Regulatory Impact Analysis of the Accrued Costs and Benefits of Options

The Staff Requirements Memorandum 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 a regulatory impact analysis of the accrued benefit and costs of the change, to include impacts to the U.S. Nuclear Regulatory Commission (NRC), Agreement States, non-Agreement States, and regulated entities. Part 1 of this enclosure describes the quantitative analysis that the Category 3 Source Security and Accountability Working Group (C3WG) conducted to identify and evaluate the costs for the proposed options. Part 2 of this enclosure, which starts on page 22, provides a summary of the accrued costs of each option and the commensurate benefits of those options, consistent with the qualitative analysis of pros and cons in Enclosure 2.

Part 1: Detailed Cost Analysis of Options

This cost analysis measures the incremental costs of each option relative to a "baseline" that reflects anticipated behavior in the event the NRC undertakes no additional action (the "no action" option). This option is equivalent to the status quo and serves as a baseline to measure against the other options. As part of the baseline used in this analysis, the C3WG assumes full licensee compliance with existing NRC or compatible Agreement State regulations.

The C3WG used information provided by subject matter experts, data from NRC documents, and knowledge gained from past rulemakings to collect data and develop assumptions and estimates for this analysis.

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 of the general assumptions used in the cost analysis followed by the specific assumptions and cost analysis for the options to address each concern.

General Assumptions

The licensees who are likely to be impacted by the potential options are those who possess Category 3 sources but are not required to implement the enhanced security requirements in 10 CFR Part 37, "Physical Protection Of Category 1 And Category 2 Quantities Of Radioactive Material." The majority of Category 3 sources are used in industrial and medical applications. Examples of industrial applications include licensees possessing fixed industrial gauges, such as level, conveyor, thickness, blast furnace, dredger, and pipe gauges; some licensees performing radiography operations; and licensees who conduct well logging services. An example of a medical application would be licensees possessing a high dose rate

brachytherapy afterloader. It is assumed that licensees such as well loggers and brachytherapy licensees have the potential to possess Category 3 sources that in the aggregate, can reach a Category 2 quantity of radioactive material. It is also assumed that this group of licensees consist of approximately 1,550 licensees (150 NRC and 1,400 Agreement State licensees).

The estimated number of NRC licensees authorized to possess Category 3 quantities of radioactive material and those authorized to possess less than Category 3 quantities of radioactive material were developed by performing a search in the Web-Based Licensing (WBL) System by select program codes (type of use of radioactive material) and authorized quantities. The estimated total number of Agreement State licensees authorized to possess Category 3 quantities of radioactive material was obtained by the License Verification and Transfer of Category 3 Sources Working Group (see ADAMS Accession No. ML16309A284).

In order to develop accurate cost estimates for license verification[1] and authentication[2] options, the numbers of licensees were further broken down into licensees likely to have frequent transfers of material in a calendar year (i.e., frequent transferors/receivers, who were assumed to have four transfers per year on average), and those performing less frequent transfers (i.e., non-frequent transferors/receivers, who were assumed to have one transfer every 3 years, or 0.33 transfers per year). The frequency of transfers are based on the half-life of the materials that licensees are likely to possess. Table 1 provides the estimates for the number of impacted licensees by category as well as the number of licensees that are expected to conduct frequent and non-frequent transfers.

For the purposes of estimating number of licensees, percentages, and costs, all the numbers in this cost analysis have been rounded to the nearest whole number.

Table 1: Impacted Licensees by Category

Impacted licensee	# of licensees	NRC	Agreement States (AS)	NRC frequent transferors/ receivers	NRC non-frequent	AS frequent	AS non-frequent
Licensees possessing Category 3 quantities of radioactive material	4,500	299	4,201	77	222	1,082	3,119
Licensees possessing radioactive material in quantities below the Category 3 threshold	13,786	1,937	11,849	61	1,876	373	11,476
Total licensees	18,286	2,236	16,050	138	2,098	1,455	14,595

[1] 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 license verification process 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.

[2] 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 can occur. The review would solely be intended to provide reasonable assurance that a license is valid. The review would involve the corroboration of the licensee name, license address, license number, license amendment or issue date, and the address where the material is authorized to be stored. It would not involve the review of any isotopes or quantities.

The C3WG estimates that approximately 50 percent of licensees will utilize the License Verification System (LVS) to verify licenses and the remaining 50 percent will use the manual process. This breakdown is based on data regarding the current use of LVS by licensees possessing Category 1 and Category 2 quantities of radioactive material. Tables 2 and 3 identify the estimated number of NRC and Agreement State licensees that are expected to use LVS to perform license verification versus use of the manual process for both frequent and non-frequent transfer transactions, respectively.

Table 2: Estimated Number of NRC and Agreement State Frequent Transferors/Receivers that will use LVS vs. the Manual Process

Impacted licensee	# of licensees	(NRC & AS) Frequent transferor/receivers	LVS (50%)	Manual (50%)
Licensees possessing Category 3 quantities of radioactive material	4,500	1,159	580	580
Licensees possessing radioactive material in quantities below the Category 3 threshold	13,786	434	217	217
Total # of licensees possessing radioactive material in quantities below the Category 2 threshold	18,286	1,593	797	797

Table 3: Estimated Number of NRC and Agreement State Non-Frequent Transferors/Receivers that will use LVS vs. the Manual Process

Impacted licensee	# of licensees	(NRC & AS) Non-Frequent transferor/receivers	LVS (50%)	Manual (50%)
Licensees possessing Category 3 quantities of radioactive material	4,500	3,341	1,671	1,671
Licensees possessing radioactive material in quantities below the Category 3 threshold	13,786	13,352	6,676	6,676
Total # of licensees possessing radioactive material in quantities below the Category 2 threshold	18,286	16,693	8,347	8,347

General Industry Assumptions

The industry licensees are generally divided into two groups, the manufacturers and distributors (M&Ds) and their customers (licensee users). Once the radioactive material decays, the users (e.g., industrial facilities, hospitals, other medical facilities such as surgery centers) will need to obtain new material (i.e., replacement sources) from the M&Ds.

For the purposes of this analysis, the C3WG anticipates that the primary employees that would be impacted by regulatory changes such as license verification or source tracking would be the "Occupational Health and Safety Specialist" who acts in the capacity of the Radiation Safety Officer (RSO). Estimates for licensee labor rates were obtained from Bureau of Labor Statistics

National Wage Data, for calendar year 2017, available on the Bureau of Labor Statistics Web site.[3] The C3WG selected an appropriate mean hourly labor rate depending on the listed industry and the occupation, and multiplied it by 1.5 to account for pension, insurance, and other legally-required benefits. The labor rate multiplier is used by the NRC as the standard method to estimate appropriate industry labor rates. The current labor rate multiplier was obtained from NUREG/BR-0058, "U.S. Nuclear Regulatory Commission Guidance on Performing Benefit-Cost Analyses, Revision 5" (ADAMS Accession No. ML15336A003). Because exact hourly rates can vary significantly, the C3WG used nationwide mean hourly rates. The C3WG applied the following hourly rates in this analysis:

- "Occupational Health and Safety Specialist" — $51.14 ($34.09 x 1.5)
- "General Office Clerk" — $22.05 ($14.70 x 1.5)
- "Lawyer" — $91.20 ($60.80 x 1.5)
- "Life Scientists, Agreement State inspectors/license reviewers, All other" — $59.97 ($39.98 x 1.5)

General NRC and Agreement State Assumptions

In order to alter the infrastructure for source security and accountability in the options developed by the C3WG, regulatory agencies would need to perform rulemaking and update guidance. Based on the average resource burden to revise and publish a rule and related guidance, the C3WG estimates five Full-time Equivalents (FTE) for the NRC to complete rulemaking and update its guidance. It is estimated that the Agreement States would need 0.5 FTE ("Lawyer" for the rulemaking and "Life Scientists" for the guidance/procedures update) to complete rulemaking and update their guidance/procedures. It is assumed that the regulatory agencies will conduct the inspections of licensees possessing radioactive material in quantities below the Category 2 threshold following their normal inspection schedule, which equals an estimated 20 percent of licensees annually.

