Description of Options and Associated Pros/Cons

The Staff Requirements Memorandum (SRM) for COMJMB-16-0001, "Proposed Staff Re-Evaluation of Category 3 Source Accountability" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16292A812), directed the staff to perform an evaluation of the pros and cons of different methods of requiring transferors of Category 3 sources to verify the validity of a transferee's license prior to transfer; an evaluation of the pros and cons of including Category 3 sources in the National Source Tracking System (NSTS); and an assessment of any additional options for addressing the Government Accountability Office (GAO) recommendations on source accountability. The SRM also directed the U.S. Nuclear Regulatory Commission (NRC) staff to discuss potential actions considered by the NRC staff that would not require rulemaking, such as changes to guidance and training, and to identify any relevant factors that would bear on the Commission's deliberation of options presented. Finally, the Commission directed the NRC staff to assess the risks posed by the aggregation of Category 3 sources into Category 2 quantities when conducting the evaluations referenced above.

In its efforts to address the tasks in SRM-COMJMB-16-0001, the Category 3 Source Security and Accountability Working Group (C3WG) considered the recommendations made by two previous NRC/Agreement State working groups (the Enhancements to the Pre-Licensing Guidance Working Group (PLWG), and the License Verification and Transfer of Category 3 Sources Working Group) that were formed in response to materials licensing audit GAO-16-330, entitled "NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain." The working group also considered the results of the Congressionally-mandated review of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," which was completed in December 2016 (ADAMS Accession No. ML16348A230) to inform its evaluations.

The options considered by the C3WG are broken down into the following four areas of concern to address source security and accountability of Category 3 quantities of radioactive material:

- **Concern 1:** The ability to obtain a valid license using a fictitious company or by providing false information;
- **Concern 2:** The ability to alter a valid license to obtain more or different radioactive material than authorized or to counterfeit a license to obtain radioactive materials illicitly;
- **Concern 3:** The ability to accumulate or aggregate Category 3 sources to a Category 2 quantity of radioactive material requiring enhanced security; and
- **Concern 4:** The limited accountability, lack of pre-licensing evaluations, and lack of routine oversight of Category 3 sources contained within generally licensed devices.

The sections below include a discussion and description of the options and the associated pros/cons for each option.

Concern 1: The ability to obtain a valid license using a fictitious company or by providing false information

This analysis presents one option related to the concern of obtaining a valid license using a fictitious company or by providing false information. In order to address this concern, the C3WG considered the PLWG's evaluation of current licensing requirements and guidance that could

help prevent delivery of a license to a fictitious company. The current version of the pre-licensing guidance has been in use by the NRC and Agreement States since 2008[1] to provide a basis for confidence that radioactive material will be used as specified on a license. The other objectives of the pre-licensing guidance are to provide direction on conducting site visits for unknown applicants and to identify suspicious applicants, in which their information would be forwarded to the appropriate authority for followup.

In GAO-16-330, the GAO recommended that the NRC consider requiring on-site security reviews for all unknown applicants of Category 3 licenses to verify that each applicant is prepared to implement the required security measures before taking possession of licensed radioactive materials. In response to this GAO report, the PLWG recommended rulemaking to amend 10 CFR Parts 30, 40, and 70 to require safety and security equipment to be in place before granting a license for an unknown entity. Additional information on these recommendations can be found in SECY-17-0025, "Update on Source Security and Accountability Activities," dated February 17, 2017 (ADAMS Accession No. ML16344A108).

Concern 1, PLWG Recommendation (presented in SECY-17-0025): Initiate rulemaking to require that necessary security and safety equipment is in place prior to issuing a license to all unknown applicants. Such a requirement could be incorporated into 10 CFR 30.33, 40.32, and 70.23.

Unknown[2] applicants requesting a license would be required to have all necessary security and safety equipment in place prior to the issuance of a license. This requirement would apply to all specific licenses.

