 0.01 = Cat 4)	Categorization of Largest Applicable SS&D Certificate
Am-241	1.0	0.0006	Cat 2
Cs-137	10.0	0.0037	Cat 3
Co-60	1.0	0.0012	Cat 3
Cf-252	1.0	0.0019	Cat 4
Cm-244	1.0	0.0007	Cat 4
Am-241:Be	1.0	0.0006	Cat 4*
Ra-226**	0.1	0.0001	Cat 4
Sr-90 (Y-90)	0.1	<0.0001	Cat 4
Pm-147, Po-210	<b>none</b>	-	Cat 4
Gd-153, Ir-192, Se-75, Tm-170, Yb-169	<b>none</b>	-	none

Note: Plutonium and thorium isotopes, while radionuclides of concern, are not subject to registration because they are not byproduct material. Polonium-210 is shown because it is a nationally-tracked radionuclide.

\*The largest active certificate for a Am-241:Be device is Category 4.

\*\*pending rulemaking.

A search of NRC's records reveals that all existing Category 2 and 3 devices containing byproduct material are already subject to the current registration requirements in § 31.5(c)(13)(i). As shown in Table 2-2, of the radionuclides of concern that are not subject to registration, only promethium-147 and polonium-210 have a SS&D certificate greater than Category 4. Of the generally licensed devices approved for use in quantities greater than Category 3, only three radionuclides have been used: americium-241, cesium-137, and cobalt-60 (Table 2-3). Based on the activity to 'D' Value calculations, general license device registration is required for sources much lower than the Category 3 thresholds. Therefore, the staff does not recommend changes for radionuclides already required to be registered. The staff recommends extending the registration requirement to cover all other radionuclides of concern that are not currently registered, such as for gadolinium-153, iridium-192, polonium-210, promethium-147, selenium-75, thulium-170, and ytterbium-169. Such an expansion should also consider other radionuclides such as those shown "below the line" in Appendix I to the Code-of-Conduct as unlikely to be present in large sources (e.g. gold-198, cadmium-109, cobalt-57, iron-55, germanium-68, nickel-63, palladium-103, ruthenium-106 (rhenium-106), and thallium-204).

Table 2-3 – Sealed Source and Device Certificates Exceeding Category 3 Quantities, Approved for Use by General Licensees

<b>Radionuclide</b>	<b>Number of Certificates Approving Greater than Category 3 Quantities</b>	<b>Active Certificates Approving Greater than Category 3 Quantities</b>
Am-241	33*	12*
Cs-137	33	10
Co-60	4	3
Am-241:Be	1	0
All Others	0	0

Note: Totals include devices whose certificate shows evaluation for general license (G), both general and specific license (B), and if it is “unknown” whether the device is evaluated for general licensees (U). No “unknown” Category 3 certificates are active.

\* Includes one device which holds multiple Category 3 sources which, if aggregated, exceeds the Category 2 threshold for americium-241. Staff is, with the Agreement States, examining this certificate and current users in order to determine the appropriate course of action.

The primary benefit of expanding the registration requirement for devices generally licensed under § 31.5(c)(13)(i) to cover all radionuclides of concern would be to ensure that, should such devices ever be distributed to general licensees, there would be enhanced general licensee accountability. A secondary benefit would be that all radionuclides of concern would be treated equally. As currently structured, requiring registration for some of the radionuclides of concern creates an incentive for users to acquire non-registered devices in order to avoid the registration requirements. Registering these devices would require an incremental increase in staff effort and contractor support, which would be offset by the associated fees. The current annual fee for generally licensed devices subject to registration is proposed as \$730 per location of use or storage location.

#### *General Licensee Activity Limits – Introduction*

As shown in Table 2-1, there are no explicit activity limits in the general license provided by § 31.5. However, for practical reasons, no devices have ever been approved for use under the general license in § 31.5 in quantities greater than Category 2, and the sources in this device are all Category 3 sources. The regulations in Part 31 could be amended to prohibit the use or possession of sources, individually or in aggregate, by general licensees above an activity-based threshold. In effect, this would “cap” the general license in § 31.5. The distribution and manufacturing requirements for generally licensed devices under § 31.5 are found in Part 32.<sup>3</sup> Whereas changes to § 31.5, such as a “cap,” would affect existing and future licensees, changes to regulations in Part 32 would only affect future distribution. Therefore, the analysis of costs associated with various threshold scenarios would be very similar to that presented above, less the transition costs shown for the first year.

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<sup>3</sup>Particularly 10 CFR 32.51, 32.51a, and 32.52.