The NRC's labor rates are determined using the methodology in Abstract 5.2, "NRC Labor Rates," of NUREG/CR-4627, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the amendments. Currently, the NRC hourly labor rate is $128. The estimation of costs for rulemaking is based on professional NRC staff FTE. Based on actual data from the NRC's time and labor system, the number of hours in 1 year that directly relates to implementation of assigned duties is 1,420 (1,420 was derived by taking the annual number of hours (2,080) and accounting for leave, training, and completing administrative tasks). Therefore, an NRC professional staff FTE hourly rate is based on 1,420 hours.

Since no data is available to determine the number of productive hours in 1 year for Agreement States, and actual values are likely to vary from State to State, the FTE hours for the Agreement States are based on the number of hours estimated in OMB Circular A-76, "Performance of Commercial Activities." Therefore, the number of productive hours in 1 year for an Agreement State professional is 1,776.

[3] https://www.bls.gov/bls/blswage.htm

Concern 1: The ability to obtain a valid license using a fictitious company or by providing false information — Specific Assumptions and Costs for recommendation to require safety and security equipment to be in place before granting a license for an unknown entity

Specific Industry Assumptions

Requiring unknown entities (i.e., new license applicants) to have safety and security equipment in place before obtaining a license is assumed to result in no additional costs to the industry. The new requirement would compel an applicant to procure and install safety and security equipment during the license application process, instead of after obtaining a license, thereby altering the timing of the expense. The C3WG assumed this would not alter the expense itself.

Specific NRC and Agreement State Assumptions

To implement the new requirements, regulatory agencies would need to perform rulemaking and update guidance, in addition to performing a second visit to ensure that safety and security equipment at an unknown applicant's facility is in place before granting a license. It is estimated that each NRC regional office (Regions I, III, and IV) and the Agreement States would process 10 new applications each per year (30 for NRC and 370 for Agreement States for a total of 400 applications). Regulatory agencies would also need to conduct training for inspectors/license reviewers. Based on previous pre-licensing training experience for NRC and Agreement State inspectors and license reviewers, the C3WG estimates that training will take 2 hours, for an estimated 10 inspectors per NRC regional office/Agreement State. In addition, the regulatory agencies will incur an annual cost to conduct pre-licensing visits, which is estimated to take 10 hours per visit.

Table 4: NRC and Agreement State Costs for the Recommendation to Require Safety and Security Equipment to be in Place before Granting a License for an Unknown Entity

	NRC		**Agreement States**	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Rulemaking and updating guidance	7,100	$908,800	888	$80,986
Training	60	$7,680	20	$1,199
Average cost per Agreement State				$82,185
Total implementation cost		$916,480		$3,040,845
Annual cost				
Pre-licensing visits	300	$38,400	100	$5,997
Average cost per Agreement State				$5,997
Total annual cost		$38,400		$221,889

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 — Specific Assumptions and Costs for Options

This section includes specific assumptions and costs for the five options, as compared to Option 1 (No action), considered to address Concern 2 that would require regulatory changes related to license verification or authentication. These options are:

- Option 2: Require verification of licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority
- Option 3: Require only M&Ds to verify licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority
- Option 4: Require verification of all licenses through LVS or the regulatory authority
- 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 the Category 3 threshold through a new system or the regulatory authority
- Option 6: Require authentication of all licenses authorizing possession limits below the Category 2 threshold through a new system or the regulatory authority

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, 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. This reduction in license verification/authentication frequency for transfers to established entities would result in a reduction in the recurring and annual operating costs for the industry. Specifically, the reduction in industry annual costs would be approximately 45 percent for Option 2, 40 percent reduction for Options 4 and 5, and 15 percent for Option 6.

<u>Specific Industry Assumptions</u>

The source transfers between licensee users and the M&Ds would require the verification or authentication of a license prior to the source transfer taking place. In general, the transfer frequency assumptions are based on the half-life of the radionuclide used in the device. The longer the half-life of the radionuclide, the less frequently the source is replaced, and therefore, the fewer source transfers between licensee users and M&Ds. Conversely, licensee users utilizing devices with a shorter half-life (e.g., Ir-192) will need to replace the sources more frequently and therefore, will have more frequent transfers with the M&D. It is assumed that licensee users identified as frequent transferors/receivers and M&Ds will each average four transfers per year. Users possessing radionuclides with longer half-lives identified as non-frequent transferors/receivers will have fewer transfers with the M&Ds. It is assumed that these non-frequent transferors will average one transfer each every 3 years (i.e., 0.33 per year). It is assumed that M&Ds will either use the LVS for license verification (or a newly developed web system for authentication of a license) for all transfers. The C3WG used the following cost assumptions for license verification estimates associated with impacts to industry stakeholders:

- All M&Ds already utilize LVS to verify licenses, and would not need to get re-credentialed to access LVS. The costs assume a total of fifteen M&Ds.

- Fifty percent of licensee users would get credentialed and utilize LVS to verify licenses. The remaining fifty percent of licensee users are assumed to use the manual process for license verification, for which they would not undergo the credentialing process.
- The cost of credentialing would be $51.14 (1.0 hour x $51.14 hourly rate). The C3WG assumes that 1 person per licensee would complete the credentialing process.
- Ninety percent of licensee users and all the M&Ds would use the web search function to authenticate licenses, and the remaining ten percent would use the manual process.
- The C3WG estimates 3 hours to update existing license verification procedures and an additional hour for clerical time.
- The labor cost to verify a license (online) would be $6.14 (0.12 hours x $51.14 hourly rate).
- The labor cost to verify/authenticate a license (manual) would be $3.58 (0.07 hours x $51.14 hourly rate).
- The labor cost to authenticate a license (online) would be $1.28 (0.025 hours x $51.14 hourly rate).