Pros:

- Provides additional assurance of the validity of unknown applicants prior to authorization to possess any quantity of licensed radioactive material
- Eliminates the acceptance of written and oral assurances regarding facility completeness and required security and safety equipment
- Aligns the NRC with the majority of Agreement States which do not issue a license prior to facility completion (27 of 37 Agreement States provided input to a PLWG survey, with 78 percent of state respondents indicating that they do not issue a license prior to facility completion)
- Represents no change to the overall cost to the applicant

Con:

- Unknown applicants would have to invest in the required security and safety equipment prior to receiving the license, which is a shift in when the up-front cost is incurred

[1] Checklist to Provide a Basis for Confidence that Radioactive Material Will Be Used As Specified on a License (non-public)

[2] As used in the "Checklist to Provide a Basis for Confidence that Radioactive Materials will be Used as Specified on the License" (non-public) and in the enclosure to SECY-17-0025, an unknown applicant is an entity in which the regulatory agency does not have confidence based on previous regulatory engagement with the applicant, that it will use radioactive materials as specified on a radioactive materials license.

Concern 2: The ability to alter a valid license to obtain more or different radioactive material than authorized or to counterfeit a license to obtain radioactive materials illicitly

This analysis presents six options related to license verification/authentication to address the concern of someone being able to alter a valid license to obtain more radioactive material than authorized, and to counterfeit a license to obtain radioactive materials illicitly. In GAO-16-330, the GAO recommended that the NRC require transferors of Category 3 quantities of radioactive materials confirm the validity of a would-be purchaser's radioactive materials license with the appropriate regulatory authority before transferring any Category 3 quantities of licensed materials. The GAO also recommended that Agreement State licenses authorizing Category 3 quantities of radioactive material should be included in the Web-Based Licensing (WBL) System.

License verification refers to the review of certain license information before a transfer of any of the radionuclides of concern listed in the International Atomic Energy Agency *Code of Conduct on the Safety and Security of Radioactive Sources* occurs, to ensure that a licensee receiving radioactive material is authorized to possess it.

The current regulatory infrastructure for license verification for Category 1 and Category 2 quantities of radioactive material involves verifying the licensee name, license address, license number, license amendment number or issue date, isotopes of concern and quantities, and for Category 1 quantities of radioactive material, that the shipment location is authorized. The verification can be performed through the License Verification System (LVS), which queries WBL, or by contacting the regulatory authority that issued the license. To ensure that licenses can be verified through the LVS, most Agreement State licensing agencies not using WBL as their license tracking system voluntarily provide copies of their licenses to the NRC for inclusion into WBL. Alternately, if they choose not to submit Category 1 and Category 2 licenses to the NRC for inclusion in WBL, the Agreement State regulators must take responsibility for verification of licenses within their States.

Use of LVS requires credentialing to access the system. Therefore, licensees opting not to get credentialed to access LVS, or those receiving a message by LVS to contact the regulatory authority, must use a manual process to complete the verification of a license. To facilitate this process, the transferring licensee contacts the LVS Help Desk by phone or e-mail to provide the necessary information to populate the NRC Form 749, "Manual License Verification Report." This form can also be populated by the licensee and e-mailed to the LVS Help Desk. The transferring licensee receives a notification from the LVS Help Desk of the verification outcome as soon as the verification is complete by the license-issuing regulatory agency, which typically occurs on the same business day. The verification outcome includes a notification of whether the requested materials, quantities, and, in the case of Category 1 quantities of radioactive material, the shipment location are authorized on the license. No license copy is provided to the transferring licensee. Additional information on the manual license verification process can be found on the LVS Web site at https://www.nrc.gov/security/byproduct/ismp/lvs/procedure.html.

Use of LVS or verification through the regulatory authority are possible methods for verifying the validity of licenses for transfers of radioactive material below the Category 2 threshold (i.e., Category 3 and lower quantities of radioactive material); however, there are other acceptable methods permitted in 10 CFR 30.41, 40.51, and 70.42. Review of a paper license is the more prevalent method used to verify the validity of such licenses prior to material transfers.

Concern 2, Option 1: No action

Licensees transferring any quantity of radioactive material below the Category 2 threshold will continue to use the verification methods listed in 10 CFR 30.41, 40.51, and 70.42 before transferring any materials.