The staff examined smaller subdivisions of the IAEA categorization for the purpose of assessing the concerns that devices just below the Category 2 threshold would not be subject to source tracking. Zero devices were found containing a radionuclide of concern from 99% to 75% of the Category 2 threshold; there is no evidence that such devices have ever been in NRC jurisdiction under general license in § 31.5.

*General Licensee Activity Limits – Number of Devices*

The GLTS was searched for all records of devices that have been reported in the NRC’s jurisdiction, and filtered for those devices containing radionuclides of concern in at least Category 3 quantities. Although this method provides the broadest representation of the types of devices used under general license, it may not be appropriate for other purposes. Agreement State licensees are expected to have similar distributions of devices and collectively are estimated to have more licensees by a factor of four times that of the NRC. Counts of generally licensed devices by IAEA Categorization are presented in Table 2-4.

Two concepts in Table 2-4 are somewhat novel: D-Units and Category 2.5. Along with the well established Categories 2 and 3, Category 2.5 is presented in Table 2-4 as a subcategory. Category 2.5 should be interpreted as one-half of the Category 2 threshold. The reason for including this level is that the data naturally support a conclusion that this level should be considered as optimizing oversight of licensed material with a minimum of regulatory burden, as shown below. D-Units are a way to uniformly compare the potential for radiological consequences between sealed sources containing different radionuclides of concern. As opposed to comparing total activity, where one curie of strontium-90 is equal to one curie of californium-252, D-Units compare the two sources in a way that is weighted with respect to radiological consequences in accordance with the IAEA Categorization. One D-Unit equates to a Category 3 source, and 10 D-Units equate to a Category 2 source, per the IAEA Categorization. For comparison, a gamma knife is a device containing 201 sources with an aggregate total of 44 TBq of cobalt-60, equivalent to 1,481 D-Units. Calculation of D-Units was done in accordance with the IAEA Categorization (see IAEA, RS-G-1.9, Annex 2), as a robust and logical basis for comparing the potential for radiological consequences.

Table 2-4 – Cumulative Number of Devices Possessed and Used Under General License In NRC Jurisdiction, by Various Thresholds (using records, not necessarily active sources).

<b>Category Threshold</b>	<b>Number of Devices</b>	<b>Activity (TBq)</b>	<b>D-Units</b>
Category 2 +	16	19	303
Category 2.5 +	18	20	316
Category 3 +	257	47	674

From Table 2-4, it is shown that “capping” the general license at thresholds of Category 3 would increase regulatory oversight for considerable quantities of radioactive material. It also shows that the Category 3 threshold also increases the number of devices subject to specific licensing. The data show that between Category 2.5 and 3 there is a logical break where the activity could be capped with reasonable incremental staff effort.

The regulatory efficiency of different scenarios is presented in Table 2-5. The regulatory efficiency – the number of devices regulated per unit of potential radiological consequences – may be a factor in determining the preferred general license maximum threshold. Using such a regulatory efficiency is an objective way to balance the benefits of increased oversight of radioactive material of concern with the resources that are necessarily required to bring about those benefits. Essentially, because the burden of such a change would scale proportionally to the number of devices, and the potential for radiological consequences is proportional to the number of D-Units, this is a measure of the relative effort required for specifically licensing incremental measures of radiological consequences.

Table 2-5 – Regulatory Efficiency of Various Thresholds for Requiring Specific Licensing for Generally Licensed Byproduct Material Under § 31.5. (Using records, not necessarily active sources.)

<b>Incremental Category Threshold</b>	<b>Incremental Number of Devices</b>	<b>Incremental Potential for Radiological Consequences (D-Units)</b>
Category 2 +	16	303
Category 2 to 2.5	2	13
Category 2.5 to 3	239	359

A threshold of Category 2.5 compares relatively well with a threshold of Category 2 and has the benefit of regulating more material by way of requiring specific licensing for more sources. From Table 2-5, it is shown that although there is slightly more potential radiological consequences from the sources between Category 2.5 and 3 as there are from the sources greater than Category 2 (359 D-Units compared to 303), there are also approximately 15 times as many devices (239 compared to 16). Therefore, based on this measure of regulatory efficiency, the effort required to regulate the generally licensed sources between Category 2.5 and 3 is approximately seven times as costly as the effort required to regulate the generally licensed sources greater than Category 2.

Intuitively, for any radionuclide, larger devices may pose more potential for radiological consequences than smaller devices, but if the smaller devices are present in very large numbers, the aggregated potential for radiological consequences may be greater for the many small devices than for the fewer, larger devices. Based on the analysis of the data presented here, it seems that if an explicit limit is to be placed on the general license in § 31.5, Category 2.5 will require specific licensing for the most material while at the same time maintaining an optimal level of regulatory efficiency.