Table 5: Industry Costs for License Verification/Authentication Options

	Option 2		Option 3		Option 4		Option 5		Option 6	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Update procedures	3	$153	3	$153	3	$153	3	$153	3	$153
Update procedures - clerical	1	$22	1	$22	1	$22	1	$22	1	$22
Initial credentials for 50% of licensee users	1	$51			1	$51	1	$51		
Total average cost per licensee		$201		$175		$201		$201		$175
Total implementation cost		$904,500		$2,625		$3,666,343		$3,314,800		$3,200,050
Annual cost										
Verifying licenses via LVS - licensee users		$17,617				$36,474		$17,617		
Verifying licenses via LVS - M&Ds		$35,235		$35,235		$72,947		$35,235		
Verifying licenses manually - licensee users		$10,272				$21,266		$10,272		
Authentication - licensee users								$3,577		$9,313
Authentication - M&Ds								$7,862		$15,207
Authentication of licenses manually - licensee users								$2,199		$4,253
Total average cost per licensee		$14		$2,349		$7		$4		$2
Total annual cost		$63,124		$35,235		$130,687		$76,762		$28,773

Specific NRC and Agreement State Assumptions

To facilitate electronic verification of licenses through the LVS or authentication of licenses through a web search system, the C3WG assumed that the Agreement States that are not using WBL as their license tracking system (34 states[4]) would voluntarily provide copies of their licenses to the NRC for inclusion in WBL. This is based on the assumption that the current process for providing licenses authorizing possession of Category 1 and Category 2 quantities of radioactive material to the NRC would also be applied to licenses with lower possession levels. It is estimated that there are a total of 16,050 Agreement State licenses authorizing possession of radioactive materials at or below the Category 3 threshold, and 2,236 NRC licenses authorizing possession of radioactive materials at or below the Category 3 threshold, for a total of 18,286 licenses. For the Agreement States currently using WBL (3 States), there are approximately 160 licenses authorizing possession of radioactive materials at the Category 3 threshold, and 872 licenses authorizing possession of radioactive materials below the Category 3 threshold, for a total of 1,032 licensees. To load the Agreement State licenses into the WBL, the NRC would incur an $80 per license cost. In addition, a $30 per license cost for the NRC to perform data quality assurance is assumed, for approximately half of the licenses entered into WBL; this process verifies the integrity of license data in WBL on a sample basis. To process license verifications or authentications manually, it is estimated that the NRC and Agreement States would need 0.17 hours to complete each verification/authentication. The time estimate is consistent with the estimate provided in the final supporting statement for NRC Form 749, "Manual License Verification Report" (ADAMS Accession No. ML17173A878).

To calculate the frequency for manual license verifications/authentications, the following formula was used with the values for frequent and non-frequent transferors/receivers listed on Table 1: ((# of frequent transferors/receivers x percent of manual use) x 4) + ((# of non-frequent transferors/receivers x percent of manual use) x 0.33)).

The C3WG used the following cost assumptions for NRC and Agreement State license verification estimates:

- The labor cost for the Agreement States to verify/authenticate a license manually is $10.19 (0.17 hours x $59.97 hourly rate).
- The labor cost for the NRC to verify/authenticate a license manually is $21.76 (0.17 hours x $128 hourly rate).
- The NRC cost to credential a licensee is $132 ($5 per token and 1 labor hour to create an account).
- The NRC contractor help desk cost to process manual forms is estimated to be $30,000 per month. This cost increases to $45,000 per month to process all licenses authorizing possession below the Category 2 threshold.
- The cost for an Agreement State to initially identify the State's Category 3 licenses for inclusion in WBL would require 40 labor hours for a "life scientist" professional.
- The cost for an Agreement State to provide all the licenses to support Options 4, 5, and 6, would require 40 labor hours for a "general office clerk."

[4] As of July 26, 2017, a fourth Agreement State began using WBL as its license tracking system. At the time the C3WG performed its costs analyses, there were three Agreement States using WBL. As such, cost estimates pertaining to Agreement State impacts of options assumed that 34 states were using their own, non-NRC-hosted license tracking systems and would need to either voluntarily provide licenses to the NRC for inclusion in WBL, or perform manual license verification/authentication functions.

- In order to keep license status current in WBL, one license amendment per licensee annually is assumed. For Agreement States not using WBL, the total number of amendments needed to be provided to the NRC is 4,041 per year. Agreement State license reviewers are assumed to spend 0.08 labor hours per license to send recurring amended licenses to NRC for inclusion in WBL.
- No additional cost for the NRC to develop the license authentication web search functionality since it can take advantage of existing scripts that perform similar searches on the NRC Web site.
- The NRC initial contractor cost to develop a query, which is then used to create a file containing NRC and Agreement State license data from WBL to support license authentication is estimated to be $342; no additional cost for the NRC to update the file and upload it to the license authentication Web site since the NRC can take advantage of existing scripts.
- An additional 2 hours of inspection time is estimated for the regulatory agencies to review license verification/authentication records during a routine inspection (exclusive of travel time). It is estimated that zero hours of inspection time would be required for review of license verification/authentication records held by M&Ds, because M&Ds are currently inspected on an annual basis to verify compliance with license verification requirements. It is assumed that inspection of additional license verification/authentication records would be performed within existing inspection resources given that records are reviewed on a sampling basis.

Table 6: NRC Costs for License Verification/Authentication Options

	Option 2		Option 3		Option 4		Option 5		Option 6	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Rulemaking and updates to guidance	7,100	$908,800	7,100	$908,800	7,100	$908,800	7,100	$908,800	7,100	$908,800
Load Agreement State licenses into WBL		$323,200		$323,200		$1,196,080		$1,196,080		$1,196,080
Contractor cost for quality assurance of licenses		$60,600		$60,600		$224,265		$224,265		$224,265
Credential 50% of licensee users		$297,000				$1,206,876		$1,206,876		
Prepare file to support license authentication								$342		$342
Total implementation cost		$1,589,600		$1,292,600		$3,536,021		$3,536,363		$2,329,487
Annual cost	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**
Load Agreement State license amendments into WBL	4,041	$323,280	4,041	$323,280	15,018	$1,201,440	15,018	$1,201,440	15,018	$1,201,440
Help Desk processing of manual license verification forms		$360,000				$540,000		$540,000		$540,000
Manual license verification	191	$4,148			622	$13,538	191	$4,148		
Manual license authentication							86	$1,878	124	$2,708
Inspections	60	$15,360			447	$114,432	447	$114,432	447	$114,432
Total annual cost		$702,788		$323,280		$1,869,410		$1,861,898		$1,858,580

Table 7: Agreement State Costs for License Verification/Authentication Options

	Option 2		Option 3		Option 4		Option 5		Option 6	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Rulemaking and updates to guidance	888	$80,986	888	$80,986	888	$80,986	888	$80,986	888	$80,986
Develop/update procedures	8	$480	8	$480	8	$480	8	$480	8	$480
Provide licenses to NRC for inclusion in WBL	40	$2,399	40	$2,399	40	$882	40	$882	40	$882
Average cost per Agreement State		$83,670		$83,670		$82,276		$82,276		$82,276
Total implementation cost		$3,095,808		$3,095,808		$3,044,230		$3,044,230		$3,044,230
Annual cost	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**
Provide license amendments to NRC	4,041	$19,387	4,041	$19,387	15,032	$72,118	15,032	$72,118	15,032	$72,118
Manual license verification	2,679	$27,308			5,318	$54,218	2,679	$27,308		
Manual license authentication							528	$5,382	1,064	$10,844
Inspections	840	$100,750			3,210	$385,007	3,210	$385,007	3,210	$385,007
Average cost per Agreement State		$4,031		$524		$13,992		$13,265		$12,527
Total annual cost		$147,445		$19,387		$511,343		$489,815		$467,969