Pros:

- Various methods to verify licenses are retained
- No need to maintain additional Agreement State licenses in WBL
- No burden to regulators to verify licenses manually if electronic method is not available

Cons:

- No assurance of official authorizations to obtain specific quantities of licensed material
- No assurance of the authenticity of a license

Concern 2, Option 2: Require verification of licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority

Licensees transferring Category 3 quantities of radioactive material would be required to verify licenses through the LVS or the regulatory authority. Agreement States that do not use WBL as their license tracking system could voluntarily provide their licenses authorizing Category 3 quantities of radioactive material to the NRC, which the NRC staff would then enter into WBL, to facilitate verification through LVS. Alternately, Agreement States that choose not to provide copies of their licenses authorizing Category 3 quantities of radioactive material for entry in WBL could perform manual license verifications.

Pros:

- Eliminates reliance on paper licenses authorizing possession of Category 3 quantities of radioactive material and moves license verification to an electronic platform using LVS
- Prevents the use of counterfeit or altered licenses authorizing possession of Category 3 quantities of radioactive material

Cons:

- Does not address counterfeiting or alteration of licenses below Category 3 possession limits
- A majority of licensees authorized to possess Category 3 quantities of radioactive material are likely to use the manual verification method due to the infrequency of transfers, which increases the burden to regulators
- Increased burden to the Agreement States to maintain licenses in WBL
- Increased burden to the NRC to support Agreement States not using WBL
- Increased burden to regulators to support manual license verification
- Time lag in uploading Agreement State licenses into WBL, which could hamper the license verification process through LVS
- Increased burden on licensees to perform verification through LVS or the regulatory authority prior to radioactive material transfers, which may involve credentialing to get access to LVS

Concern 2, Option 3: Require only manufacturers and distributors to verify licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority

License verification through LVS or the regulatory authority would only be required for transfers of Category 3 quantities of radioactive material from manufacturers and distributors (M&Ds) to customer licensees. License verification requirements for licensees who are not M&Ds would remain unchanged. The C3WG estimates that transfers from M&Ds to customer licensees account for approximately 40 percent of all transactions involving Category 3 quantities of radioactive material (an additional 40 percent involve shipment back to an M&D, such that in total, 80 percent of source transactions involve an M&D). Agreement States that do not use WBL as their license tracking system would need to either voluntarily provide their licenses authorizing Category 3 quantities of radioactive material to the NRC to facilitate verification through LVS, or perform manual license verification.

Pros:

- Assures that M&Ds do not provide Category 3 quantities of radioactive material to unverified recipients
- Accounts for the majority of transfers involving Category 3 quantities of radioactive material to customer licensees
- Impacts fewer licensees and limits industry burden to M&Ds, which likely have the infrastructure and resources to handle the additional burden
- Minimizes reliance on paper licenses authorizing Category 3 quantities of radioactive material, and moves license verification to an electronic platform

Cons:

- Does not address counterfeit/altered licenses for transfers not involving an M&D
- Does not address counterfeit/altered licenses below the Category 3 threshold
- Increased burden to the Agreement States to maintain licenses in WBL
- Increased burden to the NRC to support Agreement States not using WBL
- Increased burden to regulators to support manual license verification
- Would treat transfers of Category 3 quantities of radioactive material in an inconsistent manner based solely on whether or not the transferor is an M&D
- Time lag in uploading Agreement State licenses in WBL, which could hamper the license verification process through LVS

Concern 2, Option 4: Require verification of all licenses through LVS or the regulatory authority

Licensees transferring any quantities of radioactive material would be required to verify licenses through the LVS or manually through the regulatory authority. Agreement States that do not use WBL as their license tracking system would need to either provide all of their licenses to the NRC to facilitate verification through LVS, or perform manual license verification.

Pros:

- Eliminates the need for paper licenses entirely
- Prevents the use of counterfeit or altered licenses

Cons:

- A majority of licensees authorized to possess Category 3, 4, and 5 quantities of radioactive material are likely to use the manual verification method due to the infrequency of transfers, which increases the burden to regulators
- Increased burden to the Agreement States to maintain licenses in WBL
- Increased burden to the NRC to support Agreement States not using WBL
- Time lag in uploading Agreement State licenses into WBL, which could hamper license verifications through LVS
- Increased burden on licensees to perform verification through LVS or the regulatory authority prior to radioactive material transfers, which may involve credentialing to get access to LVS

Concern 2, Option 5: Require verification of licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority and authenticate all licenses authorizing limits below Category 3 threshold through a new system or the regulatory authority

Licensees transferring Category 3 quantities of radioactive material would be required to verify licenses through the LVS or through the regulatory authority. Agreement States that do not use WBL as their license tracking system would need to either voluntarily provide all of their licenses to the NRC to facilitate verification through LVS and authentication through a new system, or perform manual license verification/authentication.