#### *General Licensee Activity Limits – Labor Expenditures*

Specific licensee labor rates are estimated from the Fiscal Year 2007 budget. Due to the limitations of the data available for analysis, an accurate count of the devices still in service was not obtainable in the time allotted, so the data may overestimate the burden. It should be noted that multiple generally licensed devices may be used and possessed by a single person or individual; the staff’s best estimate for an overall average is that about three devices are held by a one person or individual who would be required to apply for a specific license.

Requiring specific licenses for devices currently in use under general license will necessarily require more regulatory oversight. For each new licensee, the appropriate regulatory agency will have to approve the application, respond to license amendment requests, and renew licenses. Materials licenses are currently issued for 10-year periods. The new specific licensees would be inspected. Based on current licensing prioritization, and assuming the “new” specific licensees would be Priority 5 materials licensees, inspections would occur (nominally) on a five-year cycle. With experience and satisfactory licensee performance, the inspections could occur less frequently, and inspections may be made by telephone in the future. Labor costs for the NRC would occur in the first year, as the new applications are submitted, at approximately 0.008 full time equivalent (FTE) per application. Ongoing labor costs would be necessary to inspect the new licensees (0.014 FTE per inspection), renew licenses (0.007 FTE per license), and also to review applications that otherwise would not be required. Table 2-6 shows the costs per new licensee, given the current materials labor rate.

Table 2-6 – Labor Costs Associated With Specific Licensing Currently Generally Licensed Devices, NRC Jurisdiction Only.

General License Maximum Threshold	Number of “New” Licensees* (Upper Range)	First Year Labor Costs** (000's of \$)	Ongoing Annual Labor Costs (000's of \$)			
			Inspection (5 yr cycle)	Renewal (10 yr cycle)	New Apps (est.)	Annual Total**
Category 2	5	\$7	\$3	\$1	\$1	\$5
Category 2.5	6	\$9	\$3	\$1	\$2	\$6
Category 3	86	\$125	\$44	\$11	\$25	\$80

Notes: \*The number of new licensees was generated by dividing the number of affected devices by three, to reflect that the new licensees are expected to possess multiple devices. \*\*These costs should be viewed as an upper limit, and are limited by the data that is available at this time. The unit rates per licensee and proportions (ratio of one threshold to another) are accurate, however. Essentially all of the uncertainty is due to estimating the number of new licensees that would be created. License amendments are ignored by this analysis at this time, but would cost 0.0047 FTE per amendment, and so would only contribute marginally to the overall costs.

The costs shown in Table 2-6 are just the licensing costs for the NRC staff to specifically license current general licensees. Agreement States would have to expend FTE proportionally to the number of their affected general licensees. This analysis of labor costs associated with specific licensing of current generally licensed devices does not consider the costs borne by the general licensees, which could be considerable given the regulatory change (e.g. preparing and submitting a license application, hiring an radiation safety officer, complying with 10 CFR 19, 20, and 21, etc.).

### Proposed Changes to the General License Distributor Requirements in Part 32

From the data collected so far, it appears that limiting the distribution of Category 2 and Category 2.5 devices for distribution under §§ 32.51 and 32.51a would effectively and efficiently prevent sources of concern from being distributed to general licensees. Such a change would

affect a small number of distributors. There are few active SS&D certificates that authorize such distribution, and staff estimates that only 11 vendors would be affected by such a change. It is plausible that the devices would be re-evaluated to use smaller sources or to inactivate certain certificates. Of these certificates, only one is issued by the NRC, so Agreement State cooperation is vital, especially for those jurisdictions where the 11 active vendors are located.

A change to limit the distribution of Category 3 sources does not appear to justify the additional costs associated with the change when evaluated relative to the costs associated with Category 2 and Category 2.5. An analysis of the SS&D certificates shows that approximately 54 unique vendors possess active certificates for generally licensed devices, and these vendors and other stakeholders could be consulted as part of any rulemaking to amend the generally licensed device distributor regulations.