Concern 3: The ability to accumulate or aggregate Category 3 sources to a Category 2 quantity of radioactive material requiring enhanced security — Specific Assumptions and Costs for Options

This section includes specific assumptions and costs for the four options, as compared to Option 1 (No action), considered to address Concern 3 that would require regulatory changes. These options are:

- Option 2: Require licensees to report transactions involving Category 3 sources to the National Source Tracking System (NSTS) with the same reporting requirements as Category 1 and Category 2 sources
- Option 3: Require licensees to report transactions involving Category 3 sources to the NSTS with changes to reporting requirements and changes to the NSTS
- Option 4: Require licensees to report inventories of Category 3 sources to the NSTS annually
- 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

To simplify the efforts of estimating the costs associated with the reporting of Category 3 source transactions and inventory to NSTS, the C3WG used the regulatory analysis developed for the NSTS expansion proposed rule (ADAMS Accession No. ML091390235) as a reference. In the regulatory analysis for that proposed rule, the NRC staff estimated 1,000 specific licensees who possess Category 3 quantities of radioactive material and 5,200 Category 3 sources. The C3WG estimates that there are currently approximately 4,500 specific licensees who possess Category 3 quantities of radioactive material. Therefore, the C3WG made assumptions by averaging, extrapolating, and adjusting the costs for the higher number of licensees authorized to possess Category 3 quantities of radioactive material assumed for the proposed options in this analysis.

Specific Industry Assumptions

Tracking Category 3 sources would require licensees who manufacture, transfer, receive, disassemble, or dispose of a nationally tracked source to: (a) perform a one-time function to report its initial inventory to NSTS; (b) perform an annual verification and reconciliation of the licensee's data compared to data in NSTS reports; and (c) report all transactions either by using the NSTS system or by completing and submitting a National Source Tracking Transaction Report (NRC Form 748).

Option 5 in this analysis does not involve any accounting of sources in NSTS; rather, it focuses on implementing the 10 CFR Part 37 access authorization program, including background checks on all individuals with the ability to aggregate Category 3 sources into a Category 2 quantity of radioactive material. To simplify the efforts of estimating the initial and recurring costs pertaining to Option 5, the assumptions in the regulatory analysis developed for the 10 CFR Part 37 rule (ADAMS Accession No. ML112920114) were used as reference. The following assumptions were used to develop cost estimates for Option 5:

- 1,550 licensees are estimated to be impacted by Option 5.
- It is estimated that licensees would spend 100 hours developing an access authorization program (i.e., procedure development).

- Each licensee would incur a cost of approximately $7,700 to initially conduct background checks (e.g., employment history, education history, personal references, criminal history) for an average of 12 individuals per licensee.
- Licensees would need to conduct an access authorization program review annually at an estimated cost of $5,000 per licensee.
- Licensees would need to conduct new background checks for an average of 2 individuals per year, at a cost of $1,284.
- One individual per licensee would need to be re-investigated (only criminal history) every 2.5 years (i.e., 0.4 per year). This effort includes 2 labor hours plus a fingerprinting processing fee of $10 each.

Table 8: Industry Costs for NSTS Options

	Option 2		Option 3		Option 4	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Develop procedures	3	$153	3	$153	2	$102
Develop procedures – clerical	1	$22	1	$22	1	$22
NSTS account set up and training	10.5	$537	10.5	$537		
Initial inventory reporting	1	$51	1	$51	1	$51
Average implementation cost per licensee		$764		$764		$175
Total implementation cost		$3,438,000		$3,438,000		$787,500
Annual cost						
Transaction reporting		$30		$30		
Annual reconciliation	1	$51	1	$51	1	$51
Average annual cost per licensee		$81		$81		$51
Total annual cost		$364,500		$364,500		$229,500

Table 9: Industry Costs for Option to Implement Access Authorization Program

	Option 5	
Implementation costs	**Labor hours**	**Mean/Best estimate**
Develop access authorization program, including procedures	80	$4,091
Develop procedures - clerical	20	$441
Background checks		$7,700
Develop access list	1	$51
Average implementation cost per licensee		$12,283
Total implementation cost		$19,038,650
Annual Costs	**Labor Hours**	**Mean/Best Estimate**
Background checks		$1,284
Update access list	1	$51
Re-investigations (criminal history only)	2	$45
Annual review of access authorization program		$5,000
Average annual cost per licensee		$6,380
Total annual cost		$9,889,000

Specific NRC and Agreement State Assumptions

To support the expansion of NSTS to track Category 3 sources, the NRC would need to make necessary changes to NSTS as well as credential new users. In addition, 2 hours of inspection time is estimated for the regulatory agencies to review the additional NSTS records during a routine inspection (exclusive of travel time).

Option 3 of this analysis includes a one-time system modification cost to the NRC to integrate NSTS with WBL, for a total of $150,000. In addition, Agreement States would need to provide their licenses to the NRC to be added to WBL. To load the Agreement State licenses into the WBL, the NRC would incur an $80 per license cost. The C3WG also included a $30 per license cost for data quality assurance, for approximately half of the licenses entered into WBL.

For Option 5, it is assumed that the 1,550 impacted licensees would be comprised of approximately 150 NRC and 1,400 Agreement State licensees. The NRC would need to process the initial and recurrent fingerprinting submissions of the impacted licensees. The time to process each licensee fingerprint submission is estimated at 0.25 hours (15 minutes). In addition, 2 hours of inspection time is estimated for the regulatory agencies to review the access authorization program records during a routine inspection (exclusive of travel time).

Table 10: NRC Costs for NSTS Options

	Option 2		Option 3		Option 4	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Rulemaking and updates to guidance	7,100	$908,800	7,100	$908,800	7,100	$908,800
Load Agreement State licenses into WBL				$323,200		
Contractor cost for quality assurance of licenses				$60,600		
Contractor cost for expansion of NSTS		$500,000		$650,000		$200,000
Account setup and training		$600,000		$600,000		
Total implementation cost		$2,008,800		$2,542,600		$1,108,800
Annual cost	**Frequency**		**Frequency**		**Frequency**	
Inspections	60	$15,360	60	$15,360	60	$15,360
Load Agreement State license amendments into WBL				$323,200		
NSTS maintenance		$600,000		$600,000		$300,000
Total annual cost		$615,360		$938,560		$315,360

Table 11: NRC Costs for Option to Implement Access Authorization Program

	Option 5	
Implementation cost	**Labor hours**	**Mean/Best estimate**
Rulemaking and updates to guidance	7,100	$908,800
Fingerprinting		$595,200
Total implementation cost		$1,504,000
Annual cost	**Frequency**	**Mean/Best estimate**
Fingerprinting		$99,200
Reinvestigations		$19,840
Inspections	30	$7,680
Total annual cost		$126,720

Table 12: Agreement State Costs for Options to Address Concern 3 (Aggregation)

	Option 2		Option 3		Option 4		Option 5	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Rulemaking and updating of guidance	888	$80,986	888	$80,986	888	$80,986	888	$80,986
Update procedures	8	$480	8	$480	8	$480	8	$480
Provide licenses to NRC			40	$2,399				
Average cost per Agreement State		$81,466		$83,865		$81,466		$81,466
Total implementation cost		$3,014,242		$3,095,808		$3,014,242		$3,014,242
Annual cost	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**	**Frequency**	**Mean/Best estimate**
Inspections	840	$100,750	840	$100,750	840	$100,750	279	$33,463
License updates			4,041	$19,387				
Average cost per Agreement State		$2,723		$3,247		$2,723		$904
Total annual cost		$100,750		$120,137		$100,750		$33,463