Licensees transferring any quantities of radioactive material below the Category 3 threshold would be required to authenticate certain information on a recipient's license through a new system or manually through the regulatory authority. License authentication would be a process similar to license verification and would involve the review of limited license information before a transfer of radioactive material could occur. The review would solely be intended to provide reasonable assurance that a license is valid, and as such, it would involve the corroboration of the licensee name, license address, license number, license amendment or issue date, and the address where the radioactive material is authorized to be stored. The review would not involve the review of any isotopes or quantities. The authentication would be performed through a search functionality developed in the NRC's public webpage or by contacting the regulatory authority. Users of the search functionality would not need to get credentialed to access the system. To ensure that licenses can be authenticated through the web search functionality, Agreement States not using the WBL as their license tracking system could voluntarily provide copies of all their licenses to the NRC for inclusion in WBL. The NRC would then create a file containing license information from NRC and Agreement State licensees to feed the web search functionality.[3] Alternately, Agreement States could perform manual license authentication.

Pros:

- Eliminates reliance on paper licenses authorizing Category 3 quantities of radioactive material
- Prevents the use of counterfeit or altered licenses authorizing Category 3 quantities of radioactive material
- Prevents the use of counterfeit licenses below the Category 3 threshold

[3] An example of the authentication system that the C3WG envisions is similar to that of the Canadian Nuclear Safety Commission's Nuclear Substances and Radiation Devices Licenses Search that can be accessed from http://nuclearsafety.gc.ca/eng/nuclear-substances/licensing-nuclear-substances-and-radiation-devices/licence-search/index.cfm.

- Verification/authentication of licenses is expected to be quick and accurate when using the online systems
- Licensees do not need credentials to authenticate licenses

Cons:

- Does not address alterations of licenses below the Category 3 threshold
- Increased burden to regulators to support manual license verification/authentication
- Increased burden to Agreement States to maintain licenses in WBL
- Increased burden to the NRC to support the Agreement States not using WBL
- Burden to the NRC to maintain a new system
- Increased burden on licensees to perform verification through LVS or the regulatory authority prior to transfers of Category 3 quantities of radioactive material, which may involve credentialing to get access to LVS
- Burden to licensees to learn a new system and to perform newly required authentications for licenses authorizing quantities below the Category 3 threshold
- Time lag for uploading Agreement State licenses into WBL, which could hamper license verifications and authentications through LVS and the new system

Concern 2, Option 6: Require authentication of all licenses authorizing possession limits below the Category 2 threshold through a new system or the regulatory authority

Licensees transferring any quantity of radioactive material below the Category 2 threshold would be required to authenticate certain information on a recipient's license through a new system or the regulatory authority. Agreement States that do not use WBL as their license tracking system would need to either voluntarily provide all of their licenses to the NRC to facilitate license authentication through the new system, or perform manual license authentication.

Pros:

- Prevents the use of counterfeit licenses below the Category 2 threshold
- Authentication is expected to be quick when using the online system
- Licensees do not need credentials to authenticate licenses

Cons:

- Does not prevent the use of legitimate licenses with altered authorizations
- Increased burden to the Agreement States to maintain licenses in WBL or provide alternate means of authentication
- Increased burden to the NRC to support Agreement States not using WBL
- Burden to the NRC to develop and maintain a new authentication system
- Burden to licensees to learn the new system and to perform newly required authentications
- Time lag for uploading Agreement State licenses into WBL, which could hamper license authentications through the new system

Reduction in License Verification/Authentication Frequency for Concern 2, Options 2, 4, 5, and 6

For Options 2, 4, 5, and 6, the C3WG considered a reduction in license verification/authentication frequency for transfers to established licensees (i.e., M&Ds, reactors, fuel cycle facilities, and waste disposal facilities). In this scenario, licensees transferring any

quantity of radioactive material to an established licensee would only have to verify/authenticate a license once a year, or before transferring the material if transfers occur less frequently than once per year.