The decision to amend § 31.5 in addition to Part 32 will have to balance several qualitative factors. Any proposed change to the general license in § 31.5, which applies to the device users, should consider the potential negative consequence that the devices would become unwanted at the time of the regulatory change. Besides the costs to the NRC, the licensees who have to apply for specific licenses will also be subjected to up-front and ongoing costs associated with the regulatory changes. As these costs would be significant relative to their current costs, it is possible that some of these devices will become unwanted. On one hand, if the only regulatory change is to prohibit the manufacturers from distributing certain devices to general licensees in the future, the existing devices already distributed would, in effect, be “grandfathered” and not subject to the same regulatory oversight as identical devices in the future. There could also be an incentive for existing licensees to retain their “grandfathered devices” longer than they would otherwise. Based on available data on NRC’s licensees, the population of general licensees using Category 2 and Category 2.5 devices appears small enough that their regulatory status can be examined on a case-by-case basis. The NRC would have to work with the affected licensees and States to (1) determine if the sources in Agreement States have similar characteristics, (2) ensure that all such licensees are capable of ensuring the desired level of controls for their devices, and (3) determine if a disposition path exists for any unwanted devices as a result of these regulatory changes. This interaction would involve relatively few licensees, and could be completed within one year.

In conclusion, currently available information indicates that requiring a specific license for Category 3 sources is not necessarily ruled out by prohibitive NRC licensing costs. However, given that the majority – approximately 80% – of licensees who would be affected by a general license “cap” at the Category 3 threshold are licensed by the Agreement States, and only a few (no more than 25) vendors distribute such devices, the staff requests particular interaction with these stakeholders to gather data to confirm that such a cap would have moderate costs. Prior to any data collection efforts, an Office of Management and Budget (OMB) clearance would be needed to comply with Paperwork Reduction Act requirements. This data would be gathered within one year. The staff would support a requirement for a specific license for all devices greater than Category 2 or one-half the Category 2 threshold (Category 2.5), due to the very modest expected costs and relatively large benefits.

### *Summary, Consolidated Recommendations, and Resources*

The general licenses provided by the NRC's regulations were examined in light of the IAEA categorization. Enhanced controls do not appear justified for most general licenses by this measure. The general licenses in §§ 40.22 and 31.5 are exceptions because they have the potential to authorize Category 1 and Category 2 sources to be used or possessed by general licensees.

The specific recommendations and resources needed to effectively prevent the use and possession of sources of concern under § 40.22 are detailed in Draft Rulemaking Plan: "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License," (SECY-01-0072), dated April 25, 2001, and assigned under RM#564. That rulemaking plan estimates that the whole rulemaking (e.g. proposed rule and final rule) will require up to 4.75 FTE and \$190,000 in total, spread over three fiscal years. As part of the recommended rulemaking, the staff recommended that a limit should be placed in § 40.22 to prohibit the use or possession of isotopically separated source material under this general license.

The specific recommendations for changes to the general license in § 31.5 are to (1) amend paragraph § 31.5(c)(10) so that byproduct material general licensees would not be exempted from the requirements of reporting to the NSTS (10 CFR 20.2207, as proposed), (2) expand the registration requirement to include all applicable radionuclides of concern so that every byproduct material radionuclide of concern is regulated similarly, and (3) limit or "cap" the authorization of greater than Category 2.5 activities of radionuclides of concern under this general license so that only specific licensees may use or possess the sources with the highest potential for radiological consequences. The impacts of a general license "cap" below a threshold of Category 2.5 should be further examined with State and stakeholder input prior to any specific recommendation for changes to the general licensed device manufacturer regulation in § 32.51.

The resources required for the changes to the regulations in Parts 31 and 32 would be due to rulemaking. Program costs and regulatory impacts will be estimated as part of the rulemaking process as the detailed amendments are developed. Therefore, depending on resource prioritization, such a rulemaking is likely to take 24 months. This effort is currently budgeted by the Office of Nuclear Material Safety and Safeguards for a total of 2.0 FTE and \$60,000 in contracted technical support.

## Resource and Commitment Matrix

Option	Task	Resources		Result
		FTE	\$ (000s)	
2 – Collect Data and Evaluate Use of Category 3 Sources <b>(Recommended)</b>	Identify Licensees	0.2		Identify licensees who possess Category 3 sources nationwide.
	Identify Category 3 Sources	0.4 - 0.8	110 - 240	“Interim Inventory” for Category 3
	Further analyze risks of Category 3 Sources	0	160	
	Subtotal	0.6 - 1.0	270 - 400	
3 – Amend General Licenses <b>(Recommended)</b>	Source Material General Licensees (§ 40.22)	-- <sup>(1)</sup>	-- <sup>(1)</sup>	Modify 5 <sup>th</sup> option in rulemaking plan (SECY-01-0072)
	Rulemaking Plan <sup>(2)</sup>	0 - 0.5	0 - 25	
	Byproduct Material General Licensees (§ 31.5) Proposed Rule	1.0	30 - 45	
	Byproduct Material General Licensees (§ 31.5) Final Rule	1.0	30	
	Subtotal <sup>(1)</sup>	2.0 - 2.5	60 - 100	Amend regulations for generally licensed sources
4 – Inventory Reporting Requirement	Develop Technical Basis	0.5		
	Rulemaking Plan <sup>(2)</sup>	0 - 0.5	0 - 25	
	Proposed Rule	1.0	50 - 100	
	Final Rule	1.0	0 - 25	
	Subtotal	2.5 - 3.0	50 - 150	Establish inventory reporting requirement
<b>Total Recommended</b>		<b>2.6 - 3.5</b>	<b>330 - 500</b>	