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

This section of the analysis includes specific assumptions and costs for the three options, as compared to Option 1 (No action), considered to address Concern 4 that would require regulatory changes. These options are:

- 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
- 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
- Option 4: Require general licensees possessing Category 3 generally licensed devices to be specifically licensed

Generally licensed devices are designed to be operated by an individual who has little or no radiation protection knowledge. All Category 3 generally licensed devices are subject to registration requirements in 10 CFR 31.5(c)(13) or compatible Agreement State regulations. This registration includes an annual update of the devices in the possession of the general licensee. The C3WG applied the following assumptions to the evaluation of options to address the concern regarding generally licensed devices:

- The NRC has 13 general licensees with devices (all gauging devices) containing Category 3 sources. Given that gauging devices are used throughout the country, a simple ratio was used to estimate the number of Category 3 general licenses in Agreement States. Based on the ratio of 6.5 to 1 with regard to Agreement State to NRC specific licensees, this evaluation estimates at least 85 Category 3 general licenses in Agreement States. For costing purposes, the estimate of 85 general licenses in Agreement States was doubled to 170 facilities as an upper bound of the range.
- The number of new applicants seeking to acquire Category 3 generally licensed devices on an annual basis is low. For the purposes of this evaluation, five new applicants per year (one NRC and four Agreement States) are assumed.
- Since general licensees are not currently subject to inspection, it is estimated that each inspection requires 24 hours to conduct (preparation, travel, on-site, and post-inspection documentation). This estimate is based on the average number of hours to conduct a fixed gauge, specific license inspection from Fiscal Year 2015 data. The inspection frequency of 5 years for a fixed gauge licensee was also used in this cost estimate.
- It is estimated that a pre-licensing visit will take 10 hours.
- The number of licensees to be inspected on an annual basis is estimated at 3 for the NRC, and 37 for Agreement States.
- To conduct the review of a new fixed gauge license application, 12 hours was assumed. This is based on the average number of hours to prepare a new fixed gauge specific license from Fiscal Year 2015 data.
- There are 22 active sealed source and device registry sheets for generally licensed devices that contain Category 3 quantities of radioactive material in the national registry – all the sheets are for gauging devices used in industry and for contraband monitoring at ports. Should specific licensing be required for devices containing Category 3 quantities of radioactive material, NRC would need to revise these 22 registry sheets. It is assumed that 36 NRC staff hours would be required to revise each affected sheet.

Specific Industry Assumptions

- The existing registration costs paid annually by general licensees is estimated at $400 for NRC licensees and $200 for Agreement State licensees. For Option 3, these registration costs are increased for regulatory agencies to recover fees associated with inspections. Therefore, the additional cost to general licensees above the baseline is estimated at $400 for NRC licensees and $200 for Agreement State licensees.

Table 13: Industry Costs for Category 3 General License Options

	Option 2		Option 3		Option 4	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Develop procedures	3	$153	3	$153	3	$153
Develop procedures - clerical	1	$22	1	$22	1	$22
Training for new RSO					40	$2,046
Develop radiation safety program					20	$1,023
Prepare license application					5	$256
Application fee for NRC licensees						$2,600
Application fee for Agreement State licensees						$1,300
Average implementation cost per NRC licensee		$175		$175		$6,100
Average implementation cost per Agreement State licensee		$175		$175		$4,800
Total implementation cost		$32,025		$32,025		$895,300
Annual cost						
Registration for NRC licensees (increase from existing cost)				$400		
Registration for Agreement State licensees (increase from existing cost)				$200		
Maintain radiation safety program					100	$5,114
NRC annual fee (increase from existing cost)						$7,600
Agreement State annual fee (increase from existing cost)						$3,800
Average implementation cost per NRC licensee				$400		$12,714
Average implementation cost per Agreement State licensee				$200		$8,914
Total annual cost				$39,200		$1,680,662

Table 14: NRC Costs for Category 3 General License Options

	Option 2		Option 3		Option 4	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Rulemaking and updates to guidance	7,100	$908,800	7,100	$908,800	7,100	$908,800
Training	20	$2,560	20	$2,560	20	$2,560
Update inspection procedures			150	$19,200	150	$19,200
Review initial applications					36	$19,968
Initial Inspections			72	$39,936	72	$39,936
Pre-licensing visits					130	$16,640
Amend the sealed sources & device registry sheets for Category 3 general licenses to specific licenses					792	$101,376
Total implementation cost		$911,360		$970,496		$1,108,480
Annual cost						
Inspections			72	$9,216	72	$9,216
Pre-licensing visits	10	$1,280	10	$1,280	10	$1,280
Total annual cost		$1,280		$10,496		$10,496

Not counting the cost of rulemaking, training, and updating guidance, the cost to the NRC to convert the general licenses to specific licenses would involve the review of the initial license applications, performing initial inspections, and amending the sealed source and device registry sheets for 13 general licensees. The total cost of these efforts is estimated at $140,544. This cost is offset by the revenue generated from the fee change associated with 13 general licensees becoming specific licensees. The NRC would incur a total initial loss of $36,544 for the conversion effort, but would see positive revenue on an annual basis.

In terms of annual costs, the 13 new specific licensees would have to pay an annual license fee of $7,600, for a total combined cost of $98,800. Using the general assumption of inspecting 20 percent of licensees a year, the NRC would inspect 3 of these licensees per year at a total cost of $9,216. It is estimated that the NRC would have a total annual gain of approximately $89,584. The initial loss would be recovered in the second year for a total gain of $53,040 for that year, and $89,584 every year after unless alterations are made to the fee structure.

Table 15: Agreement State Costs for Category 3 General License Options

	Option 2		Option 3		Option 4	
Implementation cost	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**	**Labor hours**	**Mean/Best estimate**
Rulemaking and updates to guidance	888	$80,986	888	$80,986	888	$80,986
Training	20	$1,199	20	$1,199	20	$1,199
Updates to inspection procedures			20	$1,199	20	$1,199
Initial inspections			120	$7,196	120	$7,196
Review of application					60	$3,598
Pre-licensing visits					50	$2,999
Average annual cost per Agreement State		$82,185		$90,581		$97,178
Total implementation cost		$3,040,845		$3,351,460		$3,595,549
Annual Cost						
Inspections			24	$1,439	24	$1,439
Pre-licensing visits (a total of 4 visits distributed among 37 states)	1.08	$65	1.08	$65	1.08	$65
Total average per Agreement State		$65		$1,504		$1,504
Total annual cost		$2,405		$55,648		$55,648

Part 2: Summary of Accrued Costs and Benefits of Options

This summary provides a tally of cost data[5] presented in Part 1 of this enclosure, and presents that cost data alongside a summary of the benefits that were identified in Enclosure 2 for each option considered.