Pro:

- Low burden to licensees to perform license verifications/authentications

Con:

- Due to the infrequency of performing license verifications/authentications, licensees would be more likely to use the manual license verification/authentication method rather than interface with LVS or the new system, increasing burden to regulators to support manual license verification/authentication

Concern 3: The ability to accumulate or aggregate Category 3 sources to a Category 2 quantity of radioactive material requiring enhanced security

This analysis presents five options related to the accounting of Category 3 sources to address the concern of someone being able to aggregate or accumulate Category 3 sources to a Category 2 quantity of radioactive material. In GAO-16-330, the GAO recommended that the NRC include all Category 3 sources in NSTS.

Concern 3, Option 1: No action

Accounting for sources in NSTS would not be changed and would be limited to Category 1 and Category 2 sources only.

Pros:

- No additional burden to licensees to report transactions involving Category 3 sources
- No additional burden to regulators to expend resources to maintain user accounts or resolve escalated problems (e.g., issues with use of NSTS that require technical support or investigation, such as discrepancies in source activities or identification numbers)

Con:

- Category 3 source information would not be provided to regulatory agencies and agencies responsible for national security/emergency response, preventing the agencies from being able to use the information for planning, oversight, or decisionmaking[4]

Concern 3, Option 2: Require licensees to report transactions involving Category 3 sources to the NSTS with the same reporting requirements as Category 1 and Category 2 sources

Transactions involving Category 3 sources would be reported to the NSTS with the same reporting requirements as Category 1 and Category 2 sources (by close of business the following day).

[4] The NRC currently shares NSTS data on Category 1 and 2 sources periodically with the Federal Bureau of Investigation, and U.S. Customs and Border Protection, among others.

Pros:

- Provides accountability for Category 3 sources
- Category 3 source information could be provided to regulatory agencies and agencies responsible for national security/emergency response, allowing the agencies to use the information for planning, oversight, or decisionmaking
- When combined with license verification through the LVS, the transferor would be alerted to conduct manual verification through the regulatory authority if the recipient's NSTS inventory has exceeded the possession limit on the license

Cons:

- Burden to licensees to report transactions and reconcile annual inventory for Category 3 sources
- Without the combination of having to conduct license verification through LVS, does not address the issue of licensees being able to obtain additional sources above their possession limit
- Burden to the NRC to credential a large number of licensees for NSTS access
- Increased burden to the NRC to process Category 3 source transactions in NSTS
- Burden to the NRC/Agreement States to process additional annual inventory reconciliations
- Increased cost to the NRC/Agreement States to process additional source accounting information issues or data errors, conduct training, develop guidance, etc.
- Increased burden to licensees to become credentialed to get access to NSTS

Concern 3, Option 3: Require licensees to report transactions involving Category 3 sources to the NSTS with changes to reporting requirements and changes to the NSTS

Transactions involving Category 3 sources would be tracked in the same way as Category 1 and Category 2 sources are currently tracked, but reporting of all transactions (Category 1, 2, and 3) would be required before a source is physically shipped. The NSTS would be modified to interact with WBL to calculate whether a pending source transfer would put the receiving licensee over its possession limit. In addition, the pending source transfer would count against the receiving licensee's inventory before shipment of the source has actually been initiated to prevent additional shipments from occurring simultaneously. This modification to NSTS, if pursued, would require conforming changes to NSTS requirements for Category 1 and Category 2 sources.

Pros:

- Eliminates the potential for a licensee to obtain more sources than authorized
- Prevents source shipment based on an altered license
- Category 3 source information could be provided to regulatory agencies and agencies responsible for national security/emergency response, allowing the agencies to use the information for planning, oversight, or decisionmaking

Cons:

- Burden to licensees to report Category 3 source transactions to NSTS and reconcile inventory annually
- Burden to licensees to report all Category 1, 2, and 3 source transactions to NSTS prior to shipment