**Notes:**

(1) Costs for amending source material general licenses are not included in the totals for this Commission paper, because they were presented in SECY-01-0072. Total costs are estimated in that paper to be 4.75 full time equivalent (FTE) and \$190,000 in technical support.

(2) Commission could direct staff to proceed directly from the technical basis to the proposed rule and to not develop a rulemaking plan.

Option 1 – No Action

This option would not constitute any new resource allocation.

Option 2 – One-Time Data Collection of Category 3 Sources (Recommended)

None of the resources required for this option are currently budgeted. The Office of Nuclear Materials Safety and Safeguards (NMSS) would be the office largely affected by option 2.

Task	FY2006		FY2007		FY2008	
	FTE	\$ (000s)	FTE	\$ (000s)	FTE	\$ (000s)
Identify Licensees	0.2	0	0	0	0	0
Identify Sources	0	0	0.4 - 0.8	110 - 240	0	0
Analyze Risks	0	0	0	0	0	160
<b>Total</b>	<b>0.2</b>	<b>0</b>	<b>0.4 - 0.8</b>	<b>110 - 240</b>	<b>0</b>	<b>160</b>

Option 3 – Amendments to the General Licenses (Recommended)

The NMSS full time equivalent (FTE) required for this recommended option are currently budgeted. The total budgeted resources for contract support (\$60,000 total) is within the range of the projected needs (\$60,000 - \$100,000). NMSS would be the lead office responsible for this option. Other offices expected to review and concur on the rulemaking packages are: Office of the Chief Financial Officer (CFO), Office of the General Counsel (OGC), Office of Nuclear Security and Incident Response (NSIR), Office of Enforcement (OE), Office of Administration (ADM), Office of Information Services (OIS), and the Office of State and Tribal Programs (OSTP).

Task	FY2007		FY2008	
	FTE	\$ (000s)	FTE	\$ (000s)
Source Material General License (§ 40.22) Amendments	Provided in SECY-01-0072		Provided in SECY-01-0072	
Rule Plan*	0 - 0.5*	0 - 25*	0	0
Proposed Rule	1.0	30 - 45	0	0
Final Rule	0	0	1.0	30
<b>Total</b>	<b>1.0 - 1.5</b>	<b>30 - 70</b>	<b>1.0</b>	<b>30</b>

Note: \*the resources attributable to produce a rule plan are provided should the Commission determine that one is warranted. If a rule plan is to be developed, the implication would be that the subsequent activities (proposed rule, final rule) would be pushed back six to nine months.

Option 4 – Inventory Reporting Requirement (Not Recommended)

This option is not recommended, but the resources are projected to allow full consideration of this option. None of the resources required for this option are currently budgeted. If selected, NMSS would be the lead office responsible for this option. Other offices expected to review and concur on the rulemaking packages are: Office of the Chief Financial Officer (CFO), Office of the General Counsel (OGC), Office of Nuclear Security and Incident Response (NSIR), Office of Enforcement (OE), Office of Administration (ADM), Office of Information Services (OIS), and the Office of State and Tribal Programs (OSTP).

Task	FY2007		FY2008		FY2009	
	FTE	\$ (000s)	FTE	\$ (000s)	FTE	\$ (000s)
Technical Basis	0.5	0	0	0	0	0
Rule Plan*	0	0	0 - 0.5*	0 - 25*	0	0
Proposed Rule	0	0	1.0	50 - 100	0	0
Final Rule	0	0	0	0	1.0	0 - 25
<b>Total</b>	<b>0.5</b>	<b>0</b>	<b>1.0 - 1.5</b>	<b>50 - 125</b>	<b>1.0</b>	<b>0 - 25</b>

Note: \*the resources attributable to produce a rule plan are provided should the Commission determine that one is warranted. If a rule plan is to be developed, the implication would be that the subsequent activities (proposed rule, final rule) would be pushed back six to nine months.