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

In considering the concern related to obtaining a valid license using a fictitious company or by providing false information, the NRC staff determined that the rulemaking and non-rulemaking-related recommendations made by the Enhancements to the Pre-Licensing Guidance Working Group, and endorsed by its Steering Committee, fully addressed this concern. As such, only one option was considered. This option entails rulemaking to amend 10 CFR Parts 30, 40, and 70 to require that necessary security and safety equipment is in place prior to issuing a license to all unknown applicants. The costs and benefits of implementing non-rulemaking-related recommendations were not considered by the C3WG as they are being managed separately through implementation of an action plan that is already in progress.

The total implementation costs associated with the rulemaking recommendation to address Concern 1 consist of $3,957,325 in one-time costs and $260,289 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: No cost - In estimating the costs for the recommended change, the C3WG assumed that applicants would not incur any additional costs beyond those that would already be required to conduct licensed activities (e.g., purchase of equipment for source storage). However, applicants would incur costs sooner because the safety and security equipment would have to be in place earlier in the process.
- Cost to NRC: $916,480 (one-time costs to perform rulemaking and update guidance) and $38,400 (annual/recurring costs to perform additional pre-licensing visits to ensure that safety and security equipment is in place before granting a license).
- Cost to Agreement States (total cost for all states): $3,040,845 (one-time costs to perform rulemaking and update guidance) and $221,889 (annual/recurring costs to perform additional pre-licensing visits to ensure that safety and security equipment is in place before granting a license).

The substantial benefits of implementing this recommendation were determined to be cost-justified by the NRC staff because, if implemented, the rulemaking would: (1) provide additional assurance of the validity of unknown applicants prior to authorization to possess any quantity of licensed radioactive material; (2) eliminate the acceptance of written and oral assurances regarding facility completeness and required security and safety equipment; (3) align the NRC with the majority of Agreement States which do not issue a license prior to facility completion; and (4) represent no change to the overall cost to the applicant.

[5] Note that, in some cases, changes to license or registration fees would offset costs to the regulatory authority; however, for the purposes of conservatism, these tallies do not reflect such offsets. Where applicable, Part 1 of this enclosure describes such offsets.

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

The NRC staff considered six options to address this concern. The accrued costs and benefits of each option are described individually below.

Concern 2, Option 1: No action

Because this option would entail continued use of existing license verification methods, there would not be any new implementation costs associated with this option. The benefit of this option is that there is no additional burden to licensees and regulatory authorities because existing license verification methods would be retained. Specifically, licensees would not be required to change current processes for license verification; the NRC would not be required to maintain additional Agreement State licenses in WBL; and regulators would not need to perform manual license verification functions in the event that the electronic method is not available or not used by the licensee.

This option was ultimately selected by the NRC staff because, although other options would provide enhanced security to prevent the alteration or counterfeiting of a license in order to obtain radioactive material illicitly, the benefits of regulatory changes considered are not cost-justified in light of current threat, vulnerability, and consequence information.

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

The total implementation costs associated with this option consist of $5,589,908 in one-time costs and $913,357 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $904,500 (one-time costs to update procedures and obtain credentials to use LVS) and $63,124 (annual/recurring costs to perform license verification).
- Cost to NRC: $1,589,600 (one-time costs to perform rulemaking and update guidance, load Agreement State licenses into WBL and perform data quality assurance, and credential users) and $702,788 (annual/recurring costs to load new and amended Agreement State licenses into WBL, process manual verification forms in support of Agreement State manual license verification functions, perform manual license verification for NRC licensees, and conduct inspection of licensee implementation of license verification requirements).
- Cost to Agreement States (total cost for all states): $3,095,808 (one-time costs to perform rulemaking and update guidance; and provide Agreement State licenses to the NRC for entry into WBL) and $147,445 (annual/recurring costs to provide new and amended Agreement State licenses to the NRC for entry into WBL, perform manual license verification, and conduct inspection of licensee implementation of license verification requirements).

The benefits of this option are that it would eliminate reliance on paper licenses authorizing possession of Category 3 quantities of radioactive material and, in doing so, would move license verification to an electronic platform using LVS. This would provide increased security to prevent the use of counterfeit or altered licenses authorizing possession of Category 3 quantities of radioactive material. Notwithstanding, the NRC staff determined that the benefits of requiring verification of licenses authorizing possession of Category 3

quantities of radioactive material through LVS or the regulatory authority are not cost-justified in light of current threat, vulnerability, and consequence information.

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

The total implementation costs associated with this option consist of $4,391,033 in one-time costs and $377,902 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $2,625 (one-time costs to update procedures) and $35,235 (annual/recurring costs to perform license verification).
- Cost to NRC: $1,292,600 (one-time costs to perform rulemaking and update guidance, and load Agreement State licenses into WBL and perform data quality assurance) and $323,280 (annual/recurring costs to load new and amended Agreement State licenses into WBL and conduct inspection of licensee implementation of license verification requirements).
- Cost to Agreement States (total cost for all states): $3,095,808 (one-time costs to perform rulemaking and update guidance, and provide Agreement State licenses to the NRC for entry into WBL) and $19,387 (annual/recurring costs to provide new and amended Agreement State licenses to the NRC for entry into WBL, and conduct inspection of licensee implementation of license verification requirements).

The NRC staff identified several benefits associated with the option of requiring M&Ds to verify licenses authorizing possession of Category 3 quantities of radioactive material through LVS or the regulatory authority. Specifically, implementation of this option would: (1) assure that M&Ds do not provide Category 3 quantities of radioactive material to unverified recipients; (2) account for the majority of transfers involving Category 3 quantities of radioactive material to customer licensees; (3) represent an impact to fewer licensees by limiting industry burden to M&Ds, which likely have the infrastructure and resources to handle the additional burden; and (4) minimize reliance on paper licenses authorizing Category 3 quantities of radioactive material. Although the NRC staff acknowledged the benefits of increased protection against counterfeit or altered licenses that would be achieved through this option, the NRC staff did not recommend moving forward with this option because the costs could not be justified given current threat, vulnerability, and consequence information.

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

The total implementation costs associated with this option consist of $10,246,594 in one-time costs and $2,511,440 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $3,666,343 (one-time costs to update procedures and obtain credentials to use LVS) and $130,687 (annual/recurring costs to perform license verification).
- Cost to NRC: $3,536,021 (one-time costs to perform rulemaking and update guidance, load Agreement State licenses into WBL and perform data quality assurance, and credential users) and $1,869,410 (annual/recurring costs to load new and amended

Agreement State licenses into WBL, process manual verification forms in support of Agreement State manual license verification functions, perform manual license verification for NRC licensees, and conduct inspection of licensee implementation of license verification requirements).

- Cost to Agreement States (total cost for all states): $3,044,230 (one-time costs to perform rulemaking and update guidance, and provide Agreement State licenses to the NRC for entry into WBL) and $511,343 (annual/recurring costs to provide new and amended Agreement State licenses to the NRC for entry into WBL, perform manual license verification, and conduct inspection of licensee implementation of license verification requirements).

The benefits of this option include complete elimination of the need for paper licenses, which would result in robust protection against the use of counterfeit or altered licenses. The NRC staff determined that the extensive costs associated with this option, which exceed $10 million in initial costs, could not be justified in the absence of a change in current threat, vulnerability, or consequence information.