- Agreement States would need to provide their licenses that authorize Category 3 quantities of radioactive material to the NRC for inclusion in WBL in order to enable the determination of whether a pending source transfer would put the receiving licensee over its possession limit
- Increased cost to the NRC to enter Agreement State license information and images into WBL for States not using WBL as their license tracking system
- Time lag for uploading licenses that authorize Category 3 quantities of radioactive material into WBL could hamper the source transfer process
- Increased cost to the NRC to credential a large number of licensees for NSTS access
- Increased burden to the NRC to process Category 3 source transactions in NSTS
- Increased need for NRC/Agreement State resources to process source accounting information issues, conduct training, develop guidance, and resolve other issues (e.g., issues with use of NSTS that require technical support or investigation, such as discrepancies in source activities or identification numbers).
- Cost to the NRC to modify NSTS and integrate it with WBL
- Increased burden to licensees to get credentialed to get access to NSTS

Concern 3, Option 4: Require licensees to report inventories of Category 3 sources to the NSTS annually

Licensees possessing Category 3 sources would report their inventory to the NSTS annually, but would not report on a transactional basis. Requirements for reporting Category 1 and Category 2 sources to NSTS would not change.

Pros:

- Information would be available to Federal and State agencies for situational awareness/emergency response
- Low burden to licensees to report their inventory annually since they are currently required, per regulation or license conditions, to conduct a physical inventory twice per year

Cons:

- Reporting of inventory would not prevent a licensee from obtaining additional sources that would put them above their possession limit
- Increased cost to the NRC to manually process inventory information in NSTS, if not entered electronically by licensees
- Increased need for NRC/Agreement State resources to process source accounting information issues, conduct training, develop guidance, etc.
- Source information (possession, location, etc.) would likely be out-of-date due to the reporting only being done once per year

Concern 3, Option 5: Require licensees that have the potential to aggregate Category 3 sources into a Category 2 quantity of radioactive material to implement Subpart B of 10 CFR Part 37

These licensees would be required to develop an access authorization program, including the conduct of background checks on all individuals who would have unescorted access to radioactive materials, based upon license possession limits, not the actual amount of material in the licensee's possession. This would ensure that personnel with unescorted access to the radioactive material are trustworthy and reliable in the case where a licensee inadvertently

aggregates radioactive material to a Category 2 quantity, generally through a failure of operational controls.[5]

Pros:

- Provides reasonable assurance that individuals with the ability to aggregate Category 3 quantities of radioactive material into a Category 2 quantity would not aggregate the material for malicious purposes
- Provides a graded approach to security for licensees possessing Category 3 quantities of radioactive material that, if aggregated, meets or exceeds the Category 2 threshold

Con:

- Significant burden on licensees to develop and implement an access authorization program regardless of whether or not they were likely to actually aggregate sources based upon operational practice

Concern 4: The limited accountability, lack of pre-licensing evaluations, and lack of routine oversight of Category 3 sources contained within generally licensed devices

This analysis presents four options related to the concern of limited accountability, lack of pre-licensing evaluations for either safety or security, and lack of routine oversight of Category 3 sources contained within generally licensed devices.

For options to address this concern, the C3WG acknowledged that generally licensed devices are designed to be operated by an individual who has little to no radiation protection knowledge. However, the isotope and quantity of radioactive material in a generally licensed device is no different than that contained in a specifically licensed device, so the C3WG determined that evaluating the need for regulatory changes in this area was warranted. The options considered by the C3WG to address this concern were limited to only Category 3 sources contained within generally licensed devices (i.e., Category 4 and Category 5 sources contained within generally licensed devices were not considered as part of this evaluation).

Concern 4, Option 1: No action

This option would maintain the current general license (GL) program which has minimal requirements commensurate with the low risk of using a generally licensed device. Under this option, Category 3 generally licensed devices would continue to be subject to registration requirements in 10 CFR 31.5(c)(13) or compatible Agreement State regulations. This registration includes an annual update to the inventory record of the devices in the possession of the general licensee. General licensees are required to conduct and maintain records of leak tests and shutter tests, report lost or stolen devices and incidents involving their devices to their regulatory authority, and transfer the device only to authorized entities. The NRC does not conduct routine inspections of general licensees, but will conduct reactive inspections as warranted. A minority of Agreement States have an inspection program for their general licensees.