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 the Category 3 threshold through a new system or the regulatory authority

The total implementation costs associated with this option consist of $9,895,393 in one-time costs and $2,428,475 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $3,314,800 (one-time costs to update procedures and obtain credentials to use LVS) and $76,762 (annual/recurring costs to perform license verification and authentication).
- Cost to NRC: $3,536,363 (one-time costs to perform rulemaking and update guidance, load Agreement State licenses into WBL and perform data quality assurance, and credential users) and $1,861,898 (annual/recurring costs to load new and amended Agreement State licenses into WBL, process manual verification/authentication forms in support of Agreement State manual license verification/authentication functions, perform manual license verification/authentication for NRC licensees, and conduct inspection of licensee implementation of license verification/authentication requirements).
- Cost to Agreement States (total cost for all states): $3,044,230 (one-time costs to perform rulemaking and update guidance, and provide Agreement State licenses to the NRC for entry into WBL) and $489,815 (annual/recurring costs to provide new and amended Agreement State licenses to the NRC for entry into WBL, perform manual license verification/authentication, and conduct inspection of licensee implementation of license verification/authentication requirements).

The benefits of this option include elimination of the need for paper licenses authorizing Category 3 quantities of radioactive material, which would prevent the use of counterfeit or altered licenses for transfers involving Category 3 quantities of radioactive material. This option would also implement a quick and accurate authentication system that would provide assurance of the validity of recipients seeking to acquire Category 4 and Category 5 quantities of radioactive material at a reduced burden when compared to use of LVS. Nonetheless, the NRC staff determined that, similar to Option 4 above, the extensive costs

associated with this option, which approach $10 million in initial costs, could not be justified in light of current threat, vulnerability, and consequence information.

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

The total implementation costs associated with this option consist of $8,573,767 in one-time costs and $2,355,322 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $3,200,050 (one-time costs to update procedures) and $28,773 (annual/recurring costs to perform license authentication).
- Cost to NRC: $2,329,487 (one-time costs to perform rulemaking and update guidance, and load Agreement State licenses into WBL for use in populating new authentication system and perform data quality assurance) and $1,858,580 (annual/recurring costs to load new and amended Agreement State licenses into WBL, process manual authentication forms in support of Agreement State manual license authentication functions, perform manual license authentication for NRC licensees, and conduct inspection of licensee implementation of license authentication requirements).
- Cost to Agreement States (total cost for all states): $3,044,230 (one-time costs to perform rulemaking and update guidance, and provide Agreement State licenses to the NRC for entry into WBL for use in populating new authentication system) and $467,969 (annual/recurring costs to provide new and amended Agreement State licenses to the NRC for entry into WBL, perform manual license authentication, and conduct inspection of licensee implementation of license authentication requirements).

The option of implementing license authentication for transfers involving quantities of radioactive material below the Category 2 threshold would be beneficial in that it would protect against the use of counterfeit licenses below the Category 2 threshold. This would be achieved through the use of a reduced-burden online system that would not require the use of credentials. Although the NRC staff acknowledged the improved level of security that this option would provide, the staff also concluded that the option was not cost-justified because it would not prevent the use of altered licenses, would require regulators and licensees to learn a new system, and would entail significant initial and recurring costs.

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

The NRC staff considered five options to address this concern. The accrued costs and benefits of each option are described individually below.

Concern 3, Option 1: No action

Because this option would entail no change (i.e., no expansion of NSTS to include reporting of Category 3 and lower threshold sources), there would be no new implementation costs associated with this option. The benefit of this option is that there is no additional burden to licensees and regulatory authorities because accounting for sources in NSTS would be limited to Category 1 and Category 2 sources only. This option was ultimately selected by the NRC staff because, although other options would provide source tracking and inventory information to regulatory agencies and agencies responsible for national security/emergency response to facilitate planning, oversight, and decisionmaking functions, the benefits of regulatory changes considered are not cost-justified in light of current threat, vulnerability,

and consequence information. This conclusion was also consistent with the results of the 10 CFR Part 37 program review.

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 2 sources

The total implementation costs associated with this option consist of $8,461,042 in one-time costs and $1,080,610 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $3,438,000 (one-time costs to develop procedures, perform credentialing, setup accounts, conduct training, and complete initial NSTS inventory reporting) and $364,500 (annual/recurring costs to report source transactions and perform annual inventory reconciliation).
- Cost to NRC: $2,008,800 (one-time costs to perform rulemaking and update guidance, facilitate account setup, conduct training for new users, and expand NSTS capacity to allow for inclusion of Category 3 sources) and $615,360 (annual/recurring costs to maintain NSTS and conduct inspection of licensee implementation of NSTS requirements).
- Cost to Agreement States (total cost for all states): $3,014,242 (one-time costs to perform rulemaking and update guidance) and $100,750 (annual/recurring costs to conduct inspection of licensee implementation of NSTS requirements).

The benefits of implementing NSTS requirements for transactions involving Category 3 sources include: (1) increased accountability for Category 3 sources; and (2) the ability to provide Category 3 source information to regulatory agencies and agencies responsible for national security/emergency response in order to allow the agencies to use the information for planning, oversight, and decisionmaking. Notwithstanding these benefits, the NRC staff determined that pursuing this option was not cost-justified because it involved significant burden to both the regulators and industry and, in the absence of requiring license verification through LVS, would not address the issue of licensees being able to obtain additional sources above their possession limit.

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

The total implementation costs associated with this option consist of $9,076,408 in one-time costs and $1,423,197 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $3,438,000 (one-time costs to develop procedures, perform credentialing, setup accounts, conduct training, and complete initial NSTS inventory reporting) and $364,500 (annual/recurring costs to report source transactions and perform annual inventory reconciliation).
- Cost to NRC: $2,542,600 (one-time costs to perform rulemaking and update guidance, facilitate account setup, conduct training for new users, load Agreement State licenses into WBL and perform data quality assurance, expand NSTS capacity to allow for inclusion of Category 3 sources, and modify NSTS to facilitate compliance with license possession limits) and $938,560 (annual/recurring costs to maintain NSTS, load new and amended Agreement State licenses into WBL, and conduct inspection of licensee implementation of NSTS requirements).

- Cost to Agreement States (total cost for all states): $3,095,808 (one-time costs to perform rulemaking and update guidance, and provide Agreement State licenses to the NRC for entry into WBL) and $120,137 (annual/recurring costs to conduct inspection of licensee implementation of NSTS requirements and provide new and amended Agreement State licenses to the NRC for entry into WBL).

Similar to Option 2 described above, this option would provide for increased accountability of Category 3 sources and make Category 3 source information accessible to regulatory agencies and agencies responsible for national security/emergency response in order to allow the agencies to use the information for planning, oversight, and decisionmaking. This option would also provide benefits by: (1) eliminating the potential for a licensee to obtain more sources than authorized, and (2) preventing the shipment of sources in conjunction with an altered license. Although the NRC staff acknowledged the benefits of this option, the NRC staff determined that the extensive costs associated with these regulatory changes could not be justified given current threat, vulnerability, and consequence information.

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

The total implementation costs associated with this option consist of $4,910,542 in one-time costs and $645,610 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $787,500 (one-time costs to develop procedures and complete initial NSTS inventory reporting) and $229,500 (recurring costs to perform annual inventory reconciliation).
- Cost to NRC: $1,108,800 (one-time costs to perform rulemaking and update guidance, and expand NSTS capacity to allow for inclusion of Category 3 sources) and $315,360 (annual/recurring costs to maintain NSTS and conduct inspection of licensee implementation of NSTS inventory reporting requirements).
- Cost to Agreement States (total cost for all states): $3,014,242 (one-time costs to perform rulemaking and update guidance) and $100,750 (annual/recurring costs to conduct inspection of licensee implementation of NSTS inventory reporting requirements).

This option includes the benefit of making source information available to Federal and State agencies for situational awareness/emergency response while presenting a low burden to licensees. Nonetheless, the NRC staff determined that this option did not provide a significant security benefit, and as such, was not cost-justified when considering current threat, vulnerability, and consequence information.

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

The total implementation costs associated with this option consist of $23,556,892 in one-time costs and $10,049,183 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $19,038,650 (one-time costs to develop an access authorization program, including procedures, and conduct background investigations) and $9,889,000

(annual/recurring costs to conduct background investigations and perform annual review of access authorization program).

- Cost to NRC: $1,504,000 (one-time costs to perform rulemaking and update guidance, and process fingerprint cards submitted by licensees) and $126,720 (annual/recurring costs to process fingerprint cards submitted by licensees and conduct inspection of licensee implementation of access authorization program requirements).
- Cost to Agreement States (total cost for all states): $3,014,242 (one-time costs to perform rulemaking and update guidance) and $33,463 (annual/recurring costs to conduct inspection of licensee implementation of access authorization program requirements).

The NRC staff identified two primary benefits with respect to this option: (1) it would provide 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; and (2) it would represent a graded approach to security for licensees possessing Category 3 quantities of radioactive material that, if aggregated, meet or exceed the Category 2 threshold. The NRC staff determined, however, that these benefits were not substantial enough in nature to justify the significant burden to licensees to develop and implement an access authorization program. This burden is reflected in the cost analysis, which estimates over $19 million in initial costs for industry implementation, followed by nearly $10 million in annual costs.

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 NRC staff considered four options to address this concern. The accrued costs and benefits of each option are described individually below.

Concern 4, Option 1: No action

Because this option would not involve a change to the existing provisions of the general license program, there would not be any new implementation costs associated with it. The benefits of this option include the low burden to licensees commensurate with risk of generally licensed devices, paired with annual registration and inventory requirements that provide a graded level of accountability for generally licensed devices. Although the NRC staff identified several concerns with maintaining the general license program as it is currently defined (including the lack of pre-licensing evaluations, license verifications for source transfers, and inspections to verify compliance with safety and security requirements), the staff determined that a cost-justified basis did not exist to support increased security and accountability requirements for generally licensed devices based on current threat, vulnerability, and consequence information.

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 total implementation costs associated with this option consist of $3,984,230 in one-time costs and $3,685 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $32,025 (one-time costs to develop procedures) and no recurring costs because registration fees are not changed.
- Cost to NRC: $911,360 (one-time costs to perform rulemaking and update guidance, and conduct staff training) and $1,280 (annual/recurring costs to conduct pre-licensing evaluations).
- Cost to Agreement States (total cost for all states): $3,040,845 (one-time costs to perform rulemaking and update guidance, and conduct staff training) and $2,405 (annual/recurring costs to conduct pre-licensing evaluations).

In terms of the benefits of this option, it would have limited impact on general licensees nationally, would provide regulators with information from unknown device purchasers on how they intend to use the radioactive material, and would likely enhance the device owners' understanding of their safety and security responsibilities. Nonetheless, the NRC staff determined that the benefits of performing a pre-licensing evaluation prior to the transfer of a Category 3 generally licensed device to an unknown entity were not significant enough to justify the cost to the industry and regulatory authorities, especially given that the option lacked an inspection program component to verify compliance with safety and security regulations.

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 total implementation costs associated with this option consist of $4,353,981 in one-time costs and $105,344 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $32,025 (one-time costs to develop procedures) and $39,200 (recurring costs to account for change in annual registration fees needed to offset the regulator's oversight costs).
- Cost to NRC: $970,496 (one-time costs to perform rulemaking and update guidance, conduct staff training, prepare inspection procedures, and conduct initial inspections of existing licensees) and $10,496 (annual/recurring costs to conduct pre-licensing evaluations of unknown applicants and perform routine inspections of licensee compliance with safety and security requirements).
- Cost to Agreement States (total cost for all states): $3,351,460 (one-time costs to perform rulemaking and update guidance, conduct staff training, prepare inspection procedures, and conduct initial inspections of existing licensees) and $55,648 (annual/recurring costs to conduct pre-licensing evaluations of unknown applicants and perform routine inspections of licensee compliance with safety and security requirements).

With respect to the benefits associated with this option, similar to Option 2 described above, it would have limited impact on general licensees nationally, would provide regulators with

information from unknown device purchasers on how they intend to use the radioactive material, and would likely enhance the device owners' understanding of their safety and security responsibilities. In addition, this option incorporates an inspection program component to verify compliance with safety and security regulations. Although the NRC staff acknowledged the benefits of this option, the NRC staff determined that the costs associated with these regulatory changes could not be justified given current threat, vulnerability, and consequence information.

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

The total implementation costs associated with this option consist of $5,599,329 in one-time costs and $1,746,806 in annual/recurring costs. These costs are distributed as follows:

- Cost to industry: $895,300 (one-time costs to develop procedures, establish a radiation safety program, conduct staff training, prepare license applications, and submit application fees) and $1,680,662 (annual/recurring costs to maintain the radiation safety program and submit annual license fees).
- Cost to NRC: $1,108,480 (one-time costs to perform rulemaking and update guidance, conduct staff training, update inspection procedures, review license applications, conduct pre-licensing evaluations of unknown applicants, update sealed source and device registry sheets, and perform initial inspections of existing licensees); and $10,496 (annual/recurring costs to conduct pre-licensing evaluations of unknown applicants and perform routine inspections of licensee compliance with safety and security requirements).
- Cost to Agreement States (total cost for all states): $3,595,549 (one-time costs to perform rulemaking and update guidance, conduct necessary staff training, update inspection procedures, review license applications, conduct pre-licensing evaluations of unknown applicants, and perform initial inspections of existing licensees); and $55,648 (annual/recurring costs to conduct pre-licensing evaluations of unknown applicants and perform routine inspections of licensee compliance with safety and security requirements).

The conversion of Category 3 generally licensed devices to a specific licensing infrastructure would involve a number of benefits, including: (1) addition of a routine radiation protection program which could enhance the protection provided to public health and safety; (2) conduct of a pre-licensing evaluation of unknown applicants to ensure that radioactive material will be used as stated on the license application; and (3) increased licensee awareness of, and compliance with, regulatory requirements through the specific licensing process and the conduct of routine inspections by the regulatory authority. Additionally, this option would affect a small number of general licensees nationally, and would enable oversight costs to be offset by specific license fees. Notwithstanding these benefits, the staff determined that the threat environment has not changed sufficiently since 2010 to warrant changes to the general license program based on security. However, some commenters and NRC staff offered perspectives that argue for a re-evaluation of current practices for generally licensing Category 3 sources to ensure that the current infrastructure continues to protect public health and safety.