[5] Current regulations in 10 CFR 20.1801 require licensees who store Category 3 and lower sources to secure licensed material from unauthorized removal or access. Such licensees, particularly those with Category 3 quantities, implement administrative and operational controls to ensure that sources will not be inadvertently aggregated to a quantity that meets or exceeds the Category 2 threshold, thus requiring the implementation of 10 CFR Part 37 requirements. For example, licensees often develop procedures and operational controls to address circumstances in which aggregation of sources to the Category 2 or higher threshold could occur, such as during leak testing activities or at the beginning or end of the work day as sources are gathered from or returned to storage.

Pros:

- Maintains low burden to licensees commensurate with risk of generally licensed devices
- Annual registration and inventory requirements provide some level of accountability

Cons:

- No pre-licensing evaluation of unknown device purchaser, resulting in lack of information from the device purchaser on how they intend to use the radioactive material
- No license verification for transfers and the potential for source transfer to occur without timely update of the registration certificate
- No inspection program to verify compliance with safety and security regulations

Concern 4, Option 2: Require M&Ds to notify the regulator prior to initially transferring a Category 3 generally licensed device in order to allow for the performance of a pre-licensing evaluation

The notification by the M&Ds, per 10 CFR 32.52, to the regulator would change from reporting quarterly (after the fact) to prior to the initial transfer of the Category 3 generally licensed device. The timeframe for reporting would allow for the NRC and Agreement States to perform a pre-licensing evaluation and site visit using existing pre-licensing guidance (see footnote 1).

Pros:

- Maintains a burden to licensees commensurate with risk of the generally licensed device
- Includes a pre-licensing evaluation of unknown device purchasers to (1) provide regulators with information from the device purchaser on how they intend to use the radioactive material, and (2) enhance the device owners' understanding of their responsibilities
- Affects a small number of general licensees nationally

Cons:

- No inspection program component to verify compliance with safety and security regulations
- Additional wait time to complete pre-licensing evaluation for unknown device purchasers
- Additional burden to regulators to maintain and track pre-licensing records

Concern 4, Option 3: Require M&Ds to notify the regulator prior to initially transferring a Category 3 generally licensed device in order to allow for the performance of a pre-licensing evaluation and implementation of an inspection program

The notification by the M&Ds to the regulator would change from reporting quarterly (after the fact) to prior to the initial transfer of the Category 3 generally licensed device. The timeframe for reporting would allow for the NRC and Agreement States to perform a pre-licensing evaluation and site visit. In addition, the NRC and Agreement States would inspect facilities possessing Category 3 generally licensed devices once every 5 years.

Pros:

- Maintains a burden to licensees commensurate with risk of the generally licensed device
- Includes a pre-licensing evaluation of unknown device purchasers to (1) provide regulators with information from the device purchaser on how they intend to use the

radioactive material, and (2) enhance the device owners' understanding of their responsibilities
- Includes an inspection program to verify compliance with safety and security regulations
- Affects a small number of general licensees nationally

Cons:
- Increased annual registration fees would be necessary to recover the regulator's increased inspection costs
- Additional wait time to complete pre-licensing evaluations for new device purchasers
- Additional burden to regulators to maintain and track pre-licensing records

Concern 4, Option 4: Require general licensees possessing devices containing Category 3 sources to be specifically licensed

General licensed devices containing Category 3 sources would be specifically licensed. The NRC regulations would be amended to limit the quantity of certain byproduct material allowed in a generally licensed device to below Category 3 thresholds; facilities with devices containing byproduct material at or above the Category 3 threshold would be required to obtain a specific license. These licensees would be required to implement and maintain a radiation protection program with a radiation safety officer and authorized users. The NRC and Agreement States would perform a pre-licensing evaluation of unknown applicants and then inspect them on a regular basis.

Pros:
- Adds a routine radiation protection program with radiation safety officers and authorized users, and other infrastructure, thereby enhancing the protection provided to public health and safety
- Includes a pre-licensing evaluation of unknown applicants to ensure that radioactive material will be used as stated on the license application
- Includes an inspection program to verify compliance with safety and security regulations
- Increased licensee awareness of, and compliance with, regulatory requirements through the specific license process and the inspection program
- Affects a small number of general licensees nationally
- Increased costs to regulators would be offset by specific license fees

Cons:
- Eliminates the convenience of the GL program for Category 3 sources
- Significant increase in annual fees for affected licensees
- Could add significant burden to licensees to implement and maintain a radiation protection program